A Review of the Status of Implementation of Decree 21 and the International Code of Marketing of Breastmilk Substitutes in Vietnam



Prepared by the Institute for Social and Medical Studies



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The Institute of Social and Medical Studies (ISMS), a nongovernment organization based in Hanoi, was responsible for conducting the desk review, performing data management and analysis for the monitoring study, and writing the joint report.

Acronyms

A&T Alive & Thrive
AA Arachidonic Acid

CCHE Center for Communication Health Education
CPFC Commission for Population, Family, and Children

CPM Center for Preventive Medicine

DHA Docosahexaenoic Acid

DHI Department of Health Inspection

FHSA Food Hygiene and Safety Administration
IBFAN International Baby Food Action Network
ICDC International Code Documentation Center
IEC Information, Education and Communication

ISMS Institute for Social and Medical Studies

IYCF Infant and Young Child Feeding

MARD Ministry of Agriculture and Rural Development

MOC Ministry of Construction

MOCI Ministry of Culture and Information

MOCST Ministry of Culture, Sport and Tourism

MOET Ministry of Education and Training

MOH Ministry of Health

MOIT Ministry of Industry and Trade

MOLISA Ministry of Labor, Invalids and Social Affairs

MOST Ministry of Science and Technology

NIN National Institute of Nutrition

Ob/Gyn Obstetrics & Gynecology
PEM Protein-Energy Malnutrition
RHC Reproductive Health Center

SIM Forms Standard IBFAN Monitoring Forms

TOT Training of Trainers

UNICEF United Nations Children's Fund

WHA World Health Assembly
WHO World Health Organization

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EXECUTIVE SUMMARY

Purpose

Adopted in 2006, *Decree 21 on the Trade and Use of Nutrition Products for Young Children* aims to promote optimal breastfeeding practices by limiting how and where breastmilk substitutes and other nutrition products for young children can be promoted.

Alive & Thrive (A&T) is a 5-year initiative (2009-2013) to improve infant and young child nutrition by increasing rates of exclusive breastfeeding and improving complementary feeding practices. A&T aims to reach more than 16 million children under 2 years old in Bangladesh, Ethiopia, and Vietnam. A&T is working closely with the Vietnam Ministry of Health (MOH) and the United Nations Children's Fund (UNICEF) to strengthen monitoring and compliance of Decree 21. Decree 21 is slated to be revised in 2011. This joint report provides recommendations for revision of Decree 21 based on findings from an analysis of the Decree's provisions and implementation processes as well as evidence of compliance with and violations of the Decree and the *International Code of Marketing of Breastmilk Substitutes* (International Code) and subsequent World Health Assembly (WHA) resolutions.

Findings were compiled from:

- 1. Reports generated by 63 Provincial and City Departments of Health and National Pediatrics and Obstetrics and Gynecology (Ob/Gyn) hospitals and compiled by the Legislative Department;
- 2. UNICEF-supported inspections conducted by the Department of Health Inspection (DHI) in 8 provinces; and
- 3. Monitoring data collected by A&T-trained health staff in health facilities, pharmacies and retailers in 10 provinces.

Findings: Strengths and Achievements

Decree 21 represents an important step to implementing the International Code in Vietnam. The Decree covers a broad range of products, including nutrition products for children from birth to 24 months old, feeding bottles, teats and dummies. Many sections of the current Decree are more comprehensive than previous versions, and the recommendations for infant and young child feeding (IYCF) are up-to-date with current scientific knowledge and international recommendations.

Since its adoption in 2006, the Decree has contributed to important gains in promoting optimal IYCF practices in Vietnam:

- a. Information, Education and Communication (IEC) activities that promote breastfeeding and disseminate information on Decree 21 have increased substantially in recent years. IYCF-related training for health staff and IEC activities for the public, such as Breastfeeding Week, have helped spread the message about the benefits of breastfeeding.
- b. **Systems and structures for monitoring and supervision of Decree 21 are in place**, and the Department of Health Inspection of MOH and provincial and city departments conduct periodic inspections on Decree compliance.
- c. Heads of health facilities are generally aware of Decree 21, and compliance with the Decree has been found to be relatively high in health facilities. Most of the reviewed hospitals meet or are working to meet the 10 conditions for successful breastfeeding. In addition, more and more health workers are reported to support breastfeeding and provide breastfeeding counseling to women.
- d. Some provinces -such as Phu Tho, Yen Bai, Bac Kan and Lao Cai -report **high prevalence levels of initiation of breastfeeding within an hour of birth** among mothers in hospitals compared to the national average of 62% (A&T, 2010).

Findings: Weaknesses and Limitations

Although it has many strengths, the Decree has yet to meet the minimum standard set by the International Code and subsequent WHA Resolutions and is therefore categorized as a second level "many provisions law" by the International Code Documentation Center (ICDC), an organization dedicated to keeping track of International Code implementation and compliance worldwide. Wording in the Decree's provisions opens up numerous loopholes and gaps which companies exploit to promote breastmilk substitutes and other nutrition products for young children within the scope of the Decree. In addition, Vietnam still faces obstacles to implementation of Decree 21, including weak monitoring of Decree compliance and enforcement of its sanctions.

Key weaknesses in the provisions of Decree 21

- a. Scope and definitions: Feeding bottles, teats and dummies are left out of many provisions of Decree 21.
 - Decree 21does not provide clear definitions for nutrition product companies such as those found in the International Code, an omission which may lead to confusion over who is responsible for compliance with the Decree.
- b. **Contact with mothers:** Unlike the International Code, Decree 21 **does not restrict contact with individuals outside of health facilities.** These contacts serve to discourage

breastfeeding as company representatives promote their products, offer incentives to use their products such as gifts or samples, or advise mothers on IYCF practices.

Decree 21 allows for companies to contact mothers within health facilities to promote or sell nutrition products for children older than 12 months, many of which greatly resemble the products restricted by the Decree (milk products for children under 12 months of age and food products for infants under 6 months of age). This age specification creates confusion about Decree violations and creates a loophole for companies to work around the Decree provisions. The International Code does not include similar age specifications.

c. Information, education and communication: Some important informational points specified in the International Code are missing from the Decree's provisions on IEC, including: the negative effects of partial bottle-feeding on breastfeeding; the difficulty of reversing the decision not to breastfeed; and maternal nutrition as it relates to the preparation for and maintenance of breastfeeding.

Unlike the International Code, Decree 21 does not regulate donations of informational and educational materials or equipment from nutrition product companies.

- d. Advertising: Decree 21 allows for advertising of milk products for children from 12 to 24 months of age, with some restrictions. This provision is not inline with the International Code, which states that there should be no advertising of products within the scope of the Code. This provision is also at odds with the internationally recognized recommendation that breastfeeding to be maintained for up to 24 months or beyond. Moreover, allowing for advertising or promotion of products for children over 12 months old enables companies to indirectly promote nutrition products for children under 12 months old that closely resemble these products.
- e. **Promotion in retail shops:** Many promotional tactics employed by nutrition product companies outside of health facilities are not covered by Decree 21even though the International Code recommends that there should be no promotion to the general public of products within the scope of the Code. These include the use of displays, special showcases, discounts, special offers, samples, gifts, and incentives for retail staff. Companies also work around the advertising restrictions by prominently displaying their names and logos on banners, posters and other promotional materials within retail shops and health facilities.
- f. **Promotion in health facilities**: A weak point in Decree 21 is the inclusion of **an exception for hospital pharmacies** in its provisions regulating the sale, display and promotion of nutrition products for young children in health facilities. In addition, the Decree contains a **loophole by failing to prohibit the display of company names on advertisements or**

promotional materials within health facilities. Only the names of the nutrition products are banned from these materials. Allowing this practice implies that the health facilities endorse the products of that company.

Decree 21 is weakened by the **inclusion of age limits** for products that fall under the scope of some of its provisions. These articles only restrict practices related to milk products for children under 12 months of age and food products for infants under 6 months of age. By failing to include milk products for children older than 12 months and food products for children older than 6 months, these provisions **create confusion among health staff as to what is or is not prohibited and allows companies to work around the Decree** and promote their products in health facilities. The International Code does not include similar age specifications in its provisions.

g. Labeling: Although extensive, the Decree's provisions on the labeling of nutrition products for young children do not fully meet the minimum requirements set by the International Code.

In addition, only images or photos of infants less than 12 months old are prohibited under Decree 21. This age limit makes it more difficult to determine true violations of the Decree and creates a potential loophole for companies. This weakness is also found within the International Code.

Decree 21 goes beyond the International Code by including labeling provisions for feeding bottles and teats. However, the labeling provisions for feeding bottles and teats should be strengthened as they do not include any prohibitions against the use of: a) images or photos of infants and young children; b) images or text idealizing use of the product; c) images or text that encourage the use of breastmilk substitutes; or d) text that implies that the product is similar to a mother's nipple.

- h. **Sponsorship:** The Article of Decree 21 that restricts the granting of scholarships or funds provided by nutrition product companies contains a weakness by including the phrase: "for the purpose of promoting the sale or use of milk products for children under 12 months of age and food products for children under 6 months of age." The phrase compromises the provision by: a) including an age limit on the regulated products and b) **providing a ready-made defense for companies as they can claim that their financial support is for purposes other than promotion or sale of their products.**
- i. **Sanctions:** Decree 21 does not contain any provisions for sanctioning violations. **Sanctions** are stipulated in Decree 45, and not all provisions of Decree 21 are covered by Decree 45.

***** Key weaknesses in the implementation of Decree 21

- a. Cohesiveness, coordination and consultation: There is a lack of cohesiveness, coordination and consultation between the multiple sectors involved in the implementation of Decree 21. This problem is due in part to an absence of direction documents and guidelines provided to or created by provincial agencies. The problem is exacerbated by the low level of priority placed on Decree 21 in many provinces and the resultant lack of funding available for implementation. Consequently, agencies and organizations that are responsible for implementation do not clearly understand their roles and responsibilities in the implementation process.
- b. Inspections: While systems and structures are in place to monitor and enforce Decree 21, inspections are infrequent and inconsistent. Monitoring and supervision of the Decree is a low political priority and not considered important enough to warrant rigorous inspections. Decree 21 inspections are often conducted as part of broader food safety and hygiene inspections, which interferes with the thoroughness of the inspections. When inspections are carried out, limited numbers of inspectors are expected to handle a huge volume of work.
- c. Uncovering violations: Violations to Decree 21 are not always easy to uncover. Confusion remains as to what is or is not a violation, and some of the provisions of the Decree contain wording that make this more difficult. Violations in advertising are particularly difficult to monitor and control as advertising becomes more pervasive and sophisticated, especially when the internet and new technologies are utilized.
- d. **Sanctions:** The sanctions against Decree21 violations are weak. Under Decree 45, companies or health staff that violate Decree 21 can be sanctioned, usually in the form of fines ranging from 3 to 10 million VND (150 to 500 USD), depending on the violation committed. **These fines, when levied at all, are too low to be an effective deterrent**.
- e. **IEC activities:** A lack of coordination and limited funding lead to communication activities that are **inconsistent and at times poor in quality, quantity and reach**. The lack of written guidance and coordination of IEC activities leaves the heads of provincial agencies unclear about their roles and responsibilities. IEC activities also face the challenge of **competing with large nutrition product companies that spend vast sums of money on advertising**, greatly outspending breastfeeding promotion efforts.
- f. **Training of health staff:** Training for health staff has made much progress, but there is still room for improvement. Trainings are **not consistently frequent, widespread or comprehensive.** Often the trainings only incorporate staff from Ob/Gyn Departments, and health workers have been found to lack knowledge about Decree 21. The shortage and limited skills of existing health staff worsen the problem.

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Findings: Practices that Violate Provisions or Exploit Loopholes of Decree 21 and the International Code

While most of the products and facilities reviewed complied with Decree 21, evidence from this review suggests that violations of the Decree are varied and relatively widespread, covering multiple provisions of the Decree and in all the provinces reviewed. Violations were carried out by numerous domestic and multinational companies and included the realms of IEC materials, promotion and advertising, labeling, and regulations in health facilities. Numerous additional cases were found in which companies or health facilities were technically in compliance with Decree 21 but violated the International Code, which is stricter than Decree 21. Furthermore, it should be noted that the number of violations may be underreported due to difficulties surrounding identification of Decree 21 violations as well as a suspicion that advanced notification was given to individuals or facilities before inspections. Violation or no, these practices serve the overall purpose of promoting the use of breastmilk substitutes and other products within the scope of the Decree and work against efforts to improve infant and young child feeding practices in Vietnam.

Contact with Mothers

Although prohibited by Decree 21, mothers were found to be contacted by nutrition product companies within health facilities. There were also reports of mothers receiving gifts and free samples of nutrition products for young children, usually in health facilities and retail shops. In some cases, gifts were provided by a member of the health staff, a prohibited practice that imbues the product with a medical endorsement. Furthermore, some mothers reported using breastmilk substitutes based on the advice of a health worker, although Decree 21 prohibits health staff from advising their patients to use nutrition products for infants unless medically necessary. At present, there are not enough barriers shielding mothers from the influence of nutrition product companies.

Thirty-eight out of 342 interviewed mothers (11.1%) were contacted directly by company representatives. Nearly one-third of these interactions (31.6%) were in health facilities. Company representatives were found to directly contact mothers in three non-baby-friendly health facilities (representatives from Abbott and HiPP). DHI inspections found at least one case in which company representatives were directly encouraging pregnant women and new mothers in health facilities to purchase their products, including milk for children under 12 months of age.

¹Violation is defined as a breach of Decree 21 or the International Code. *Loophole* is defined as an ambiguity or omission in Decree 21 by which one can avoid a penalty or responsibility.

Company representatives contacted mothers in shops, Houses of Culture, hotels, at home, and/or over the phone, usually to provide mothers with IYCF information, to try to get them to use a specific nutrition product, or to offer them gifts.

Violation: Article 5.5 of the International Code

Loophole: Article 10 of Decree 21

Out of 336 mothers, 10 (3%) reported receiving free product samples and 29 mothers (8.6%) received gifts associated with nutrition products for young children, usually in shops or health facilities. Over 80% of the 29 mothers who received gifts or samples reported receiving them from company staff or sales personnel.

Violation: Article 5.5 of the **International Code**

Loophole: Article 10 of Decree 21 (depending on where mothers received gifts)

In 7.7% of 142 non-baby-friendly health facilities, mothers received nutrition products for young children in the last 6 months, including those prohibited by Decree 21. Most often the products came from family members or relatives, but company personnel and health staff were also found to give mothers these products in 6 of these health facilities.

Violation: Article 10.2.c of Decree 21 / Articles 5.2 and 5.4 of the International Code

Loophole: Article 10 of Decree 21 (depending on which products were received and by whom)

Information, Education and Communication

Nearly all of the reviewed IEC materials available to the public and to health staff were provided by nutrition product companies. Many of these materials either directly or indirectly promoted the use of nutrition products for young children. At times, these materials directly violated Decree 21 and International Code – for example, by featuring the name or logo of a restricted product – but often, these materials promoted their products indirectly by branding the material with the companies' name/logo or including messages that promote bottle-feeding. For example, it was common for these materials to highlight the fact that mothers can measure the amount of milk they are feeding their children when bottle-feeding, a message that plays upon mothers' common fears that they do not produce enough breastmilk.

Most IEC materials for mothers fell short of meeting the informational content requirements outlined in Decree 21 and the International Code. Especially lacking was information on the disadvantages and costs of not breastfeeding and the hazards of improper or unnecessary use of nutrition products. While the IEC materials for health staff were better about containing information required under Decree 21than the IEC materials for the public, gaps in information persist.

Key Findings Violation/Loophole

61.8% of the 55 IEC materials for the public and 52.4% of 21 IEC Loophole: Article 4 of Decree 21 / materials for health staff that were provided by companies Article 4.3 of the International Code mentioned formula for infants under 6 months old.

18.2% of the 55 IEC materials for the public and 33.3% of 21 IEC Loophole: Article 4 of Decree 21 / materials for health staff provided by companies mentioned follow-Article 4 of the International Code up milk products for children older than 6 months of age. Nearly half of the IEC materials violated Decree 21 by featuring the Violation: Article 4.3.c of Decree 21 / name or logo of a restricted nutrition product for young children Article 4 of the International Code (45.5% of those for the public and 47.6% of those for health staff). Only half of the 43 IYCF-related IEC materials for mothers provided Violation: Articles 4 and 5 of Decree information on the benefits of breastfeeding; 14% of IEC materials 21 / Article 4.2 of the International covered information on the negative impact of bottle-feeding; 11.6% Code discussed the disadvantages of not breastfeeding; 16.7% provided information on maternal nutrition and the maintenance of breastfeeding. In all, only 50% of the 22 IYCF-related IEC materials for health staff Violation: Articles 4 and 5 of Decree contained information on all three of the topics: the benefits of 21 / Article 4.2 of the International breastfeeding, the disadvantages of not breastfeeding, and the Code negative impact of bottle-feeding. Loophole: Decree 21 should make it clearer that these provisions apply to IEC for health staff Violation: Article 4.3.b of Decree 21 / IEC materials were found to include messages implying that Article 4.2 of the International Code bottle-feeding or milk products are similar to or better than breastfeeding as well as messages idealizing the use of these

Sale, Promotion, Advertising of Products in Health Facilities and Retail Shops

products.

While most health facilities complied with the provisions of Decree 21, violations were found in both baby-friendly and non-baby-friendly health facilities. The age limits placed on the products covered by the Decree and other loopholes make it difficult for health staff to control promotional activities within health facilities.

Advertising violations were found to be pervasive. In all, over 100 advertising violations to Decree 21 in 70 retail shops were uncovered in this study. These violations were committed by over 20 multinational and domestic companies. It was also common for companies to work around the Decree by using other promotional strategies such as special showcases, banners, displays, discounts, special sales, product holders, and gifts.

| Practice | Violation/Loophole |
|--|--|
| DHI inspections found 4 hospitals that permitted the sale of restricted nutrition products either at kiosks or through health workers. | <u>Violation</u> : Articles 10.2.b and 11.2.a of Decree 21 / Article 6.3 of the International Code |
| | Loophole: Article 10 of Decree 21 (depending on the products promoted) |

Nine out of 152 health facilities were found to display Violation: Articles 10.2.d and 11.2.b of nutrition products for young children, including those for Decree 21 / Article 6.3 of the International children under 12 months of age. Code Loophole: Article 10 of Decree 21(depending on the products promoted) Cases were found in which the name or logo of restricted Violation: Articles 10.2.c and 12.2 of nutrition products were found on materials in 6 health facilities Decree 21 / Article 6.3 of the International such as clocks, posters and calendars. Code Loophole: Articles 10 and 12 of Decree 21(depending on the products promoted) One-third of 216 retail shops (32.4%)contained Violation: Article 6 of Decree 21 / Article advertisements of nutrition products for young children, 5.1of the International Code including those for children under 12 months old. Loophole: Article 6 of Decree (depending on the products advertised) 31.1% of retails shops contained special showcases, 16.4% Violation: Articles 5.3 and 5.4 of the used special sales, 10.7% used product holders, and 8.2% International Code used banners to promote products within the scope of the Loophole: Article 6 of Decree 21 (no Decree. prohibition) Violation: Articles 8.1 of the International Sales personnel in retail shops were found to approach mothers to encourage the purchase of breastmilk substitutes. These personnel were often prompted by companies who Loophole: Article 6 of Decree 21(no provide monetary and material incentives to sales personnel prohibition) to sell their products. Cases were found in which mothers were asked to provide Violation: Article 5.5 of the International their personal information in retail shops. They were also Code invited to attend workshops or meetings held by companies. Loophole: Article 10 of Decree 21(depending on the products promoted)

Labeling of Products within the Scope of Decree 21

In all, violations of Decree 21 labeling provisions were relatively common and were committed by over 20 domestic and multinational companies. Violations included omitting informational content required by the Decree, containing images of infants, and discouraging breastfeeding by idealizing the product in a way that does not meet scientific scrutiny.

It is the norm for labels to make nutrition and health claims about the additives put into their products, such as fatty acids, amino acids, proteins, prebiotics, and probiotics. These claims serve to make the products seem either equal or superior to breastmilk. Some common claims include that the additives enhance the immune system, improve vision, reduce allergies, and prevent infections. Other common claims found on labels examined in this study were that the nutrition product helps with brain or intellectual development, height and/or weight gain, and overall physical development. These claims can be misleading and are mostly scientifically unsubstantiated, and in that way they violate Article 4.1 of Decree 21, which states that materials must ensure objectivity and be scientifically valid.

| Key Findings | Violation/Loophole |
|---|--|
| Less than half - only 48% - of the 355 labels on nutrition products for infants under 6 months of age complied with every regulation of the Decree. | <u>Violation</u> : Article 8 of Decree 21 / Article 9 of the International Code |
| One-tenth of labels on the 355 nutrition products for infants under 6 months of age and 30.7% of the 426 products for children 6-24 months of age implied that the product is equal to or better than breastmilk. | <u>Violation</u> : Article 8.2.c of Decree 21 / Article 9 of the International Code |
| 13% of nutrition products for infants under 6 months old contained text that either discouraged breastfeeding or idealized the use of breastmilk substitutes. | <u>Violation</u> : Articles 8.2.c of Decree 21 / Article 9.2 of the International Code <u>Loophole</u> : Articles 8 and 9 of Decree 21(should be clearer about what constitutes a violation) |
| Most products make questionable health or nutrition claims about the additives in the products. | <u>Violation</u> : Articles 8.2.c of Decree 21 / Article 9.2 of the International Code and WHA resolution 62.23 |
| | <u>Loophole</u> : Article 8 of Decree 21 (<i>Provisions should be clearer</i>) |
| 13% of nutrition products for infants under 6 months old contained an image of an infant. | <u>Violation</u> : Articles 8.2.c of Decree 21 / Article 9.2 of the International Code |
| | <u>Loophole</u> : Article 8 of Decree 21(age of infant can be argued) |
| Many labels of feeding bottles and teats were found to indirectly discourage breastfeeding by idealizing bottle-feeding or featuring images of infants bottle-feeding. | <u>Loophole</u> : Article 9 of Decree 21 |

Usage of Breastmilk Substitutes among Mothers

Usage of breastmilk substitutes was high among mothers of infants under 6 months old who participated in the study. The two most commonly cited reasons for using breastmilk substitutes were: 1) they were advised to do so by a friend, family member or neighbor; and 2) they felt that they did not produce enough breastmilk for their children. As seen before, companies often convey messages that take advantage of mothers' concerns that they do not produce enough breastmilk. Concerns over the quantity or appropriateness of breastfeeding (e.g., after a Caesarean section) were also somewhat common among mothers. These findings imply that there is a lack of awareness and education about breastfeeding, including the risks of not breastfeeding, among mothers in Vietnam.

Key Findings

• Slightly more than half (52.7%) of the 349 mothers of infants under 6 months old reported using breastmilk substitutes.

- Among the 184 mothers who used breastmilk substitutes, 21.2% did so because they felt that they did not produce enough breastmilk for their children.
- Nearly one-quarter of mothers who used breastmilk substitutes (23.4%) reported being advised to do so by a health professional, a violation of Article 12.2.c of Decree 21 (unless it is medically necessary to do so).
- Among those who used breastmilk substitutes, 10.3% of mothers were influenced by advertisements to do so and 6.5% felt that these substitutes were superior to breastmilk.
- 21.7% of mothers who used breastmilk substitutes did so based on the advice of a friend.

Recommendations

- Key recommendations for revision of Decree 21
 - The following recommendations for the revision of Decree 21 aim to strengthen the provisions of the Decree by closing existing loopholes and by increasing the clarity of the Decree. The recommendations also aim to bring Decree 21 inline with the International Code.
- 1. **Include feeding bottles, teats, and dummies** in provisions where these products are currently absent.
- 2. **Clarify and provide definitions of the businesses and companies** which are regulated under the Decree as well as the representatives of these companies.
- 3. **Remove age limits** specified for the products covered under the Decree. All provisions should apply to all products within the scope of the Decree. For example, prohibit all advertisements for nutrition products for children from birth to 24 months of age.
- 4. Require that information, education and communication materials are expanded to **include all the informational points** listed in the International Code; and make it clearer that these requirements apply to materials for health staff.
- 5. **Regulate donations** of informational and educational materials, equipment, and products from nutrition product companies.
- 6. **Prohibit promotional or marketing tactics** that serve to promote products under the scope of the Decree such as point-of-sale advertising, giving of samples, special sales, etc.
- 7. **Expand the labeling provisions** to include all the points of the International Code; prohibit any images or photos of infants or young children from labels; and make labeling provisions for bottles and teats more comprehensive.
- 8. **Prohibit the use of health and nutrition claims** for nutrition products for infants and young children.
- 9. **Remove the exception for hospital pharmacies** from articles related to health facilities.
- 10. **Prohibit companies from displaying their name and/or logo** in health facilities in any form.
- 11. Prohibit company personnel from **seeking direct or indirect contact** of any kind with pregnant women, mothers, or infants and young children, including in the form of giving gifts or samples.
- 12. Tighten the sponsorship provision to **prohibit all forms of funding** for scholarships, conferences, research, seminars, courses, etc.
- **13**. Update all provisions of Decree 21 to **account for new technologies**, particularly Articles 4, 5 and 6.

Key recommendations for implementation, monitoring and supervision of Decree 21

- 1. **Establish a Steering Committee** or equivalent to improve cohesiveness, coordination, and consultation of relevant ministries (see page 32 for a list of agencies). The Committee would also provide direction and guidance for: a) drafting of a new Decree, b) implementing the Decree, and c) monitoring for Decree violations.
- 2. Develop clear guidelines on the coordination and implementation of IEC activities so the roles and responsibilities of the different players involved are better coordinated and understood. Improve the quality, quantity and reach of these activities through better management and increased funding and priority. Special focus should be given to including messages on the health hazards of the inappropriate use of breastmilk substitutes and complementary foods and the financial costs of breastfeeding.
- 3. Improve the levels of knowledge and awareness about Decree 21 and the benefits of breastfeeding among local authorities and key players involved in Decree implementation in order to help make implementation a greater priority, which could result in higher funding.
- 4. **Conduct trainings to enhance the skills of the officials** responsible for implementation. Trainings could aim to improve skills in monitoring, supervision, inspections, and other key areas as they relate to Decree 21.
- 5. Conduct more regular and comprehensive trainings of health staff, especially in district hospitals, commune health centers and private health facilities. Special focus should be given to training health staff in how to create an enabling environment for breastfeeding that includes counseling for pregnant women and mothers. Furthermore, health facilities should enhance self-regulation for Decree compliance.
- 6. Make sanctions for Decree 21 violations more punitive and more frequently enforced. These sanctions should either be incorporated into the Decree, or Decree 45 should be updated to cover all provisions outlined by Decree 21.
- 7. Make inspections related to compliance with Decree 21 a higher priority, more systematic and more regularly executed. The skills of health inspectors should be improved so that they are well-educated on the Decree's provisions as well as the implications of violations of the Decree.
- 8. The Food Safety and Health Department should **regularly review the publication of quality standards, food safety and hygiene** of nutrition products for young children.

1 Introduction

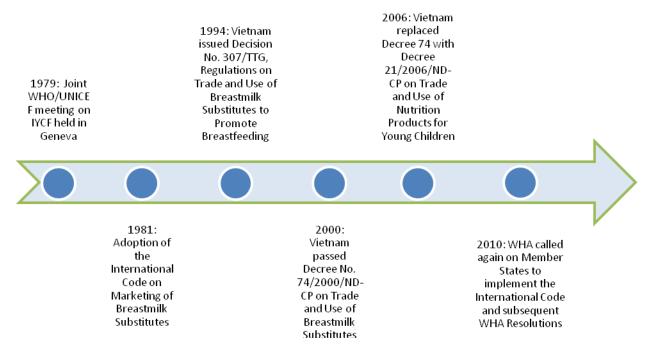
1.1 Background

Alive& Thrive (A&T) and UNICEF are working closely with the Ministry of Health (MOH) to strengthen monitoring and compliance of Decree 21 and the International Code. Decree 21 is planned for revision in 2011. This joint report provides recommendations for revision of the Decree based on findings from an analysis of the Decree's provisions and implementation processes as well as evidence of compliance with and violations of the Decree. Findings are compiled from:

- Reports by 63 Provincial and City Departments of Health and National Pediatrics and Obstetrics and Gynecology hospitals on the implementation of Decree 21 and compiled by the Legislative Department;
- The UNICEF-supported health inspection reports for 8 provinces produced by the Department of Health Inspection; and
- Monitoring data collected by the A&T-trained local health staff in 10 provinces.

Breastfeeding is a key behavior for preventing child malnutrition and improving overall child health and survival. While a number of social and cultural factors influence feeding practices, growing evidence suggests that misinformation about breastfeeding together with widespread availability and promotion of breastmilk substitutes significantly impact the decisions that families make regarding child nutrition.

Figure 1 Timeline for passage of the International Code and Decree 21



In 1979, WHO and UNICEF organized a joint meeting on Infant and Young Child Feeding consisting of 150 representatives from governments, UN organizations and other intergovernmental bodies, non-government organizations, the infant food industry and experts in related disciplines. Recognizing the need for legislative and social action to address unethical and aggressive marketing of breastmilk substitutes, the meeting called for the development of an international code for regulating the marketing of breastmilk substitutes. In response, the World Health Assembly (WHA) adopted the *International Code of Marketing of Breastmilk Substitutes* in 1981 (henceforth referred to as the International Code). The International Code outlines the minimum acceptable requirements concerning the marketing of breastmilk substitutes and related child nutrition products to be adopted by national governments. The International Code has been augmented and clarified by a series of subsequent WHA Resolutions which should be read along with the original Code.

In 1994, Vietnam took its first step to implementing the International Code when the Prime Minister issued Decision No. 307/TTG entitled *Regulations on Trade and Use of Breastmilk Substitutes to Promote Breastfeeding.* The Decision was strengthened with the passage in 2000 of

The Decree has yet to meet the minimum standard set by the International Code and subsequent WHA Resolutions and is therefore categorized as a second level "many provisions law."

Decree No. 74/2000/ND-DP, the *Decree on Trade and Use of Breastmilk Substitutes*. With support from UNICEF and the WHO, Decree 74 was replaced in 2006 with the adoption of Decree No. 21/2006/ND-CP dated 27/2/2006, entitled the *Decree on Trade and Use of Nutrition Products for Young Children*, which is currently in effect (henceforth referred to as Decree 21).

Decree 21 forms a legal base for protecting and promoting breastfeeding practices by limiting illegal and/or inappropriate marketing of nutrition products for young children, a collective term that covers breastmilk substitutes

and other complementary food products, feeding bottles, teats and dummies. The Decree also supports breastfeeding by requiring that information and communication related to infant and child nutrition clearly state the superiority of breastmilk to these products. Although it has many strengths, the Decree has yet to meet the minimum standard set by the International Code and subsequent WHA Resolutions and is therefore categorized as a second level "many provisions law" by the International Code Documentation Center (ICDC), an organization dedicated to keeping track of International Code implementation and compliance worldwide. In addition, Vietnam still faces obstacles to implementation of Decree 21, including weak monitoring of Decree compliance and low enforcement of its sanctions.

Why is Decree 21 important?

"The period between birth and age 24 months provides a unique window of opportunity to promote lifelong health and development through good nutrition. Adequate nutrition during this time can improve future growth, development, educational achievement, and economic status. In contrast, poor nutrition in the earliest months of life can irreversibly stunt a child's growth.

Research conducted by A&T indicates that most Vietnamese children age 0-24 months do not receive the nutrition that they need. Many factors contribute to determining how or what infants or young children are fed, but misinformation about breastfeeding together with widespread availability and promotion of breastmilk substitutes are cited as having a significant impact on the decisions that families make regarding nutrition.

Complying with the Decree will increase optimal infant and young child feeding practices in Vietnam. This in turn will reduce malnutrition and stunting, and ultimately increase the nation's productivity by helping to reduce the burden of disease and contribute to a thriving workforce."

-Alive & Thrive: www.aliveandthrive.org

1.2 Study Objectives

The purpose of this study is to review the implementation status of Decree 21 by accomplishing the following objectives:

- Identify common violations of the regulations stipulated in Decree 21 and the articles of the International Code;
- Examine the strengths and weaknesses of Decree 21;
- Provide recommendations for revision of Decree 21 to strengthen the *Decree on Trade and Use of Nutrition Products for Young Children* in Vietnam and to bring the Decree up to the standards of the International Code and subsequent WHA Resolutions; and
- Outline further recommendations for enhancing implementation and enforcement of the *Decree on Trade and Use of Nutrition Products for Young Children* in Vietnam.

2 Study Design

This joint report is divided into two main parts: a desk review and a monitoring study. For the desk review, the research team examined relevant documents and reports related to the implementation of Decree 21 in Vietnam. These documents are described in more detail in the following section. The desk review also examines the International Code, subsequent WHA resolutions and related laws and policies in Vietnam in an effort to provide a context for the review of Decree 21.

The monitoring study was carried out by A&T in 10 cities/provinces in 2010-2011. This study was independent of the inspections conducted by MOH. A&T trained local health staff to collect

monitoring data from health facilities, pharmacies and retailers in the provinces to gather evidence of Decree 21 and International Code adherence and violations. Results from the data analysis are presented here.

2.1 Desk review

To begin, the research team conducted a desk review of the documents related to the enactment and implementation of Decree 21 (Annex 3). The review is based primarily on:

- The *International Code of Marketing of Breastmilk Substitutes* and subsequent WHA Resolutions (Annex 4), and related laws and policies in Vietnam;
- An Assessment Report produced by the Legislative Department which is based on the compilation of results from the five-year assessment reports generated by 63 Provincial and City Departments of Health and National Pediatrics and Obstetrics & Gynecology (Ob/Gyn) hospitals on the implementation of Decree 21 (Annex 5); and
- Two UNICEF-supported health inspection reports for 8 provinces produced by the Department of Health Inspection of MOH (Annex 6).

In May 2011, the Legislative Department synthesized a report based on the assessments the five-year implementation of Decree 21 conducted by 63 Provincial and City Departments of Health and the National Pediatric and Ob/Gyn hospitals under direct supervision of MOH. These reports were sent to the Legislative Department for compilation in early 2011. The Legislative Department Assessment Report details the passage and dissemination of legal documents related to Decree 21; the achievements and obstacles to implementation of the Decree; and examples of violations of the Decree. It goes on to offer recommendations for strengthening Decree 21.

The Department of Health Inspection (DHI) is responsible for enforcing Decree 21 and carrying out annual monitoring of the Decree in collaboration with other MOH departments. This desk review consults two Inspection Reports developed by DHI in 2011 which document the findings from the UNICEF-supported inspections carried out on the compliance of Decree 21 in 8 provinces in Vietnam. The first inspection was carried out in Hanoi, Quang Ninh, Khanh Hoa, and Da Nang in January 2011, while the second inspection took place in Dien Bien, Ninh Thuan, An Giang and Dong Thap in April 2011. The inspections were conducted at a total of 42 health facilities and 33 distributors located in these provinces/cities. The reports detail achievements and limitations to Decree 21 compliance and implementation as well as violations of the provisions of the Decree.

2.2 Monitoring study

The second part of this joint report presents information and findings from an A&T study which monitored the compliance with and violations of Decree 21 and the International Code in 10 cities/provinces in Vietnam. The monitoring study included both an assessment of health facilities, retailers, and pharmacies by observation. In addition, structured face-to-face interviews with mothers were conducted to gather information on their attitudes about and usage of nutrition

products for young children as well as their experiences of being contacted by nutrition companies and/or offered samples and gifts.

2.2.1 Study sites

The monitoring study was conducted in 10 cities/provinces in which A&T activities are implemented including Hanoi, Tien Giang, Quang Nam, Quang Ngai, Vinh Long, Quang Tri, Quang Binh, Hai Phong, Thanh Hoa, and Thai Nguyen.

2.2.2 Sampling

In each of the study sites, the following health facilities were assessed: hospitals at all levels, provincial and district Reproductive Health Centers (RHCs), maternity homes, and commune health centers. Pharmacies that were included were those in and around the provincial and district hospitals and RHCs. In addition, retailers in the areas surrounding the provincial and district hospitals and RHCs were included in the assessment.

The number of health facilities and retailers for each study site were determined based on discussions between the A&T team and health staff (focal people working for the A&T project within the study sites) during the training of trainer (TOT) course in Hanoi (Annex 7).

The mothers who participated were recruited from the assessed health facilities, pharmacies and retailers.

2.2.3 Data collection

Personnel

Staff members from the Health Inspection Departments, Departments of Medical Professional Monitoring and Supervision, and Departments of Food Safety Inspection of the Provincial and City Departments of Health served as field supervisors (two per province). Most of them were focal people of the A&T project.

The field supervisors trained the data collectors. One data collection team was assembled for each study site. Each team consisted of about 12 to 16 staff members from the district Departments of Health, RHCs, and provincial Departments of Health (including staff from the Health Inspection Departments and Departments of Medical Professional Monitoring and Supervision).

Training of trainers and data collectors

A two-day TOT course for health staff from the A&T project provinces was conducted in Hanoi by A&T in collaboration with MOH. Each province sent two health workers to the TOT course.

A one-day training course for data collectors was led in each study site by the trainers who participated in the TOT course in Hanoi. The A&T team supported the training in each study site. The training content included: Introduction to Decree 21; Assessment and monitoring procedures; Interview and observation procedures; and Administration of the SIM forms.

Data collection tools

Data was collected using a tool developed by the International Baby Food Action Network (IBFAN) to monitor compliance with the International Code and subsequent WHA resolutions – the Standard IBFAN Monitoring (SIM) Forms (Annex 2). While the primary objective of the study was to review Decree 21, this tool allowed the data collection team to gather evidence of both International Code and Decree 21 adherence and violations in a systematic and standardized manner. The SIM Forms are divided into the following categories:

- SIM 1: Interview with mothers
- SIM 2: Advertisement at sales places
- SIM 3: Hospitals and clinics
- SIM 4A: Labeling of milk products for infants under 6 months of age
- SIM 4B: Labeling of milk for infants over 6 months of age, complimentary foods and other breastmilk substitute products
- SIM 4C: Labeling of bottles and teats
- SIM 5A: Informational materials for health workers
- SIM 5B: Informational materials for companies' target audience

SIM forms were used to collect observational data from health facilities, pharmacies and retailers and to collect data from mothers of children under 6 months old.

2.2.4 Data management and analysis

EpiData software was used for data entry of all SIM forms. After fixing entry mistakes identified in the data entry comparison report, the data were set in EpiData. The data were then transferred to SPSS, a statistical analysis software program, and an SPSS dataset with fully labeled variables and response values was finalized.

SPSS version 17.0 was used for data analysis. Descriptive analyses of key indicators in the SIM forms were performed, including mothers' attitudes and behaviors related to the use of nutrition products for infants; interaction/contact between nutrition product companies and mothers/health workers; promotional activities, advertising and informational materials related to nutrition products for young children; labeling of nutrition products covered under Decree 21; and adherence to and violations of Decree 21.Qualitative responses to open-ended questions in the SIM forms were analyzed following qualitative analysis methodology.

3 Study Limitations

The following limitations should be considered when reading this report.

3.1 Limitations of desk review

- It should be noted that the desk review is a summary of the findings presented in the reports provided by the Legislative Department and DHI. The authors of the present review have not elaborated upon nor altered any conclusions drawn by these Departments. In some instances, the information provided in these reports was incomplete (e.g., number of trainings, number of health staff reached, number or location of Decree 21 violations, etc.). In addition, the research team has noted a few areas of contradiction or inconsistency, such as statements of significant progress later followed by examples of far-reaching problems or barriers. This is probably due in large part to incomplete information in the reports provided to the Legislative Department by the provinces. In addition, there were some inconsistencies between the two reports with regards to Decree 21 violations (i.e., DHI reported more Decree violations than the Legislative Department).
- The Legislative Department Assessment Report and the DHI Inspection Reports were descriptive rather than analytic in nature. They listed and described activities without conducting any analyses on the effectiveness and/or results of those activities, making it difficult to interpret their success or impact.
- The Legislative Department Assessment Report compiled information from reports generated by the Provincial and City Departments of Health in 63 provinces. These reports were not based on standard forms or protocol (e.g., SIM forms), and therefore the content and quality of the reports varied by province. In this way, some provinces may be underrepresented in some of the findings, so the desk review should not be considered a comprehensive overview of Vietnam as a whole.
- The sampling procedures for the DHI inspections were purposive, not systematic or random and therefore are not representative of the provinces as a whole. Conclusions can only be drawn on the facilities and shops inspected.
- The inspection procedures were not clearly defined for the DHI inspectors, which increases the likelihood that they did not capture all of the Decree 21 violations.
- With regards to the DHI inspections, DHI did not specify whether or not these inspection visits were unannounced. There is some concern over the possibility of health facilities being given advance notification of inspections and then conducting "clean-ups" before the inspectors' arrival, as has been suspected in past observations.² If this is the case, the number of violations detected by the DHI would be artificially low. It is difficult to ascertain how much or if this influenced the results.

²Report to UNICEF Hanoi to Review Code Implementation in Vietnam by ICDC, 2008.

- The Legislative Department and DHI reports pointed out limitations to Decree 21 implementation at the provincial level, but failed to give detailed explanations for why these limitations exist. For example, the reports mention a lack of support from local authorities but are not clear about why this is so.
- Noticeably, neither the Legislative Department Assessment Report nor the DHI Inspection Reports mention instances where sanctions were given in response to Decree 21 violations (with one exception). It is unclear if this is because no punitive actions were taken against the violators or if these reports just failed to mention these actions.
- The reports did not provide reliable information on the core IYCF indicators (e.g., early initiation of breastfeeding within one hour of birth and exclusive breastfeeding) due to the lack of availability and reliability of data from the provinces and other health facilities.
- The reports did not always give specific recommendations for the revision of Decree 21 as they often only mentioned 'what' should be revised, but not always 'how' to do so.

3.2 Limitations of monitoring study

- The SIM forms used for data collection were designed for monitoring the implementation of the International Code, not Decree 21. Therefore, Decree 21 compliance and violations were sorted out during the data analysis phase. Much of the data relied upon the written observations of the data collection teams, which were not always very clear or detailed. Consequently, it is likely that some of the Decree violations went undetected in the final report.
- There were limitations in the standardization of data collection. A large number of data collectors were involved, and out of necessity, these collectors attended different trainings based on the province they were in. While the training courses were conducted in a standardized manner, 11 training courses were conducted by different trainers in 11 provinces.
- Although the data collectors underwent training before the study, due to the confusing nature of some of the Decree's provisions, it is possible that the data collectors did not capture all of the violations of Decree 21. There is also the possibility that some of the recorded violations were in fact cases in which companies exploited the loopholes present in Decree 21, and therefore not technically violations (especially in the case where the Decree sets age limits in its provisions). However, this likely applies only to a small number of the recorded violations as the data analysis favored a conservative approach to recording violations. When it was unclear, the research team categorized cases as non-violations. Moreover, those cases that exploit loopholes are almost always violations of the International Code and serve the overall purpose of promoting nutrition products over breastfeeding. The findings of this report should not be considered conclusive, but rather an overview of the situation of Decree 21 and International Code implementation in Vietnam.

• Due to budget and time limitations, a full monitoring or inspection study could not be carried out in all 63 provinces in Vietnam. Sampling in each of the included provinces was not systematic: the facilities, retailers, and mothers were chosen purposively. Therefore, the monitoring study provides a general snapshot of the implementation of Decree 21, but may not be representative of the provinces or Vietnam as a whole.

4 Results from Desk Review

| Ways in which Decree 21 does not meet the minimum requirements set by the International Code | | |
|--|---|--|
| International Code | Decree 21 | |
| Article 3. Definitions | Does not define key terms such as: distributor, manufacturer, or marketing personnel. | |
| Article 4. Information and Education | Provisions for IEC content do not cover all of the informational points contained in the International Code. | |
| | Donations of informational and educational equipment or materials are not regulated outside of health facilities. | |
| Article 5. General Public and Mothers | Allows for the advertising of breastmilk substitutes for children aged 12-24 months, with some restrictions. | |
| | Does not prohibit manufacturers and distributors from providing samples to pregnant women, mothers or their families or from conducting other promotional sales tactics at retail shops. | |
| | Only disallows contact with women and their families within health facilities and only when that contact is to sell or promote milk products for children under 12 months old and food products for infants under 6 months old. | |
| Article 6. Health Care Facilities | Allows for the sale, promotion and advertisement of milk products for children under 12 months old and complementary food products for infants under 6 months old in hospital pharmacies. | |
| | Does not prohibit the advertising or donation of milk products for children older than 12 months or food products for those older than 6 months in health care facilities. | |
| Article 7. Health Workers | Allows health staff to receive breastmilk substitutes for children older than 12 months. | |
| | Does not specify requirements for informational content in IEC materials provided to health care workers. | |
| Article 8. Persons Employed by Manufacturers and Distributors | Contains no provisions banning the use of quotas and bonuses tied to sales volume for marketing personnel. | |
| and Distributors | Does not ban marketing personnel from performing educational functions in relation to pregnant women or mothers of young children. | |

| Article 9. Labeling Does not require a warning against the health hazards of inapp preparation of nutrition products under the scope of the Decree. | |
|---|---|
| | Does not require a warning be included on food products that can be modified to meet the requirements for infant formula. |
| | Does not require that labels state the storage conditions necessary for preservation of the products. (However, this is covered by the Law on Food Hygiene and Safety.) |

4.1 Comparison with the International Code of Marketing of Breastmilk Substitutes

Article 2: Scope of the Code

Article 2 of the International Code states that the Code applies to products that are marketed or otherwise represented as a partial or total replacement for breastmilk, including infant formula, other milk products, food and beverages. It also applies to feeding bottles and teats.

The scope of Decree 21 is covered in Articles 1 and 2. In Article 1, entitled 'Scope and Application,' Decree 21 defines the scope of the Decree as information, education, advertising, marketing and use of <u>nutrition products</u> for young children, feeding bottles, teats, and dummies. In Article 2, 'Definitions,' the Decree specifies that nutrition products for young children include milk and food products for children 0-6 months of age, milk for children 6-24 months of age, and complementary food for children 6-24 months of age.

Unlike the International Code, Article 1 of Decree 21 does not explicitly mention product quality or availability, nor does it contain information concerning the use of mentioned products.

Article 3: Definitions

In general, Article 2 of Decree 21 provides definitions for most key concepts/words/phrases defined in Article 3 of the International Code such as infant formula and complementary food.

Different from the International Code, however, Decree 21 does not define an equivalent term to the term 'breastmilk substitute' to emphasize the products' replacement (partial or total) for breastmilk. A general term - 'nutrition products for young children' is defined instead and this term covers milk and complementary food for young children from birth to 24 months of age.

In Article 2, Decree 21 does not have definitions for 'distributor', 'manufacturer' or 'marketing personnel' as does the International Code.

Decree 21 applies to:

- Milk and food products for infants under 6 months of age
- Milk products for children between 6 and 24 months of age
- Feeding bottles
- Teats and dummies

Article 4: Information and Education

In Chapter 2, Article 3 entitled 'Information, education and communication on the benefits of breastfeeding,' Decree 21 is compatible with the International Code (Article 4.1) as it clearly states the responsibilities of the Government and other related ministries and sectors in providing information and education on the benefits and superiority of breastmilk, the importance of exclusive breastfeeding and maintenance of breastfeeding.

In Chapter 2, Articles 4 and 5, Decree 21 covers in detail the information and education on key points specified in the International Code (Article 4.2) including: the benefits and superiority of breastfeeding; the preparation for and maintenance of breastfeeding; the negative effects of not breastfeeding; negative effects of bottle-feeding for infants under 6 months of age; the social and financial implications of the use of infant formula; and the health hazards of complementary food for infants under 6 months of age.

Although Decree 21's Chapter 2 on information and education is extensive, some important points are not mentioned including: the negative effects of partial bottle-feeding on breastfeeding; the difficulty of reversing the decision not to breastfeed; and the proper use of infant formula, whether manufactured industrially or home-prepared.

Additionally, donation of informational and educational equipment or materials is not included in Chapter 2 of Decree 21. The International Code regulates all donations made by manufacturers and distributors (Article 4.3), but Decree 21 only regulates donations to health facilities and health staff (Article 10.2.c). While the International Code stipulates that donations should be made only at the request and with written approval from a government authority and that should only be distributed through the health care system, Decree 21 does not have these regulations.

Article 5: General public and mothers

While the International Code does not allow for any advertising or other forms of promotion of products to the general public (within the scope of the International Code), **Decree 21 (Article 6) allows for advertising of milk products, including breastmilk substitutes, for children 12-24 months of age** so long as this advertising contains the statement, "Breastmilk is the best food for the health and overall development of infants" and conforms to the Advertising Ordinance and Articles 4 and 5 of the Decree. (Decree 21 prohibits advertising of milk products for children less than 12 months of age and milk/complementary foods for infants less than 6 months old).

Decree 21 does not have an equivalent article to International Code Article 5.2 prohibiting manufacturers and distributors from providing samples of products, directly or indirectly, to pregnant women, mothers or members of their families.

Decree 21 does not have an equivalent article to International Code Article 5.3 regarding no point of sale advertising, giving of samples, or any other promotional device to induce sales directly to the consumer at the retail level.

Articles 5.4 and 5.5 of the International Code prohibit marketing personnel from seeking direct or indirect contact of any kind with pregnant women and mothers. These Articles also prohibit manufactures and distributors from giving any gifts to pregnant women or mothers which may promote the use of breastmilk substitutes or bottle-feeding. On these issues, Decree 21 is not as prohibitive as the International Code. Article 10.2.b of Decree 21 prohibits company representatives from contacting mothers, pregnant women, or family members at health facilities only in order to sell or promote milk products for children less than 12 months of age or complementary food for infants less than 6 months of age; by default, the Decree allows for contact with mothers to promote milk products for children aged 12 to 24 months or complementary food products for those over 6 months of age.

Decree 21 only focuses on company representatives' contact with mothers at health facilities and prohibits health workers from helping these representatives give gifts to mothers. **Under the Decree, company representatives are not prohibited from contacting pregnant women and mothers outside of health facilities or indirectly via the mail or internet.**

Article 6. Health care systems

The International Code is stronger than Decree 21 since it prohibits all advertising, promotion, and sale of all products within its scope at health facilities. By contrast, Decree 21 prohibits advertising, promotion, and sale of milk products for infants less than 12 months and complementary food for infant less than 6 months of age at health facilities with the **exception of hospital pharmacies**. There is no prohibition on advertising of breastmilk substitutes for infants older than 12 months of age or complementary food products for infants older than 6 months of ate. The Decree also allows for advertising of milk products at hospitals' pharmacies.

Article 10.2.c of Decree 21 is similar to Article 6.8 of the International Code, but it is not as prohibitive. Like the International Code, Decree 21 prohibits donation of nutrition products for young children as well as materials or other forms of expression from bearing the names or logos of these products (these materials may bear the donating company's name or logo). Decree 21 only applies to milk products for infants under 12 months old and complementary food products for infants under 6 months old. Therefore, **donations of milk products for children 12 to 24 months of age and complementary food products for children older than 6 months are not prohibited, nor are any materials bearing the names or logos of these products.**

Article 7. Health workers

In Article 12.2, Decree 21 prohibits health staff from receiving milk products for infants under 12 months of age and complementary food for infants under 6 months of age or materials with the name of these products. The Decree does not prohibit health staff from receiving breastmilk substitutes for infants older than 12 months or complementary food products for infants older than 6 months.

In terms of responsibilities of health workers in encouraging breastfeeding and providing instructions to mothers on the use of nutrition products for young children, Decree 21 is compatible with the International Code.

Article 7.2 of the International Code requires that IEC materials for health professionals contain the information specified in Article 4.2 of the Code. **This provision is missing from Article 10.1 of Decree 21.**

Article 8. Persons employed by manufacturers and distributors

Decree 21 does not have an equivalent article to Article 8 of the International Code, which prohibits applying quotas to the sale of products covered in the International Code and prohibits including the volume of sales in the calculation of bonuses given to marketing personnel. Article 8 of the International Code also prohibits marketing personnel from performing educational functions in relation to pregnant women or mothers of infants and young children.

Article 9. Labeling

Decree 21 does not fully comply with the International Code on labeling of nutrition products for young children. First, while Decree 21 requires labels to include instructions for the proper use of nutrition products for young children, it does not specify that there should also be a warning against the health hazards of inappropriate preparation as specified in the International Code. Second, the Decree does not contain a provision comparable to Article 9.3 of the International Code regarding food products that can be modified to meet requirements for infant formula. According to the International Code, these products' labels should carry a warning that the unmodified product cannot be the sole source of nourishment for an infant. Third, Decree 21 does not explicitly require that labels state the storage conditions required for preservation of the food products, although this is required under the Law on Food Hygiene and Safety.

Article 9 of Decree 21 goes beyond the International Code by applying labeling provisions to bottles and teats.

Article 10. Quality

Decree 21 does not have a separate article equivalent to Article 10 of the International Code. However, the quality of nutrition products covered in the Decree is mentioned under Articles 7 and 10. Article 7 stipulates that the regulated products must announce or inform the public of their quality standards in accordance with national law (i.e., Law on the Quality of Products and Goods and the Law on Food Hygiene and Safety.) Article 10.1.a. states that the heads or legal representatives of manufacturers must only sell products in accordance with food safety and hygiene standards in accordance with national law.

4.2 Decree 21 in relation to laws, regulations, and policies

In Vietnam, there is no unified food law nor is there one government ministry charged with overseeing all regulations related to food products. Rather, there are separate laws/provisions that regulate the quality of goods in general as well as food products specifically. Multiple government ministries are responsible for the implementation of these regulations.

While Decree 21 specifically regulates nutrition products for young children, these products are also subject to regulations of food products and goods in general. The chart below provides a summary of the government ministries and laws related to the regulation of those products within the scope of Decree 21.

| Government ministries responsible for the regulation of nutrition products for young children within the scope of Decree 21 | | |
|--|---|---|
| Ministry | Law or Ordinance | Roles/Responsibilities |
| Ministry of Agriculture and Rural Development (MARD) | Law on Food Hygiene and Safety (Article 63, Clause 3) Dated July 22, 2010, with effect from July 1, 2011 | Responsible for food hygiene and safety during the processes of production, preservation, transportation, import/export, and trade of food stuffs, including fresh milk |
| Ministry of Industry and Trade (MOIT) Law on Food Hygiene and S (Article 64, Clause 2) | | Responsible for food hygiene and safety during the processes of production, preservation, transportation, import/export, and trade of food stuffs, including processed milk |
| Dated June 14, 2005 of domestic and imported | | Responsible for trade, marketing, and labeling of domestic and imported commodities and protecting consumer rights |
| Ministry of Health (MOH) | Law on Food Hygiene and Safety | Sets standards for hygiene and safety of food products, including milk products |
| | Regulations on Announcing Food Standards | Processes applications for food registration from all individuals and organizations that produce food products and food additives; and conducts periodic inspections of these products |
| -Ministry of Education and Training (MOET) -Ministry of Culture, Sport and Tourism (MOCST) -Ministry of Labor, Invalids and Social Affairs (MOLISA) -Ministry of Health (MOH) | Law on Protection, Care and Education of Children Dated June 15, 2004 | Responsible for the protection, care and education of children in coordination with mass organizations such as the Women's Union, Youth Union, and Fatherland Front Committee |
| Ministry of Culture, Sport and Tourism (MOCST) | Advertising Ordinance Dated November 16, 2001 | Responsible for oversight of advertisements. Ordinance states that "advertisements should be accurate, clear, faithful, and should not be harmful for producers, traders or consumers." |

| -Ministry of Culture and Information (MOCI) -Ministry of Health (MOH) | Inter-ministerial Circular 01/2004/TTLT-BVHTT-BYT on Advertising Activities in the Domain of Health Dated January 12, 2004 | Responsible for ensuring that food advertisements "accurately describe the quality of the food products" and "include guidance on use and preservation of those foods for which guidance is required." |
|---|--|--|
| Ministry of Science and Technology (MOST) | Law on the Quality of Products and Goods Dated July 1, 2008 | Responsible for quality of commodities, including food. Law forbids the "untruthful information or advertisements on the quality of products, commodities and original sources." |

Similar to food laws in Vietnam, multiple laws and provisions apply to the implementation of Decree 21. Implementation involves the coordination of multiple government ministries and agencies. The following chart outlines the laws and provisions related to the implementation of the Decree.

| Laws and provisions related to the implementation of Decree 21 | | |
|--|---|--|
| Law/Provision | Details | |
| Joint Circular No. 10/ 2006/ TTLT-BYT-BTM-BVHTT-UBDSGDTE Dated August 25, 2006 | Issued by the MOH, MOIT, MOCI, and the Commission for Population, Family and Children (CPFC), it guides the implementation of Decree 21. | |
| Decree No. 45/2005/ND-CP Dated April 6, 2005 | Details sanctions on administrative violations in the health sector, including penalties for violations of regulations on the production, advertising, marketing, and use of products within the scope of Decree 21. | |
| Decree No. 89/2006/ND-CP Dated August 30, 2006 | Key legislation on the labeling of goods, including those within the scope of Decree 21; it applies to all goods produced in Vietnam for distribution within the country and for export. It applies equally to foreign-made goods imported for sale in Vietnam. | |
| Decree No. 24/2003/ND-CP Dated March 13, 2003 | Provides detailed regulations for implementing the Advertising Ordinance. | |
| Circular No. 43/2003/TT-BVHTT Dated July 16, 2003 | Issued by MOCI, it provides further guidelines for implementing Decree 24 and the Advertising Ordinance. | |
| Joint Circular No. 06/2007/TTLT-BVHTT-BYT-BNN-BXD Dated February 28, 2007 | Issued by MOCI, MOH, MARD and the Ministry of Construction (MOC), it provides detailed procedures for obtaining advertising permits for food products and food additives, including those regulated under Decree 21. | |
| Circular No. 30/2010/TT-BYT Dated June 2, 2010 | Issued by MOH, it provides national technical standards for liquid milk products. | |
| Circular No. 31/2010/TT-BYT Dated June 2, 2010 | Issued by MOH, it provides national technical standards for powdered milk products. | |

| Circular No. 32/2010/TT-BYT Dated June 2, 2010 | Issued by MOH, it provides national technical standards for cheese products. |
|---|--|
| Circular No. 33/2010/TT-BYT Dated June 2, 2010 | Issued by MOH, it provides national technical standards for dairy fat products. |
| Master plan for Vietnam dairy development up to 2020, with a vision to 2025 | Developed by MOIT, it includes industry standards, technical regulations, and manuals for managing the production and trade of dairy products. |

4.3 Implementation of Decree 21 at the provincial level

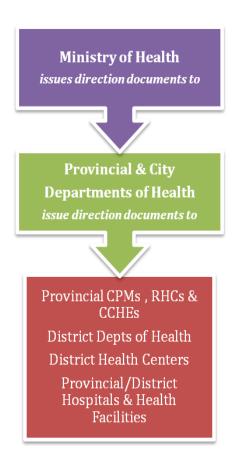
Legal documents to implement Decree 21 at the provincial level

According to reports by some Provincial Departments of Health, in order to mobilize the cooperation and support from all relevant sectors in implementing Decree 21, the Provincial People's Committee (in consultation with the Provincial Department of Health) issues documents specifying the responsibilities for each relevant provincial agency (e.g., Department of Health, Department of Culture and Information, Department of Trade, Department of Market Supervision, Provincial Television, CPFC, Women's Union, Youth Union, etc.) in implementing Decree 21 and

Joint Circular 10. The rest of the reports from the Provincial Departments of Health do not mention any intersectoral cooperation in the implementation of Decree 21. Without intersectoral cooperation, implementation of Decree 21 will be less effective because the Decree crosses the domains of multiple sectors.

Every year, following annual direction documents from MOH, the Provincial and City Departments of Health issue documents directing district Departments of Health, District Health Centers, provincial hospitals, district hospitals, Centers for Preventive Medicine (CPMs), RHCs, Centers for Communication and Health Education (CCHEs), and health facilities to implement Decree 21 by following the guidelines outlined in Joint Circular 10. In most localities, the Provincial PMC and RHC are placed in charge of direct coordination and implementation of Decree 21.

The implementation of Decree 21 and Joint Circular 10 in the provinces is put into practice through a series of action plans that incorporate the documents' stipulations. Some examples include the Action Plan for Infant Feeding; Child Survival Action Plan; Action Plan Month for Children; Annual Malnutrition Prevention Plan; Breastfeeding Week; Nutrition and Development Week; and the Baby-Friendly Hospital Maintenance and Implementation Plan.



Among those Provincial and City Departments of Health with enough funding, interdisciplinary inspection and supervision activities have been established to monitor business practices for compliance with the provisions of Decree 21 and related regulations.

Communication and dissemination of the Decree 21 and Joint Circular 10 at the provincial level

Documents related to the implementation of Decree 21 are disseminated to representatives of the Departments of Health and the Central Hospital. Information regarding Decree 21 and Joint Circular 10 is communicated to health facilities through organized events such as conferences and training courses for leaders, inspectors, and heads of health facilities. Additionally, content from the Decree and Circular are often integrated into related programs for health staff including informational campaigns and training courses on encouraging breastfeeding and discussions on care of pregnant women and infant nutrition. For example, the Kon Tum Department of Health incorporated content from these regulations into its annual communication plan for legal education.

Content from Decree 21 has also been compiled into books and documents for distribution to mothers, health workers, and mass media outlets (e.g., radio and television stations). Some provinces that have utilized mass media for communication include NgheAn, Ba RiaVung Tau, Ha Nam and Ben Tre.

4.4 Achievements in the implementation of Decree 21

Key Achievements in Decree 21 Implementation

- Breastfeeding is promoted through IEC campaigns such as National Breastfeeding Week, Nutrition and Development Week, and Micronutrient Day.
- Some provinces and cities have made significant progress in promoting breastfeeding to the
 public through activities such as counseling from health staff, breastfeeding and nutrition
 classes, community forums, and dissemination of informational materials like brochures,
 leaflets and flyers.
- Over the last 5 years, IEC activities and trainings for health staff have increased in provinces throughout Vietnam. These activities aim to increase health staffs' knowledge and awareness of optimal IYCF practices, maternal and child nutrition, and Decree 21.
- Many health facilities were found to be implementing the 10 conditions for successful breastfeeding.
- All 8 localities inspected by DHI had conducted annual Decree 21 inspections as part of broader food hygiene and safety inspections.
- The reports conclude that, in general, most hospitals comply with most of the regulations of

Decree 21.

- Many health staff working directly in Ob/Gyn and pediatrics were found by DHI to be enthusiastic and experienced in promoting and encouraging breastfeeding.
- Most nutrition products for young children were found to meet quality standards set by the FHSA, and <u>most</u> comply with labeling provisions.

4.4.1 Achievements in information, education, communication and advertising

IEC activities and trainings for health staff

The task of promoting IEC related to Decree 21 falls primarily to the Provincial and City RHCs and CCHEs. According to the Legislative Department Assessment Report, over the last five years, improving IYCF has been given priority in IEC programs that aim to reduce malnutrition in children. The report details a number of IEC activities implemented throughout the country that support the goals and provisions of Decree 21.

The Legislative Department reported that in the last five years, Provincial and City CCHEs have conducted IEC activities reaching most of the health staff in their provinces/cities (including doctors, nurses, hospital employees and other medical personnel) and collaborators. IEC activities take a variety of forms such as training courses, conferences, lessons integrated into lectures for postgraduate and medical students, presentations for health staff, informational materials posted in

Ob/Gyn departments, local mass media, and the Protein-Energy Malnutrition (PEM) Program. Topics covered in these activities include: a) caring for mothers and children; b) regular nutrition; c) the importance and benefits of breastfeeding; d) how to conduct IEC activities related to breastfeeding and proper nutrition; e) providing breastfeeding counseling and support to mothers, especially those who are encountering problems; and f) contents of Decree 21 and the consequences of Decree violations as outlined in Decree 45. It should be noted, however, that the Legislative Department Assessment Report did not provide information on the exact number or proportion of health staff reached by these activities, nor did it provide details on specific activities.

The DHI Inspection Reports confirm that breastfeeding was regularly discussed in trainings and professional development at health facilities. In particular, these reports stated these events focused on creating the 10 conditions

Optimal infant and young child feeding practices

- Breastfeeding within an hour of birth
- Exclusive breastfeeding for the first
 6 months of life, defined as
 breastfeeding only, not even other
 liquids such as water
- Beginning nutritious complementary foods at age 6 months, along with continued breastfeeding up to two years, and beyond, if desired

for successful breastfeeding in health facilities and training health staff to encourage and support mothers to engage in optimal IYCF practices.

For example, according to the Legislative Department, the Central Children's Hospital has engaged in a number of training activities for its staff. It opened a new training course for health staff on how to disseminate knowledge and education about breastfeeding and proper nutrition. The hospital has also integrated breastfeeding topics into lectures for postgraduate students and pediatric medical students practicing at the hospital. Skills related to advocacy, guidance and assistance with breastfeeding for mothers with children less than 1 month old have been included as one of the evaluation criteria for nurses working with infants and young children. Moreover, some hospitals have posted materials on the "10 conditions for successful breastfeeding" in Ob/Gyn and pediatrics divisions, and the DHI Inspection reports state that, in general, the inspected health facilities are implementing the 10 conditions.

Annually, numerous Provincial and City RHCs implement trainings for health staff and conduct IEC activities to promote knowledge and skills related to breastfeeding. These activities are included as part of the PEM Program activities such as Breastfeeding Week, Nutrition and Development Week, and Micronutrient Day. For example, with the support of the Breastfeeding Program, trainings on breastfeeding have been organized for health staff of the Reproductive Health Care Team of the Pediatrics and Ob/Gyn departments of provincial and district general hospitals and commune health centers. Provinces that have adopted this method of IEC include Son La, Ha Nam, Hai Duong, Ninh Binh, Lao Cai, Tuyen Quang, Hai Phong, Dien Bien, Bac Giang, Bac Kan, Thanh Hoa, Da Nang, Quang Nam, Khanh Hoa, Dak Nong, Ba Ria Vung Tau, Tay Ninh, Long An, Ho Chi Minh City, Dong Thap, Dong Nai, and Hau Giang.

Achievements in IEC activities for pregnant women, mothers of infants and young children and the general public

The Legislative Department reports that a number of RHCs, CCHEs, hospitals, and Departments of Health have organized IEC activities for pregnant women, mothers of Suboptimal breastfeeding accounts for 1.4 million deaths in children under 5 annually.

Benefits of Breastfeeding:

- Provides all nutrition infants need in the first 6 months of life
- Breastmilk contains antibodies that protect babies from infections
- Breastfeeding helps mothers bond emotionally with their babies
- Breastfed children perform better on intelligence tests later in life
- Breastfeeding is associated with long-term health benefits including reduced incidence of cancer, diabetes, ulcerative colitis
- Breastfeeding confers health benefits to mothers as well
- Costs less than breastmilk substitutes

Risks of <u>NOT</u> breastfeeding:

- In <u>children</u>, increased risk of:
 - diarrhea& gastroenteritis
 - ear infection
 - eczema
 - leukemia
 - diabetes
 - childhood obesity
 - sudden infant death syndrome
- In mothers, increased risk of:
 - breast cancer
 - ovarian cancer
 - retained weight gain after delivery
 - diabetes
 - heart attack

Sources

Bhutta et al. (2008). What Works? Interventions for maternal and child undernutrition and survival. The Lancet, Vol 371(9610).

Steube A. (2009) The Risks of not breastfeeding. Review in Obstetrics and Gynecology. Vol 2 (4).

young children, and Women's Union members in the form of counseling and training. Some of the topics covered include: how to breastfeed and express breastmilk; initiating breastfeeding within an hour of birth; benefits of breastfeeding and consequences of bottle-feeding; infant and child care, including safe IYCF practices; detecting and combating childhood illnesses; nutrition for pregnant women, mothers and children; and Decree 21.

At the provincial and city level, some of the IEC and advertising activities that promote breastfeeding and Decree 21 to pregnant women, mothers and the general public involve counseling, trainings, and classes. A number of hospitals state that health staff trained in breastfeeding offer direct guidance and support to mothers and pregnant women. The Legislative Department Assessment Report provides some examples: the Central Obstetrics Hospital, Central Children's Hospital, and hospitals in Son La, Da Nang and Tuyen Quang arranged for counseling for pregnant women in antenatal clinics via videos, talking directly with mothers, and offering pregnant women and mothers of young children instructions on nutrition practices. Other examples are the Thai Nguyen Department of Health, which has organized 40 classes on

breastfeeding at the provincial and district levels and held 3500 community forums on the subject, and the Da Nang Department of Health, which provides nutrition counseling for an average of 1200 mothers per year.

In addition to offering counseling and training to mothers and pregnant women, IEC materials such as flyers, leaflets, brochures and guides are often distributed to women and their family members in Ob/Gyn hospitals or health centers. For instance, the Legislative Department reports that the Kon Tum Department of Health developed, printed and distributed a large number of IEC materials on breastfeeding and Decree 21 to city and district health centers, including but not limited to 1000 handbooks

The Da Nang Department of
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breastfeeding.

entitled *Breastfeeding*; 80,000 leaflets and 16,500 posters called *Safe Motherhood and Infant Care*; and thousands of leaflets called *A Hallmark of Violations of Decree 21*. Additionally, the Ben Tre Department of Health distributed 6000 *Handbooks of nutrition care for pregnant women* to women attending examinations at Ob/Gyn clinics and commune and ward health centers in Can Tho city. Other Provincial and City Departments of Health that have compiled and distributed similar IEC materials include those in Ho Chi Minh City, Ha Nam, Hau Giang, and Thai Nguyen.

The Legislative Department Assessment Report goes on to state that localities have also used banners, Women's Union meetings and events, community talks, workshops, seminars, community loudspeakers, mass media and other means to communicate IYCF messages. One of the most visible campaigns occurred during Breastfeeding Week in which UNICEF partnered with MOH and other organizations to carry out a range of activities throughout the country to promote and encourage breastfeeding. These activities have included radio and television spots, including a segment on "Sunday at Home," a popular television program in Vietnam.

The Ho Chi Minh City Department of Health employed an innovative method by developing a Web-Medinet forum as well as electronic and printed newspapers to promote optimal IYCF practices and to publicize violations of Decree 21. The Dong Nai Department of Health utilized a local area network to deliver health messages to women directly in their hospital beds, especially those in the Ob/Gyn division. These patients received further support from breastfeeding consultant team.

Also innovative is the Long An Department of Health's establishment of 72 breastfeeding clubs and organization of 10 breastfeeding contests in which contestants were tested on their IYCF and nutrition knowledge. In at least one case, IEC activities have reached beyond health staff and mothers. The Ho Chi Minh City Department of Health held a workshop for 52 reporters on the need for strengthening breastfeeding. In addition, the Legislative Department reports that mass media organizations in Quang Nam have agreed not to run advertisements for any nutrition products for young children.

4.4.2 Achievements in monitoring and supervision of Decree 21

At the national level, MOH, in coordination with MOIT, MOCST, and CPFC, is in charge of monitoring and supervision of the implementation of Decree 21. The Department of Health Inspection of MOH carries out annual monitoring in collaboration with other MOH departments and relevant agencies. In recent years, DHI has conducted inspections in health facilities in select provinces and cities, including Hanoi, Quang Ninh, Khanh Hoa, Da Nang, Dien Bien, Ninh Thuan, An Giang and Dong Thap.

The DHI Inspection Reports state that all eight localities inspected in 2011 have conducted annual inspections and supervision on the compliance with Decree 21 within their province/city. Although there was often no separate inspection or supervision focusing solely on the implementation of Decree 21, these activities were incorporated in the inspection and supervision of food safety and hygiene.

4.4.3 Compliance with Decree 21 among nutrition product companies

DHI found that most of the inspected retailers had obtained a Certificate of Hygiene and Safety Registration, the certificate needed in order to advertise a food product or food additive. Those facilities without certificates were in the process of applying for certificates. According to the Legislative Department Assessment Report, most manufacturers of nutrition products for young children meet quality standards. Similarly, the DHI inspection also found that most dairy products in retail outlets met the product standards of the Food Hygiene and Safety Administration (FHSA). While the Legislative Department reports that no products examined for the assessment were past their expiration dates and all displayed a certification number for quality standards, the DHI inspections found cases in which products had expired or were missing quality standard certificates.

The Legislative Department and DHI reports state that <u>most</u> of the nutrition products for young children being sold by distributors had full and correct labeling in accordance with Decree 21 provisions. Additionally, the Legislative Department reported that advertisements for nutrition products for young children did not violate Decree 21 in the provinces Ha Nam, Phu Tho, Hai Duong, and Long An.

4.4.4 Compliance with Decree 21 among health facilities

The provincial reports and Legislative Department Assessment Report conclude that, in general, hospitals comply with most of the regulations of Decree 21. In addition, hospitals and pediatric divisions are periodically monitored to ensure they meet the 10 conditions for successful breastfeeding, and the results of the DHI Inspection Reports indicate that, in general, most of the inspected health facilities met the 10 conditions. In addition, a majority of the heads and health staff of health facilities complies with the interdicts of Decree 21.

The assessment conducted by the Legislative Department and the provincial reports did not identify any health staff who received nutrition products for young children that are prohibited under the Decree or material benefits or products featuring the names or logos of regulated products. Moreover, the assessment failed to find health workers who advised women to use nutrition products for young children unless it was deemed medically necessary to do so. DHI confirmed that no cases were detected of health staff providing restricted milk products directly in hospitals.

The Legislative Department Assessment Report and provincial reports state that, according to representatives of the local health facilities, nearly all facilities comply with Decree 21 by

"Health care systems, and the health professionals and other health workers serving them, have an essential role to play in guiding infant feeding practices, encouraging and facilitating breastfeeding, and providing objective and consistent advice to mothers and families about the superior value of breastfeeding..."

World Health Assembly, International Code of the disallowing the sale of food for infants under 6 months of age or milk products for those under 12 months of age, except in the facilities' pharmacies. Also in accordance with the Decree, these representatives reported that companies selling or producing the nutrition products for young children are not allowed to display their products anywhere besides the hospital pharmacy.

In general, the Legislative Department's Assessment concludes that some hospitals provide an enabling environment that supports breastfeeding and other optimal IYCF practices through guidance and counseling. For example, in Ho Chi Minh City, mothers facing difficulties in breastfeeding are given counseling over the phone. A number of other health facilities provide small areas for breastfeeding consultations, posters advocating breastfeeding, leaflets offering breastfeeding advice, and health staff ready to support mothers' breastfeeding efforts.

4.4.5 Knowledge and attitudes of health staff

Many health staff working directly in Ob/Gyn and pediatrics were found by DHI to be enthusiastic and experienced in promoting and encouraging breastfeeding to mothers. These staff were also found to promote breastfeeding within an hour of birth (except in special cases) and to provide good, clear instructions to mothers in relation to breastfeeding techniques, maintaining levels of milk even when away from infants, and encouraging breastfeeding on demand.

4.4.6 Achievements in decreasing the usage of breastmilk substitutes in health facilities

According to the Legislative Department Assessment Report, representatives from local health facilities maintain that only preterm infants, infants with pediatric pathology, abandoned infants, and those with mothers who are unable to breastfeed are fed other milk/formula in place of breastmilk. Most dairy products for children under 12 months old are provided in the hospital pharmacy and available only to those with a doctor's or nutritionist's prescription.

The proportion of mothers who breastfeed within the first 24 hours in health facilities is uneven between localities, but some localities report early initiation rates at higher than 90% (e.g., PhuTho, Yen Bai, BacKan, and Lao Cai).

4.5 Limitations to implementation of Decree 21 and violations of Decree 21

Key Limitations to Decree 21 Implementation, Monitoring and Supervision

- Decree 21 is a low political priority, and funding for enforcement of the Decree is inadequate.
- Cohesiveness, coordination and consultation between the relevant sectors involved in the implementation of Decree 21 are limited.
- Monitoring activities on compliance with Decree 21 are infrequent, incomprehensive, and poorly coordinated due in part to work overload and the limited number and skills of inspection staff.
- Violations of Decree 21 are often not pursued, and sanctions are at times unclear and not punitive enough to be a deterrent to violators.
- Numerous violations of Decree 21 were found, some of which are relatively widespread such as improper advertising and labeling of nutrition products.
- Confusion remains over what constitutes a violation of Decree 21, especially as marketing strategies of nutrition product companies become more pervasive and sophisticated.
- Breastfeeding promotion efforts and IEC materials remain inconsistent in quality, quantity, and reach. Consequently misconceptions and misunderstandings persist around Decree 21, the benefits of breastfeeding, and the risks of not breastfeeding.
- Breastfeeding promotion activities must compete with nutrition product companies which spend vast sums of money to advertise and promote their products. Plus, oversight and monitoring of advertising is weak.
- Despite improvements in training, gaps in knowledge, awareness and skills related to IYCF and Decree 21 persist among health staff. Trainings are not consistent, comprehensive, frequent or widespread.
- Many health facilities are not fully equipped with resources to provide mothers with full breastfeeding support such as counseling rooms and IEC materials.

4.5.1 Cooperation between relevant sectors

According to the Legislation Department Assessment Report, because the local governments in several provinces do not place high priority on the implementation of Decree 21, the Provincial People's Committees do not issue direction documents requesting coordination and cooperation among relevant sectors and specifying the responsibilities of each sector. In these provinces, the Department of Health has been solely responsible for monitoring and supervising the implementation of Decree 21. The lack of coordination and cooperation between multiple sectors

almost certainly results in weaknesses in the implementation of Decree 21 in these provinces. The problem is exacerbated by the limited funding for the implementation of Decree 21.

4.5.2 Limitations in monitoring and supervision of Decree 21 at the provincial level

The DHI Inspection Reports state that all eight localities inspected have conducted annual inspections and supervision of the compliance with Decree 21 within their province/city, but several obstacles and limitations remain. The Legislative Department Assessment Report states that inspections related to Decree 21 are conducted only infrequently.

Implementation of Decree 21
is a low priority among
provincial heads and local
authorities. Monitoring and
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enough to warrant separate
inspections; they are usually
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food safety and hygiene
inspections.

In general, implementation of Decree 21 is a low priority among provincial heads and local authorities. Monitoring and supervision of the Decree are not considered important enough to warrant separate inspections; they are usually incorporated into broader food safety and hygiene inspections. Additionally, limited coordination between the sectors concerned and a lack of clarity about the roles and responsibilities of each sector reduce the effectiveness of monitoring of the Decree.

Decree 21 covers a very broad range of facilities and players including hospitals, clinics and other health facilities; manufacturers of nutrition products for young children; distributors of these products including hospital pharmacies and small retailers; and marketing personnel. The scope of the Decree generates a huge volume of work to be handled by a limited number of inspectors with low levels of funding for carrying out monitoring activities.

Moreover, due to the regular rotation of inspectors, new officials are frequently placed in charge of inspections. These officials are often unclear about their duties and the handling of violations.

Confusion remains over when and how to levy fines against Decree 21 violators, and consequently, many violations are left unpunished.

Violations in advertising are particularly difficult to monitor and control as advertising for nutrition products for young children becomes more pervasive and sophisticated. Consequently, it is reported that many localities do not pursue violations of Decree 21 in spite of the guidelines outlined in Decree 45.

Sanctions against Decree 21violations are a weak point. Under Decree 45, companies or health staff that violate Decree 21 can be sanctioned, usually in the form of fines

ranging from 3 to 10 million VND (150 to 500 USD), depending on the violation committed. Confusion remains over when and how to levy fines against Decree 21 violators, and consequently, many violations are left unpunished.³

³ Report to UNICEF Hanoi to Review Code Implementation in Vietnam by ICDC, 2008.

4.5.3 Limitations in information, education, communication

IEC activities in general

While significant achievements have been made in promoting optimal IYCF practices, especially breastfeeding, throughout the provinces, there is still considerable room for improvement. A major limitation is the lack of consistency and regularity in breastfeeding promotion efforts. Many provinces only conduct communication and counseling activities during national events such as Breastfeeding Week or Nutrition and Development Week. Additionally, IEC activities are often incorporated into other programs such as the PEM Program and the Food Hygiene and Safety Program, rather than conducted separately.

Partly responsible for these shortcomings is a lack of written guidance on how to implement and

manage IEC activities at the provincial and city levels. The limited guidance and coordination of IEC activities render the heads of provincial agencies unsure of their roles and responsibilities. In addition, there are insufficient funds to fully implement these activities. As a result, IEC and promotion activities do not receive the full support and attention of local authorities, and there is no overall monitoring of IEC activities.

The limited guidance and coordination of IEC activities render the heads of provincial agencies unsure of their roles and responsibilities.

IEC materials and promotion of breastfeeding

The Legislative Department Assessment Report and DHI Inspection Reports determined that both the quality and quantity of the IEC materials are limited. These materials are not varied and do not contain comprehensive information. In particular, these materials often lack comprehensive information about the immediate and long-term benefits of breastfeeding. For example, Lao Cai province reported that the IEC materials available are unattractive, not diverse, and do not appeal to ethnic minorities or mothers living in remote, mountainous areas.

The Legislative Department Assessment Report concludes that the levels and skills of communication do not meet the requirements of Decree 21 overall. Due to limited funding and poor management, many provinces have been unable to widely produce and distribute IEC materials and often cannot afford to utilize mass media, such as television, to advertise the benefits of breastfeeding. Even in those provinces that could afford to run TV advertisements, it was reported that these advertisements failed to capture a large audience as most people watch central TV channels, not local ones. Meanwhile, central TV channels run numerous advertisements for nutrition products for young children. Because Decree 21 does not prohibit advertising for nutrition products for children over 12 months old, these advertisements are allowed to run. However, due to poor management and awareness within state agencies, there is limited oversight to ensure that they comply with Article 6 of Decree 21. Moreover, according to the Legislative Department, sanctions on advertising of nutrition products for infants under 12 months of age are not specified; therefore, officials are unclear how to proceed when the Decree is breached. Even

those advertisements that are legal under the Decree inadvertently promote nutrition products for infants under 12 months, which are similarly branded and packaged.

IEC and training of health staff

While many health facilities have incorporated training on breastfeeding and Decree 21, DHI reports that these trainings are not frequent, widespread and/or comprehensive. In addition, the trainings are often only organized for Pediatrics and Ob/Gyn Departments or are incorporated into other programs. Consequently, health staff – particularly those working in district hospitals, commune health centers and private practices – are not fully knowledgeable about Decree 21, according to DHI. This is even true among those working in Pediatrics and Ob/Gyn Departments.

Health facilities also face a shortage of medical staff in Pediatrics and Ob/Gyn Departments. Often the personnel working in these units have limited skills and qualifications in counseling; many

Even those mothers who are exposed to IEC about the benefits of breastfeeding are frequently confronted with contradictory information, making it difficult for them to determine what the best nutrition is for their children.

cases have been found wherein mothers are not consulted about breastfeeding in a timely manner and where guidelines for the promotion of breastfeeding guide are not seriously implemented.

IEC for mothers in health facilities

The DHI Inspection Reports state that most of the inspected health facilities do not have counseling rooms available in their antenatal care departments. In addition, most facilities and clinics also lack IEC equipment and materials to help women learn about breastfeeding.

Mothers receive conflicting messages about breastfeeding and nutrition products for young children. Manufacturers of

breastmilk substitutes and other nutrition products for young children spend vast sums of money on advertising their products and greatly outspend breastfeeding promotion efforts. Therefore, even those mothers who are exposed to IEC about the benefits of breastfeeding are frequently confronted with contradictory information, making it difficult to determine what the best nutrition is for their children.

4.5.4 Violations of Decree 21 provisions on advertising and marketing of nutrition products for infants and young children

In general, insufficient monitoring of advertisements from nutrition product companies allows the companies to evade consequences for violations. The Legislative Department Assessment Report and DHI Inspection Reports found that violations of the Decree's advertising regulations are relatively widespread. While the reports do not give as many specific examples of advertising violations as with labeling, the following specific examples of violations are provided:

-Advertisement of dairy products for infants under 12 months old (no companies listed)

-Stating the product has ingredients equivalent or superior to those in breastmilk:

- Meiji 1 and 2 flyers advertising milk products (Meiji Co., Ltd.)
- Physiolac milk flyers (VNA-Pharm/Gilbert Laboratories)
- Mama Colostrum advertisements (G&P Viet Nam Corp.)

Many companies were found in the DHI inspections to work around Decree 21 regulations by prominently displaying their names and logos in stores selling nutrition products for young children. Some examples of these companies are Dutch Lady, Danone-Dumex, Abbott, Mead Johnson, and Vinamilk. Companies also work around the regulations in radio and TV spots by rapidly reading or showing the required text "Breastmilk is the best food for the health and overall development of infants."

Companies found to violate Decree 21 by the Legislative Department and DHI: Meiji **Abbott VNA-Pharm G&P Viet Nam** Hanoi Milk Namyang **Danone-Dumex VitaDairy** Wakodo Nestle Miki **HiPP** Wyeth Manufacturing and Export Co, Saigon

Another practice utilized by companies that is not explicitly banned by the Decree is to entice customers by offering bonus items (e.g., blankets, pillows, bowls, etc.) along with a purchase of their product. For example, in a Dong Thap supermarket, it was observed that a customer was given one 40g can of condensed milk along with a purchase of a Vinamilk Dielac Alpha milk product.

4.5.5 Violations of Decree 21 provisions on labeling of nutrition products young children

The Legislative Department Assessment Report and the DHI Inspection Reports found numerous violations of the Decree 21 labeling provisions. These violations include omission of required text (e.g., "Breastmilk is the best food for the health and overall development of infants"); incomplete required text; making the required text too small or difficult to read; omission of a specified age appropriate for children to use the product; and not including additional labels in Vietnamese on imported products. The Inspection Report for Dien Bien, Ninh Thuan, An Giang and Dong Thap shows that out of the 85 randomly checked breastmilk substitutes and 24 randomly checked bottles and teats, 26 products (24%) had incorrect labeling or did not contain the complete required information. Moreover, the Legislative Department Assessment Report stated that, according to a 2009-2010 MOH inspection, 21% of breastmilk substitutes and 53.3% of feeding bottles and teats were found to be in breach of Decree 21 labeling regulations.

Other violations uncovered in the DHI inspections were failing to include a certificate of quality standards and having an expired certificate of quality standards. Some products' labels featured pictures of infants under the age of 12 months and/or of feeding bottles with artificial teats. Additionally, all reports stated that a number of products were found to use comparative language

implying that the product is as good as breastmilk. The products found to be in breach of Decree 21 labeling provisions identified in the Legislative Department Assessment Report and/or the DHI Inspection Reports are:

- -Omission of required text or incomplete text on breastmilk substitutes:
 - Ellac powdered milk (Manufacturing & Export Co., Saigon)
 - Solar IQ powdered milk (Hanoi Milk Co.)
 - Super Milk powdered milk (Company unlisted)
 - Imperial Kid XO powdered milk (Namyang Dairy Products Co., Ltd./Traphaco Corp.)
 - I Am Mother powdered milk (Namyang Dairy Products Co., Ltd.)
 - XO 1 and XO 2 powdered milk (Namyang Dairy Products Co., Ltd.)
 - Gain Similac infant formula (Abbott)
 - Grow powdered milk (Abbott)
 - Pediasure formula (Abbott)
 - Australian Lady powdered milk (Company unlisted)
 - HiPP herbal tea (HiPP Ltd.)
 - Similac Isomal Milk (Abbott)
 - Dumex Gold (Danone-Dumex)
- -Omission of required text or incomplete text on feeding bottles and teats:
 - Miki bottles
- -Use of comparative language to imply that milk/formula was as good as breastmilk:
 - Haihai powdered milk (Wakodo Co., Ltd.)
 - Barley Tea (Company unlisted)
 - HiPP Organic Baby foods (HiPP Ltd.)
- -No certificate of quality standards:
 - Cerelac (Nestle)
 - Colos Vita Milk (VitaDairy)
 - Meiji Milk (Meiji Co., Ltd.)
 - S26 Milk (Wyeth Nutrition)
- -Expired certificate of quality standards:
 - Mama Colostrum (G&P Viet Nam Corp.)
 - XO powdered milk (Namyang Dairy Products Co., Ltd.)
- -Featuring pictures of infants under the age of 12 months:
 - IQ Good Milk (Company unlisted)
 - Solar IQ powdered milk (Hanoi Milk Co.)
 - Imperial Kid XO powdered milk (Namyang Dairy Products Co., Ltd.)

The heads of manufacturing and distribution facilities claimed to be unaware of their responsibility to ensure proper labeling as well as the consequences of improper labeling. Owners of retail outlets selling nutrition products for young children also claimed to be unaware of the regulations detailed in Decree 21.

4.5.6 Barriers to compliance with Decree 21 and violations to Decree 21 in health facilities

As reported in the DHI Inspection Reports, while most health facilities met the 10 conditions for successful breastfeeding and complied with Decree 21, this was not true at all levels. At times, these conditions were only true in select departments having projects related to breastfeeding or in baby-friendly hospitals. With the exception of those in KhanhHoa and Hanoi Ob/Gyn hospital, almost none of the inspected health facilities provided a breastfeeding regulations board or displayed pictures/drawings encouraging breastfeeding. There were several departments/units in some health facilities that displayed out-of-date breastfeeding regulations boards.

According to both DHI Inspection Reports, breastfeeding-related knowledge and practices of some health staff were incorrect. Many of the interviewed staff did not fully understand the provisions and implications of Decree 21. Health staff did not always instruct mothers on proper breastfeeding, and at times health staff even encouraged bottle-feeding. For example, in Hoan My Hospital, midwives were found to be bottle-feeding the infants in the nursing room.

Generally, most of the health facilities visited for the DHI inspections were not found to violate

regulations of Decree 21 on the promotion and advertising of nutrition products for young children. However, some health facilities contained donated products with a milk company's name or logo (e.g., benches, chairs, pen holders, scales, counseling tables, medical books, clocks, calendars, nutrition pyramid posters, etc.). For example, in Hai Chau District, Ward 1 (Da Nang), the health station contained not only objects with milk company logos but also brochures and invitations to a workshop held by the company Danone-Dumex in which gifts were offered to attendees. The inspection also found cases in which companies were permitted to hang their company's logo in the health facilities, a way of working around the Decree's regulations.

In HaiChauDistrict, Ward 1 (Da Nang) the health station contained not only objects with milk company logos but also brochures and invitations to a workshop held by Danone-Dumex in which gifts were offered to attendees.

Other examples of Decree violations cited in the DHI Inspection Reports are provided below:

- Selling of milk for infants under 12 months of age, milk or food for infants under 6 months of age, and feeding bottles with teats at kiosks in Bai Chay Hospital, Duc Giang District Hospital, Son Tay Hospital, and Da Nang Hospital.
- At Hoan My Da Nang private hospital, company representatives were found to be directly
 encouraging pregnant women and new mothers to purchase their products, including milk
 for infants under 12 months of age, in violation of Decree 21. These representatives offered
 the women gifts and provided them with telephone numbers for the purchase of their
 nutrition products.
- According to the Legislative Department Assessment Report, in 2009, inspectors uncovered that the Hung Nguyen district hospital Ob/Gyn Department staff were selling milk for

infants under 12 months of age. Staff and the hospital heads were fined due to shortcomings in management.

 The DHI Inspection in Dien Bien, Ninh Thuan, An Giang and Dong Thap found that feeding bottles and products not in compliance with Decree 21 regulations were offered in the canteens of some hospitals.

According to the Central Hospital in Hue, it is difficult to prevent nutrition product companies from either advertising within the hospital or from contacting health staff due to a lack of guidance and/or documents from MOH forbidding these actions. In general, confusion remains as to what is or is not a violation.

4.5.7 Limitations to increasing optimal breastfeeding practices among mothers

According to the Legislative Department Assessment Report, mothers and their families have incomplete knowledge about the benefits of breastfeeding and nutrition for infants. This lack of knowledge is attributed in large part to a widely held belief that complementary foods are more nutritious than breastmilk and can help children grow and gain weight faster than they could with breastmilk. Mothers are also frequently concerned about not having enough breastmilk to adequately feed their children, and a large proportion of mothers lack confidence in their own health or believe that breastfeeding would cause them to lose weight. Those who had undergone a cesarean section expressed a fear of exposing their infants to antibiotics.

In most provinces, the percentage of children who are exclusively breastfed for the first 6 months remains very low. For example, according to the Legislative Department, the percentage in Dong Thap is 2-3%, that in Phu Tho is 12%, and in Thai Nguyen it is 10%. Nationally, the average rate of exclusive breastfeeding under 6 months of age is only 10% (A&T, 2010).

A large proportion of mothers were observed to be feeding their infants with breastmilk substitutes and feeding bottles, at times in spite of hospital workers' advice to breastfeed, according to the Legislative Department and DHI. Although health facilities have gained ground in promoting breastfeeding, misconceptions about breastfeeding and nutrition products for young children persist, and these products are usually easy to obtain either in the hospital pharmacy, the hospital

canteen, or retailers in the area. In addition, as noted above, mothers do not always receive full and comprehensive counseling support for breastfeeding and may also be influenced by the pervasive advertising of companies selling breastmilk substitutes and other nutrition products for young children, even on hospital premises.

Once they have left the hospital, the Legislative Department concludes that it is often the mothers' living circumstances that discourage them from engaging in optimal breastfeeding practices, especially exclusive breastfeeding for the first 6 months of life. Maternity leave is only four months long, so when a baby reaches

It is difficult to prevent nutrition product companies from either advertising within the hospital or from contacting health staff due to a lack of guidance and/or documents from MOH forbidding these actions. In general, confusion remains as to what is or is not a violation of the Decree.

about 3 months of age, many mothers begin feeding them other milk/formula and restrict their intake of breastmilk. Some mothers facing economic difficulties cannot afford to take maternity leave and, due in part to a lack of time, introduce other milk/formula to feed their infant.

5 Results from Monitoring Study

5.1 Contact between mothers and company representatives

Articles 5.2, 5.3, and 5.4of the International Code prohibit company representatives from directly or indirectly giving gifts, utensils, samples or other promotional devices to pregnant women and mothers. Article 5.5 of the International Code prohibits direct or indirect contact of any kind with pregnant women and mothers. However, Decree 21 is less prohibitive. Article 10.2.b of the Decree prohibits companies from directly or indirectly contacting mothers, pregnant women and their family members in health facilities for the promotion or sale of milk products for infants under 12 months of age and food products for infants under 6 months of age. This provision does not restrict company representatives from contacting individuals outside of health facilities. Furthermore, Decree 21 allows for companies to contact mothers to promote or sell milk products for children older than 12 months of age and food products for children older than 6 months of age.

| Summary of findings on direct contact between mothers and c | company representatives |
|--|--|
| Practice | Violation/Loophole |
| Thirty-eight out of 342 interviewed mothers (11.1%) were contacted directly by company representatives. Nearly one-third of these interactions (31.6%) were in health facilities. Company representatives were found to directly contact mothers in three non-baby-friendly health facilities (representatives from Abbott and HiPP). | <u>Violation:</u> Article 10.2.b of Decree 21 / Article 5.5 of the International Code |
| Company representatives contacted mothers in shops, Houses of Culture, hotels, at home, and/or over the phone, usually to provide mothers with IYCF information, to try to get them to use a specific nutrition product, or to offer them gifts. | Violation: Article 5.5 of the International Code Loophole: Article 10 of Decree 21 |
| Out of 336 mothers, 10 (3%) reported receiving free product samples and 29 mothers (8.6%) received gifts associated with nutrition products for young children, usually in shops or health facilities. Over 80% of the 29 mothers who received gifts or samples reported receiving them from company staff or sales personnel. | Violation: Article 5.5 of the International Code Loophole: Article 10 of Decree 21 (depending on where mothers received gifts) |
| In 7.7% of 142 non-baby-friendly health facilities, mothers received nutrition products for young children in the last 6 months, including those restricted under Decree 21. Most often the products came from family members or relatives, but company personnel and health staff were also found to give mothers these products in 6 of these health facilities. | Violation: Article 10.2.c of Decree 21 / Articles 5.2 and 5.4 of the International Code Loophole: Article 10 of Decree 21 (depending on which products were received and by whom) |

5.1.1 Direct contact between company representatives and mothers in general

Among the 342 mothers interviewed, 38 (11.1%) had been directly contacted or visited by a representative from a company producing or selling nutrition products for young children (Table 1). Nearly one-third of these 38 mothers (31.6%) were contacted in a health facility. While in breach of the International Code, it is unclear how many of these contacts were in violation of Decree 21 as it is uncertain whether or not these visits served to promote nutrition products for children under 12 months old. Other places mothers were contacted include retail shops, Houses of Culture, hotels, at home, and over the phone. Although not always a violation of Decree 21, direct contact between mothers and company representatives most certainly serves to discourage mothers from breastfeeding.

Table 1 Direct contact between company representatives and mothers

| | Total | | |
|---|-------|------|--|
| Indicators | n | % | |
| Contacted by company representatives | | | |
| (n=342) | | | |
| Yes | 38 | 11.1 | |
| No | 304 | 88.9 | |
| If yes, (n=38) | | | |
| Companies that contacted mothers (n=38) | | | |
| Abbott | 20 | 52.6 | |
| Fronterra Brands | 1 | 2.6 | |
| Danone-Dumex | 4 | 10.5 | |
| FrieslandCampina/Dutch Lady | 3 | 7.9 | |
| Mead Johnson | 5 | 13.2 | |
| Vinamilk | 2 | 5.3 | |
| Other (company unclear) | 3 | 7.9 | |
| Places of contact (n=38) | | | |
| Health facility | 12 | 31.6 | |
| Home | 5 | 13.2 | |
| Shop | 8 | 21.1 | |
| House of Culture | 8 | 21.1 | |
| Hotel | 1 | 2.6 | |
| Over the phone | 4 | 10.5 | |
| Purpose of visits (n=38) | | | |
| Providing IYCF information | 23 | 60.5 | |
| Stimulating usage of a specific product | 20 | 52.6 | |
| Stimulating usage of feeding bottle | 2 | 5.3 | |
| Offering sample | 1 | 2.6 | |
| Offering gift | 10 | 26.3 | |
| Other | 2 | 5.3 | |

Most commonly, company representatives provided mothers with IYCF information (reported by 60.5% of 38 contacted mothers) or attempted to convince the mothers to use a specific product (reported by 52.6% of 38 contacted mothers). Other times, representatives offered mothers gifts or samples or encouraged them to bottle-feed their children. Over half of the mothers who were contacted reported that the representatives were from Abbott (52.6%), while more than 10% stated that the representatives were from Mead Johnson (13.2%) and Danone-Dumex (10.5%). Other companies reported were FrieslandCampina/Dutch Lady (7.9%), Vinamilk (5.3%), and Fronterra Brands (2.6%).

Although not always a violation of Decree 21, direct contact between mothers and company representatives most certainly serves to discourage mothers from breastfeeding.

Only 10 out of 336 mothers (3%) reported receiving a child nutrition sample or product, including milk for infants under 6 months of age, milk for infants older than 6 months, special milk and cereal powder, a violation of the International Code, but not Decree 21 (Table 2). Five of these 10 mothers (50%) received samples/products from company staff, and 2 from a salesperson (20%). In 2 cases, these products were provided to mothers in health facilities by company staff or salespeople, a violation of Decree 21.

A larger proportion of the 336 mothers (8.6%) reported receiving gifts associated with nutrition products for young children, usually from company staff or sales representatives (Table 2). In 5 out of 29 cases, Decree 21 was violated as gifts were directly given to mothers in health facilities by company staff or sales personnel. Gifts came in the form of guidebooks, bottles, bibs, diapers, toys, etc. The guidebooks were related to IYCF and how to care for children and pregnant women. Mothers received gifts most often in shops or health facilities, but also at home, through the mail, in the market/supermarket, at Houses of Culture, or at a hotel or conference.

Companies that offered samples and/or gifts to mothers were:

- Abbott
- FrieslandCampina/Dutch Lady
- Vinamilk

- Danone-Dumex
- Fronterra Brands
- Mead Johnson

 Table 2 Samples, products, and gifts given to mothers

| | Total (N=336) | | | | Total =336) |
|---------------------------|------------------|------|--------------------------|-----|----------------------|
| Indicators | n | (%) | Indicators | n | -330 <u>)</u> (%) |
| Mothers received | | (70) | Mothers received gifts | | (,0) |
| samples, products | | | | | |
| Yes | 10 | 3.0 | Yes | 29 | 8.6 |
| No | 326 | 97.0 | No | 307 | 91.4 |
| If yes, (n=10) | | | If yes, (n=29) | | |
| Company (Brand) | | | Company | | |
| Abbott (Similac) | 2 | 28.6 | Abbott | 14 | 58.3 |
| Danone-Dumex (Dumex) | 1 | 14.3 | Danone-Dumex | 4 | 16.7 |
| FrieslandCampina/Dutch | 1 | 14.3 | FrieslandCampina/Dutch | 3 | 12.5 |
| Lady (Friso Gold) | | | Lady | | |
| Fronterra Brands (Anmum) | 1 | 14.3 | Vinamilk | 2 | 8.3 |
| Mead Johnson (Enfalac A+) | 2 | 28.6 | Mead Johnson | 1 | 4.2 |
| Type of products (n=10) | | | Type of gifts (n=29) | | |
| Infant formula < 6 months | 3 | 42.9 | Bottle | 4 | 13.8 |
| Milk for > 6 months | 1 | 14.3 | Bib | 3 | 10.3 |
| Special milk | 1 | 14.3 | Diaper | 2 | 6.9 |
| Cereal Powder | 1 | 14.3 | Bowl and spoon | 1 | 3.4 |
| Fruit/Vegetable/Meat | 0 | - | Toys | 7 | 24.1 |
| Condensed milk | 0 | - | Decorations | 3 | 10.3 |
| Bottle | 0 | - | Diaper and bottle holder | 1 | 3.4 |
| Dummies | 0 | - | Gift set | 1 | 3.4 |
| Other | 1 | 14.3 | Guidebook* | 13 | 44.8 |
| | | | Wall clock | 1 | 3.4 |
| Place of receipt (n=10) | | | Place of receipt (n=29) | | |
| Health facility | 2 | 22.2 | Health facility | 8 | 27.6 |
| Pharmacy | 0 | - | Home | 1 | 3.4 |
| Home | 2 | 22.2 | Shop | 9 | 31.0 |
| Shop | 1 | 11.1 | Via the mail | 4 | 13.8 |
| Via the mail | 2 | 22.2 | Market/Supermarket | 1 | 3.4 |
| Market/Supermarket | 2 | 22.2 | House of Culture | 4 | 13.8 |
| | | | Hotel/conference | 3 | 10.3 |
| From whom (n=10) | | | From whom (n=29) | | |
| Company staff | 5 | 50.0 | Company staff | 14 | 48.3 |
| Medical staff | 0 | - | Medical staff | 1 | 3.4 |
| Pharmacy sales person | 0 | - | Sales person | 11 | 37.9 |
| Sales person | 2 | 20.0 | Postal worker | 1 | 3.4 |
| Obtained herself | 1 | 10.0 | Friend | 2 | 6.9 |
| Unclear | 2 | 20.0 | | | |

^{*}Examples of guidebooks given to mothers: Guide on how to use milk; Guide on breastfeeding; Guide on supplementary foods; Guide for taking care of children; and Guide for caring for pregnant women

5.1.2 Direct contact between company representatives and mothers in health facilities

In addition to the reports from mothers' described above, cases of direct contact between mothers and nutrition product company representatives were observed by the study team in 3 out 154 health facilities, all of which were non-baby-friendly health facilities (Table 3). The company representatives were from Abbott in 2 cases and HiPP in one case. In these instances, the purpose of the visits was to collect personal information from the mothers, introduce the mother to a product, or to provide mothers with samples, gifts, or informational materials.

Table 3 Direct contact between company representatives and mothers in health facilities

| Indicators | Baby-friendly health facilities (n=15) | | Non-baby- friendly health facilities (n=139) | | Total (N=154) | |
|-------------------------------|--|-----|---|------|------------------|------|
| | n | % | n | % | n | % |
| Company representatives | | | | | | |
| directly contacted mothers | | | | | | |
| at health facilities | | | | | | |
| Yes | 0 | 0 | 3 | 2.2 | 3 | 1.9 |
| No | 15 | 100 | 136 | 97.8 | 151 | 98.1 |
| Purpose of visits (n=3) | | | | | | |
| Collect personal information | - | - | 1 | 33.3 | 1 | 33.3 |
| Introduce product | - | - | 2 | 66.7 | 2 | 66.7 |
| Provide samples | - | - | 1 | 33.3 | 1 | 33.3 |
| Provide gifts | - | - | 1 | 33.3 | 1 | 33.3 |
| Provide leaflets or brochures | - | - | 1 | 33.3 | 1 | 33.3 |

Findings show that mothers received products in health facilities from both company personnel and health staff, including milk products for infants under 12 months of age, a violation of Decree 21. In total, mothers in 11 out of 142 non-babyfriendly health facilities (7.7%) received a total of 15 products in the last 6 months, including those restricted under the Decree (Table 4). Most often, mothers received products from family members

Mothers received products in health facilities from company personnel and health staff, including milk products for infants under 12 months of age, a violation of Decree 21.

or relatives (in 4 out of the 11 health facilities where mothers received products). However, in violation of Decree 21, mothers received milk products for children under 12 months old from company personnel in 4 health facilities and from health staff in 2 health facilities.

Mothers received the following products in non-baby-friendly health facilities: Abbott Similac infant formula, HiPP infant formula from Van An Co., Nestle Lactogen powdered milk, Vinamilk Dielac powdered milk, and Mead Johnson Enfapro A+ follow-up formula. In addition, mothers received cereal powder and juice/meat/vegetable extract products in health facilities.

Table 4 Products provided to mothers in health facilities in the last 6 months

| Indicators | Baby-friendly health facilities (n=15) | | Non-baby-friendly health facilities (n=142) | | Total (N=157) | |
|--------------------------------|--|-----|---|--------------------------|------------------|--------------------------|
| | n | (%) | n | (%) | n | (%) |
| Mothers received products | | | | | | |
| in health facility in the last | | | | | | |
| 6 months | | | | | | |
| Yes | 0 | 0 | 11 | 7.7 | 11 | 7.0 |
| No | 15 | 100 | 131 | 92.3 | 146 | 93.0 |
| | 15 | 100 | 131 | 92.3 | 140 | 93.0 |
| From whom (n=11 | | | | | | |
| facilities) | | | 4 | 36.4 | 4 | 36.4 |
| Company staff Health staff | - | - | 4 2 | 36. 4 18.2 | 4 | 36. 4 18.2 |
| | - | - | 5 | | 2 5 | |
| Family member/relative | - | | 5 | 45.5 | 5 | 45.5 |
| Type of products (n=15 | | | | | | |
| products) | | | 0 | 60 | 0 | 60 |
| Infant formula < 6 months | - | - | 9 | 60 | 9 | 60 |
| Milk for > 6 months | - | - | 1 | 6.7 | 1 | 6.7 |
| Special milk | - | - | 1 | 6.7 | 1 | 6.7 |
| Cereal Powder | - | - | 2 | 13.3 | 2 | 13.3 |
| Juice/Vegetable/Meat | - | - | 2 | 13.3 | 2 | 13.3 |
| Condensed milk | - | - | 0 | 0 | 0 | 0 |
| Bottle | - | - | 0 | 0 | 0 | 0 |
| Dummies | - | - | 0 | 0 | 0 | 0 |
| Company (Brand) (n=15 | | | | | | |
| products) | | | | | | |
| Abbott (Similac) | - | - | 5 | 45.5 | 5 | 45.5 |
| Van An Co. (HiPP) | - | - | 2 | 18.2 | 2 | 18.2 |
| Nestle (Lactogen) | - | - | 2 | 18.2 | 2 | 18.2 |
| Vinamilk (Dielac) | - | - | 1 | 9.1 | 1 | 9.1 |
| Mead Johnson (Enfapro A+) | | | 1 | 9.1 | 1 | 9.1 |

5.2 Information, education, and communication

Both the International Code (Article 4) and Decree 21 (Articles 4 and 5) have provisions that regulate IEC materials related to IYCF and the use of nutrition products for young children. Decree 21 covers most, but not all, of the informational points recommended by the International Code for inclusion in these materials. In addition, Article 4.3 of the International Code and Article 10.2.c of Decree 21 restrict donations from companies in the form of materials or equipment, stating that these materials should not refer to a restricted product (although donated materials can bear the company's name or logo).

| Summary of findings on information, education and commu | ınication |
|--|--|
| Practice | Violation/Loophole |
| Nearly all of the reviewed IEC materials available to the public and to health staff were provided by companies. | Allowable under both Decree 21 and the International Code |
| 61.8% of the 55 IEC materials for the public and 52.4% of the 21 IEC materials for health staff provided by companies mentioned infant formula for children under 6 months old. | <u>Loophole</u> : Article 4 of Decree 21 / Article 4.3 of the International Code |
| 18.2% of the 55 IEC materials for the public and 33.3% of 21 IEC materials for health staff provided by companies mentioned follow-up milk products for children older than 6 months of age. | <u>Loophole</u> : Article 4 of Decree 21 / Article 4 of the International Code |
| Nearly half of the IEC materials featured the name or logo of a restricted nutrition product for young children (45.5% of those for the public and 47.6% of those for health staff). | <u>Violation</u> : Article 4.3.c of Decree 21 / Article 4 of the International Code |
| Only half of the 43 IYCF-related IEC materials for mothers provided information on the benefits of breastfeeding. Just 14% of IEC materials covered information on the negative impact of bottle-feeding, and a mere 11.6% discussed the disadvantages of not breastfeeding. Moreover, only one-sixth provided information on maternal nutrition and the maintenance of breastfeeding. | <u>Violation</u> : Articles 4 and 5 of Decree 21 / Article 4.2 of the International Code |
| Only half of the 22 IEC materials for health staff related to IYCF contained information on all three of the topics: the benefits of breastfeeding, the disadvantages of not breastfeeding, and the negative impact of bottle-feeding. | Violation: Articles 4 and 5 of Decree 21/ Article 4.2 of the International Code |
| regarive impact of bottle recuing. | Loophole: Decree 21 should make it clearer that these provisions apply to IEC for health staff |
| Messages implying that bottle-feeding or milk products are similar to or better than breastfeeding as well as messages idealizing the use of these products were ubiquitous in IEC materials. | <u>Violation</u> : Article 4.3.b of Decree 21 / Article 4.2 of the International Code |

5.2.1 IEC materials for mothers and the general public

A total of 55 IEC materials available to mothers and the general public were reviewed in this study, including books, leaflets, advertisements, websites, posters, and a television program (Figure 2). These materials were found in the general hospital, clinics, mothers' rooms, pharmacies, shops, magazines, on television, the internet, and in public spaces (Table 5).

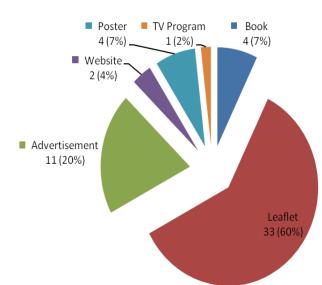


Figure 2 Types of IEC materials available to mothers and the general public

IEC materials available to the public (N=55)

Table 5 Places where IEC materials for mothers and general public found

| Place material found | Books | Leaflets | Advertise ments | Websites | Posters | TV program |
|-----------------------|-----------|-----------|--------------------|-----------|-----------|---------------|
| General Hospital | | $\sqrt{}$ | | | | |
| Clinics | $\sqrt{}$ | | | | | |
| Mother's rooms | | $\sqrt{}$ | | | | |
| Pharmacies | | $\sqrt{}$ | | | | |
| Shop/grocery store | $\sqrt{}$ | $\sqrt{}$ | $\sqrt{}$ | | $\sqrt{}$ | |
| Magazine | | $\sqrt{}$ | $\sqrt{}$ | | | |
| Public | | $\sqrt{}$ | | | | |
| Television | | | $\sqrt{}$ | | | $\sqrt{}$ |
| Internet | | | $\sqrt{}$ | $\sqrt{}$ | | |
| Other | | $\sqrt{}$ | $\sqrt{}$ | | | |

Table 6 Type of IEC materials available to the public and companies providing the materials

| | Type of IEC material | | | | | | Total |
|----------------------|----------------------|-------------------|------------------------------|---------------|-----------------|------------------------|-----------|
| Indicator | Book (n=4) | Leaflet (n=33) | Advertise -ment (n=11) | Website (n=2) | Poster (n=4) | TV program (n=1) | (N=55) |
| | n | n | n | n | n | n | n (%) |
| Name of company | | | | | | | |
| Abbott | 2 | 3 | - | - | - | - | 5 (9.1) |
| 3A Pharma (Abbott | - | - | 1 | - | - | - | 1 (1.8) |
| distributor) | | | | | | | |
| Arla | 1 | - | 1 | 1 | - | - | 3 (5.5) |
| Friesland | 1 | - | 1 | - | - | - | 2 (3.6) |
| Campina/Dutch Lady | | | | | | | |
| Vinamilk | - | 2 | - | - | - | - | 2 (3.6) |
| Mead Johnson | - | 7 | 4 | - | - | - | 11 (20.0) |
| Dumex-Danone | - | 2 | - | - | 2 | - | 4 (7.3) |
| VitaDairy (Sua Suc | - | 1 | - | - | - | - | 1 (1.8) |
| Song Vietnam) | | | | | | | |
| Biofocus | - | 2 | - | - | - | 1 | 3 (5.5) |
| G&P JSC (Mama Sua | - | 1 | - | - | 2 | - | 3 (5.5) |
| Non) | | | | | | | |
| Dunamex | - | 1 | - | - | - | - | 1 (1.8) |
| PBM | - | 1 | - | - | - | - | 1 (1.8) |
| Wakodo | - | 1 | - | - | - | - | 1 (1.8) |
| Hong Duong | - | 1 | - | - | - | - | 1 (1.8) |
| Pharmaceuticals Ltd. | | | | | | | |
| (distributor of | | | | | | | |
| Wakodo) | | | | | | | |
| SieuThanh Ltd. | - | - | 1 | - | - | - | 1 (1.8) |
| (Cacara) | | | | | | | |
| VNA-Pharm/Gilbert | - | 1 | - | - | - | - | 1 (1.8) |
| Bebivita | - | 1 | - | - | - | - | 1 (1.8) |
| Babysan | - | - | 1 | - | - | - | 1 (1.8) |
| HiPP | - | 1 | - | - | - | - | 1 (1.8) |
| DauTu K Ltd | - | 3 | - | - | - | - | 3 (5.5) |
| Other/unclear | - | 5 | 2 | 1 | - | - | 8 (14.5) |
| Type of products the | | | | | | | |
| IEC mentions | | | | | | | |
| Infant formula<6 | 3 | 18 | 7 | 2 | 2 | 1 | 34 (61.8) |
| months | | | | | | | |
| Milk>6 months | - | 8 | 1 | - | 2 | - | 10 (18.2) |
| Special milk | - | 3 | 1 | - | - | - | 4 (7.3) |
| Cereal powder | - | 2 | - | - | - | - | 2 (3.6) |
| Juice/Vegetable/meat | - | - | - | - | - | - | 1 (1.8) |
| extract | | | | | | | |
| Bottle | - | - | 2 | - | - | - | 2 (3.6) |
| Other | 1 | 1 | - | - | - | - | 2 (3.6) |
| Total n (%) | 4 | 33 | 11 | 2 | 4 | 1 | 55 (100%) |
| | (7.3%) | (60.0%) | (20.0%) | (3.6%) | (7.3%) | (1.8%) | |

A large majority of the reviewed IEC materials available to the public was provided by companies that make or sell nutrition products within the scope of Decree 21 (Table 6). Table 6 provides a list of the 20+ companies behind the materials. The kind of products mentioned most often in the 55 IEC materials was milk products for infants under 6 months old (61.8%), followed by milk products

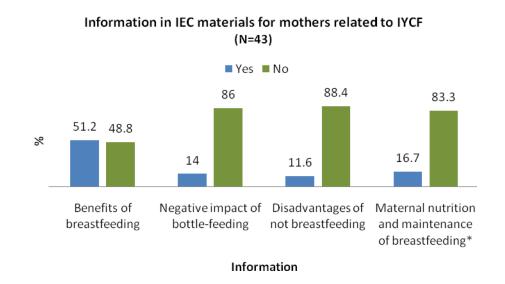
Nearly half (45.5%) of the IEC materials for the public violated Article 4.3.c of Decree 21 by containing the name or logo of a nutrition product for young children.

for children over 6 months old (18.2%), and special milk products (7.3%). Other products mentioned were cereal powder, juice/vegetable/meat extract, and bottles. Nearly half (45.5%) of the IEC materials for the public violated Article 4.3.c of Decree 21 by containing the name or logo of a nutrition product for young children. Those products included Babysan 1, Bebevita cereal, Biofocus Sua Non Smart, Mead Johnson Enfagrow A+ and Enfalac A+, HiPP infant formula, Abbott Grow infant formula, Abbott Similac Gain, Abbott Gain IQ, Abbott Similac Soy Isomil Pigeon bottles, PBM Insulac IQ, , Namyang XO infant formula, and Sieu Thanh Cacara bottles.

Content of IEC materials available to mothers and the general public

In general, the 43 IYCF-related IEC materials targeting mothers and the general public fall short of the Decree 21 requirements for informational content (Figure 3). Only half of these materials provided information on the benefits of breastfeeding. Just 14% of IEC materials covered information on the negative impact of bottle-feeding, and a mere 11.6% discussed the disadvantages of not breastfeeding. Moreover, only one-sixth provided information on maternal nutrition and the maintenance of breastfeeding.

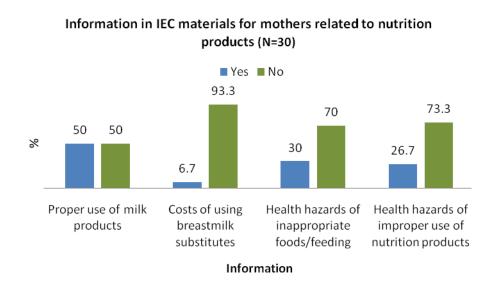
Figure 3 Precise information provided in IEC materials for mothers that are related to IYCF



*Note: This complete stipulation is present in the International Code but not in Decree 21.

Similarly, relatively few of the 30 IEC materials related to nutrition products for young children fully complied with Decree 21 guidelines (Figure 4). While half of these materials covered the proper use of nutrition products, only one-quarter provided information on the health hazards of improper or unnecessary use of these products and less than one-third discussed the health hazards of inappropriate foods or feeding methods. In addition, merely 6.7% mention the costs of using breastmilk substitutes instead of breastmilk.

Figure 4 Precise information provided in IEC materials for mothers and the public that are related to nutrition products for young children



The study team recorded key messages in the IEC materials that either implied bottle-feeding or milk products are similar to or better than breastfeeding or idealized the use of nutrition products for young children, in violation of Article 4.3 of Decree 21 (Table 7). Messages that imply that nutrition products are similar to or better than breastmilk tend to highlight the products' additives that aim to mimic the beneficial components of breastmilk, such as colostrum. For example, numerous products claim to contain cow's colostrum or components from colostrum in order to

appear to be similar to breastmilk. Nearly every product now contains additives that are meant to make the product appear similar to breastmilk. For instance, many infant formulas now include additives such as synthetic Docosahexaenoic Acid (DHA) and Arachidonic Acid (AA), fatty acids which are naturally present in breastmilk. The additives called prebiotics and probiotics are meant to mimic the digestion-enhancing properties of breastmilk. In addition to creating the idea that the product is similar to breastmilk, companies idealize their products by claiming that the additives enhance the immune system, improve vision, reduce allergies, and/or prevent

In addition to creating the idea that the product is similar to breastmilk, companies idealize their products by claiming that the additives enhance the immune system, improve vision, reduce allergies and/or prevent infections.

infections. Other messages present in the IEC materials include claims that the products will lead to enhanced growth, health, and/or mental development. These claims are made despite the fact that they are not sufficiently backed by scientific evidence.

In at least one case, the IEC material recommended using infant formula in the event that the mother is lacking in breastmilk. Given that this is a common concern cited by mothers in Vietnam (see Table 19), such claims take advantage of mothers' insecurities about their ability to produce enough breastmilk for their infants.

Table 7 Key messages in IEC materials for mothers that discourage breastfeeding

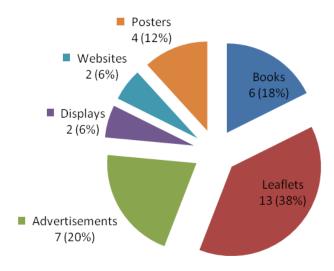
Messages implying that bottle-feeding is Messages that idealize use of similar to or better than breastfeeding nutrition products or discourage breastfeeding While mother's milk is the best for [Product] develops the brain, helps children, supplementing breastmilk with digestion, and improves weight and [product] is smart when there is a lack of height milk [Product] provides comprehensive • [Product] contains essential amino acids protection for the baby that meet the standard of mother's milk [Product] is the smart choice for Unlike breastfeeding, using bottles your baby allows you to measure the amount of [Product] helps digestion and milk reduces constipation with prebiotics • Cow's colostrum has the same components as breastmilk • Children's feces are the same when using the product as when they are breastfed • Either fully breastfeed or feed child with at least 80 ml of formula • [Product] contains components from colostrum • [Product] is supplemented with new probiotics

5.2.2 IEC materials for health staff

Types of IEC materials for health staff

The study team reviewed 34 IEC materials provided to health staff. The IEC materials came in the form of books (including one book that contained computer software), leaflets, advertisements, displays, websites and posters (Figure 5). These materials were found in the general hospital, pediatrics hospital, health centers, clinics, doctors' rooms, mothers' rooms, pharmacies, shops, and the internet (Table 8).

Figure 5 Types of IEC materials for health staff



IEC materials for health staff (N=34)

Table 8 Places IEC materials for health staff were found

| Place | Books | Leaflets | Advertise ments | Displays | Websites | Posters |
|------------------------|-----------|-----------|--------------------|-----------|-----------|-----------|
| General Hospital | | | | | | |
| Pediatrics Hospital | | $\sqrt{}$ | | | | |
| Health centers | $\sqrt{}$ | $\sqrt{}$ | | | | $\sqrt{}$ |
| Clinics | | $\sqrt{}$ | | | | $\sqrt{}$ |
| Doctors rooms | $\sqrt{}$ | | | | | $\sqrt{}$ |
| Mother's rooms | $\sqrt{}$ | $\sqrt{}$ | | | | |
| Pharmacies | | $\sqrt{}$ | $\sqrt{}$ | | | |
| Shops | | | | $\sqrt{}$ | $\sqrt{}$ | |
| Internet | | | $\sqrt{}$ | | | |

Twenty-one out of the 34 materials (61.8%) were provided to the health staff by companies that make or sell nutrition products for young children such as Abbott, FrieslandCampina/Dutch Lady, Vinamilk, Mead Johnson, and G&P Viet Nam JSC (Table 9). The type of products mentioned most often in the 21 IEC materials provided to health staff by companies were milk products for infants under 6 months old (52.4%), followed by milk products for children over 6 months old (33.3%), and special milk products (14.3%). Nearly half of these materials (47.6%) were found to violate Decree 21 by containing the nutrition products' logo/symbol. Those products include

FrieslandCampina Friso Gold, Vinamilk Dielac Alpha, Mead Johnson Enfalac A+ and Enfamil ProSobee, Abbott Similac, , and G&P Mama Sua Non Gold.

Table 9 IEC materials for health staff provided by nutrition product companies

| | | Total | | | | |
|--------------------------|----------|----------|---------|---------|---------|-----------|
| Indicator | Leaflet | Advertis | Display | Website | Poster | (N=21) |
| | (n=9) | ement | (n=2) | (n=2) | (n=2) | |
| | | (n=6) | | | | |
| | n | n | n | n | n | n (%) |
| Company | | | | | | |
| Abbott | 3 | 6 | - | - | - | 9 (42.9) |
| FrieslandCampina/Dutch | 1 | - | - | - | - | 1 (4.8) |
| Lady | | | | | | |
| Vinamilk | 1 | - | 1 | 1 | 1 | 4 (19.0) |
| Mead Johnson | 2 | - | 1 | 1 | 1 | 5 (23.8) |
| G&P Viet Nam JSC | 1 | - | - | - | - | 1 (4.8) |
| Other/unclear | 1 | - | - | - | - | 1 (4.8) |
| Type of products | | | | | | |
| Infant formula <6 months | 4 | 2 | 2 | 2 | 1 | 11 (52.4) |
| Milk for >6 months | 3 | 3 | 0 | 0 | 1 | 7 (33.3) |
| Special milk | 2 | 1 | 0 | 0 | 0 | 3 (14.3) |
| Total n (%) | 9 (42.9) | 6 (28.6) | 2 (9.5) | 2 (9.5) | 2 (9.5) | 21 (100) |

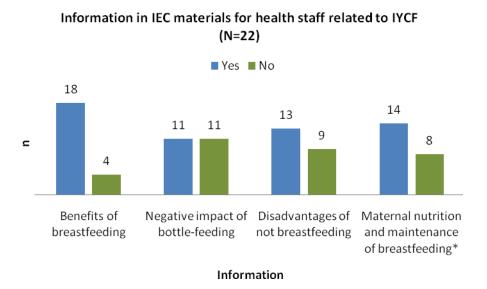
Content of IEC materials for health staff

The IEC materials for health staff covered the following topics:

- Breastfeeding and the ways to care and feed children younger than 5 years old
- Breastfeeding between the ages of 6 and 24 months
- Exclusive breastfeeding for the first 6 months of life
- Helping, protecting, and supporting mothers in breastfeeding
- Nutrition for infants aged 0-6 months
- Nutrition for infants aged 6-24 months and 2-6 years

Among the 22 materials related to IYCF methods, 18 (81.8%) discussed the benefits of breastfeeding as required by Decree 21 (Figure 6). In addition, 14 (63.6%) discussed maternal nutrition and the maintenance of breastfeeding. While most (59.1%) went into detail about the disadvantages of not breastfeeding, only half mentioned the negative impact of bottle-feeding. In all, only half of the IEC materials related to IYCF contained information on all three of the topics: the benefits of breastfeeding, the disadvantages of not breastfeeding, and the negative impact of bottle-feeding.

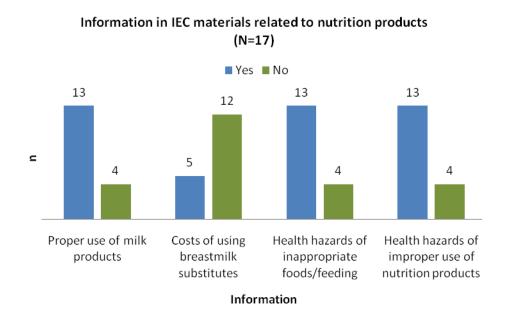
Figure 6 Precise information provided in IEC materials for health staff that are related to IYCF



*Note: This complete stipulation is present in the International Code, but not in Decree 21.

Three-quarters of 17 IEC materials for health staff related to the use of nutrition products for young children contained precise information required by Decree 21 on the following: the proper use of nutrition products; the health hazards of inappropriate foods or feeding methods; and the health hazards of improper or unnecessary use of nutrition products for young children (Figure 7). However, only 5 materials (29.4%) followed the Decree's stipulation for the inclusion of information on the economic costs of using nutrition products instead of breastfeeding.

Figure 7 Precise information provided in IEC materials for health staff



The IEC materials for health workers that contain messages that discourage breastfeeding do so in the same way as those materials targeting mothers. For example, a number of IEC materials claim that the nutrition products aid in children's development, including physical development, intellectual development, and development of the immune system (Table 10). None of these claims are backed by scientific evidence. Other materials idealize bottle-feeding by highlighting that bottle-feeding enables mothers to measure the amount of milk they are feeding their children, a message that takes advantage of mothers' concerns that they do not produce enough breastmilk. Two materials asserted that the milk product for infants under 6 months old can be used in place of breastmilk.

Highlighting that
bottle-feeding enables
mothers to measure
the amount of milk
they are feeding their
children takes
advantage of mothers'
concerns that they do
not produce enough
breastmilk.

Table 10 Key messages in IEC materials for health staff that discourage breastfeeding

Messages implying that bottle-Messages that idealize use of nutrition feeding is similar to or better than products or discourage breastfeeding breastfeeding Mothers cannot determine the amount [Product will] Break through immune of breastmilk a child receives deficiency Mothers can measure the amount of [Product] promotes child's intellectual milk they are giving their children development through bottle-feeding [Product] promotes child's physical development [Product] can be used in place of breastmilk Abbott is science for achieving a future in [Product] provides three-way protection for children [Product] supports development of immune system [Product is] safe and hygienic

5.3 Promotion and advertisement of nutrition products for young children

While the International Code recommends the prohibition of all advertising or other forms of promotion of products within the scope of the Code, Article 6 Decree 21 only prohibits advertising of milk products for children under 12 months old, food products for infants under 6 months old, feeding bottles and teats. It therefore allows for advertising of milk products for children older than 12 months of age and complementary food products for those over 6 months of age. Under this article, advertisements must contain the statement, "Breastmilk is the best food for the health and overall development of infants." Advertisements must meet the requirements outlined in Articles 4 and 5 of the Decree. In addition, all advertising must conform to the provisions of the Advertising Ordinance, and companies must register their advertisements with MOH.

Article 5.3 of the International Code recommends the prohibition of other promotional strategies such as point-of-sale advertising, giving of samples/gifts, special displays, discounts, sales, and other promotional devices at the retail level. Decree 21 does not have an equivalent article.

| Summary of findings on promotion and advertisement | t of nutrition products |
|--|--|
| Practice | Violation /Loophole |
| One-third of the 216 retail shops (32.4%) contained advertisements for nutrition products for young children, including milk products for children under 12 months old. | Violation: Article 6 of Decree 21 / Article 5.1of the International Code Loophole: Article 6 of Decree 21 (depending on the products advertised) |
| Some advertisements in retail shops featured images or photos of infants under 12 months old and/or made claims that idealize the nutrition product. | <u>Violation</u> : Articles 4.1 and 4.3.a of Decree 21 / Articles 5.1 and 4.2 of the International Code <u>Loophole</u> : Article 4 of Decree 21(not clear enough, leaves room for argument) |
| Other strategies used to promote products in retail shops include the use of special showcases, banners, displays, discounts, special sales, product holders, and gifts. | Violation: Articles 5.3 and 5.4 of the International Code Loophole: Article 6 of Decree 21(no prohibition) |
| Sales personnel in retail shops were found to approach mothers to encourage the purchase of nutrition products for young children. Companies provided monetary and material incentives to sales personnel to sell their products. | Violation: Articles 8.1 of the International Code Loophole: Article 6 of Decree 21(no prohibition) |
| Cases were found in which mothers were asked to provide their personal information in retail shops. They were also invited to attend workshops or meetings held by companies. | Violation: Article 5.5 of the International Code Loophole: Article 10 of Decree 21 (depending on the products promoted) |
| Nine out of 152 health facilities were found to display nutrition products for young children, including milk products for children under 12 months of age. | <u>Violation</u> : Articles 10.2.d and 11.2 of Decree 21 / Article 6.3 of the International Code <u>Loophole</u> : Article 10 of Decree (depending on the products promoted) |
| Cases were found in which the name or logo of restricted nutrition products was found on materials in health facilities such as clocks, posters and calendars. | <u>Violation</u> : Articles 10.2.c and 12.2 of Decree 21 / Article 6.3 of the International Code <u>Loophole</u> : Articles 10 and 12 of Decree 21(depending on the products promoted) |

5.3.1 Promotion and advertising of nutrition products for infants in retail shops

Approximately one-third of the 216 retail shops observed contained advertisements for nutrition products for young children, including those prohibited by Decree 21 (Table 11). Table 11 provides a list of the names of the 20 companies behind the advertising violations along with the names of the product brands featured in the advertisements.

Advertisements came in the form of billboards, posters, and stickers. The study team noted other violations to Decree 21 regulations. For example, at least 14 advertisements contained images of babies, including the following images: mothers breastfeeding their babies; mothers bottle-feeding their babies; dummies surrounding the babies; babies with bears; and a baby wearing a graduate cap. (Note: it is unclear the exact number of advertisements observed by the study team as they only recorded violations in 216 retail shops – they did not count the total number of advertisements, including non-violators).

Moreover, it was observed on at least 10 occasions that advertisements contained claims that are not scientifically valid or exaggerate the benefits of the nutrition product. Some examples of these claims are provided below:

- "Milex will make your child as strong as an astronaut" (Arla)
- "Strengthens immunity" (Goodhealth Viet Nam)
- "For brain development" (Abbott, Vinamilk)
- "Strengthens health" (Abbott, Vinamilk)
- "Makes child taller, healthier and more intelligent" (Bach JSC)

Table 11 Presence of advertisements of nutrition products for infants in retail shops

| | n | % |
|---|-----|------|
| Has advertisement (N=216 shops) | | |
| Yes | 70 | 32.4 |
| No | 146 | 67.6 |
| Companies (&brands) promoted | | |
| in retail shops (n=106 products) | | |
| Vinamilk(Dielac Step, Ridielac) | 22 | 15.1 |
| Abbott (Similac, Gain Plus) | 19 | 15.1 |
| FrieslandCampina (Friso) | 5 | 4.7 |
| Dutch Lady (Gold Step 2) | 7 | 6.6 |
| Mead Johnson (Enfa A+, Enfalac, Enfa Grow) | 14 | 13.2 |
| G&P Viet Nam (Mama Sua Non Colostrum, IQ, Star) | 4 | 3.8 |
| Arla (Milex) | 4 | 3.8 |
| Danone-Dumex (Dulac) | 4 | 3.8 |
| HiPP (Infant formula) | 2 | 1.9 |
| Nestle (Nan Pro) | 2 | 1.9 |
| Nutifood (Nuti-IQ) | 2 | 1.9 |
| VNA-Pharm/Gilbert (Physiolac) | 3 | 2.8 |

| Bach JSC (Smart Baby) | 1 | 0.9 |
|-------------------------------|---|-----|
| Biofocus (Sua Non Smart) | 3 | 2.8 |
| Namyang (XO) | 3 | 2.8 |
| Wyeth (Alpha Grow) | 1 | 0.9 |
| Wakodo (Gun Gun) | 2 | 1.9 |
| Bebivita nutrition | 1 | 0.9 |
| Aries Trading JSC (Colostrum) | 1 | 0.9 |
| Goodhealth Viet Nam | 1 | 0.9 |
| The GioiTuoiTho bottles | 1 | 0.9 |
| Other (unclear) | 4 | 3.8 |

Strategies and tactics used by companies to promote and sell products in retail shops

One-third of 208 retail shops demonstrated marketing strategies and tactics to promote the sale of nutrition products for young children (Table 12). Nearly one-third (31.1%) promoted these products using a special showcase. Other common promotional tactics found were special sales (16.4%), product holders (10.7%), banners (8.2%) and gifts attached to the products (6.6%). In addition, 8.2% of the tactics used involved product promotion. For example, in one shop, customers could accumulate marks for each purchase they made, and once they acquired a certain number of marks, they would receive a toy prize for their child. While these tactics are not prohibited by Decree 21, they go against the recommendations of the International Code and encourage the usage of the products over breastfeeding.

Table 12 Strategies and tactics used by companies to promote and sell products in retail shops

| Indicators | n | % |
|---|-----------|--------------|
| Strategies/tactics used by company at the retail shop (N=208 shops) | | |
| Yes No | 68 140 | 32.7 67.3 |
| Marketing tactics (N=122 cases) | | |
| Discount | 1 | 8.0 |
| Special showcase | 38 | 31.1 |
| Shopping coupon | 1 | 8.0 |
| Gift attached to product | 8 | 6.6 |
| Banner/band-roll | 10 | 8.2 |
| Product information | 6 | 4.9 |
| Special ways of sales | 20 | 16.4 |
| Bonus | 2 | 1.6 |
| Product promotion | 10 | 8.2 |
| Product holder | 13 | 10.7 |
| Other | 13 | 10.7 |
| Companies (& brands) promoted in | | |
| sale places (n=90 products) | | |

| Abbott (Gain, Similac) | 14 | 15.6 |
|-----------------------------------|----|------|
| Vinamilk (Ridielac, Dielac) | 26 | 28.9 |
| Mead Johnson (Enfalac, Enfagrow) | 7 | 7.8 |
| FrieslandCampina (Frisolac, Friso | 7 | 7.0 |
| Gold) | | 7.8 |
| Dumex-Danone (Dugro Gold, Dulac) | 5 | 5.6 |
| Dutch Lady (Gold Step) | 4 | 4.4 |
| VNA-Pharm/Gilbert (Phsyiolac) | 4 | 4.4 |
| Pigeon bottles | 3 | 3.3 |
| Biofocus (Sua non Smart) | 2 | 2.2 |
| Wakodo (Gun gun) | 2 | 2.2 |
| Namyang (XO) | 2 | 2.2 |
| HIPP (infant milk) | 2 | 2.2 |
| Arla (Milex) | 1 | 1.1 |
| VitaDairy (Vitamama) | 1 | 1.1 |
| Nutifoods (Nuti-IQ) | 1 | 1.1 |
| Mama Sua Non (New) | 1 | 1.1 |
| Bebivita | 1 | 1.1 |
| The GioiTuoiTho Co. bottle | 1 | 1.1 |
| Cosimex | 1 | 1.1 |
| Celia Vietnam (Develop) | 1 | 1.1 |
| Other (unclear) | 4 | 4.4 |

At times, customers were directly approached by sales personnel who tried to convince them to buy a specific product. These sales personnel are sometimes prompted by nutrition companies, which were found to offer money, discounts, coupons, and other incentives to sales personnel to encourage the sale of their products. In one instance, a television was offered if the salesclerk sold more of the product. Companies were also found to hold meetings with retailers.

The study team also observed that two customers were invited to meetings or trial uses of a product. In two other cases, mothers were asked to provide their contact information.

5.3.2 Promotion and advertising of nutrition products for infants in health facilities

Under Article 11.2 of Decree 21, health facilities must not allow the sale of milk products for children under 12 months of age or food products for children under 6 months of age. In addition, health facilities are prohibited from allowing companies to display nutrition products for young children, feeding bottles, teats or dummies. Hospital pharmacies are excluded from both of these provisions. Article 6 of the International Code also prohibits these activities, but it does not set age limits for the products and does not include an exception for hospital pharmacies.

Companies were found to offer money, discounts, coupons, and other incentives to sales personnel to encourage the sale of their products.

Under Article 10.2 of Decree 21, health facilities and health staff are prohibited from accepting material benefits or other forms of expression that bear the name or logos of milk products for

infants under 12 months old or food products for infants under 6 months old. The International Code contains a similar provision in Article 6.8, although it does not set age limits for the products covered.

A total of 9 of 152 health facilities (5.9%), 4 baby-friendly facilities and 5 non-baby-friendly facilities, were found to display nutrition products for young children covered by the Decree, including formula for infants under 6 months old, milk products for children over 6 months old, special milk products, powdered milk, bottles and dummies (Table 13). While most (80%) of the 17 products were received by normal trading (i.e., received in the same way that all merchandise/products are received in the facility), one was given to the facility by a seller and two were given to the facility by an HIV prevention program.

In general, the study team found few examples of strategies and tactics used by companies to promote and sell nutrition products in health facilities. Only one case of a sale promotion was reported in which customers could buy 10 cans of Abbott Similac powdered milk and get one free in a baby-friendly hospital.

Health facilities were examined for the presence of materials bearing the name or logo of nutrition companies. These materials were found in 6 of the 152 health facilities (3.9%), including 2 cases in one baby-friendly facility and 7 cases in 5 non-baby-friendly facilities. In the baby-friendly facility, the two items were seen: a clock with the Abbott logo on the wall and a Mead Johnson poster for the product Enfa A+ on the wall. In non-baby-friendly facilities, a Danone-Dumex clock with the logos for Dumex and Dupro Gold were found in a pediatric clinic. A data collector also found an Abbott calendar in one Ob/Gyn department. In addition, 3 posters and 1 work table with logos for the Friso brand of FrieslandCampina were found in pregnancy clinics and vaccination clinics. Cases of nutrition companies giving gifts to health staff were reported twice. In both baby-friendly and non-baby-friendly health facilities, Abbott ballpoint pens with an Isomil IQ label were found. While company names and logos are permitted to be featured on these materials under the Decree, the names/logos of specific products are not.

 Table 13
 Presence of nutrition products in health facilities

| Indicators | Baby-friendly health facilities (n=14) | | Non-baby health f (n=1 | acilities | Total (N=152) | | |
|------------------------|--|------|------------------------------|-----------|------------------|------|--|
| | n | % | n | % | n | % | |
| Health facility | | | | | | | |
| Has products | 4 | 28.6 | 5 | 3.6 | 9 | 5.9 | |
| Does not have products | 10 | 71.4 | 133 | 96.4 | 143 | 94.1 | |
| | | | | | | | |
| Type of products | (n | =10) | (n=7) | | (n=17) | | |
| Infant formula <6 | 3 | 30.0 | 3 | 42.9 | 6 | 35.3 | |
| months | | | | | | | |
| Milk for > 6 months | 1 | 10.0 | 0 | 0 | 1 | 5.9 | |
| Special milk | 3 | 30.0 | 0 | 0 | 3 | 17.6 | |
| Powder | 2 | 20.0 | 0 | 0 | 2 | 11.8 | |

| Bottle | 1 | 10.0 | 2 | 28.6 | 3 | 17.6 |
|--------------------|---|------|---|------|----|------|
| Dummies | U | U | 2 | 28.6 | 2 | 11.8 |
| Ways of receipt | | | | | | |
| Normal trading | 9 | 90.0 | 3 | 60.0 | 12 | 80.0 |
| Given by seller | 1 | 10.0 | - | - | 1 | 6.7 |
| Through an HIV | - | - | 2 | 40.0 | 2 | 13.3 |
| prevention program | | | | | | |

5.4 Labeling of nutrition products for infants and young children

Under Article 8 of Decree 21, labels of **nutrition products for young children** <u>MUST</u>:

- Contain the text: "ATTENTION: Breastmilk is the best food for the health and overall development of infants. The anti-infection factors, especially antibodies, available in breastmilk only, help prevent and control diarrhea, respiratory infections and several other infectious diseases in children." The height of the letters must not be less than 2 mm.
- Contain the text: "Use the product only under physicians' instructions. Strictly follow preparation instructions. Feed children by clean cups and spoons." The height of the letters must not be less than 1.5 mm.
- Include instructions in Vietnamese on how to prepare the product that are easy to follow and accompanies by simple tables.
- Clearly indicate the age of the child that the product is designed for.
- Include a certified number of published standards of quality, hygiene and food safety and include the origin, production/expiration date, ingredients.
- Adhere to laws on labeling of products for domestic, imported or exported goods.

Labels of nutrition products for young children MUST NOT:

- Imply that the product is equal to or better than breastmilk.
- Feature images or pictures of infants under 12 months of age, bottles, teats or dummies.

Under Article 9 of Decree 21, labels of **feeding bottles** <u>MUST</u>:

- Include the text: "Strictly follow the instructions on hygiene and sterilization. The use of feeding bottles may make children refuse breastfeeding or increase the risk of diarrhea." The height of the lowercase letters must not be less than 2 mm.
- Provide instructions on proper use and sterilization.
- Include the name and exact address of the manufacturing and distribution facilities.

Labels of **dummies** <u>MUST</u>:

• Include the text: "Using dummies may have a negative effect on breastfeeding." The height of the lower-case letters must not be less than 2 mm.

Labeling regulations also apply to all feeding bottles, teats and dummies imported to Vietnam.

| Summary of findings on labeling of products within the scope of the Decree | | | | | | | |
|---|---|--|--|--|--|--|--|
| Practice | Violation /Loophole | | | | | | |
| In all, labeling violations were relatively common and were committed by over 20 domestic and multinational companies. | <u>Violation</u> : Article 8 of Decree 21 / Article 9 of the International Code | | | | | | |
| Less than half - only 48% - of the 355 labels on nutrition products for infants under 6 months of age complied with every regulation of the Decree. | <u>Violation</u> : Article 8 of Decree 21 / Article 9 of the International Code | | | | | | |
| One-tenth of labels on the 355 nutrition products for infants under 6 months of age and 30.7% of the 426 products for children 6-24 months of age implied that the product is equal to or better than breastmilk. | <u>Violation</u> : Article 8.2.c of Decree 21 / Article 9 of the International Code | | | | | | |
| 13% of nutrition products for infants under 6 months old contained text that either discouraged breastfeeding or idealized the use of breastmilk substitutes. | Violation: Articles 8.2.c of Decree 21 / Article 9.2 of the International Code Loophole: Articles 8 and 9 of Decree 21(should be clearer about what constitutes a violation) | | | | | | |
| Labels often made questionable health claims, including: helps babies' brains and eyes develop, strengthens immunity, supports digestion, increases intelligence, prevents disease, and/or improve children's height. | <u>Violation</u> : Articles 8.2.c of Decree 21 / Article 9.2 of the International Code and WHA resolution 62.23 <u>Loophole</u> : Article 8 of Decree 21 (provisions should be clearer) | | | | | | |
| 13% of labels on nutrition products for infants under 6 months old contained an image of an infant. | Violation: Articles 8.2.c of Decree 21 / Article 9.2 of the International Code Loophole: Article 8 of Decree 21 (age of infant can be argued) | | | | | | |
| Many labels of feeding bottles and teats were found to indirectly discourage breastfeeding by idealizing bottle-feeding or featuring images of infants bottle-feeding. | <u>Loophole</u> : Article 9 of Decree 21 | | | | | | |

5.4.1 Labeling of products for infants under 6 months of age

Decree 21 regulations for labeling of nutrition products for young children are listed above. The International Code includes these regulations, but also adds two more: that labels include a warning on improper preparation of the product and that labels provide instructions for preservation of the product.

In general, most of the 355 nutrition products for infants under 6 months of age examined in the study complied with these regulations when each regulation was examined separately (Table 14). For example, more than 90% of products contained the text: "Breastmilk is the best food for the health and overall development of infants." In addition, more than 90% were written in understandable Vietnamese, had an expiration date and product serial number, and came with instructions for preparation and preservation.

Less than half - only 48% -of labels on nutrition products for infants under 6 months of age contained every point of information required under Decree 21.

Fewer products contained the word "Attention" or similar (61.1%), a warning on improper preparation (68.6%) and the text: "Use the product only under physicians' instructions" (80.6%).

While inclusion of information is high when considered separately, less than half - only 48% - of labels on nutrition products for infants under 6 months of age contained every point of information required under Decree 21 (Table 14).

In violation of Decree 21, 10% of the 355 reviewed products for infants under 6 months old contained words that implied that the product was similar to or better than breastmilk (Table 15). Some examples include:

- Has colostrum composition like mother's milk;
- Contains antibodies:
- Has proteins with the same properties as mother's milk;
- Contains components found in mother's milk and colostrum;
- Made with the same components as mother's milk;
- Contains supplements according to the standard of mother's milk

The study team found 46 labels (13%) of nutrition products for infants under 6 months of age that included words that discouraged breastfeeding or idealized the use of breastmilk substitutes. For example, labels stated that the product:

- Has DHA and AA to help your baby's brain and eyes develop;
- Contains necessary nutrients for the growth and development of the brain;
- Strengthens your baby's immunity;
- Helps achieve comprehensive development;
- Helps develop height;
- DHA for intelligence;
- Contains bacteria that help strengthen your baby;
- Provides needed nutrition to supply your child with enough energy;
- Supports digestion;
- For your child's future and the important stages of life;
- Makes your child taller and more intelligent.

Table 14 Percentage of nutrition products for infants under 6 months of age that provide information as required by the International Code and Decree 21

| | Type of Product | | | | | | | |
|---|--|---------------|-------------------------|--------------|--------|-------------------|-------------|---------------|
| | Milk/formula Special milk (n=29) (n=322) n (%) | | Other (n=4) n (%) | | (N=: | tal 355) %) | | |
| Label contains | No | Yes | No | Yes | No | Yes | No | Yes |
| Text "Attention" or similar | 130 | 192 | 6 | 23 | 2 | 2 | 138 | 217 |
| | (40.4) | (59.6) | (20.7) | (79.3) | (50.0) | (50.0) | (38.9) | (61.1) |
| Text "Breastmilk is the best" | 14 | 308 | 8 | 21 | 0 | 4 | 22 | 333 |
| | (4.3) | (95.7) | (27.6) | (72.4) | (0) | (100) | (6.2) | (93.8) |
| Warning on improper preparation [†] | 91 | 230 | 17 | 12 | 3 | 1 | 111 | 243 |
| | (28.3) | (71.7) | (58.6) | (41.4) | (75.0) | (25.0) | (31.4) | (68.6) |
| Text "Use as directed by your doctor" | 53 | 269 | 15 | 14 | 1 | 3 | 69 | 286 |
| | (16.5) | 83.5) | (51.7) | (48.3) | (25.0) | (75.0) | (19.4) | (80.6) |
| Clear and understandable instructions for preparation and use | 10 (3.1) | 312 (96.9) | 3 (10.3) | 26 (89.7) | 0 (0) | 4 (100) | 13 (3.7) | 342 (96.3) |
| Understandable local language | 11 | 311 | 0 | 29 | 0 | 4 | 11 | 344 |
| | (3.4) | (96.6) | (0) | (100) | (0) | (100) | (3.1) | (96.9) |
| Clearly visible expiration date | 3 | 319 | 2 | 27 | 0 | 4 | 5 | 350 |
| | (0.9) | (99.1) | (6.9) | (93.1) | (0) | (100) | (1.4) | (98.6) |
| Instructions for preservation† | 7 | 315 | 1 | 28 | 0 | 4 | 8 | 347 |
| | (2.2) | (97.8) | (3.4) | (96.6) | (0) | (100) | (2.3) | (97.7) |
| Product serial number | 20 | 301 | 9 | 20 | 0 | 4 | 29 | 325 |
| | (6.2) | (93.8) | (31.0) | (69.0) | (0) | (100) | (8.2) | (91.8) |
| Ingredients | 9 (2.8) | 313 (97.2) | 3 (10.3) | 26 (89.7) | 0 (0) | 4 (100) | 12 (3.4) | 343 (96.6) |
| Labels that provide all precise information required by Decree 21 | 161 | 160 | 20 | 9 | 3 | 1 | 184 | 170 |
| | (50.2) | (49.8) | (69.0) | (31.0) | (75.0) | (25.0) | (52.0) | (48.0) |

 $^{^{\}dagger}$ Regulation is included in the International Code but not in Decree 21.

Moreover, 8.2% of labels featured images or photos of infants, and 7.3% contained images that idealized the use of breastmilk substitutes, both of which are direct violations of Decree 21 (Table 15). Some examples of images are the following:

- Babies under 1 year old
- Mothers breastfeeding their children
- Babies surrounded by dummies

- Contained the text: "Protective nutrients"
- Baby standing next to a tape measure to measure his/her height

Table 15 Percentage of nutrition products for infants under 6 months of age that provide information as required by the International Code and Decree 21

| | | Type of product | | | | | | |
|--|-----------------|----------------------------------|------------------------|--------------|-------------|----------------|---------------|--------------|
| | for in (ordi | ormula fants nary) 322) | Special milk (n=29) | | | Other (n=4) | | tal 355) |
| Label contains | n (| %) | n (%) | | n (%) | | n (%) | |
| | No | Yes | No | Yes | No | Yes | No | Yes |
| Words such as "similar to breastmilk" or equivalent | 290 (90.1) | 32 (9.9) | 25 (86.2) | 4 (13.8) | 3 (75.0) | 1 (25.0) | 318 (89.6) | 37 (10.4) |
| Words that discourage breastfeeding or idealize breastmilk substitutes | 279 (86.6) | 43 (13.4) | 26 (89.7) | 3 (10.3) | 4 (100) | 0 (0) | 309 (87.0) | 46 (13.0) |
| Picture or image of infant | 303 (94.1) | 19 (5.9) | 19 (65.5) | 10 (34.5) | 4 (100) | 0 (0) | 326 (91.8) | 29 (8.2) |
| Picture or image idealizing the use of breastmilk substitutes | 297 (92.2) | 25 (7.8) | 28 (96.6) | 1 (3.4) | 4 (100) | 0 (0) | 329 (92.7) | 26 (7.3) |

| Companies with products for infants under 6 months of age found to violate the labeling regulations of Decree 21 | | | | | | | |
|--|------------------------|------------------------|--|--|--|--|--|
| Abbott | Nestle | Biofocus | | | | | |
| Arla | Mead Johnson | Wyeth Nutrition | | | | | |
| Vinamilk | Nutifoods | Cosimex | | | | | |
| FrieslandCampina/Dutch Lady | G&P Viet Nam Corp. | Hero Baby | | | | | |
| VNA Pharm/ Gilbert | Namyang Dairy Products | PBM Products | | | | | |
| Laboratories | /Traphaco | Xpert Nutrition | | | | | |
| Danone-Dumex | Celia | Manufacturing & | | | | | |
| Wakodo | Goodhealth Viet Nam | Export Co., Saigon | | | | | |
| HiPP/Van An Co. | | | | | | | |

5.4.2 Labeling of nutrition products targeting children aged 6 to 24 months of age

A large majority (97.9%) of the 426 reviewed labels on nutrition products for children aged 6 to 24 months clearly indicated the age range for the products' use (Table 16), a requirement of Decree 21. Thirty-five labels (8.3%) violated Decree 21 by suggesting the product be used with a feeding bottle as opposed to a clean cup and spoon. Nearly one-third (30.7%) of the labels were similar to labels for milk products for infants under 6 months old produced by the same company, and 30 labels (7.2%) suggested that infants under 6 months old use the product. Moreover, 56 (13.3%) of the examined labels breached Decree 21 by featuring a picture or image of an infant.

The study team recorded observations of violations of the labeling provisions of Decree 21, provided below:

Omission of required text or having text that is too small (under 2 mm)

• Omission of the word "Attention" or equivalent

Containing language or images implying that product is similar to or better than breastmilk

- Similar to the peptides in mother's milk
- Is a valuable source of nutrients from mother's love
- With nutrients according to the breastmilk standard

Idealizes use of nutrition product

- For children's retinas and a healthy immune system
- Prevents disease
- Contains active ingredients necessary for brain development
- Convenient for mom, great for children
- Feeds babies' immune system
- Supports digestion and optimal brain development

| Companies with products for children 6 to 24 months of age found to violate the labeling regulations of Decree 21 | | | | | | | |
|---|------------------|--------------------|--|--|--|--|--|
| Abbott | Nestle | Danone-Dumex | | | | | |
| Vinamilk | Arla | HiPP/Van An Co. | | | | | |
| FrieslandCampina/Dutch Lady | Mead Johnson | Goodhealth Vietnam | | | | | |
| VNA Pharm/Gilbert Laboratories | Namyang/Traphaco | Meiji | | | | | |
| G&P Viet Nam Corp | Celia | Hero Baby | | | | | |

Table 16 Percentage of labels on products for children from 6 months to under 2 years old of age that violate Decree 21 regulations

| | Type of product | | | | | | | |
|-----------------------------------|-----------------|--------|---------|---------|-------|-------------------|---------|--------|
| | Milk pr | oducts | Compler | nentary | Ot | ther Total | | tal |
| | (n= | 58) | foo | ds | (n | =3) | (N=426) | |
| Indicators | | | (n=3 | 365) | | | | |
| | n (| %) | n (| %) | n | (%) | n (| %) |
| | Yes | No | Yes | No | Yes | No | Yes | No |
| Products for children from 6 | 58 | 0 | 356 | 9 | 3 | 0 | 417 | 9 |
| months to under 2 years of age | (100) | (0) | (97.5) | (2.5) | (100) | (0) | (97.9) | (2.1) |
| with labels that clearly indicate | | | | | | | | |
| a range of age to use | | | | | | | | |
| On the label there is/are | | | | | | | | |
| Suggestion to use product with | 6 | 52 | 29 | 332 | 0 | 3 | 35 | 387 |
| bottle | (10.3) | (89.7) | (8.0) | (92.0) | (0) | (100) | (8.3) | (91.7) |
| | 8 | 50 | 47 | 312 | 1 | 2 | 56 | 364 |
| Picture or image of an infant | (13.8) | (86.2) | (13.1) | (86.9) | (33.3 | (66.7) | (13.3) | (86.7) |
| | | | | |) | | | |
| Similar to labels on milk | 15 | 42 | 110 | 240 | 1 | 2 | 126 | 284 |
| products for infants under 6 | (26.3) | (73.7) | (31.4) | (68.6) | (33.3 | (66.7) | (30.7) | (69.3) |
| months of the same company | | | | |) | | | |
| Suggestion for infants under 6 | 6 | 51 | 24 | 334 | 0 | 3 | 30 | 388 |
| months old to use | (10.5) | (89.5) | (6.7) | (93.3) | (0) | (100) | (7.2) | (92.8) |

5.4.3 Labeling of bottles, teats and dummies

The provisions in Decree 21 for the labeling of bottles, teats and dummies are less stringent than those for nutrition products for young children. It should be noted that the following provisions are not required under Decree 21 or the International Code, which does not give recommendations for the labeling of feeding bottles, teats or dummies. However, the indicators in Table 17 do serve to indirectly discourage breastfeeding by idealizing the use of feeding bottles, teats or dummies.

The study team examined a total of 135 feeding bottles and teats. Approximately one-third (32.6%) of these products featured an image of a newborn, infant or child feeding from a bottle, and over one-tenth (11.7%) contained images or text that idealized the product (Table 17). Only one teat encouraged the use of breastmilk substitutes, and only 6 teats implied that the product was similar to a mother's nipple. The study team noted some instances in which bottle labels were not in Vietnamese, and one case in which the label was inside the bottle and unreachable.

Table 17 Labeling of feeding bottles and teats

| Indicators | Bottle (n=66) | | Nipple (n= | - | Total (N=135) | | |
|---|------------------|--------|---------------|--------|------------------|--------|--|
| | Yes | No | Yes | No | Yes | No | |
| Label on bottle and/or teat has | n (⁰ | %) | n (| %) | n (%) | | |
| Image of a newborn baby or an infant or a child sucking a bottle | 23 | 42 | 20 | 47 | 43 | 89 | |
| | (35.4) | (64.6) | (29.9) | (70.1) | (32.6) | (67.4) | |
| Images or text idealizing the product | 6 | 58 | 9 | 55 | 15 | 113 | |
| | (9.4) | (90.6) | (14.1) | (85.9) | (11.7) | (88.3) | |
| Encouragement of use of breastmilk substitutes | 0 | 64 | 1 | 64 | 1 | 128 | |
| | (0) | (100) | (1.5) | (98.5) | (0.8) | (99.2) | |
| Images or text which imply that product is similar to mother's nipple | 0 | 64 | 6 | 60 | 6 | 124 | |
| | (0) | (100) | (9.1) | (90.9) | (4.6) | (95.4) | |

| Companies that produce bottles or teats with labels containing one or more of the four characteristics in Table 17 | | | | | |
|--|------------------------------|--|--|--|--|
| Sieu Thanh Ltd. | The Gioi Tuoi Tho Co. | | | | |
| Gerber | Pigeon | | | | |
| Jumi Viet Nam | Van An Co. | | | | |
| Heinz | Farling Industrial Co., Ltd. | | | | |
| AGI | Angel Co. Viet Nam | | | | |

5.5 Usage of breastmilk substitutes among mothers

Summary of findings on usage of breastmilk substitutes among mothers of infants under 6 months old

- Slightly more than half (52.7%) of the 349 mothers of infants under 6 months old reported using breastmilk substitutes.
- The 184 mothers who fed their children breastmilk substitutes cited numerous reasons for doing so. The two most commonly cited reasons were: 1) they were advised to do so by a friend, family member or neighbor (21.7%); and 2) they felt that they did not produce enough breastmilk for their children (21.2%).
- Concerns over the quantity or appropriateness of breastfeeding (e.g. after a Caesarean section) were somewhat common among mothers.
- Nearly one-quarter of the mothers who used breastmilk substitutes (23.4%) reported being advised to do so by a health professional, a violation of Article 12.2.c of Decree 21 (unless it is medically necessary to do so).
- Among those who used breastmilk substitutes, 10.3% of mothers were influenced by advertisements to do so and 6.5% felt that these substitutes were superior to breastmilk.

5.5.1 Usage of breastmilk substitutes among mothers of infants under 6 months old

Slightly more than half (52.7%) of the 349 mothers of infants under 6 months old reported using breastmilk substitutes (Table 18). The most commonly used product was VinamilkDielac or Ridielac followed by Abbott Similac. About one-tenth of mothers reported using G&P Mama Sua Non brands, Mead Johnson Enfa, FrieslandCampina Friso, and Nestle Nan Pro or Lactogen.

5.5.2 Reasoning for usage of breastmilk substitutes

The mothers interviewed gave numerous reasons for feeding their infants breastmilk substitutes. Over one-fifth (21.2%) of the 184 mothers who used these products reported that they did not believe that they produced enough breastmilk for their child (Table 19). An additional 6.5% felt that they had either no or reduced breastmilk after undergoing a Caesarean section (C-section), and 4.3% of women cited the fact that they had C-sections as their reason for forgoing breastfeeding, although they did not provide more details than that.

A relatively large proportion of mothers used breastmilk substitutes based on the advice of others. For example, 7.1% were advised to do so by a doctor, 1.6% by a nutritionist, 9.8% by a nurse, and 4.9% by other medical staff. Put together, nearly one-quarter (23.4%) of the mothers who use breastmilk substitutes reported that they do so at the advice of a health worker. Additionally, one-fifth (21.7%) were following the advice of friends, neighbors or family members to use these products, while one-tenth were basing their behavior on a past experience feeding a child.

 Table 18
 Usage of breastmilk substitutes among mothers and brands used

| Indicators | Total (N=349) | | |
|--------------------------------------|---------------|------|--|
| | n | (%) | |
| Gives breastmilk substitute to child | | | |
| Yes | 184 | 52.7 | |
| No | 165 | 47.3 | |
| Company (Brand) (n=175) | | | |
| Abbott (Similac) | 33 | 18.9 | |
| Vinamilk (Dielac, Ridielac) | 36 | 20.6 | |
| Mead Johnson Enfa (Enfa) | 18 | 10.3 | |
| FrieslandCampina (Friso) | 18 | 10.3 | |
| Dutch Lady | 3 | 1.7 | |
| Mama Sua Non (A+, New, Star) | 20 | 11.4 | |
| Dumex-Danone (Dupro Gold, Dulac, | 13 | 7.4 | |
| Dumex) | | | |
| Namyang (XO) | 6 | 3.4 | |
| Nestle (Nan Pro, Lactogen) | 18 | 10.3 | |
| Arla (Milex) | 2 | 1.1 | |
| HiPP (HIPP infant formula) | 2 | 1.1 | |
| Nutifood (Nuti-IQ) | 2 | 1.1 | |
| Wyeth (S26 Gold 1 Alpha Pro) | 1 | 0.6 | |
| Other (unclear) | 3 | 1.7 | |

Advertising influenced one-tenth of mothers to use breastmilk substitutes, and 6.5% of mothers felt that these products are superior to breastmilk.

Work or school interfering with exclusive breastfeeding was also cited as a reason by 10.9% of mothers.

Nearly one-quarter (23.4%) of mothers who use breastmilk substitutes reported that they do so at the advice of a health worker.

Table 19 Reasons for usage of breastmilk substitutes among mothers of infants under 6 months of age

| Reasons | Total (N=184) | | |
|--|---------------|------|--|
| | n | % | |
| Consulted by doctor | 13 | 7.1 | |
| Consulted by nurse | 18 | 9.8 | |
| Consulted by nutritionist | 3 | 1.6 | |
| Consulted by other medical staff | 9 | 4.9 | |
| Advised by friends/neighbors/family | 40 | 21.7 | |
| Experience from feeding older child | 17 | 9.2 | |
| Advertisement | 19 | 10.3 | |
| Belief that products are superior to breastmilk | 12 | 6.5 | |
| Advised by sales personnel | 1 | 0.5 | |
| Mother following advice on product | 1 | 0.5 | |
| Work/school interferes with breastfeeding | 20 | 10.9 | |
| Mother had a C-section | 8 | 4.3 | |
| Belief that mother has no/reduced milk after C-section | 12 | 6.5 | |
| Mother feels she does not have enough breastmilk | 39 | 21.2 | |
| Mother on antibiotics | 1 | 0.5 | |
| Child is abandoned | 1 | 0.5 | |
| Other/unclear | 2 | 1.1 | |

6 Conclusions

6.1 Violations of Decree 21

While most products and facilities reviewed complied with Decree 21, evidence from this review suggests that violations of Decree 21 are varied and relatively widespread, covering multiple provisions of the Decree and in all the provinces reviewed. Violations were

Evidence from this review suggests that violations Decree 21 are varied and relatively widespread, covering multiple provisions of the Decree and in all provinces reviewed.

carried out by multiple domestic and multinational companies and included the realms of IEC materials, promotion and advertising, labeling, and regulations in health facilities. Numerous additional cases were found in which companies or health facilities were technically in compliance with Decree 21 but violated the International Code, which is stricter than Decree 21. Violation or no, these practices served the overall purpose of discouraging breastfeeding by promoting the use of breastmilk substitutes and other products within the scope of the Decree.

Representatives from nutrition product companies were found to contact mothers within health facilities although this practice is prohibited by Article 10.2.b of Decree 21. In addition to being contacted by company representatives within health facilities, there were reports of mothers receiving gifts associated with company products at health facilities. In at least one case, this gift was provided by a member of the health staff, a practice that is prohibited (Article 12.2.b) and imbues the product with a medical endorsement. Furthermore, nearly one-quarter of the 184 mothers of infants under 6 months old who use breastmilk substitutes report that they do so based on the advice of a health worker, although Article 12.2.c prohibits health staff from advising their patients to use nutrition products for infants unless medically necessary.

While most health facilities complied with Decree 21, violations were found in both baby-friendly and non-baby-friendly health facilities.

While most health facilities complied with the provisions of Decree 21, violations were found in both baby-friendly and non-baby-friendly health facilities. Nine out of 152 health facilities – 4 baby-friendly and 5 non-baby-friendly – were found to violate Article 11.2.b of Decree 21 by permitting the display of products within the facility, including milk products for infants under 12 months of age, feeding bottles, and dummies. DHI inspections also uncovered violations of Articles 10.2.band 11.2.ain some hospitals that permitted the

sale of restricted nutrition products either at kiosks or through health workers. Six hospitals were also found to violate Article 12.2.a by containing material benefits with the names and logos of products restricted under the Decree, and 2 cases were found in which health staff were given gifts from these companies.

Nearly half of the reviewed IEC materials violated Article 4.3.c of Decree 21 by displaying the logo or symbol of nutrition products restricted under the Decree. This was true for IEC materials targeting mothers and the general public as well as those targeting health staff. Most IEC materials

for mothers related to IYCF and the use of nutrition products for young children fell short of meeting the informational content requirements outlined in Articles 4 and 5, such as the providing

Over 100 advertising violations in 70 retail shops were uncovered. These violations were committed by over 20 multinational and domestic companies.

information on the benefits of breastfeeding, the disadvantages and costs of not breastfeeding, the negative impact of bottle-feeding, and the hazards of improper or unnecessary use of nutrition products. While most IEC materials for health workers covered the topics required, violations were also found amongst these materials, and only 5 out of 22 materials comply with Article 5.5 requiring that the costs of using nutrition products for young children be described.

Article 6.1 of Decree 21 bans advertising of milk products for children under 12 months old, food products for infants under 6 months old, feeding bottles, teats, and dummies. However, over 100 advertising violations in 70 retail shops were uncovered in this study. These violations were committed by over 20 multinational and domestic companies. Some of these advertisements featured images of babies, including images of babies using feeding bottles.

Article 8 of Decree 21 details the precise information that is required for inclusion on the labels of nutrition products for young children. While Decree compliance is high when each informational point is considered separately, only half of the 355 labels on nutrition products for infants under 6 months of age contained every informational point required under the Decree. Moreover, nearly one-tenth of labels on these products featured an image or photo of an infant under 12 months old or of dummies, prohibited by Article 8.2.c. Some labels violated Article 8.1.b by suggesting that the milk product be used with a bottle instead of a clean cup and spoon.

Violations of Decree 21 were commonly found in three areas: IEC materials, advertising, and labeling of products within the scope of the Decree. These violations were much the same in these three areas, all of which serve the aim of product promotion and are therefore referred to as "promotional materials" henceforth. Many of these promotional materials contained images or language that implied that a nutrition product for young children is equal to or better than breastmilk, a violation of Article 4.3.b. In some cases, the promotional material made the outright claim that the product could be used in place of breastmilk, while others made claims that the

product meets the "standard of mother's milk." Many products now contain additives such as fatty acids (e.g., DHA and AA), amino acids, proteins, prebiotics, and probiotics, which serve to make the products seem more like breastmilk. The promotional materials often idealize the products through claims that the additives enhance the immune system, improve vision, reduce allergies, and prevent infections. These claims are usually misleading and mostly scientifically unsubstantiated, and in that way they violate Article 4.1 of Decree 21, which states that materials must ensure objectivity and be scientifically

Violations of Decree 21 were commonly found in three areas: IEC materials, advertisements, and labeling of products within the scope of the Decree.

valid. Other common, yet scientifically unproven claims were that the nutrition product helps with brain or intellectual development, height and/or weight gain, and overall physical development. Furthermore, several promotional materials implied that bottle-feeding is superior to breastfeeding because mothers can measure the amount of milk they are feeding their children, an assertion that plays on the common fear mothers hold that they are not producing enough breastmilk.

6.2 Strengths and weaknesses of Decree 21 and its implementation

6.2.1 Strengths of Decree 21 and its implementation

Decree 21 contains many strengths as a tool for promoting breastfeeding and optimal IYCF practices in Vietnam. These strengths are highlighted below⁴:

- a. Decree 21 is well-organized and easily comprehendible. Use of the term "nutrition products for young children" as a collective term for the milk and food products within the scope of the Decree allows for the Decree to be more concise and understandable.
- b. The Decree covers a broad scope, covering not only nutrition products for young children, but also feeding bottles, teats and dummies.
- c. Chapter 2 on information, education, communication, media and advertising is more extensive than earlier versions of the Decree.
- d. The incorporation of the recommendation to breastfeed for up to 24 months or longer brings the Decree up to date with current scientific knowledge and international recommendations.
- e. The ban on donations in health facilities brings the Decree more up-to-date with relevant WHA Resolutions.
- f. The provisions of Articles 11 and 12 of Decree 21 that restrict the promotion of nutrition products for young children in health facilities are almost comprehensive.
- g. Article 8 of Decree 21 on the labeling requirements for nutrition products for young children is almost comprehensive as nearly all of the informational points recommended for inclusion by the International Code are present. Moreover, Decree 21 goes beyond the International Code by applying labeling provisions to bottles and teats in Article 9.
- h. Article 10.2.e of the Decree bans the use of scholarships or funds for research, training, conferences, seminars, courses, concerts, counseling services by phone or any other form to directly or indirectly promote certain nutrition products for young children. Vietnam is one of the few countries in the world to ban sponsorship in this way. This provision serves to

⁴Some strengths included here are referred from the Report to UNICEF Hanoi to Review Code Implementation in Vietnam by ICDC, 2008.

minimize conflicts of interest between nutrition product companies and health staff, researchers, and other professionals.

Strengths in the implementation of Decree 21 include:

- a. IEC activities that promote breastfeeding and disseminate information on Decree 21 have increased substantially in recent years. Improving IYCF practices has been given priority as a method for combating child malnutrition. Breastfeeding is now commonly incorporated into the trainings and professional development in health facilities. Additionally, numerous IEC activities are also directed at mothers, pregnant women and the general public. Initiatives such as Breastfeeding Week and Nutrition and Development Week have made gains in spreading information about the benefits of breastfeeding.
- b. Systems and structures for monitoring and supervision of Decree 21 are already in place. In recent years, DHI has conducted inspections in health facilities, including inspections in 8 provinces as described in this report. DHI reports that provinces and cities conduct annual inspections on compliance with Decree 21.
- c. The heads of health facilities are generally aware of Decree 21, and most hospitals have been found to comply with the provisions of the Decree. In addition, most meet or are working to meet the 10 conditions for successful breastfeeding. In recent years, health workers have been reported to support breastfeeding, and more and more of these workers are trained in providing breastfeeding counseling to mothers.

6.2.2 Weaknesses of Decree 21 and its implementation

Weaknesses in Decree 21 provisions

Decree 21 does not meet the minimum standard set by the International Code and subsequent WHA resolutions, and it is therefore classified as a second tier "many provisions law" by ICDC. One difficulty faced by the drafters of the Decree is that many concepts discussed in the International Code do not have equivalent terms in Vietnamese, and therefore some accuracy is lost when the International Code is translated into Vietnamese. For example, there is no equivalent term in Vietnamese for "marketing," so this is often translated as "trade." This fact may explain some, but not all, of the discrepancies between the International Code and Decree 21.

While compliance with Decree 21 was relatively high overall, nutrition product companies were found to exploit numerous loopholes or gaps present in the Decree. Weaknesses to specific provisions of Decree 21 are the following:

a. <u>Scope and definitions</u>: Given that Article 2.1 includes "food produced by industrial methods" (i.e., manufactured food), it can be strictly interpreted that complementary foods for children under 6 months of age are within the scope of the Decree. However, Article 2.1.a does not give complementary foods for children under 6 months old as an example.

While feeding bottles, teats and dummies are within the scope of the Decree, these products do not fall under the term "nutrition products for young children," and therefore are left out of many provisions of the Decree, including Articles 3, 10, 11 and 12.

Article 2 of the Decree does not provide clear definitions for nutrition product companies as does Article 3 of the International Code. For example, there are not definitions for "distributors," "manufacturers" or "marketing personnel." This omission may lead to confusion over who is responsible for compliance with the Decree.

b. <u>Contact with mothers</u>: Article 10.2.b of Decree 21 prohibits nutrition product companies from directly or indirectly contacting mothers, pregnant women and family members in health facilities for the promotion or sale of milk products for infants under 12 months of age and food products for infants under 6 months of age. This provision does not restrict contact with individuals outside of health facilities, so companies often work around this provision by contacting mothers and pregnant women in their homes, shops, Houses of Culture, and hotels or via the internet, mail or phone. These contacts serve to discourage breastfeeding as company representatives promote their products, offer mothers incentives to use their products such as gifts or samples, or advise mothers on IYCF practices.

Furthermore, the provision allows for companies to contact mothers to promote or sell nutrition products for children older than 12 months, many of which greatly resemble the products restricted by the provision. This age specification creates confusion about what constitutes a violation of Decree 21, and it creates a loophole for companies to work around the Decree provisions.

- c. <u>Information</u>, <u>education</u> and <u>communication</u>: Although Articles 4 and 5 of Decree 21 are extensive, some important points are missing, including: the negative effects of partial bottle-feeding on breastfeeding; the difficulty of reversing the decision not to breastfeed; the proper use of breastmilk substitutes, whether manufactured or home-prepared; and maternal nutrition as it relates to the preparation for and maintenance of breastfeeding.
 - Chapter 2 of Decree 21 does not include a provision comparable to Article 4.3 of the International Code on donations of informational and educational materials or equipment from nutrition product companies. While the International Code stipulates that donations should be made only at the request and with written approval from a government authority and that should only be distributed through the health care system, Decree 21 does not have these regulations.
- d. Advertising: Article 6 allows for advertising of milk products for children from 12 to 24 months of age, after registration pursuant to Article 6.3. The internationally recognized recommendation is for breastfeeding to be maintained for up to 24 months or beyond, so this provision of the Decree is not in line with international standards. Moreover, follow-up milks and growing-up milks for children aged 1 to 3 years often use labels and brand names that resemble those for products targeting children under 12 months and 6 months of age. Due to these similarities, allowing for advertising or promotion of products for children over

12 months old allows companies to indirectly promote the restricted nutrition products for children under 12 months old. Nearly one-third of the milk products for children aged 6 to 24 months reviewed in this study resembled those products for infants under 6 months of age.

There are no provisions under Article 6 stipulating the speed of reading of the required text: "Breastmilk is the best food for the health and overall development of infants." Advertising on television and radio often read this too quickly to be discernible.

- e. <u>Promotion in retail shops</u>: Many promotional tactics employed by nutrition product companies outside of health facilities are not covered by Decree 21. These include the use of displays, special showcases, discounts, special offers, samples, gifts, and incentives for retail staff. For example, Decree 21 does not prohibit companies from giving mothers gifts or samples related to their products so long as this is done outside of health facilities, and five companies were found to take advantage of this gap. Additionally, one-third of the reviewed retail shops employed one of these promotional tactics, including the offering of money, discounts, and other material benefits to sales personnel for selling more products. Companies also work around the advertising restrictions by prominently displaying their names and logos on banners, posters and other promotional materials within retail shops and health facilities.
- f. Promotion in health facilities: Articles 10.2.d and 11.2.a of Decree 21 weaken the Decree by allowing for the sale, display and promotion of nutrition products for young children in hospital pharmacies, which often serve as retail outlets. In addition, wording of Article 11.2.b of Decree 21 opens a loophole by failing to prohibit the display of company names on advertisements or promotional materials within health facilities. Only the names of the nutrition products are banned from these materials. Companies were found to abuse this provision by simply displaying their names and/or logos in health facilities. Allowing this practice implies that the health facilities endorse the products of that company.

The provisions under Article 10.2, 11.2 and 12.2 of Decree 21 that place prohibitions on nutrition product company representatives are weakened by the inclusion of age limits for the regulated products. These provisions include Article 10.2.b, Article 10.2.c, Article 10.2.d, Article 10.2.e, Article 11.2.a, and Article 12.2.a. These articles only restrict actions related to milk products for children under 12 months of age and food products for infants under 6 months of age. By failing to include milk products for children older than 12 months of age and food products for children older than 6 months of age, these provisions create confusion among health staff as to what is or is not prohibited and allows for companies to work around the Decree and promote their products in health facilities.

g. <u>Labeling</u>: The Decree's provisions on the labeling of nutrition products for young children do not fully meet the minimum requirements set by the International Code Article 9. Article 8 of the Decree does not prescribe that labels of nutrition products for young children include a warning about the health hazards of improper preparation, as specified in the International Code. Nor does the Decree contain a provision comparable to Article 9.3 of the

International Code regarding food products that can be modified to meet requirements for infant formula, which stipulates that these products' labels should carry a warning that the unmodified product cannot be the sole source of nourishment for an infant. Lastly, only images or photos of infants less than 12 months old are prohibited, which implies that infants older than 12 months are acceptable. This age limit makes it more difficult to determine true violations of the Decree and creates a potential loophole for companies.

While labeling provisions for bottles and teats outlined in Article 9 are good, they do not include any prohibitions against featuring images or photos of infants and young children. Nor do these provisions include prohibitions on the use of: a) images or text idealizing the product; b) images or text that encourage the use of breastmilk substitutes; and c) text that implies that the product is similar to a mother's nipple. All of these practices were found in this review.

Article 8 does not require that the name and address of the manufacturing, distribution, production or packaging facilities be included. This sometimes leads to confusion among consumers over the origins of the product.

- h. Sponsorship: Article 10.2.e restricting the granting of scholarships or funds provided by nutrition product companies contains a weakness by including the phrase: "for the purpose of promoting the sale or use of milk products for children under 12 months of age and food products for children under 6 months of age." The phrase compromises the provision by: a) including an age limit on the products, and b) providing a ready-made defense for companies as they can claim that their financial support is for purposes other than promotions or sales of their products.
- i. <u>Sanctions</u>: Decree 21 does not contain any provisions for sanctioning violations. Sanctions are stipulated in Decree 45, and not all provisions of Decree 21 are covered by Decree 45.

Implementation, monitoring and supervision

A major barrier to regulating the marketing and trade of nutrition products for young children lies in the weak implementation and enforcement of Decree 21. The following are weaknesses in implementation, monitoring and supervision of the Decree:

a. <u>Cohesiveness</u>, <u>coordination</u> and <u>consultation</u>: The lack of cohesiveness, coordination and consultation between the multiple sectors involved greatly inhibits implementation of Decree 21. This problem is due in part to an absence of direction documents and guidelines provided to or created by provincial agencies (e.g., Provincial People's Committees) that are needed to initiate and guide coordination between the relevant organizations. The problem is exacerbated by the low level of priority placed on Decree 21 in many provinces and the resultant lack of funding available for implementation. Consequently, agencies and organizations that are responsible for implementation do not clearly understand their roles and responsibilities in the implementation process.

- b. <u>Inspections</u>: While systems and structures are in place to monitor and enforce Decree 21, inspections are infrequent and inconsistent. Monitoring and supervision of the Decree is a low political priority and not considered important enough to warrant separate or rigorous inspections. When inspections are carried out, limited numbers of inspectors must handle a huge volume of work. There is also some confusion about the roles and responsibilities of the different players involved with regards to monitoring and supervision. It is important to focus on utilizing the existing systems and structures to enforce the Decree at the national and provincial levels.
- c. <u>Identifying violations</u>: Violations of Decree 21 are not always easy to uncover. For example, according to hospital staff, it is difficult to prevent nutrition product companies from either advertising within health facilities or from contacting health staff due to a lack of guidance and/or documents from MOH forbidding these actions. Moreover, confusion remains as to what is or is not a violation, and some of the provisions of the Decree (such as those placing age limits to the products regulated) only heighten confusion. Violations in advertising are particularly difficult to monitor and control as advertising becomes more pervasive and sophisticated, especially when the internet and new technologies are utilized.
- d. <u>Sanctions</u>: The sanctions against violations of Decree 21 are weak. Under Decree 45, companies or health staff that violate Decree 21 can be sanctioned, usually in the form of fines ranging from 3 to 10 million VND (150 to 500 USD), depending on the violation committed. These fines, when levied at all, are too low to be an effective deterrent.
- e. <u>Implementation of IEC activities</u>: While significant achievements have been made in promoting Decree 21 and optimal IYCF practices, the lack of coordination and funding lead to communication activities that are inconsistent and sometimes poor in quality, quantity and reach. For example, often these activities only take place during national events such as Breastfeeding Week. The materials do not come in a variety of forms (e.g., brochures, leaflets, posters, etc.) and often do not contain comprehensive information, especially that related to the immediate and long-term benefits of breastfeeding and the health hazards of inappropriate use of breastmilk substitutes and complementary foods. Consequently, many individuals still possess misconceptions or misunderstandings about Decree 21, the benefits of breastfeeding, and the consequences of not breastfeeding. This is true not only for the general public, but also for those involved in implementation such as government authorities and health staff.

The lack of written guidance and coordination of IEC activities leaves the heads of provincial agencies (e.g., RHC, CPM, and CCHE) unclear about their roles and responsibilities. IEC activities also face the challenge of competing with large nutrition product companies that spend vast sums of money on advertising, greatly outspending breastfeeding promotion efforts.

f. <u>Training of health staff</u>: Training of health staff has made much progress, but there is still room for improvement. Trainings are not consistently frequent, widespread or comprehensive. Often the trainings only incorporate staff from the Ob/Gyn Department, and, although they are generally aware of the Decree, health staff have been found to lack

detailed knowledge about Decree 21. The shortage and limited skills of existing health staff worsen the problem.

Loopholes in Decree 21

The Decree allows for the **advertising of milk products for children aged 12 to 24 months**, which is against international recommendations and enables companies to indirectly promote their similarly packaged products for children under 12 months old.

Companies can **display their names and logos** in retail shops and in health facilities or on materials within these facilities, a way to indirectly promote products within the scope of the Decree.

By including an **exception for hospital pharmacies** for the sale, display and promotion of nutrition products for young children in health facilities, the Decree allows for easy access to these products in health facilities.

Setting age limits on provisions allows companies to promote the use of milk products for children older than 12 months and food products for those older than 6 months by:

- Contacting mothers in health facilities to promote these products
- Selling and displaying these products in health facilities
- Donating these products to health staff or health facilities
- Displaying the name and logo of these products on materials donated to health facilities
- Funding scholarships, research, training, etc. that directly or indirectly introduce and promote these products

Company representatives are not prohibited from **contacting mothers outside of health facilities** to promote their products.

There are no regulations on the use of **promotional devices** such as special displays, showcases, discounts, gifts, special sales, banners, bonus items, incentives for sales personnel, etc. which serve to promote products within the scope of the Decree.

Granting of scholarships or funds is only restricted for "the purpose of promoting the sale or use of milk products for children under 12 months of age and food products for infants under 6 months of age." Companies can therefore make the claim that their funding is not explicitly for these purposes.

Does not ban marketing personnel from **performing educational functions** in relation to pregnant women or mothers of young children, although these functions are almost certain to promote use of nutrition products for young children or discourage breastfeeding, either directly or indirectly.

Feeding bottles, teats and dummies are excluded from many provisions, including Articles 3, 10, 11 and 12

Only **images or photos of infants** less than 12 months old are prohibited, which implies that infants older than 12 months are acceptable.

7 Recommendations

7.1 Recommendations for revision of Decree 21

Based on the findings of this review, in order to strengthen Decree 21 and eliminate the identified loopholes, the following recommendations are made for the revision of Decree 21:

- Article 1 should be more clearly defined and specific. It should be expanded to explicitly state the scope of the Decree includes product quality and availability, and information concerning the use of nutrition products for young children. It should also incorporate regulations on the importing and trading of nutrition products for young children from foreign countries.
- 2. For clarity, Article 2.1.a should include the phrase "complementary foods for children under 6 months" as an example of products within the scope of the Decree.
- 3. Article 2 should provide definitions for the businesses and companies that are regulated by the Decree as well as the representatives of these companies. Following Article 3 of the International Code, the following terms should be included and defined: distributor, manufacturer, and marketing personnel.
- 4. The Decree should include feeding bottles, teats, and dummies in provisions where these products are currently absent, including Articles 3, 10, 11 and 12.
- 5. Provisions of the Decree that set age limits for the nutrition products for young children covered (Article 6, Article 10.2.b, Article 10.2.c, Article 10.2.d, Article 10.2.e, Article 11.2.a, and Article 12.2.a) should be broadened to include all nutrition products for children up to 24 months.
- 6. In accordance with the International Code, Article 6 on the advertising of nutrition products for young children should be broadened to ban advertising of all products within the scope of the Decree including milk products for children under 24 months of age, food products for infants under 6 months of age, feeding bottles, teats and dummies.
- 7. Articles 4 and 5 of the Decree should be expanded to include all the informational points in Article 4.2 of the International Code, including: the negative effects of partial bottle-feeding on breastfeeding; the difficulty of reversing the decision not to breastfeed; the proper use of breastmilk substitutes, whether manufactured or home-prepared; and maternal nutrition as it relates to the preparation for and maintenance of breastfeeding.
- 8. Chapter 2 of the Decree should incorporate a provision comparable to Article 4.3 of the International Code that regulates donations of informational and educational materials or

equipment from nutrition product companies. Donations should receive government approval, should be distributed through the health care system, and should not promote the products within the scope of the Decree.

- 9. Promotional or marketing tactics (e.g., displays, special showcases, discounts, special offers, gifts or samples, and sales incentives) that serve to promote the products within the scope of the Decree should be prohibited. The Decree should incorporate the following provisions of the International Code:
 - a. Following Article 5.3 of the International Code, there should be no promotional devise to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, etc. for products within the scope of the Decree; and
 - b. Following Article 8of the International Code, the volume of sales of products within the scope of the Decree should not be included in the calculation of bonuses, nor should quotas be set for the sale of these products. Marketing personnel should not perform educational functions in relation to pregnant women, mothers, or infants and young children.

This should be further broadened to prohibit company representatives from providing incentives to retail sales personnel for the sale of products within the scope of the Decree.

- 10. Article 8 of Decree 21 on the labeling of nutrition products for young children should be modified to include the following provisions of the International Code:
 - a. A warning about the health hazards of improper preparation, as specified in the International Code Article 9.2; and
 - b. On food products that can be modified to meet requirements for infant formula, there should be a warning that the unmodified product cannot be the sole source of nourishment for an infant, as specified in Article 9.3 of the International Code.

It is also recommended that Article 8 is modified so that any images of infants or young children are prohibited on nutrition products within the scope of the Decree.

Furthermore, Article 8 should require labels to include the exact name and address of the manufacturing and distribution facilities as well as the name of the production or packaging facilities.

11. Article 9 on the labeling of feeding bottles and teats should include provisions that prohibit the use of: a) images or photos of infants and young children, b) images or text idealizing the product; c) images or text that encourage the use of breastmilk substitutes; and d) text

- that implies that the product is similar to a mother's nipple. In addition, a provision should be added requiring that labels are in Vietnamese.
- 12. Article 10.1 concerning information to health staff should be revised since there is no mention of the information required under Article 4.2 of the International Code, or of the fact that the information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It should be made clearer that informational materials for health staff is required to contain all the informational points outlined in Article 4.2 of the International Code.
- 13. In accordance with WHA Resolution 63.23 of 2010, a provision should be included in the Decree to prohibit the use of health and nutrition claims about nutrition products within the scope of the Decree on IEC materials and labels.
- 14. The Decree should revise Articles 10.2.d and 11.2.a so that they do not include an exception for hospital pharmacies. In addition, a provision should be added that prohibits companies making or selling nutrition products for young children from displaying their name and/or logo in health facilities in any form (e.g., banners, posters, promotional materials, IEC materials, etc.).
- 15. Article 10.2.b should be revised to incorporate the provisions of the International Code as follows:
 - a. Following Article 5.2 of the International Code, the Decree should ban companies from providing, directly or indirectly, samples of products within the scope of the Decree to mothers, pregnant women or their families.
 - b. Following Article 5.4 of the International Code, the Decree should ban companies from distributing to pregnant women, mothers, or infants and young children any gifts which may promote the use of nutrition products for young children or bottle-feeding.
 - c. Following Article 5.5 of the International Code, the Decree should ban marketing personnel or other company representatives from seeking direct or indirect contact of any kind with pregnant women, mothers, or infants and young children.
- 16. Article 10.2.e should be revised to exclude the phrase: "for the purpose of promoting the sale or use of milk products for children under 12 months of age and food products for children under 6 months of age."
- 17. The Decree should incorporate sanctions for violations of the provisions of the Decree, including larger fines that would serve as a stronger deterrent for violations.

18. All provisions of Decree 21 should be updated to account for new technologies, particularly Articles 4, 5 and 6.

7.2 Recommendations for implementation, monitoring and supervision of Decree 21

To enhance the effectiveness of the implementation, monitoring and supervision of Decree 21, or the new Decree to replace Decree 21, the following actions are recommended⁵:

1. <u>Improve cohesiveness</u>, <u>coordination</u>, <u>and consultation</u>: As nutrition issues are cross-sectional and are included in several different policy documents, including laws, ordinances, decrees and circulars, there is a need for continual attention and efforts to ensure compliance and compatibility across all these relevant policies. This is only possible with the coordination among relevant ministries (i.e., MOH, MOCI, MOCST, MOIT, MARD, etc.) in charge of executing and managing nutrition and food-related issues.

To enhance cohesiveness, coordination and consultation in the implementation of the Decree, a Steering Committee or equivalent should be established with the responsibility of providing direction and guidance in the implementation of Decree 21 with assistance from international agencies like UNICEF, WHO, A&T, and groups like IBFAN. Members of the Steering Committee could be those from one of the Technical Teams on IYCF already established under the National Action Plan.

The Steering Committee's terms of reference in relation to the Decree should include:

- Drafting a new Decree to replace Decree 21 that incorporates the recommended revisions outlined above.
- Initiating monitoring of Decree implementation in public and private health facilities and markets. The actual activity of monitoring could be out-sourced to independent NGOs or experienced individuals. This monitoring is to be differentiated from "inspections" done by the DHI leading to prosecution. Monitoring is more of a 'shaming' device and can happen in parallel, in support and in addition to inspections. It should also be noted that monitoring should be systematic and continuous. But to be sustainable, monitoring needs not be a large project or require large resources.
- Receiving complaints on violations;
- Reporting on complaints to relevant departments;
- Recommending investigation and further action and appropriate response by relevant departments;

⁵Some recommendations included here are referred from a Report to UNICEF Hanoi to Review Code Implementation in Vietnam by ICDC, 2008.

- · Reviewing progress; and
- · Mobilizing funds and other resources.
- 2. <u>Information</u>, <u>education</u> and <u>communication</u>: With the help of the Steering Committee, clear guidelines should be developed on the coordination and implementation of IEC activities so the roles and responsibilities of the different players involved are better coordinated and understood. For example, Provincial People's Committees can provide guidelines for mass media outlets for the dissemination of IEC that promotes breastfeeding.
 - In addition, IEC activities are in need of higher funding from national, provincial or outside sources to improve the quality, quantity and reach of these activities. Special attention should be made to ensuring that IEC materials include not only the long-term benefits of breastfeeding, but also the risks of not breastfeeding and the financial costs of using breastmilk substitutes.
- 3. Advocacy and training of implementation officials: The levels of knowledge and awareness about Decree 21 and the benefits of breastfeeding should be improved among local authorities and key players involved in Decree implementation. To do so, there is a need for guidance and coordination among the players, which could be facilitated by the Steering Committee. Advocacy activities directed at local, provincial, and national leaders and authorities would also help make implementation a greater priority, which could result in higher funding.
 - Also important is conducting trainings to enhance the skills of the officials responsible for implementation. For example, members of MOH, MOIT, MOCI, CPFC, FHSA, and provincial agencies (e.g., Department of Health, RHC, CCHE, CPM, People's Committees, Women's Union, etc.) could participate in trainings aimed at improving their skills in monitoring, supervision, inspections, and other key skills as they relate to Decree 21.
- 4. Training of health staff: Training of health staff should be conducted more regularly and should be more comprehensive, especially in district hospitals, commune health centers and private health facilities. Some provinces provide examples of good practices by incorporating trainings about breastfeeding support into the curricula of courses for medical students and professional development activities for health staff. Special focus should be given to training health staff to create an enabling environment for breastfeeding that provides counseling to pregnant women and mothers. Furthermore, health facilities should enhance self-regulation for Decree compliance.
- 5. <u>Sanctions</u>: Sanctions for Decree 21 violations should be more punitive and more frequently levied. Specifically, heavier fines should be introduced. Money received from these fines can be used to support monitoring activities and/or promotional activities related to encouraging breastfeeding. Because fines are not always a deterrent to multinational corporations, other sanctions should be considered as well, including loss of the license to trade for repeat offenders and criminal liability for company heads or directors. These

- sanctions should either be incorporated into the Decree or Decree 45 should be updated to cover all provisions outlined by the Decree. For example, Decree 45 should include provisions related to imposing fines for violations to advertising in health facilities.
- 6. <u>Inspections</u>: Inspections related to compliance with Decree 21 need to be made a higher priority. Guidelines should be updated to ensure that inspections are conducted more regularly and systematically. In addition, enforcement of sanctions must be strengthened. Enforcement actions should be publicized to help promote compliance among other companies, health facilities, and health workers. The skills of health inspectors should be improved so that they are well-educated on the Decree's provisions as well as the implications of violations of the Decree. Due to the limited funding and resources of DHI, inspections should focus on areas where violations are the worst and choose strong cases for prosecution.
- 7. <u>Food Safety and Health Department</u>: The Food Safety and Health Department should regularly review the publication of quality standards, food safety and hygiene of nutrition products for young children. Companies should be required to extend their registration after 3 years of the grant or renewal date. In addition, the Department of Health should be notified when nutrition products are being sold past their expiration dates.

8 Annexes

Annex 1: Examples of Decree 21 Violations and Loopholes Found in Monitoring Study



Company: Abbott

Details: IEC booklets **Products:**

PediaSure BA Similac 1 Similac Gain 2 Gain Plus 3 Gain Kid 4

- Advertising of milk product for children under 12 months old (Violation of Article 6)
- IEC materials contain name and logo of nutrition products (Violation of Article 4)
- Pictures/text idealize use of products and therefore discourage breastfeeding, making scientifically unsubstantiated health/nutrition claims (Violation of Article 4)

• IEC materials do not include of all required information under Article 4

Label

Brochures/Advertisements





"Scientists point out that nutrition of cow's colostrum has properties similar to mother's colostrum."

"With Mama Sua Non Growth, your baby will be healthy, smart and tall."

"Uses: for children ages 0-12 months, especially if mother has lost milk or the quality of milk is not high."

"But with an increasingly hurried life, women work more in intellectual labor and have headaches. The environment is increasingly toxic. So, women lose milk in childbirth or produce milk slowly, or the quality of milk is not very high."

Company: G&P Viet Nam

Details: Label for Mama Sua Non New infant formula (0-12 months)

Brochures for Mama Sua Non products including:

- -Mama Sua Non Colostrum Growth
- -Mama Sua Non Baby & Mama Sua Non Baby A+/2+
- -Mama Sua Non Star
- -Mama Sua Non IQ

While the photos do not indicate ages for use, the brochure states that Mama Sua Non Colostrum is for 0-12 months and Mama Sua Non Star 1-3 is for children 1-3 years.

Decree 21 Violations:

- Advertising of milk product for children under 12 months old (Violation of Article 6)
- Label features an infant under 12 months of age. (Violation of Article 8)
- Implies product is similar to breastmilk (Violation of Article 4)
- Makes claims idealizing product: prevents rickets, helps bone development, helps brain and retina development, supports immunity (Violation of Article 4)
- Advertisements and IEC materials do not include of all required information under Article 4 and discourage breastfeeding

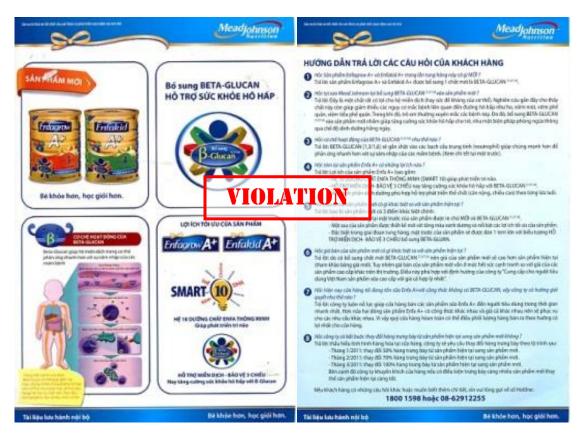


Company: Mead Johnson

Details: IEC booklet for health workers in Hai Phong

Products: Enfakid A+ / Enfagrow A+ /EnfaMama A+ (for children 12 months and older)

- IEC materials contain name and logo of nutrition products under the Decree (Violation of Article 4)
- Pictures/text idealize use of products and therefore discourage breastfeeding, making scientifically unsubstantiated health/nutrition claims (Violation of Article 4)
- Include a photo of a breastfeeding infant above the company logo implies the products are similar to breastmilk (Violation of Article 4)
- IEC materials do not include of all required information under Article 4



Company: Mead Johnson

Details: Poster/Advertisement

Products: Enfagrow A+ 3 (for children 1-3 years old); Enfakid A+ 4 (For children 4 years old and above)

- Pictures/text idealize use of products and therefore discourage breastfeeding, making scientifically unsubstantiated health/nutrition claims (Violation of Article 4)
- Advertises milk products for children older than 12 months, which is legal under Decree 21. However, these products are similarly labeled and branded as those for children under 12 months, which are restricted under the Decree. Such packaging is a way of working around the Decree.



Buy 1 box, get a smaller box for free

Company: Biofocus

Details: Poster/Advertisement

Products: Sua Non Smart Colostrum (milk product for children 0-12 months old)

Sua Non Smart Plus 1 (milk product for children 1-3 years old)

Decree 21 Violations/Loopholes:

- Advertisement of milk product for children under 12 months old (Violation of Article 6)
- Label features an infant under 12 months of age. (Violation of Article 8)
- Photo implies that product is similar to breastmilk (Violation of Article 4)
- Loophole: Promotional device (special sale) is not covered by the Decree, but is a violation of International Code Article 5



"With anti-colic air valve nipple"

Company: Camera Baby Corporation

Details: Label

Products: Smooth-neck feeder (feeding

bottle and teat)

- No instructions or information in Vietnamese (Violation of Article 9)
- Does not include required text: "The use of feeding bottles may cause children to quit breastfeeding and increase the risk of diarrhea." (Violation of Article 9)
- Makes questionable health claim about prevention of colic (loophole in Decree, no prohibition)

Annex 1 (continued): Examples of Decree 21 Violations found on the internet



Company: Vinamilk

Source: http://www.youtube.com/watch?v= VTVVL7vHkZ8&feature=related

Date: June 28, 2011 (Uploaded December 16, 2009)

Product: Dielac powdered milk for children 6-24 months of age

Decree 21 Violations:

- Advertisement of milk product for children under 12 months old (Article 6)
- Does not make statement "Breastmilk is the best food for the health and overall development of children." (Article 6)
- Features children under 12 months old (Article 4)
- Does not include all information in Articles 4 and 5
- Makes claims that idealizes the product (Article 4).



BABYSAN 1 (450GR)

VIOLATION

Hỗ trợ hệ tiêu hóa: Bobyson 1 chẳng táo bón, tầng khả năng hấp thu đạm, chắt báo Products: có trong sửa, vi sủa Estrysan được chế biển bằng công nghệ cao và sáy bằng công -Babysan 1 infant formula for 0 to 6 months nghệ động khô. Vì thể các loại men tiêu hóa, đạm và chất béo không no có trong sửa tượi không bị phá hốy.

Tầng cương hệ miền dịch và phát triển chiều cao cho trẻ : Bhhysen bố sung Decree 21 Violations: Yitamin và khoáng chất phủ họp nhằm kích thích hệ thống miễn dịch hoạt đặng, hạn chế một số biện thông thường hay giáp ở trẻ so sinh (thư lưa miệng, lưa lười, khác đếm ...) • Advertising of milk product for children Giúp phát triển trí não của trẻ : Trong Babysan có chứa Cholne, Taurine, DHA tá những chất cần thết cho sự sốn sinh re tế bào thần kinh, giúp phát thên bí nấu của biể

Babysan offers a club for mothers who can

Makes claims: aids the digestive system, supports development of the child's brain, strengthens the immune system and develops child's height

Doctor's advice on website: "Leading nutrition experts around the world say that the perfect [complementary] feeding time for a well-rounded child is at 5 months. At age 6 months onwards, the quality of breastmilk decreases."

Company: Babysan

Source: http://www.babysan.vn/ Date: June 27, 2011

- -Babysan 2 infant formula for 6-12 months

- under 12 months old (Article 6)
- write IYCF questions and receive advice from someone claiming to be a doctor. The doctor encourages the women to use Babysan products over breastfeeding and makes claims that go against scientific evidence and international recommendations (Article 4.1)



um ano

"A nutrition revolution in recent years, cow's colostrum is an extremely useful additive to the human body. It contains the same natural antibodies that are essential for child development."

VIOLATION

"Overcome anorexia in children."
"Helps your child achieve overall
healthy development."

"Help children strengthen the immune system. They will not suffer from diseases like measles, whooping cough, respiratory infections, and diarrhea."

Company: Bach ISC

Source:

http://www.smartbabysuanon.com.vn

Date: June 27, 2011

Products:

-Smart Baby for newborns (for children under 12 months of age)
-Smart Baby for babies 1-3

Decree 21 Violations:

- Advertisement of milk product for children under 12 months old (Article 6)
- Label features an infant under 12 months of age. (Article 8)
- Implies product is similar to colostrum of breastmilk (Article 4)
- Makes claims idealizing product: prevents rickets, helps bone development, helps brain and retina development, supports immunity (Article 4)
- No inclusion of required information such as "Breastmilk is the best food for the health and overall development of children," or other requirements under Article 4 (e.g., disadvantages of not breastfeeding.)



Company: PBM Nutrition

Source: http://insulacvietnam.com/

Date: June 28, 2011

Products:

-Insulac IQ 1, powdered milk (0-6 months)

montnsj

-Insulac IQ 2, powdered milk (6-12 months)

Decree 21 Violations:

 Advertisement of milk product for children under 12 months old (Article
 6)



"Scientists point out that nutrition of cow's colostrum has properties similar to mother's colostrum."

"With Mama Sua Non Growth, your baby will be healthy, smart and tall."

"Uses: for children ages 0-12 months, especially if mother has lost milk or the quality of milk is not high."

"But with an increasingly hurried life, women work more in intellectual labor and have headaches. The environment is increasingly toxic. So, women lose milk in childbirth or produce milk slowly, or the quality of milk is not very high."

Company: G&P Viet Nam

Source: http://mamasuanon.com.vn/

Date: June 27, 2011

Product:

- -Mama Sua Non Growth, milk product for children older than 6 months of age
- -Mama Sua Non Gold (0-12 months)
- -Mama Sua Non-Star (1-3 years)

Decree 21 Violations:

- Advertisement of milk product for children under 12 months old (Article 6)
- Label features an infant under 12 months of age. (Article 8)
- Implies product is similar to colostrum of breastmilk (Article 4)
- Makes claims idealizing product: prevents rickets, helps bone development, helps brain and retina development, supports immunity (Article 4)
- Advertisements and IEC materials do not include of all required information under Article 4; discourage breastfeeding by making claims about "toxic environments" for working mothers and mothers losing milk or having low-quality milk

Online informational chat session on preschool website



"Prebiotics in breastmilk - the role of Prebiotics in human milk is to enhance the child's immune system, (to avoid constipation), and keep the digestive system healthy. The Prebiotics mixture studied by Danone has a similar structure to human milk oligosaccharides. This mixture enhances the child's immune system and is clinically certified." - Hoang Manh Hai, Director of Nutrition, Dumex Vietnam Milk Company

Company: Dumex Vietnam

Source: http://bluestars.vn/
Date: October 21, 2008

Details: Online informational chat sessions with the theme "Choosing milk after the melamine storm" on the website of Blue Stars Preschool, Hanoi

Guests invited included:

- Dr. Nguyen Thi Hoa, Head of Nutrition Children's Hospital
- Hoang Manh Hai, Director of Nutrition at the Dumex Vietnam Milk Company Guests answered questions in an online exchange with VietNamNet readers

Decree 21 Violation:

In the exchange, breastmilk substitute products were promoted and recommended for use, and claims were made about the similarity of these products to breastmilk (Article 4). This also violates Article 8.2 of the International Code which prohibits company representatives from performing educational functions for mothers of young children.



Company: PBM Nutrition

Source: http://insulacvietnam.com/

Date: June 28, 2011

Products:

-Insulac IQ 3 powdered milk for children 1-3 years

Decree 21 LOOPHOLE/International Code VIOLATION:

In violation of Articles 5.3 and 5.4 of the International Code, the advertisement promotes the product by offers gifts in exchange for labels of their product. However, it not a violation of Decree 21, which does not regulate the use of such promotional devices despite the fact that these tactics promote the usage of breastmilk substitutes.



Company: Mead Johnson

Source:

http://www.youtube.com/watch?v=A2DbZt2qmXs

Date: June 27, 2011 Uploaded August 2, 2007

Product: Enfagrow A+

Decree LOOPHOLE/International Code VIOLATION:

While the TV advertisement does not violate Decree 21, it is a good example of how companies exploit the Decree's loopholes. The phrase, "Breastmilk is the best food for the overall health and development of children," is read in the beginning very quickly before viewers are aware of what the commercial is even about. It is also undermined by the presence of breastmilk substitutes below the caption. Cleverly, only the outlines of the nutrition products restricted by the Decree are shown, showing only A+. However, these products are similarly branded as the products for older children, and it is clear that this image is referring to nutrition products for younger children.

The advertisement violates Article 5 of the International Code.



Company: Namyang
Source: http://tintuc.xalo.vn
Date: June 30, 2011

Products: Kids XO powdered milk for ages 1-9 years

Details: A sponsored event featuring a series of puppet shows held for 30 preschools in HCMC in June 2011.

Decree 21 LOOPHOLE/International Code VIOLATION: It

works around the Decree because it advertises milk products for children aged 1-9 years old. It also uses a promotional device not covered by Decree.

It is a violation of Articles 5.1 of the International Code that prohibits promotion of breastmilk substitutes within the scope of the Code.



Message at January 2010 event: Baby angel says to deer, "I like to drink milk because I want to grow to be tall, healthy and intelligent like you, Deer!"

"Children like to grow, and mothers help children grow tall by giving them formula."

Company: Abbott

Source: http://www.eva.vn/lam-me/thoi-nen-sinh-nhat-cung-ban-huou-con-c10a23607.html& http://blog.gymboreeclasses.com.vn/birthday-event-with-abbott

Date: January 2010 & September 2010

Products: Gain Plus EyeQ – growing up formula for children aged 1-3 years
Grow Advance EyeQ- growing up formula for children aged 1-3 years

Details:

January 2010: An event for mothers and children with contests and a play featuring an angel and cute animals.

September 2010: An Abbott birthday event featuring activities for children and numerous objects and gifts displaying logo for products (e.g., balloons, cake, etc.). Held at Sheraton hotel in HCMC

Decree 21 LOOPHOLE/International Code VIOLATION:

Events work around the Decree because they advertise milk products for children aged 1-3 years old. They also use a promotional device not covered by Decree. Also, the Decree allows for company representatives to contact mothers and children outside of health facilities.

However, these events are a violation of Articles 5.1, 5.4, and 5.5 of the International Code.

Annex 2: Data collection tools

| | | Place | Monitor | # |
|--|-------------------------------|--------------------------|---------------|--|
| Date/ | | | | 1 |
| F | orm SIM 1: Interview moth | ier | | |
| General Guide: This form is used for n | nother with children unde | r 6 months. | | |
| Childmonths old. Do you feed your child with form Which formula you feed your ch | | No (if No | o, move on to | 5 question) |
| Type of formula | Rea | ason to use ¹ | | |
| A | | | | |
| B C | | | | |
| ¹ Reason to use this type of formula?: C. Consulted by nutrition doctor feeding older child; F. Advertiseme in column "Reason to use") | | dical staff; | E. Exp | ulted by nurse perience fron rs H. Others (fil |
| 4) Which type of complementary f | ood you gave to your child an | nd why? | | |
| Type of complementary food | Rea | ason to use ¹ | | |
| A | | | | |
| B C | | | | |
| ¹ Reason to use this type of formula?: C. Consulted by nutrition doctor feeding older child; F. Advertiseme in column "Reason to use") | | dical staff; | E. Exp | ulted by nurse perience fron rs H. Others (fil |

5) Is there any formula company's staff to meet you? If yes, fill the details in the following table

Formula company reaches mothers: Only record if formula product introduced by the company is subject to Code's regulation, including the contact between company staff and pregnant women.

| Company | Where ¹ | Purpose ² | Details (use additional paper if needed) |
|---------|--------------------|----------------------|--|
| A | | | |
| В | | | |

| С | | | | | |
|---|----------------------|------------------------------|--------------------|-----------------------|-------------------|
| ¹ Place to meet: | | ty; B. Phai | rmacy; C. Home; | D. Shop; | E. Other (fill in |
| column "Where Purpose: | - | CF information; | R Stimulating usa | ge of a specific pro | duct: |
| C. Stimulating us (fill in column "I | sage of feeding b | | D. Offering sample | | |
| Company | owing table Product | Type of product ¹ | Where/How | By whom? ³ | Product attached? |
| 6a | | | | | |
| 6a details: | , | <u>.</u> | - | , | |
| 6b | | | | | |
| | | | | | |

7) Do you receive any guide book or gift? If yes, fill in the following table.

Gift: List all

6c details:

6с

- gift from a company whose products are subject to the Code's regulations and
- gift related to products which are subjects to the Code's regulations and
- gift with name of the product or distributor related to children

List all materials given to mothers by company, including IYCF information. Must find out the books, leaflets, pictures... that mothers received from prenatal class or via email. Normally the contact number is printed in these materials for mothers to contact for further IYCF counseling.

| Company | Type of gift ⁴ | Where/How | By whom? ³ | Product attached? (Yes/No) |
|---------------|---------------------------|-----------|-----------------------|----------------------------------|
| 7a | | | | |
| 7a details 7b | 1 | | 1 | |
| 7b details | | | | |
| 7c | | | | |
| 7c details | • | • | | |

¹Type of product: A. Milk for infant; B. Milk for over 6 months children; C. Special milk; D. Cereal Powder; E. Fruit/Vegetable/Meat; F. Condense milk; G. Bottle; H. Dummies; L. Others (fill in "Type of gift").

² Where/How: A. Health facility; B. Pharmacy; C. Home; D. Shop; E. Postage; F. Other (fill in "Where/How")

³ By whom?: A. Company staff; B. Medical staff; C. Pharmacy Sales Person; D. Sales person; E. Other (fill in "By whom").

⁴ Type of gift: A. Bottle; B. Bib; C. Diaper; D. Toy; E. Decoration; G. Diaper and bottle holder; G. Gift set; H. Other (fill in "Type of gift").

 Place
 Monitor
 #

 Date.../...../
 -- 1---

Form SIM 2: Advertisement at Sales Places

| General guide: This fo | orm is used for all retail | shop, inclu | uding pharmacies | |
|------------------------|--|----------------------------------|--|--------------------------------|
| • | | | y at your shop to promote IYCF r | nutritious products? I |
| company) to directly | or not directly contact | with consu | sentative (or marketing staff who mer. Record all contacts/approa or provide IYCF information. | |
| Company | Name of product | | Supervision | |
| 1a | | | | |
| 1a Details: | | | | |
| 1b | | | | |
| 1b Details: | | | | |
| 1c | | | | |
| 1c Details: | | | | |
| • | eting tactics as below us nies for IYC at your shop | - | note sales of nutritious product/ s in the following table | feeding |
| _ | vertisement on discount, take picture with samp | _ | or free, or any way to directly ma | arket to retail |
| Company | Name of pro | Name of product Marketing tactic | | Sample attached (Yes/No) |
| 2a | | | | |
| 2a Details: | | | | |
| 2b | | | | |
| 2b Details: | | | | |
| 2c | | | | |
| 2c Details: | | | | |

1 Advertisement Type: A. Discount; B. Special showcase; C. Shopping coupon; D. Sample; E. Gift attached to product; F. Banner/band-roll; G. Product Information*; H. Special ways of sales; I. Bonus (buy 1 get 1, 2...); J. product promotion; K. Product holder; L. Other (fill in "Marketing tactics")

| Place | Monitor | # | |
|-------|---------|---|--|
| | | 4 | |
| | | 1 | |

Form SIM 3: Hospital and Clinic

| Facili | ty Name: | | Is Child | dren Frien | dly Hospital? | Yes | | No |
|--------|--------------------|---------------|-------------|--------------|-------------------|--------------|-----|----|
| 1) | Is this facility s | ubject to Cod | e's regulat | ions/ Fill d | etail in the foll | lowing table | | |
| ml . | | | 1 | | 1 | 1 1 | 0.1 | |

This form is used for scanning products at facility that subject to Code's regulations. Only record products available at facility for recent 6 months

Date..../......

| Name of company | Label of product | Type of product ¹ | How does facility receive this? |
|---------------------|------------------|------------------------------|---------------------------------|
| $1^{\underline{a}}$ | | | |
| 1a Details: | | | |
| 1b | | | |
| 1b Details: | | | |
| 1c | | | |
| 1c Details: | | | |

2) Do mothers receive product sample at facility? If yes, fill detail in table

Product sample: List all products that mothers received. Only record for recent 6 months.

| Name of company | Label of product | Type of product ¹ | By whom? ³ | Product attached (Yes/No) |
|-----------------|------------------|------------------------------|-----------------------|------------------------------|
| 2 <u>a</u> | | | | |
| 2a Details: | | | | |
| 2b | | | | |
| 2b Details: | | | | |
| 2c | | | | |
| 2c Details: | | | | |

¹ Type of product: A. Infant formula; B. Formula for over 6 months; C. Special milk; D. Bét; E. Juice/vegetable/minced meat; F. Condense milk; G. Bottle; H. Dummies; L. Other (fill in Type of product).
² How? A. Normal trading; B. Buying other product; C. Discounted or on promotion; D. Free of charge (the company issues invoice but does not take payment from health facility); E. Gift as at company's will; F. Gift as health facility requested; F. Gift given in other manner (fill in "By...").

3 By whom? A. Company staff; B. Health facility staff; C. Other (fill in "By whom").

| 3) | Does facility hang | company's banner, | poster, o'clock, | pictures or of | ther? If yes, fill | the details |
|----|--------------------|-------------------|------------------|----------------|--------------------|-------------|
|----|--------------------|-------------------|------------------|----------------|--------------------|-------------|

Product showcased, banner, poster, calendar...: list all company's stuff with product logo/label which are subject to Codes' regulations, including name or logo of the IYCF related company

| Company | of the ny/logo | Things posted/showed | Company name and logo on showed stuff (write "No" if there is no label) | | and logo on showed stuff (write "No" if | | and logo on showed stuff (write "No" if | | and logo on showed stuff (write "No" if | | and logo on showed stuff (write "No" if | | and logo on showed stuff (write "No" if | | Where this things posted/showed | Sample attached? (Yes/No) |
|-------------|-------------------|-------------------------|---|--|---|---|---|--|---|--|---|--|---|--|---------------------------------------|---------------------------------|
| 3 <u>a</u> | | | | | | | | | | | | | | | | |
| 3ª Details: | | | | | | | | | | | | | | | | |
| 3b | | | | | | | | | | | | | | | | |
| 3b Details: | | | | | | | | | | | | | | | | |
| 3c | | | | | | | | | | | | | | | | |
| 3c Details: | | | | | | _ | | | | | | | | | | |

4) Does company representative meet mothers at health facility? If yes, fill the details

List all cases, including contacts between marketing staff and mothers to promote products subjected to Codes' regulations in recent 6 months.

| Company Name | Contact purpose | Product label promoted by company (write "No" if there is no label. | Product sample | Gift | Leaflet/ Book | Sample attached? (Yes/No) |
|-----------------|-----------------|---|-------------------|------|------------------|---------------------------------|
| 4a | | | | | | |
| 4a Details | | | | | | |
| 4b | | | | | | |
| 4b Details | | | | | | |
| 4c | | | | | | |
| 4c Details | | | | | | |

5) Do companies provide medical staff with o'clock, memo note, pen holder, prescription book, note book, calendar book, ruler, pen... If yes, fill the details.

Gifts to medical staff:

Record:

- 1. all gifts including advertisement items for a product that subject to Code's regulations. Companies usually provide pen, pen holder, working calendar, prescription... which mothers easily see. Record all gift items with children and food's images, company name and their product's name on it. Pay attention to stimulation images such as cartoon or lovely animal, vegetable where company's logo and their products are easily seen. Eg: pen holder with company name and text "best for your baby" or in teddy bear, "Mr. Carrot" shapes.
- 2. all personal gifts. Manufactures and distributors subjected to Code's regulations are prohibited to produce gift to medical workers. Gifts are meals, flowers, confectionaries, money or services.

According to Code, company prohibited to provide scholarship, tourist, sponsorship, funding for studying or attending workshop. Even small personal gift considered bribe (means "exchange relation").

Only record for things happened in recent 6 months.

| Company | Gift description | Product label on gift? (write No if there is no label) | Are the company and logo gift | y name on the | Sample attached? (Yes/No) |
|-------------|------------------|--|-------------------------------|------------------|---------------------------------|
| | | | Name | Logo | |
| 5a | | | | | |
| 5a Details: | | | | | |
| 5b | | | | | |
| 5b Details: | | | | | |
| 5c | | | | | |
| 5c Details: | | | | | |

| 6) | Do company | sponsor or | provide other | kind of offer? | If yes, | , fill in the | details |
|----|------------|------------|---------------|----------------|---------|---------------|---------|
|----|------------|------------|---------------|----------------|---------|---------------|---------|

According to Code, the following kinds of sponsor or offer to medical staff are prohibited:

- Pick up service (transportation)
- Travel allowance
- Cash

Should record cases that you are not sure it is bribe (such as media brief, articles) as well.

Not all the sponsorships are violation. WHA Resolution 49.15 (1996) affirms to make sure that sponsorships for IYCF-related medical staff are not conflict with other benefits.

Therefore, should collect as much as possible information on events (workshop, conferences... relates to formula companies) to see exactly what the company sponsored for, what product they introduced?

Record all events in recent 6 months.

| Sponsorship/service1 | Company Name | Description |
|----------------------|--------------|-------------|
| 6a | | |
| 6a Details | | |
| 6b | | |
| 6b Details | | |
| 6c | | |
| 6c Details | | |

¹ Sponsorship/service...: Planning/consultant; B. Pick up service; C. Sponsorship for studying; D. Travel; E. Cash; G. Stationeries (pen, note, mug...); H. Scholarship; I. Funding for workshop/conference fee; J. IEC products; K. Other

| Location | Monitored by | # |
|----------|--------------|----|
| | | 4A |

m. Describe picture or image of infant

Form SIM 4A: Label of Infant Milk Products

| This form applies to label of infant milk products (or if a product is labeled with "follow-up formula" or infants, this form should be used, but not Form 4B. Label of infant foods including follow-up milk should be used. | "follow-on formula" b | ut for under-6-m | |
|---|-------------------------|---------------------|-------------------|
| | Y | | |
| Company | Kind of product | | |
| | ☐Milk for infant (ord | | |
| Brand: | ☐ Milk for infant (wi | th soybean conte | nt) |
| Manufactured country: | ☐ Special milk | | |
| | □Other | | |
| | | No | Yes |
| a. With the word "Attention" or similar | | | |
| b. With the text "Breastmilk is the best" | | | |
| c. Warning on improper preparation | | | |
| d. With the text "With doctor prescription" | | | |
| e. Instruction of preparation and use is clear and un | nderstandable | | |
| f. Write in the understandable local language | | | |
| g. Expiry date is clearly visible (check at the bottom) \qed | | | |
| h. With instruction of preservation | | | |
| i. Product serial (usually at the bottom) | | | |
| j. Content | | | |
| The Code requires precise information. Tick "No" if | relevant information | is not found. Tic | k "Yes" if found. |
| The Code does not allow information on the label w | which idealizes the pro | oduct. | |
| k. Write down words such as "similar to breastmilk | x", "similar to human r | nilk" or similar, i | f any. |
| l. Write down words which mean discouraging breasubstitutes, if any. | astfeeding or idealizin | g the use of brea | stmilk |

| n. Describe picture or image which idealize the use of formula (Please attach picture of popular products) |
|---|
| |
| Other additional details and recommendations: (use this part if find out other details which are not included in the above questions) |
| |
| |
| |

| Location | Monitored by | # |
|----------|--------------|----|
| | | 4B |

Form SIM 4B: Label of milk for over 6 month old infant, complimentary foods and other breastmilk substitute products

Use this form for:

- All kinds of follow-up milk for infant from 6 months old but not over 2 years old.
- All kinds of foods and drinks for infant under 6 months old (except milk)
- All kinds of foods and drinks with picture or image of infant under 6 months old.
- All kinds of foods and drinks without age indication but encourage feeding infant with bottle.

Though "1-2-3 Milk/Grow-up Milk" is usually for grown children but sometimes used as breastmilk substitutes. SIM Forms focus to monitor companies which have advertisements of milk products for newborn children and under 2-year old infants.

If possible, please attach picture or photo to this form.

| Receiving | Date:/ | | Company: |
|--|--|----------------------------|-----------------------|
| Product La | ıbel: | | Manufactured Country: |
| | | | |
| Product | □ Follow-up milk | ☐ Powder with milk | |
| | ☐ Powder without milk | □ Powder milk | |
| | □ Juice/Vegetable Extract/Meat Extract | ☐ Liquid milk | |
| | ☐ Foods for children | ☐ Sweetened condensed | milk |
| | ☐ Juice for children | □ Water (for children) | |
| | □ Tea for children | Others | |
| 1. Age to u | se product is indicated on the label? | | □ Yes □ No |
| _ | ch age: months of other words: | | |
| | abel, there is/are: | | |
| a. Suggesti | on to use product with bottle? | | □ Yes □ No |
| b. Picture | or image of an infant? | | □ Yes □ No |
| (If Yes, ple | ase attach a picture of the label) | | |
| c. Similarit | y to the milk products for infant of the s | \square Yes \square No | |
| d Suggestion to use this product for under 6 month old infant? | | | □ Ves □ No |

| Other additional details and recommendations: (use this part if find out other details which are not included in the above questions) |
|---|
| |
| |
| |

| Location Monitored by | | # |
|-----------------------|--|----|
| | | 4C |

Form SIM 4C: Label of Bottle and Nipple

| To this silver of Bottle and Hippie | | | | |
|---|---------------|--|--|--|
| General Guide: Bottle and nipple are under the coverage of the Code. Advertisement on mass media, at retailers and health facilities violate the Code. On the label, instruction on proper use is required and it must not discourage breastfeeding. If possible, please attach picture or photo to this form. | | | | |
| Company: | Product: | | | |
| □ Bottle | | | | |
| Product Label: | □ Nipple | | | |
| 1. On the label, there is/are: | | | | |
| a. Picture or image of a newborn baby or an infant or a child sucking a bottle | e? □ Yes □ No | | | |
| b. Picture or words which idealize the use of the product? If Yes, how? | ☐ Yes ☐ No | | | |
| | | | | |
| c. Encouragement of use of breastmilk substitutes? If Yes, how? | □ Yes □ No | | | |
| | | | | |
| d. Words or text which imply that the product is similar to mother nipple? If Yes, how? | □ Yes □ No | | | |
| Manufactured Country | j | | | |
| Other additional details and recommendations: (use this part if find out other in the above questions) | | | | |

| Location Monitored by | | # |
|-----------------------|--|----|
| | | 5A |

3.

☐ A. General Hospital

Where's the material found?

☐ B. Mother's room

Form SIM 5A: Information Materials for Health Workers

Section I

| General Guide: List and analyze in Section I | | | | |
|---|---|------------|----------------|----------------------------------|
| Materials by com Code. | | | | |
| | describe in Section II. | о и оросии | p | |
| If possible, please attach | picture or photo to this fo | rm. | | |
|) | nys of discouragement of beer the coverage of the Cod | | ng when the ma | terials do not refer |
| Title of the Material: | | | | |
| 1. The material refer | 1. The material refers to product? | | | |
| Company | Type of product | -1 | | luct Label there is no label) |
| | | | | |
| ¹ Type of product: A. Milk for infant; B. Milk for over 6 month old infant; C. Special Milk; D. Cereal Powder; E. Juice/Vegetable Extract/Meat Extract; F. Sweetened Condensed Milk; G. Bottle; H. Nipple; L. Others | | | | |
| 2. Type of material: | | | | |
| □ A. Book | □ B. Leaflet | □ C. Adver | | □ Video cassette |
| ☐ E. Cassette | ☐ F. CD/VCD/DVD | | | □ Website |
| ☐ I. Poster | ☐ J. Software ☐ K. Others | | | |

☐ C. Pediatric Hospital

☐ Clinic

| ☐ E. Doctor's room | ☐ F. Health Center | ☐ G. Pharmacist | ⊔ Email | |
|---|-------------------------------|------------------------------|---------|--|
| ☐ I. Professional | ☐ J. Internet | ☐ K. Others | | |
| Magazine | | | | |
| 4. Name of mass med Date of publication (if any) Where the material is foun | | nd | | |
| 5. If the material is fo | or mother, tick the box below | w and describe more if neces | sary: | |
| \Box A. Through company's representative \Box B. Through health workers \Box C. Others | | | | |
| Description: | | | | |
| 6. Write down all information which encourage (not breastfeeding) or is not scientific and realistic. | | | | |

| Location | Monitored by | # |
|----------|--------------|----|
| | | 5A |

| 7. The Code requires precise information about formula, milk for over foods and bottle/nipple. If the material does not refer to these products "No" if relevant information is not found. Tick "Yes" if found. | | |
|---|---------------------|---------------------|
| | No | Yes |
| a. Benefit of breastfeeding | | |
| b. Bad impact of bottle feeding | | |
| c. Difficulties of not breastfeeding | | |
| d. Benefit of breastfeeding in regard of nutrition for mother; breastmill maintenance. | k 🗆 | |
| 8. Requirements to milk products for infant. If it is not milk products "No" if relevant information is not found. Tick "Yes" if found. | cts for infant, mov | ve to Point 9. |
| | No | Yes |
| a. Refer to proper use of milk | | |
| b. Refer to economic and social expenses if use the formula | | |
| d. Refer to threats to health when not feed properly | | |
| e. Refer to threats to health when formula or breastmilk substitutes are used improperly. | | |
| 9. Content of the material | | |
| a. Write down all sentences which imply bottle feeding is similar of | | astfeeding. |
| | | |
| b. Describe image or words which idealize the use of breastmilk so | ubstitute product | S. |
| | | |
| | | |
| Other additional details and recommendations: (use this part if find out in the above questions) | other details whi | ch are not included |
| | | |

| | ~~~~~~~~~~ | Section II | ~~~~~~~~~~ | |
|---|---------------------------|------------|--|-----|
| - · · · · · · · · · · · · · · · · · · · | er and grow-up milks). De | | ne Code directly but discourage materials in this section and att | - , |
| | | | | |
| | | | | |

| Location | Monitored by | # |
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| | | 5B |

Form SIM 5B: Information Materials for company's audience

Section I

| General Guide: List and analyze in Section I 1. Advertisement on IYCF on mass media including medical and professional magazines. 2. Materials by company such as leaflet, brochure on products under the coverage of the Code. 3. Materials by company which do not refer to a specific product but erode the belief in breastfeeding. Many materials of milk companies do not refer specifically to product name. However, by using image of picture of cute cartoon animals or vegetables, it makes people easily recognize the product of such company. If possible, please attach picture or photo to this form. Section II is for listing ways of discouragement of breastfeeding when the materials do not refer to a specific product under the coverage of the Code. | | | | | |
|---|------------------------------|--|--|--|--|
| Title of the Material: | | | | | |
| Company | Type of product ¹ | Product Label (note "No" if there is no label) | | | |
| | | | | | |

¹ Type of product: A. Milk for infant; B. Milk for over 6 month old infant; C. Special Milk; D. Cereal Powder; E. Juice/Vegetable Extract/Meat Extract; F. Sweetened Condensed Milk; G. Bottle; H. Nipple; L. Others.

Type of material:

| □ A. Book | ☐ B. Leaflet | ☐ C. Advertisement | ☐ Video cassette |
|---------------|-----------------|--------------------|------------------|
| ☐ E. Cassette | ☐ F. CD/VCD/DVD | ☐ G. Display | □ Website |
| ☐ I. Poster | ☐ J. Software | ☐ K. Others | |

| 2 | Whor | o'c tha | material | found? |
|---|------|---------|----------|--------|

| ☐ A. General Hospital | ☐ B. Mother's room | ☐ C. Pediatric Hospital | □ Clinic |
|-----------------------|--------------------|-------------------------|----------|

| ☐ E. Doctor's room | ☐ F. Health Center | ☐ G. Pharmacist | □ Email |
|-------------------------------|------------------------------|-----------------|---------|
| ☐ I. Professional | ☐ J. Internet | ☐ K. Others | |
| Magazine | | | |
| | | | |
| | | | |
| 4. Name of mass med | ia where the material is fou | nd | |
| Date of publication (if any). | | | |
| Where the material is found | d 🗆 Public area | 🗆 Private area | |
| | | | |

5. Full description of advertisement on TV or radio. If possible, please attach video cassette or disk.

| Location | Monitored by | # |
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| | | 5B |

| 6. The Code requires precise information about formula, milk for or foods and bottle/nipple. If the material does not refer to these pr Tick "No" if relevant information is not found. Tick "Yes" if found | oducts, move to Poin | |
|---|------------------------|--------------------|
| | No | Yes |
| a. Benefit of breastfeeding | | |
| b. Bad impact of bottle feeding | | |
| c. Difficulties of not breastfeeding | | |
| d. Benefit of breastfeeding in regard of nutrition for mother; breastr maintenance. | milk 🗆 | |
| 7. Requirements to milk products for infant. If it is not milk products "No" if relevant information is not found. Tick "Yes" if fo | | e to Point 8. |
| | No | Yes |
| a. Refer to proper use of milk | | |
| b. Refer to economic and social expenses if use the formula | | |
| d. Refer to threats to health when not feed properly | | |
| e. Refer to threats to health when formula or breastmilk substitutes a used improperly. | are 🗆 | |
| 8. Content of the material: | | |
| a. Write down all sentences which imply bottle feeding is simil | | stfeeding. |
| | | |
| b. Describe image or words which idealize the use of breastmil | | |
| | | |
| Other additional details and recommendations: (use this part if find on the above questions) | out other details whic | h are not included |
| | | |

| ~~~~~~~~~~~ | Section II | ~~~~~~~~~~ | |
|--------------------------------|------------|--|---|
| her and grow-up milks). De | | he Code directly but discourage breastfeeding (materials in this section and attach the material | • |
| | | | |
| | | | |

Annex 3: Decree No. 21/2006/ND-CP

| GOVERNMENT ***** | SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness |
|-------------------|---|
| No: 21/2006/ND-CP | Hanoi, 27/02/2006 |

DECREE

ON TRADE AND USE THE NUTRITION PRODUCTS FOR YOUNG CHILDREN

GOVERNMENT

Pursuant to the Law on Government Organization of December 25, 2001;

Pursuant to the Law on Protection, Care and Education of Children of June 15, 2004;

Pursuant to the Trade Act of June 14, 2005;

Pursuant to the Advertisement Ordinance of November 16, 2001;

Pursuant to the Ordinance on Goods Quality of December 24, 1999;

Pursuant to the Ordinance on Food Hygiene and Safety of July 26, 2003;

At the proposal of the Minister of Health,

DECREE:

Chapter 1:GENERAL PROVISIONS

Article 1. Scope and Application

- 1. This Decree applies to the information, education, communication, media, advertisements, trade and use of nutrition products for young children, feeding bottles, teats, and dummies.
- 2. This Decree applies to organizations and individuals in the country and foreign organizations and individuals present in Vietnam.

Article 2. Definitions

In this Decree, the terms below are construed as follows:

- 1. *Nutrition products for young children* are milk and food produced by industrial methods. To ensure the standards prescribed are in accordance with the physiology and stages of child development, these products include:
 - a) Milk, food from animals, and plants fed to infants under 6 months of age; and
 - b) Milk fed to infants from 6 months to 24 months of age.
- 2. *Complementary food* is processed food used to supplement breastmilk or other milk for children from 6 months to 24 months of age.
- 3. *Infants* are children from birth to 24 months of age.
- 4. *Labels on nutrition products for young children* are any pictorial or other descriptive matter, written, printed, marked, displayed on, or attached to, a package or container of nutrition products for young children.
- 5. *Gifts or samples of nutrition products for young children* are nutrition products for young children provided free of charge in a small amount.
- 6. Advertisement for nutrition products for young children is the promotion of nutrition products for young children in any way for profit.
- 7. *Medical establishments* include hospitals, specialized obstetrics hospitals, pediatrics hospitals, maternity hospitals, clinics, and specialized obstetrics clinics, pediatrics clinics, general clinics, and health centers in communes, wards and towns.
- 8. *Physicians and medical personnel* are the people who possess medical qualifications. They are medical doctors, physicians, nurses and midwives working in the medical establishments.

Chapter 2:INFORMATION, EDUCATION, COMMUNICATION, MEDIA AND ADVERTISEMENT

Article 3. Information, education, and communication on the benefits of breastfeeding

- 1. Information, education, and communication on the benefits of breastfeeding and infant feeding methods must be given priority in information, education and communication programs on health protection of mothers and children and programs on the prevention of malnutrition in children.
- 2. The Ministry of Health coordinates with the Ministry of Culture and Information; Ministry of Trade; Ministry of Education and Training; National Committee for Population, Family and Children; Central Committee of the Vietnam Fatherland Front; Vietnam Women's Union; Central Communist Youth Union of Ho Chi Minh; Central Vietnam Farmers' Association; General Confederation of Labor of Vietnam; and other social agencies and organizations to propagate and educate about the superiority of breastmilk, the importance of exclusive breastfeeding of young infants and maintenance of breastfeeding.

Article 4. Information, education and communication on infant feeding

- 1. Informational and educational materials related to education and communication on the feeding of infants should be clear, readable, and understandable, and should ensure objectivity and scientific validity.
- 2. Informational and educational materials related to education and communication on the feeding of infants should contain the following points:
 - a) The benefits and advantages of breastfeeding, and the finding that breastmilk is confirmed to be the best food for the health and overall development of infants;
 - b) Guidelines for feeding children exclusively with breastmilk from birth to 6 months of age and for continuing to breastfeed up to 24 months of age or longer as well as suitable complementary food for children aged 6 months and older;
 - c) The anti-infection factors, especially antibodies, available in breastmilk only, help prevent and control diarrhea, respiratory infections and several other infectious diseases in children;
 - d) The disadvantages of not breastfeeding;
 - e) The negative impact of bottle-feeding, dummy usage, and eating complementary foods before 6 months of age; and
 - f) Instructions for processing, storage and usage of complementary foods for children at home using simple methods to ensure safety and proper nutrition with the available foods.
- 3. The following are prohibited from informational and educational materials related to education and communication on the feeding of infants:
 - a) Pictures or text that encourage bottle-feeding or do not promote breastfeeding;
 - b) Comparative pictures or text implying that nutrition products for young children are similar to or better than breastmilk;
 - c) The name or logo of nutrition products for young children, feeding bottles, teats, and/or dummies.

Article 5. Information, education, and communication on the use of nutrition products for young children

The contents of any materials related to information, education, and communication on the use of nutrition products for young children must include the following:

1. Instructions on the proper use of nutrition products for young children;

- 2. Instructions for cleaning and sterilizing equipment used for feeding infants;
- 3. Instructions for feeding infants with clean cups and spoons;
- 4. The possible adverse effects of bottle-feeding on children's health; and
- 5. The costs of feeding children with nutrition products.

Article 6. Advertisement for nutrition products for young children

- 1. Advertisements for milk products for infants under 12 months of age, food products for infants under 6 months of age, feeding bottles, teats and dummies are prohibited in any form.
- 2. Advertisements for milk products for children aged 12 months to 24 months of age must meet the following requirements:
 - a) The first part of the advertisement must contain: "Breastmilk is the best food for the health and overall development of infants;"
 - b) Advertised content must conform to the provisions of Article 4 and Article 5 of this Decree and other provisions of the Law on Advertising.
- 3. Before making advertisements for milk products for infants ages 12 months to 24 months, organizations and individuals have to submit advertisement registration documents to the Ministry of Health in accordance with the Law on Advertising.

Chapter 3: TRADE OF NUTRITION PRODUCTS FOR YOUNG CHILDREN

Article 7. Publish of quality standards, hygiene, and food safety

Before nutrition products for young children are brought out to the market, they must publish the quality standards, food hygiene and safety in accordance with the Law on the Quality of Products and Goods, and the Law on Food Safety and Hygiene.

Article 8. Regulations for the labeling of nutrition products for young children

- 1. Labeling of nutrition products for young children must meet the following requirements:
 - a) There must be a note (printed) "ATTENTION" then the text (in lowercase) as follows: "Breastmilk is the best food for the health and overall development of infants. The anti-infection factors, especially antibodies, available in breastmilk only, help prevent and control diarrhea, respiratory infections and several other infectious diseases in children." The height of the letters must not be less than 2 mm;
 - b) There must be the words (in lowercase): "Use the product only under physicians' instructions. Strictly follow preparation instructions. Feed children by clean cups and spoons." The height of the letters must not be less than 1.5 mm;

- c) The age of the child that the product is designed for must be clearly indicated;
- d) There must be a certified number of published standards of quality, hygiene and food safety on the product label.
- 2. Other contents on the labels of nutrition products for young children must comply with the laws on the labeling of products for domestic, imported, or exported goods, and must meet the following requirements:
 - a) Labels must include instructions on how to prepare the food, which are in Vietnamese, easy to follow and accompanied by simple tables;
 - b) Labels must include full and correct information of the origin, production date, expiration date, ingredients, published certification number of quality standards, hygiene and food safety and nutrition information of the product;
 - c) Labels must not have photos, pictures or drawings of children under 12 months of age, feeding bottles, teats, or dummies; labels must not use language or images that imply that the product is similar in quality to or better than breastmilk.

Article 9. The label of feeding bottles and dummies

- 1. Feeding bottle labels must meet the following requirements:
 - a) There must be the words (in lowercase): "Strictly follow the instructions on hygiene and sterilization. The use of feeding bottles may make children refuse breastfeeding or increase the risk of diarrhea." The height of the lowercase letters must not be less than 2 mm;
 - b) Labels must include instructions on proper use and sterilization;
 - c) Labels must include the name and exact address of the manufacturing and distribution facilities.
- 2. Packaging or labels of dummies must have the words (in lowercase): "Using dummies may have a negative effect on breastfeeding." The height of the lower-case letters must not be less than 2 mm.
- 3. Labels apply to feeding bottles with teats and dummies within the scope in Articles 1 and 2 above. Labeling regulations for bottles and dummies also apply to all feeding bottles, teats and dummies imported to Viet Nam.

Article 10. Responsibilities of the heads of manufacturing and business establishments of nutrition products for young children or their legal representative

1. The heads of the manufacturing or business facilities or their legal representatives must:

- a) Sell nutrition products for young children that are in accordance with published standards of quality, hygiene and food safety;
- b) Provide physicians and medical personnel with scientific information or proper methods of using nutrition products for young children.
- 2. The heads of the manufacturing or business facilities or their legal representatives must not:
 - a) Manufacture or sell nutrition products for young children which do not meet published quality standards on hygiene and food safety, products which are expired, or products that are missing labels or packaging;
 - b) Appoint staff to directly or indirectly contact mothers, pregnant women or their family members at medical establishments for product promotions or selling of milk products for children under 12 months of age and food products for infants under 6 months of age;
 - c) Arrange to offer to physicians, medical personnel or medical establishments any of the following: food products for infants under 6 months of age, milk products for infants under 12 months of age, or material benefits or other forms of expression featuring the names or logos of milk products for children under 12 months of age and food products for infants under 6 months of age;
 - d) Display, sell, or promote milk products for children under 12 months of age and food products for infants under 6 months of age at medical establishments, with the exception of hospital pharmacies;
 - e) Grant scholarships or funds for research, training, conferences, seminars, courses, concerts, counseling services by phone or any other form to directly or indirectly promote the sale or use of milk products for children under 12 months of age and food products for infants under 6 months of age.

Chapter 4: USE OF NUTRITION PRODUCTS FOR YOUNG CHILDREN

Article 11. Responsibilities of the heads of medical establishments

- 1. The heads of medical establishments must:
 - a) Organize communication and promotion of breastfeeding;
 - b) Create conditions that support initiation of breastfeeding within the first hour after birth.
- 2. The heads of medical establishments must not:
 - a) Sell or permit the sale of milk products for children under 12 months of age and food products for infants under 6 months of age at medical establishments, with the exception of hospital pharmacies;

b) Allow manufacturing or business establishments of nutrition products for young children to display the name of nutrition products for young children, feeding bottles, teats, or dummies at medical establishments, with the exception of hospital pharmacies.

Article 12. Responsibilities of physicians and medical personnel in medical establishments

- 1. Physicians and medical personnel in medical establishments must:
 - a) Organize communication on breastfeeding;
 - b) Provide proper guidance to mothers or their family members on how to use nutrition products for young children in special cases where the use of these products is necessary.
- 2. Physicians and medical personnel in medical establishments must not:
 - a) Directly or indirectly accept milk products for children under 12 months of age and food products for infants under 6 months of age or material benefits featuring the names or logos of these products from manufacturing or business establishments or their representatives;
 - b) Assist manufacturing or business establishments offer samples or gifts related to nutrition products for young children;
 - c) Guide, counsel and/or prescribe for pregnant women to use nutrition products for young children unless it is necessary to use such products.

Chapter 5: Implementing Provisions

Article 13. Management responsibilities

- 1. Ministry of Health administers and coordinates with the Ministry of Trade, Ministry of Culture and Information, National Committee for Population, Family and Children and related ministries and agencies that have responsibility for managing the use of nutrition products for young children; managing the quality, hygiene and safety of nutrition products for young children; and organizing the inspection and supervision of the implementation of the provisions of the Decree.
- 2. The Ministry of Culture and Information administers and coordinates with the Ministry of Trade and Ministry of Health in information management and advertisement of nutrition products for young children under the assigned authority.

Article 14. Implementation effect

This Decree takes effect 15 days from the date of publication.

Repeal of Decree No. 74/2000/ND-CP of December 6, 2000 by the Government on Trade and Use of Breastmilk Substitutes to Protect and Encourage Breastfeeding.

Article 15. Responsibility for implementation

- 1. The Minister of Health administers and coordinates with the Minister of Trade, Minister of Culture and Information, Chairman of the National Committee for Population, Family and Children to guide the implementation of this Decree.
- 2. The ministers, heads of ministerial-level agencies, heads of governmental agencies, Chairmen of People's Committees of provinces and cities directly under the Central Government shall implement this Decree. /.

On behalf of the government,

PRIME MINISTER

Phan Van Khai

Annex 4: International Code of Marketing of Breastmilk Substitutes

Introduction

THE WORLD HEALTH ORGANIZATION (WHO) and the United Nations Children's Fund (UNICEF) have for many years emphasized the importance of maintaining the practice of breast-feeding—and of reviving the practice where it is in decline—as a way to improve the health and nutrition of infants and young children. Efforts to promote breast-feeding and to overcome problems that might discourage it are a part of the overall nutrition and maternal and child health programmes of both organizations and are a key element of primary health care as a means of achieving health for all by the year 2000.

A variety of factors influence the prevalence and duration of breast-feeding. The Twenty-seventh World Health Assembly, in 1974, noted the general decline in breast-feeding in many parts of the world, related to sociocultural and other factors including the promotion of manufactured breast-milk substitutes, and urged "Member countries to review sales promotion activities on baby foods to introduce appropriate remedial measures, including advertisement codes and legislation where necessary".

The issue was taken up again by the Thirty-first World Health Assembly in May 1978. Among its recommendations were that Member States should give priority to preventing malnutrition in infants and young children by, *inter alia*, supporting and promoting breast-feeding, taking legislative and social action to facilitate breast-feeding by working mothers, and "regulating inappropriate sales promotion of infant foods that can be used to replace breast milk".⁷

Interest in the problems connected with infant and young child feeding and emphasis on the importance of breast-feeding in helping to overcome them have, of course, extended well beyond WHO and UNICEF. Governments, nongovernmental organizations, professional associations, scientists, and manufacturers of infant foods have also called for action to be taken on a world scale as one step towards improving the health of infants and young children.

In the latter part of 1978, WHO and UNICEF announced their intention of organizing jointly a meeting on infant and young child feeding, within their existing programmes, to try to make the most effective use of this groundswell of opinion. After thorough consideration on how to ensure the fullest participation, the meeting was convened in Geneva from 9 to 12 October 1979 and was attended by some 150 representatives of governments, organizations of the United Nations system and other intergovernmental bodies, nongovernmental organizations, the infant-food industry, and experts in related disciplines. The discussions were organized on five main themes: the encouragement and

⁶Resolution WHA27.43 (Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume II, 4th ed., Geneva, 1981, p.58).

⁷Resolution WHA31.47 (Handbook of Resolutions and Decisions.... Volume II, 4th ed., p.62).

support of breast-feeding; the promotion and support of appropriate and timely complementary feeding (weaning) practices with the use of local food resources; the strengthening of education, training and information on infant and young child feeding; the promotion of the health and social status of women in relation to infant and young child health and feeding; and the appropriate marketing and distribution of breast-milk substitutes.

The Thirty-third World Health Assembly, in May 1980, endorsed in their entirety the statement and recommendations agreed by consensus at this joint WHO/UNICEF meeting and made particular mention of the recommendation that "there should be an international code of marketing of infant formula and other products used as breast-milk substitutes", requesting the Director-General to prepare such a code "in close consultation with Member States and with all other parties concerned".⁸

To develop an international code of marketing of breast-milk substitutes in accordance with the Health Assembly's request, numerous and lengthy consultations were held with all interested parties. Member States of the World Health Organization and groups and individuals who had been represented at the October 1979 meeting were requested to comment on successive drafts of the code, and further meetings were held in February and March and again in August and September in 1980. WHO and UNICEF placed themselves at the disposal of all groups in an effort to foster a continuing dialogue on both the form and the content of the draft code and to maintain as a basic minimum content those points which had been agreed upon by consensus at the meeting in October 1979.

In January 1981, the Executive Board of the World Health Organization at its sixty-seventh session, considered the fourth draft of the code, endorsed it, and unanimously recommended9to the Thirty-fourth World Health Assembly the text of a resolution by which it would adopt the code in the form of a recommendation rather than as a regulation.¹0In May 1981, the Health Assembly debated the issue after it had been introduced by the representative of the Executive Board.¹¹It adopted the code, as proposed, on 21 May by 118 votes in favour to 1 against, with 3 abstentions.¹²

⁸See resolution WHA33.32, reproduced in Annex 2.

⁹See resolution EB67.R12, reproduced in Annex 1.

¹⁰The legal implications of the adoption of the code as a recommendation or as a regulation are discussed in a report on the code by the Director-General of WHO to the Thirty-fourth World Health Assembly; this report is contained in document WHA34/1981/REC/1, Annex 3.

¹¹See Annex 3 for excerpts from the introductory statement by the representative of the Executive Board.

¹²See Annex 1 for the text of resolution WHA34.22, by which the code was adopted. For the verbatim record of the discussion at the fifteenth plenary meeting, on 21 May 1981, see document WHA34/1981/REC/2.

The Member States of the World Health Organization:

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

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

Recognizing that the health of infants and young children cannot be isolated from the health and nutrition of women, their socioeconomic status and their roles as mothers;

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

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

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

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

Convinced that it is important for infants to receive appropriate complementary foods, usually when they reach four to six months of age, and that every effort should be made to use locally available foods; and convinced, nevertheless, that such complementary foods should not be used as breast-milk substitutes;

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

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

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

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

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

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

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

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

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

THEREFORE:

The Member States hereby agree the following articles which are recommended as a basis for action.

Article 1. Aim of the Code

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

Article 2. Scope of the Code

The Code applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottlefed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.

Article 3. Definitions

For the purposes of this Code:

| "Breast-milk substitute" | means | any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose. |
|--------------------------|-------|---|
| "Complementary food" | means | any food whether manufactured or locally |

any food whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either become insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called "weaning food" or breast-milk supplement".

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

"Distributor"

means

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

"Health care system"

means

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

"Health worker"

means

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

"Infant formula"

means

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

| "Label" | means | any tag, brand, marks, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container (see above) of any products within the scope of this Code. |
|-----------------------|-------|--|
| "Manufacturer" | means | a corporation of other entity in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code. |
| "Marketing" | means | product promotion, distribution, selling, advertising, product public relations, and information services. |
| "Marketing personnel" | means | any persons whose functions involve the marketing of a product or products coming within the scope of this Code. |
| "Samples" | means | single or small quantities of a product provided without cost. |
| "Supplies" | means | quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need. |

Article 4. Information and education

- 4.1 Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover either the planning, provision, design and dissemination of information, or their control.
- 4.2 Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include clear information on all the following points: (a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; (d) the difficulty of reversing the decision not to breast-feed; and (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breast-milk substitutes. Such materials should not use any pictures or text which may idealize the use of breast-milk substitutes.
- 4.3 Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval of the appropriate government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.

Article 5. The general public and mothers

- 5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.
- 5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.
- 5.3 In conformity with paragraphs 1 and 2 of this Article, there should be no point of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.

- 5.4 Manufacturers and distributors should not distribute to pregnant women or mothers or infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.
- 5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

Article 6. Health care systems

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

Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.

6.8 Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.

Article 7. Health workers

- 7.1 Health workers should encourage and protect breast-feeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.
- 7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottlefeeding is equivalent or superior to breast-feeding. It should also include the information specified in Article 4.2.
- 7.3. No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.
- 7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.
- 7.5 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

Article 8. Persons employed by manufacturers and distributors

8.1 In systems of sales incentives for marketing personnel, the volume of sales of products within the scope of this Code should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.

8.2 Personnel employed in marketing products within the scope of this Code should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children. This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with the written approval of the appropriate authority of the government concerned.

Article 9.Labelling

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

Article 10. Quality

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

Article 11. Implementation and monitoring

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

11.7 The Director-General shall report in even years to the World Health Assembly on the status of implementation of the Code; and shall, on request, provide technical support to Member States preparing national legislation or regulations, or taking other appropriate measures in implementation and furtherance of the principles and aim of this Code.

Annex 1

Resolutions of the Executive Board at its Sixty-seventh Session and of the Thirty-fourth World Health Assembly on the International Code of Marketing of Breast-milk Substitutes

Resolution EB67.R12 Draft International Code of Marketing of Breast-milk Substitutes

The Executive Board,

Having considered the report by the Director-General on the Draft International Code of Marketing of Breast-milk Substitutes;

- 1. ENDORSES in its entirety the Draft International Code prepared by the Director-General;
- 2. FORWARDS the Draft International Code to the Thirty-fourth World Health Assembly;
- 3. RECOMMENDS to the Thirty-fourth World Health Assembly the adoption of the following resolution:

28 January 1981

[The text recommended by the Executive Board was adopted by the Thirty-fourth World Health Assembly, on 21 May 1981, as resolution WHA34.22, reproduced overleaf.]

Resolution WHA34.22

International Code of Marketing of Breast-milk Substitutes

The Thirty-fourth World Health Assembly,

Recognizing the importance of sound infant and young child nutrition for the future health and development of the child and adult;

Recalling that breast-feeding is the only natural method of infant feeding and that it must be actively protected and promoted in all countries;

Convinced that governments of Member States have important responsibilities and a prime role to play in the protection and promotion of breast-feeding as a means of improving infant and young child health;

Aware of the direct and indirect effects of marketing practices for breast-milk substitutes on infant feeding practices;

Convinced that the protection and promotion of infant feeding, including the regulation of the marketing of breast-milk substitutes, affect infant and young child health directly and profoundly, and are a problem of direct concern to WHO;

Having considered the draft International Code of Marketing of Breast-milk Substitutes prepared by the Director-general and forwarded to it by the Executive Board;

Expressing its gratitude to the Director-General and to the Executive Director of the United Nations Children's Fund for the steps they have taken in ensuring close consultation with Member States and with all other parties concerned in the process of preparing the draft International Code;

Having considered the recommendation made thereon by the Executive Board at its sixty-seventh session;

Confirming resolution WHA33.32, including the endorsement in their entirety of the statement and recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding held from 9 to 12 October 1979;

Stressing that the adoption of and adherence to the International Code of Marketing of Breast-milk Substitutes is a minimum requirement and only one of several important actions required in order to protect health practices of infant and young child feeding;

- 1. ADOPTS, in the sense of Article 23 of the Constitution, the International Code of Marketing of Breast-milk Substitutes annexed to the present resolution;
- 2. URGES all Member States:

- (1) to give full and unanimous support to the implementation of the recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding and of the provisions of the International Code in its entirety as an expression of the collective will of the membership of the World Health Organization;
- (2) to translate the International Code into national legislation, regulations or other suitable measures;
- (3) to involve all concerned social and economic sectors and all other concerned parties in the implementation of the International Code and in the observance of the provisions thereof:
- (4) to monitor the compliance with the Code;
- 3. DECIDES that the follow-up to and review of the implementation of this resolution shall be undertaken by regional committees, the Executive Board and the Health Assembly in the spirit of resolution WHA33.17.
- 4. REQUESTS the FAO/WHO Codex Alimentarius Commission to give full consideration, within the framework of its operational mandate, to action it might take to improve the quality standards of infant foods, and to support and promote the implementation of the International Code;
- 5. REQUESTS the Director-General:
 - (1) to give all possible support to Member States, as and when requested, for the implementation of the International Code, and in particular in the preparation of national legislation and other measures related thereto in accordance with operative subparagraph 6(6) of resolution WHA33.32;
 - (2) to use his good offices for the continued cooperation with all parties concerned in the implementation and monitoring of the International Code at country, regional and global levels;
 - (3) to report to the Thirty-sixth World health Assembly on the status of compliance with and implementation of the Code at country, regional and global levels;
 - (4) based on the conclusions of the status report, to make proposals, if necessary, for revision of the text of the Code and for the measures needed for its effective application.

21 May 1981

Annex 2

Resolution of the Thirty-third World Health Assembly on Infant and Young Child Feeding

Resolution WHA 33.32 Infant and young child feeding

The Thirty-third World Health Assembly,

Recalling resolutions WHA27.43 and WHA31.47 which in particular reaffirmed that breast-feeding is ideal for the harmonious physical and psychosocial development of the child, that urgent action is called for by governments and the Director-General in order to intensity activities for the promotion of breast-feeding and development of actions related to the preparation and use of weaning foods based on local products, and that there is an urgent need for countries to review sales promotion activities on baby foods and to introduce appropriate remedial measures, including advertisement codes and legislation, as well as to take appropriate supportive social measures for mothers working away from their homes during the lactation period;

Recalling further resolutions WHA31.55 and WHA32.42 which emphasized maternal and child health as an essential component of primary health care, vital to the attainment of health for all by the year 2000;

Recognizing that there is a close interrelationship between infant and young child feeding and social and economic development, and that urgent action by governments is required to promote the health and nutrition of infants, young children and mothers, *inter alia* through education, training and information in this field;

Noting that a joint WHO/UNICEF Meeting on Infant and Young Child Feeding was held from 9 to 12 October 1979, and was attended by representatives of governments, the United Nations system and technical agencies, nongovernmental organizations active in the area, the infant-food industry and other scientists working in this field;

1. ENDORSES in their entirety the statement and recommendations made by the joint WHO/UNICEF meeting, namely on the encouragement and support of breastfeeding; the promotion and support of appropriate weaning practices; the strengthening of education, training and information; the promotion of the health and social status of women in relation to infant and young child feeding; and the appropriate marketing and distribution of breast-milk substitutes. This statement and these recommendations also make clear the responsibility in this field incumbent on the health services, health personnel, national authorities, women's and other nongovernmental organizations, the United Nations agencies and the infant-food industry, and stress the importance for countries to have a coherent food and nutrition policy and the need for pregnant and lactating women to be adequately nourished; the joint Meeting also recommended that "There should be an

international code of marketing of infant formula and other products used as breast-milk substitutes. This should be supported by both exporting and importing countries and observed by all manufacturers. WHO and UNICEF are requested to organize the process for its preparation, with the involvement of all concerned parties, in order to reach a conclusion as soon as possible";

- 2. RECOGNIZES the important work already carried out by the World Health Organization and UNICEF with a view to implementing these recommendations and the preparatory work done on the formulation of a draft international code of marketing of breast-milk substitutes;
- 3. URGES countries which have not already done so to review and implement resolutions WHA27.43 and WHA32.42;
- 4. URGES women's organizations to organize extensive information dissemination campaigns in support of breast-feeding and healthy habits;
- 5. REQUESTS the Director-General;
 - (1) to cooperate with Member States on request in supervising or arranging for the supervision of the quality of infant foods during their production in the country concerned, as well as during their importation and marketing;
 - (2) to promote and support the exchange of information on laws, regulations, and other measures concerning marketing of breast-milk substitutes;
- 6. FURTHER REQUESTS the Director-General to intensity his activities for promoting the application of the recommendations of the joint WHO/UNICEF Meeting and, in particular:
 - (1) to continue efforts to promote breast-feeding as well as sound supplementary feeding and weaning practices as a prerequisite to healthy child growth and development;
 - (2) to intensify coordination with other international and bilateral agencies for the mobilization of the necessary resources for the promotion and support of activities related to the preparation of weaning foods based on local products in countries in need of such support and to collate and disseminate information on methods of supplementary feeding and weaning practices successfully used in different cultural settings;
 - (3) to intensify activities in the field of health education, training and information on infant and young child feeding, in particular through the preparation of training and other manuals for primary health care workers in different regions and countries;

- (4) to prepare an international code on marketing of breast-milk substitutes in close consultation with Member States and with all other parties concerned including such scientific and other experts whose collaboration may be deemed appropriate, bearing in mind that:
 - (a) the marketing of breast-milk substitutes and weaning foods must be viewed within the framework of the problems of infant and young child feeding as a whole;
 - (b) the aim of the code should be to contribute to the provision of safe and adequate nutrition of infants and young children, and in particular to promote breast-feeding and ensure, on the basis of adequate information, the proper use of breast-milk substitutes, if necessary;
 - (c) the code should be based on existing knowledge of infant nutrition;
 - (d) the code should be governed *inter alia* by the following principles:
 - (i) the production, storage and distribution, as well as advertising, of infant feeding products should be subject to national legislation or regulations, or other measures as appropriate to the country concerned;
 - (ii) relevant information on infant feeding should be provided by the health care system of the country in which the product is consumed;
 - (iii) products should meet international standards of quality and presentation, in particular those developed by the Codex Alimentarius Commission, and their labels should clearly inform the public of the superiority of breast-feeding;
- (5) to submit the code to the Executive Board for consideration at its sixty-seventh session and for forwarding with its recommendations to the Thirty-fourth World Health Assembly, together with proposals regarding its promotion and implementation, either as a regulation in the sense of Articles 21 and 22 of the Constitution of the World Health Organization or as a recommendation in the sense of Article 23, outlining the legal and other implications of each choice;
- (6) to review the existing legislation in different countries for enabling and supporting breast-feeding, especially by working mothers, and to strengthen the Organization's capacity to cooperate on the request of Member States in developing such legislation;

(7) to submit to the Thirty-fourth World Health Assembly, in 1981, and thereafter in even years, a report on the steps taken by WHO to promote breast-feeding and to improve infant and young child feeding, together with an evaluation of the effect of all measures taken by WHO and its Member States.

23 May 1980

Annex 3

Excerpts from the Introductory Statement by the Representative of the Executive Board to the Thirty-fourth World Health Assembly on the Subject of the Draft International Code of Marketing of Breast-milk Substitutes¹³

The topic "infant and young child feeding" was extensively reviewed and discussed in May 1980 at the Thirty-third World Health Assembly, and it has also been extensively discussed this morning. Delegates will recall last year's Health Assembly's resolution WHA33.32 to this effect, which was adopted unanimously and which among other things requested the Director-General "to prepare an international code of marketing of breast-milk substitutes in close consultation with Member States and with other parties concerned". The need for such a code and the principles on which it should be developed were thus unanimously agreed upon at last year's Health Assembly. Health Assembly. Health assembly therefore not be necessary in our deliberations today to repeat this review and these discussions.

There are two issues before the Committee today: firstly, the content of the code; and secondly, the question of whether the code should be adopted as a regulation in the sense of Articles 21 and 22 of the WHO Constitution or as a recommendation in the sense of Article 23.

The proposal now before the Committee in document A34/8 is the fourth distinct draft of the code; it is the result of a long process of consultations carried out with Member States and other parties concerned, in close cooperation with UNICEF. Few, if any, issues before the Executive Board and the Health Assembly have been the object of such extensive consultations as has the draft code.

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During the Executive Board's discussion on this item at its sixty-seventh session, in January 1981, many members addressed themselves to the aim and the principles of the code and stressed that, as presently drafted, it constituted the minimum acceptable requirements concerning the marketing of breast-milk substitutes. Since even at this late date, as reflect in recent newspaper articles, some uncertainty persists with respect to the content of the code, particularly its scope, I believe it would be useful to make some

¹³This statement by Dr TorbjørnMork (Director-General of Health Services, Norway), representative of the Executive Board, was delivered before Committee A on 20 May 1981. The summary records of the discussion of this topic at the thirteenth, fourteenth and fifteenth meetings of Committee A are contained in document WHA34/1981/REC/3.

¹⁴See document WHA33/1980/REC/1, Annex 6; document WHA33/1980/REC/2, page 327; and document WHA33/1980/REC/3, pages 67-95 and 200-204.

remarks on this point. I hasten to remind delegates, however, that the scope of the code was not the source of difficulty during the Board's discussion.

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

Products other than *bona fide* breast-milk substitutes, including infant formula, are covered by the code only when they are "marketed or otherwise represented to be suitable for use as a partial or total replacement of breastmilk". Thus the code's references to products used as partial or total replacements for breast milk are not intended to apply to complementary foods unless these foods are actually marketed 22as breast-milk substitutes, including infant formula, are marketed 22as being suitable for the partial or total replacement of breast milk. So long as the manufacturers and distributors of the products do not promote them as being suitable for use as partial or total replacements for breast milk, the code's provisions concerning limitations on advertising and other promotional activities do not apply to these products.

The Executive Board examined the draft code very carefully. 15 Several Board members indicated that they considered introducing amendments in order to strengthen it and to make it still more precise. The Board considered, however, that the adoption of the code by the Thirty-fourth World Health Assembly was a matter of great urgency in view of the serious situation prevailing, particularly in developing countries, and that amendments introduced at the present stage might lead to a postponement of the adoption of the code. The Board therefore unanimously recommended to this Thirty-fourth World Health Assembly the adoption of the code as presently drafted, realizing that it might be desirable or even necessary to revise the code at an early date in the light of the experience obtained in the implementation of its various provisions. This is reflected in operative paragraph 5(4) of the recommended resolution contained in resolution EB67.R12. The second mina questions before the Executive Board was whether it should recommend the adoption of the code as a recommendation or as a regulation. Some Board members expressed a clear preference for its adoption as a regulation in the sense of Articles 21 and 22 of the WHO Constitution. It became clear, however, that, although there had not been a single dissenting voice in the Board with regard either to the need for an international code or to

¹⁵The summary record of the Board's discussions is contained in document EB67/1981/REC/2, pages 306-322.

its scope or content, opinion was divided on the question of a recommendation versus a regulation.

It was stressed that any decision concerning the form the code should take should be based on an appreciation of which alternative had the better chance of fulfilling the purpose of the code — that is, to contribute to improved infant and child nutrition and health. The Board agreed that the moral force of a unanimous recommendation could be such that it would be more persuasive than a regulation that had gained less then unanimous support from Member States. It was considered, however, that the implementation of the code should be closely monitored according to the existing WHO constitutional procedures; that future Assemblies should assess the situation in the light of reports from Member States; and that the Assembly should take any measures it judged necessary for its effective application After carefully weighing the different points raised during its discussion, the Board unanimously adopted resolution EB67.R12, which contains the draft resolution recommended for adoption by the World Health Assembly. In this connexion I wish to draw the Committee's particular attention to the responsibilities outlined in the draft resolution: those of Member States, the regional committees, the Director-General, the Executive Board, and the Health Assembly itself for appropriate follow-up action once the code has been adopted.

In carrying out their responsibilities, Member States should make full use of their Organization — at global, regional and country levels — by requesting its technical support in the preparation of national legislation, regulations or other appropriate measures, and in the monitoring of the application of the code.

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I think that I can best reflect the sentiments of the Board by closing my introduction with a please for consensus on the resolution as it was unanimously recommended to the World Health Assembly by the Board. We are not today dealing with an economic issue of particular importance only to one or a few Member States. We are dealing with a health issue of essential importance to all Member States, and particularly to developing countries, and of importance to the children of the world and thus to all future generations.

Annex 5: Legislation Department Assessment Report (translated into English)

| MINISTRY | OF | HEALTH | | | |
|-----------|----|--------|--|--|--|
| INSPECTOR | | | | | |

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

Number: / BC-BYT

Hanoi, May 2011

REPORT

Assessment of 5-year Implementation of Decree No. 21/2006/ND-CP dated 02/27/2006 of Government on Trade and Use of Nutrition Products for Infants

To: Heads of the Ministry of Health

Breastmilk has been confirmed as the best food for the development of infants and young children. Studies show that exclusive breastfeeding for first six months of life and continued breastfeeding for up to at least 2 years will bring many health benefits, including helping children avoid diseases such as malnutrition, pneumonia, diarrhea and other diseases. Breastfeeding also helps mothers prevent and combat breast cancer, provides a natural method of birth control, and strengthens the emotional and physiological ties between mothers and infants. Moreover, breastfeeding helps families, especially young families, to reduce the economic burden of child-rearing by refraining from using unnecessary or improper breastmilk substitutes. According to the World Health Organization, breastmilk provides 100% of nutritional requirements for infants during the first 6 months of life, and 50% of those demands for the period from 6 to 12 months of age. In the second year, breastmilk can still provide 33% of nutritional needs for children.

Vietnam is the first country in Asia and is the second country in the world to ratify the International Convention on the Rights of the Child. In Vietnamese legal system, child rights have become an important legal issue. The Party and State goals for policies related to children are that, "All Vietnamese children are born physically and intellectually healthy, develop in a holistic way, live in a healthy, safe environment, have the full love and protection of the family and the community....so that as adults, they can become forces that can grasp new science and technology, and as citizens and the real owners of the country, they can be completely confident to participate in the process of integration and globalization of the century."

To protect and support the holistic development of infants and young children, the State has issued many important legal documents, including the Decree No. 21/2006/ND-CP dated 27 / 2 / 2006 of the Government on the Trade and Use of Nutrition Products for Infants (hereinafter referred to as Decree No. 21/2006/ND-CP).

After more than four years of implementing Decree No. 21/2006/ND-CP, we have achieved some results such as the fact that more and more mothers are knowledgeable about the benefits of breastfeeding. In addition, the rate of malnutrition among children under 5 years of age nationwide is dropping at 1.5% annually, from 25.2% in 2005 to 18.9% in 2009, exceeding the target of 20% set for 2010.

However, business establishments involved in manufacturing and distribution of nutrition products for children make high profits. These businesses have regularly advertised that their products are beneficial for infants, leading many mothers to believe that supplementing their children's diets with nutrition products for infants will improve the intelligence and development of their children. As a result, instead of breastfeeding, many mothers supplement their children's diets with nutrition products. These practices have a negative impact on the development of children and reduce their immunity against child diseases.

To provide a basis for the proposed amendment, complement or promulgation of a new decree to replace Decree No. 21/2006/ND-CP, the Legislative Department conducted an integrated five-year review of the implementation of the Decree No. 21 / 2006/ND-CP dated 27/02/2006 in 63 Provincial and City Departments of Health, the Central Maternity Hospital, Central Pediatric Hospital, and General Hospital. The present report provides details of this review.

Part One

Results of the implementation of the Decree No. 21/2006/ND-CP dated 27/02/2006 of trading and using of nutrition products for infants

I. RESULTS OF CONSTRUCTION AND PROMULGATION OF DOCUMENTS

1. Construction of legal documents relating to trading and using of nutrition products for infants of the central government

After Decree No. 21/2006/ND-CP was issued, the Government issued Decree No. 89/2006 / ND-CP dated 30/8/2006 on the Labeling of Goods. In addition, the Ministry of Health in cooperation with the Ministry of Trade, Ministry of Culture and Information, and the National Committee for Population, Family and Children issued Joint Circular No. 10/2006/TTLT-BYT-BTM-BVHTT-UBDSGDTE dated 08/25/2006 to guide the implementation of Decree No. 21/2006/ND-CP. On 28/02/2007, the Ministry of Culture and Information, Ministry of Health, Ministry of Agriculture and Rural Development, Ministry of Construction issued Joint Circular No. 06/2007/TTLT-BVHTT-BYT-BNN-BXD to guide the procedures for granting permission for advertising of food and food additives.

Performing functions and tasks of state management by the Government, the Ministry of Industry and Trade is charged with making and approving the development plans of Vietnamese dairy processing industry as of 2010. Under the approved plan, the enterprises ensure development complies with state regulations on investment, production and trading of dairy products. To date, the Ministry of Industry and Trade has developed a master plan for Vietnam dairy development until 2020, with a vision to 2025, and has constructed industry standards, technical regulations, and manuals for the management of production and trading activities of dairy products.

The Ministry of Health also issued Circular No. 30/2010/TT-BYT dated 02/6/2010 on national technical standards for liquid milk products; Circular 31/2010/TT-BYT dated 02/6/2010 on national technical standards for powdered milk products; Circular 32/2010/TT-BYT dated 02/6/2010 on technical standards for national cheese products; and Circular 33/2010/TT-BYT dated 02/6/2010 on national technical standards for dairy fat products.

2. Issuance of documents to urge and direct the implementation of Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE in the localities.

Each year, the Provincial and City Departments of Health directly under the Central Government issue written guidance and coordinate to strictly implement Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE. Most assigned the Reproductive Health Center and Preventive Medicine Center to urge the implementation of these documents.

To put the contents of Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE into practice, the localities issued a series of plans such as the Action Plan

for Infant Feeding; Child Survival Action Plan; Action Plan Month for Children; Annual Malnutrition Prevention Plan; Breastfeeding Week; Nutrition and Development Week; and the Baby-Friendly Hospital Maintenance and Implementation Plan.

Some localities perform these works well such as the Ben Tre Province Department of Health, which issued 05 official documents, including: a) 01 document directing the implementation of Decree No. 21/2006/ND-CP; b) Document No. 814/SYT-NVY dated 22/06/2009 on enhancing the implementation of Decree No. 21/2006/ND-CP; c) Document No. 1549/SYT-NVY dated 26.8.2009 on restricting the sale of milk for infants in health facilities; d) Document No. 1943/SYT-NVY 26/9/2009 on Nutrition and Development Week; and e) Document No. 1073/SYT-NVY dated 07/28/2010 on breastfeeding. The Department of Health of Ba RiaVung Tau issued 08 documents related to an implementation plan and written directions urging the implementation of Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE.

3. Organizing communication and dissemination of Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE

Each year, the Ministry of Health issued documents directing and urging the Provincial and City Departments of Health to thoroughly implement Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE and to conduct communication and dissemination of these documents to 02 representatives from the Department of Health and the Central Hospital to inspect and supervise the implementation of Decree 21/2006/ND-CP in health facilities in select provinces and cities including Hanoi, Quang Ninh, Khanh Hoa, and Da Nang.

According to local reports, 100% of health facilities were made fully aware of Decree No. 21/2006/ND-CP and joint circular 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE by different ways such as conferences and training courses for leaders, inspectors and heads of units under the Obstetric and Pediatric Departments at provincial and district hospitals. In addition, the content of these 02 documents were integrated into the propaganda program, programs for dissemination of knowledge about nutrition, and training for officials and employees of the Obstetric and Pediatric hospitals related to encouraging breastfeeding, increasing knowledge about the value of breastmilk, raising the importance of breastfeeding, improving counseling skills and educating about the practices of breastfeeding among pregnant women. Some maternity hospitals held talks and provided guidance on nutrition care of pregnant women and infants; hygiene regimens for pregnant women, mothers babies: and proper breastfeeding and practices.

The contents of Decree No. 21/2006/ND-CP have also been compiled into books and documents for distribution to mothers and medical personnel (e.g., Dong Nai and Central Obstetrics Hospitals) and have been promulgated on the mass media such as radio and television (e.g., Nghe An, Ba Ria-Vung Tau, Ha Nam, and Ben Tre).

In addition, in 2011, supervision and enhancement of implementing Decree No. 21/2006/ND-CP has been one of the key priorities of targeted programs for prevention of child malnutrition in Da Nang. Kon Tum province also incorporated the contents of Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT-BYT-BTM-BVHTT-UBDSGDTE into its annual propaganda plan and dissemination of legal education.

II. Results of the implementation of Decree No. 21/2006/ND-CP and Joint Circular No. 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE

A. Achievements:

1. Regarding information, education, promulgation and advertisement

Reproductive Health Centers and Centers for Communication and Health Education were usually assigned to conduct health education and advocacy activities in order to inform mothers and pregnant women raising their young children about the benefits of breastfeeding and nutritional foods for young children. The methods of infant feeding were given priority in information, education and communication programs related to health protection of mothers and children and the prevention of malnutrition in children.

Each year, the Departments of Health in provinces/cities had programs for planning and advocating on the trade and use of nutrition products for infants or integrated programs in the prevention campaign of malnutrition in children. The specific activities for information, education, communication and advertising include:

a) Organization of conferences that trained participants in skills for taking care of mothers and children, including breastfeeding

Hospital employees, medical staff and collaborators were trained in regular nutrition and breastfeeding. Contents of the conferences and training emphasized the importance of implementing the 10 breastfeeding conditions at health facilities and the role of medical personnel in consulting and helping mothers initiate breastfeeding within an hour of birth, practice exclusive breastfeeding for the first 6 months, supplement children's diets with reasonable nutrition and continue breastfeeding from 6 months to 2 years of age. The benefits of breastfeeding and nutritional values of breastmilk were also covered. The Central Children Hospital has opened a new training course for nurses, new doctors, and re-training classes on communication and education of knowledge about nutrition including breastfeeding and proper nutrition. It has also integrated breastfeeding into lectures for postgraduate students or students who were pediatric doctors practicing at the hospital. Skills related to breastfeeding advocacy, guidance and assistance for mothers with children less than 1 month old was added as one of the evaluation criteria for nurses working with infants.

Some hospitals have organized counseling classes for pregnant women about breastfeeding in antenatal clinics in the form of: videos, talking directly with mothers and providing instructions on nutrition practice for pregnant women and mothers raising young children (e.g., Central Obstetrics Hospital, Central Children's Hospital, Son La, Tuyen Quang, and Da Nang Hospitals).

The Thai Nguyen Department of Health held 40 classes on breastfeeding at the provincial and district levels and 3500 talks in the community. The Da Nang Department of Health held classes on nutrition practices for pregnant women and mothers raising young children including 12-24

classes/year and direct counseling for 1,200 mothers on average/year. The Department also organized nutrition practices classes including 04 classes/commune/year.

The Ho Chi Minh City Department of Health held 01 workshop to strengthen breastfeeding for 52 reporters and 01 scientific and technical event for 28 medical personnel on the benefits of breastfeeding.

b) Compiling books and materials (brochures, leaflets, posters, guides on breastfeeding and 10 regulations on breastfeeding) to communicate and educate on breastfeeding and requirements when using nutrition products for infants.

Some localities received funding from the project or targeted programs to prevent child malnutrition, and they were therefore able to compile books for the purpose of communicating and educating on breastfeeding and requirements when using nutrition products for infants. The Kon Tum Department of Health wrote, printed and disseminated communication materials on breastfeeding, including updated provisions of Decree No. 21 / 2006/ND-CP, to the city and district health centers. These materials included: 800 painting files with 4 components related to the topic "Breastfeeding;" 3000 picture files, 80,000 leaflets and 16,500 posters related to the topic "Safe Motherhood and Infant Care," which also mentioned breastfeeding; 1000 handbooks entitled "Breastfeeding;" and thousands of leaflets entitled "A hallmark of violations of Decree No. 21/2006 / ND-CP" in the districts of Ngoc Hoi, DakGlei, Dak To and Dak Ha. The Ben Tre Department of Health distributed 6000 books entitled "Handbook of nutrition care for pregnant mothers," to patients at the obstetrics and commune and ward health stations of Can Tho city. The Ho Chi Minh City Department of Health published nearly 16 types of publications on the benefits of breastfeeding and food supplements for young children, with more than 20,000 copies/publication distributed to the public.

Hospitals have placed leaflets guiding breastfeeding and suspended board with "10 adopted regulations on Breastfeeding" in obstetrics and pediatrics; frequently distributed flyers to both pregnant women and their family members when they came to obstetric hospitals or health stations; The content of leaflets and guide for pregnant women was: how to breastfeed, detection, backup, and tackle some common diseases in infants, including breastfeeding guide in first 6 months, how to express breastmilk, hygienically feed by cup and spoon when the baby was poor breastfeeding.

Quantity: Ha Nam Department of Health printed 100,000 leaflets, 01 panel, 50,000 posters, Ha Nam Health Newspaper published 01 copy per quarter on the benefits of breastfeeding; HauGiang Department of Health issued 10,000 leaflets on information, education and communication about breastfeeding; 10,000 leaflets on supplementation feeding; Thai Nguyen Department of Health issued 200,000 leaflets on the benefits of the breastfeeding; bad influence of bottle feeding, sucking dummies and eating supplementation foods before 6 months of age; 150,000 leaflets on

information, education and communication about requirements when using nutrition products for infants ...

c) Other forms of information, education, communication and advertisement:

There was a range of forms of information, education, communication and advertisement on the benefits of breastfeeding between localities. Some localities did banners, propaganda slogans about the benefits of breastfeeding (Son La) and integrated this content into the women's events or village meetings. Some localities built columns and seminars or wrote reports on the news media systems, broadcasted on radio and television in the province (Ha Nam, Da Nang, Ho Chi Minh, Dong Nai, and Yen Bai) or mobile communication. Ho Chi Minh City also built Web-Medinet forum, electronic and printed newspapers to promote the benefits of breastfeeding, exclusive breastfeeding for first 6 months: real was not easy, easier said but hard work; removing barriers to breastfeeding; and other violations in advertising, trading and using of products for young children. Long An Department of Health built 72 social clubs on breastfeeding with the main theme was Breastfeeding with 1,405 times/23,986 turns of mothers breastfeeding to attend. The contest was organized at provincial and district levels with the content of breastfeeding attracted thousands of participants (in 2005, there were 10 contests in 9 districts and the whole province with the content of "Family knowledge-children's health" attracted 810 people attended. In 2007, there were 14 contests in 13 districts and the whole province with the content of "breastfeeding knowledge" attracted 910 participants. In 2009, the competition was about "Knowledge of taking care and nurturing infants" with 1084 participants). Dong Nai Department of Health used LAN to communicate information to hospital bed, especially in obstetrics, built consultant team (directly or via phone) on breastfeeding in the Department to support the breastfeeding.

2. Regarding the business of nutrition products for infants

The business facilities of nutrition products for infants were trading products certified standards and obeyed regulations on trading and using of products for infants. Most localities did not detect violations in the implementation of regulations on business, advertising, and promulgation of milk and nutrition products for infants.

Some Departments of Health of provinces and cities, which had the funding, organized and coordinated with relevant units to establish interdisciplinary inspection and supervision of activities in business of nutrition products for infants. Basically, the regulations on labeling of nutrition products for infants, source, origin, production date of products made in earnest, no photos, and paintings of children under 12 months of age (Yen Bai, Dong Thap ...).

The products complied with regulations on nutritional product labels for infants with the words printed "CAUTION," then the text content: "Breastmilk is the best food for health and holistic development of young children. The anti-bacterial factors, particularly antibody is only in breastmilk, help children prevent of diarrhea, respiratory infections and some other infectious

diseases ..., how to prepare, the source origin, production date, term use, no photos, paintings of children under 12 months old ... " were Dutch Lady, Enfalac, Similac, Nan, Dumex, Milex, Lactogen.

Medical staff in the health facilities did not receive from the manufacturers and business facilities of nutrition products for infants: milk for infants under 12 months old, food for infants under 6 months of age, material benefits or other forms of expression with names or logos of milk for infants under 12 months old. They did not provide instructions, advice or prescription to maternal on the use of nutrition products for infants in the case was not necessary to use. They created an enabling environment to help and support breastfeeding through guidance and counseling for mothers initiate breastfeeding in 1 hour after birth, the benefits of breastmilk, how to breastfeed properly, how to maintain breastfeeding, exclusive breastfeeding in first 6 months. They periodically monitored the 10 conditions of breastfeeding in hospitals and pediatrics. Most dairy products for children less than 12 months of age were at the medicines counter of the hospitals and trading with doctor's prescription. The supplement food products traded in stalls introducing nutrition products at hospitals with prescriptions of doctors or nutrition engineers.

At the health facilities, only the infants that were pediatric pathology or preterm (no mother or mother discharged from the hospital) or abandoned children were fed milk/formula instead of breastmilk (Ho Chi Minh City Department of Health).

3. Regarding the use of nutrition products for infants

There was a range of forms of communication and advocating of breastfeeding between localities: in communes, there were talking or consultations at the small areas or at the household; at the health facilities, there were posters with pictures of breastfeeding mothers hanged; leaflets on 10 advices of appropriate child raising and guidance for breastfeeding immediately after birth; medical personnel consulted directly to mothers immediately after birth the way of breastfeeding; infants lying near mother postpartum, the methods for mothers gaining more milk.

There was implementation of prophylactic antibiotics before surgery, infants were created conditions to lie near their mothers and had initiated breastfeeding. Ho Chi Minh City also maintained milk banks (more than 2 liters per day), did the kangaroo method of feeding with main nutrient was breastmilk. Counseling group also consulted by phone when mothers faced difficulty in breastfeeding.

The proportion of mothers' breastfeeding within the first 24 hours in health facilities was uneven among localities. Some provinces' percentage was rather high such as: PhuTho Province reached 96%, Yen Bai 92%. Low rate was in some provinces such as Dong Nai at 70%, at Central Children's Hospital, this rate only reached 40%.

For mothers had no milk or were unable to breastfeed (maternal heart disease, tuberculosis, HIV), they were instructed to feed their children nutrition products to replace breastmilk properly.

According to local health facilities, they implemented relatively well the interdicts to the heads, physicians, and medical personnel in health facilities. There were no organization or permission of

trading milk for infants under 12 months old, food for infants under 6 months in the hospital (excluding hospital pharmacies); production and trading facilities were not permitted to display the name of the listing nutrition products for infants, feeding bottles and artificial nipples, dummies at the hospitals; the hospitals did not receive directly or indirectly milk for children under 12 months old, food for infants under 6 months old, the material benefits or other forms of expression of milk for infants under 12 months presented by production and business facilities of nutrition products for infants or their representatives.

B. The limitations, difficulties, obstacles and reasons in the implementation of Decree No. 21/2006/ND-CP

1. The limitations, difficulties and obstacles in the implementation of Decree No. 21/2006/ND-CP

Some provinces have only focused on communication and counseling on breastfeeding in the events such as weeks of breastfeeding, Nutrition Week and the growth (Hai Phong). This work has not been carried out regularly but only in batches. This was not of a concern of provincial heads, specifically, there was no written guidance in the coordination of communications as well as the responsibilities of each sector in the monitoring of the implementation of Decree No. 21/2006/ND-CP in the provinces (Dong Thap, Yen Bai). Advertisement on television only focused on products substituted for breastmilk that did not focus on knowledge dissemination of breastmilk, the benefits of immediate and long-term breastmilk to children.

Number of communication materials was limited; forms of communication materials were not varied, poor content, especially the requirements of the use of nutrition products for infants. Funding was not enough for information, education, communication and advertising about the benefits of breastmilk, particularly for those on television. Many localities did not have counseling rooms for antenatal care, before birth; they did not have equipment for mothers watching films or reading information and guidance about breastfeeding in a regional clinics and other locations in the facility.

The implementation of regulations on product labels of bottles and dummies was not in an earnest manner. The heads of production and business facilities of nutrition products for infants were not aware of the responsibility as well as the consequences of improper labeling.

Decree No. 21/2006/ND-CP prohibits on advertising milk for infants under 12 months old, food for infants under 6 months old, feeding bottles and artificial nipples and dummies in any form. However, the inspection results in the year 2009 - 2010 of Ministry of Health found that many health facilities, production and business facilities were in breach of the regulations on advertising, labeling of nutrition products for young children, 21% of nutrition products for infants and 53.3% of feeding bottles and dummies checked to incomplete labeling in accordance with the regulations. In fact, 26/124 product labels did not have indication or did have incomplete indication of "Breastmilk is the best food for the development of infants and young children". 23/124 product items missed or not fully inscribed the words "Only use this product as directed by your doctor ... feeding children with clean cups and spoons". Or all 8 products of the Mama Colostrum Company

examined did not have the label matched with the registered label. 39/60 products did not have or did have the uncompleted note "Using dummies is adverse to the breastfeeding. The use of feeding bottles for infants may cause the child quitting breastfeeding and risk of diarrhea".

Besides, the words "Breastmilk is the best food for health and holistic development of children" was too small and difficult to read. A number of nutrition products for infants violating regulations on the label: they did not print a certificate of published quality standards, food safety and hygiene (Cerelac Nestle cereals); The certification standards published quality, food safety and hygiene had expired: XO powdered milk from Korea with the number 5507/2006/YT-CNTC CBCL; Mama colostrum had 599/2007/YT-CNTC CBCL; Having kids pictures under 12 months old at IQ Good Milk for brain development, IQ Good Milk for good appetite for infants, Solar IQ powdered milk, Imperiod Kid XO powdered milk. There was none of the lowercase "Only use this product as directed by your doctor. The preparation is according to the instructions. Feeding children with hygiene cups and spoons" at Ellac powdered milk; Solar IQ powdered milk, Super Milk powdered milk, Imperiod Kid XO Powdered milk, I am a mother powdered milk, XO 1 and XO 2 powdered milk (Traphaco Pharmaceuticals Corporation-Address: 75 Yen Ninh, Ba Dinh District, Hanoi was the importer and distributor); Gain Similac infant formula, Grow powdered milk; Pedia Sure formula (3A Pharmaceutical Company - Address: 18 Luy Ban Bich, Tan Phu District, Ho Chi Minh City- was the importer and distributor); Australian Lady powdered milk (Viet Food Processing Company Limited Company - Address: 20 Luong The Vinh, Tan Binh District, Ho Chi Minh City was the importer and distributor).

There was no capital letters "WARNING" followed by the words (in lower case) the contents of note: "Breastmilk is the best food for health and holistic development of young children. The bacteria anti-infection factors, particularly antibodies in breastmilk only works to help children prevent of diarrhea, respiratory infections and some other infectious diseases" such as Solar IQ formula, XO 1 and XO 2 powdered milk (Traphaco Pharmaceuticals Corporation) BA Pedia Sure (3A Pharmaceutical Company) Australian Lady powdered milk (Viet Food Processing Company Limited Company).

The implementation of regulations on the label of feeding bottles and nipples of some products did not follow the regulations; they did not have the note "strictly comply with hygiene and sterilization guidelines. The use of feeding bottles can cause kids quitting breastfeeding and risk of diarrhea" Pack or label did not have note followed regulations, no additional labels in Vietnamese for imported products (Miki bottles). There were bottles of unknown origin.

Not only violating of labeling regulations but many companies also deliberately violated as advertising their milk having the equivalent ingredients with breastmilk, was as good as breastmilk. Some milk advertisement exaggerated that the milk/formula had the preferential nature which breastmilk did not have. For example, Meiji 1 and 2 Milk Products flyers, Physiolac milk for 0-5 month old baby flyers, content of Mama colostrum advertisement compared with similar components and better than breastmilk ... In order to mothers to know their products, many

companies not only advertised their products on television, but also had their printed advertising dairy products flyers at medical clinics, hospitals ...

Some mothers still used feeding bottles with a dummy for their children in spite of hospital officials' consultation and advice. There were feeding bottles with dummies for infants traded at some hospital canteens. In addition, misconceptions of mother about nutrition products, partly due to the influence of advertising, partly due to not receive careful advice from health workers and, mothers could easily to purchase nutrition products for infants in anywhere.

The percentage of children were exclusive breastfed until 6 months old was very low (Dong Thap was only at 2-3%, Phu Tho reached about 12%, Hai Phong at 13.4%, Thai Nguyen at 10% ...). The percentage of stunting malnutrition children suffering from diseases related to diarrhea, respiratory infections and other infectious diseases remained high.

| Indexes | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
|-------------------------------|------|------|------|------|------|------|------|------|------|------|
| Rate of stunting malnutrition | 20.5 | 19.4 | 18.5 | 18.5 | 17.4 | 22.4 | 28.4 | 28.1 | 26.6 | 24.6 |
| Rate of low weigh birth | 4.5 | 3.2 | 4.2 | 3.7 | 3.7 | 3.7 | 3.9 | 3.9 | 3.8 | 5.1 |

Data source: Hai Phong Department of Health

Traders were not equipped or lacked of certain knowledge of trading of nutrition products for infants.

The percentage of children less than 06 months old were exclusive breastfeed, did not use feeding bottles with artificial nipples or dummies was low but we did not have a survey carried out to provide correct and comprehensive statistics for the whole country.

Some mothers still fed their children milk/formula or used feeding bottles with artificial nipples when feeding their children at health facilities in spite of medical personnel's advice. In addition, at some health facilities, they still sold milk/formula for infants in canteen and some dairy companies or business facilities marketed and advertised their milk to mothers and consumers.

In 2009, Hung Nguyen district hospital checked its obstetrics as reflected by the patient that there remained trading milk for infants, then obstetrical staff and the hospital heads were fined due to shortcomings in management. Handling administrative violations in trading and using of nutrition products for infants did not happen at many localities in spite of the Decree No. 45/2006/ND-CP.

The State agencies conducted infrequently inspection and supervision on the business of nutrition products for infants.

2. The reasons of the limitations, difficulties and obstacles in the implementation of Decree No. 21/2006/ND-CP

Families, especially mothers had incomplete knowledge about the benefits of breastfeeding and maternal nutrition for infants. It was caused by habit and backward thinking that feeding children with supplemented foods to make the children to be full and to ensure nutrition, feeding children with milk/formula so they would be stout than with breastmilk or some people even thought that breastmilk was hot and made young children would be slowly gaining weight, the mountainous people still used poor quality and cheap milk. Some mothers had not enough breastmilk and fed children with milk/formula instead of breastmilk, some mothers having cesarean and they were afraid of that their breastmilk contained antibiotics so that they should not breastfeeding. Many mothers lacked confidence about your own health or thought of breastfeeding would lose "body" and they did not breastfeed but milk/formula-fed. Besides, because mothers' work nature had only 04 months for maternity leave so when the new baby was 3 months old, the mothers had to feed baby milk/formula and restricted breastmilk. On the other hand, due to difficult economic conditions of many families so that mothers had to go to work, earned money and did not have time to breastfeed. Therefore, exclusive breastfeeding until young children would be 6 months of age was very difficult to implement.

Propagation and dissemination of the benefits of breastfeeding had not been extensive. Communications levels and skills for the implementation of Decree No. 21/2006/ND-CP did not meet the requirements. There were not enough medical staff in obstetrics and pediatrics, some medical staff working in reproductive health care with limited consultant qualifications and responsibility; they did not timely remind as finding mothers feeding children with milk/formula; some units did not seriously implement breastfeeding guide.

Funding for the implementation of Decree No. 21/2006/ND-CP was very limited, could not meet real needs. State agencies had not well managed over the advertisement on mass media. Sanction on advertising milk for infants under 12 months of age was not specified. Information dissemination, education, and advertising on the benefits of breastfeeding lacked of funds while milk firms had huge investment for advertisement on the benefits of milk/formula with different forms. The regular and continuous advertising of milk firms made mothers confused in selection between breastmilk and milk/formula to make their children smart and strong.

Legal awareness and sense of obeying the laws of a number of organizations, agencies and individuals, the production and the business facilities of nutrition products for infants was limited and not high.

There was no coordination in the implementation of Decree No. 21/2006/ND-CP between the sectors concerned.

There were no specific provisions for those who were entitled to guide the use of breastmilk substitutes, or nutrition products for young children. Only your nutritional physician may guide and counsel the use of nutrition products for infants.

Part Two

Supposed amendment, complement or issue new decree to replace Decree No. 21/2006/ND-CP

I. RECOMMENDATIONS

- 1. Strengthen the leadership and direction of all government levels and inter-sectoral coordination for supervision and inspection regulations relating to advertising and business of nutrition products for infants.
- 2. Sustain funding to localities in organizing and promulgation on benefits of breastfeeding and Decree No. 21/2006/ND-CP.
- 3. Enhance promulgation and guidance on breastfeeding, especially in the remote areas and ethnic minorities.
- 4. Restrict the advertising of milk companies in the mass media.
- 5. Provide the maternity leave regime for officials and staff in line with "Exclusive breastfeeding in first six months" regulations.
- 6. Complement sanctions against administrative violations in trading and using of nutrition products for infants, particularly provide the specific provisions in the advertisement at health facilities and responsibilities of the health facilities' heads.
- 7. There should have remedies on the mass media on milk advertising, especially the note "Breastmilk is the best food for health and holistic development of children" talked too fast and could not look in time on television.

II. PROPOSAL, AMENDMENT AND COMMPLEMENT TO THE FOLLOWING CONTENTS:

- 1. Scope and application subjects need to be specified and defined more clearly.
- 2. Additional funding need to be granted to pay for information promulgation.
- 3. The import and trading of nutrition products for infants from foreign countries need to be regulated.
- 4. Amend from Article 10 to Article 16 of Decree No. 21/2006/ND-CP.
- 5. Complement to Article 8 with the content: "The exact name and address of the manufacturing and distribution facilities or imported raw materials and the name of production or packaging facilities." This regulation prevents the business facilities in providing domestic nutrition products for infants, but the advertisement does not specify the origin so that the consumers misunderstand that the products imported and purchase with high price.

6. Article 10 of Decree No. 21/2006/ND-CP regulated "The head of the production, business facilities or their legal representative must not:

Use the form of funding scholarships, research, training, conferences, seminars, courses, concerts, consulting services by phone or any other forms to directly or indirectly introduce the product to promote the business or use the milk for infants under 12 months old, food for infants under 6 months old". Currently, in order to support any funding and support for promotional activities of breastfeeding, scientific research (since this funding is limited), so the decree may be considered flexibly to take advantage of this funding. The content on scholarships, research, and training is recommended to redesign as follows: "Use the form of funding conferences, seminars, courses, concerts, consulting services by phone or any other forms to directly or indirectly introduce the product to promote the business or use of the milk for infants under 12 months old, food for infants under 6 months old".

7. Complement provisions of content of advertising nutrition products for infants: Advertising nutrition products for infants on radio and television stations needs to read slowly, clearly and easy to understand, ensure objectivity and science.

III. PROPOSAL OF NEW DECREE REPLACED THE DECREE No. 21/2006/ND-CP WITH THE CONTENTS AND REASONS:

Currently a number of foundations based to issue Decree No. 21/2006/ND-CP as the Ordinance on Goods Quality and Ordinance on Hygiene and Food Safety were expired and replaced with the Law on product goods quality and Food Safety Law. Some provisions of Decree were no longer fit the current situation so the nutrition products company or the manufacturer can thread their ways through advertisement law to encourage mothers to use nutrition products for infants without encouraging the breastfeeding; management agencies face difficulty in managing the inspection and handling violations; children were stunted and the rate of children with diseases relating digestion and nutrition was still quite high.

Many contents were no longer fit with the actual situation (Chapter 3 and 4 of Decree No. 21/2006/ND-CP) and the progress of the Internet has made the business enterprises of nutrition products for infants take the advantages of techniques, technologies to promote their products.

With the highest goal is to ensure the holistic development of infants and young children, a new Decree need to be issued to replace Decree No. 21/2006/ND-CP to limit more and more violations of the company, manufacturer of nutrition products for infants, to raise awareness of people, especially the mothers, and to emphasize the role of medical personnel, medical facilities in promoting breastfeeding, to provide prohibition as a basis for the introduction of sanctions.

IV. OTHER PROPOSALS

1. To the Government:

- a) Amend the provisions on maternity leave regime for women as officials and staff from 4 months to 6 months so that mothers have more time for child care and facilitation of exclusive breastfeeding for first 6 months.
- b) Amend Decree No. 45/2005/ND-CP dated 06/4/2005 of the Government on handling administrative violations in the health sector, including provisions on violations of producing, trading and using of nutrition products for infants.
- c) Restrict the advertising of milk, food for infants on television.

2. To the Ministry of Health

- a) Food Safety Department needs regularly review the publishing of quality standards, food safety and hygiene of nutrition products for infants to require traders to extend certification after 03 years from the grant date of registration certificate or renewal; timely notice to the Department of Health in provinces and cities updating nutrition products for infants expired but exist in localities.
- b) To agencies compiling information, education and communication on infant feeding (Institute of Nutrition, Communication Office-Central Health Education, Provinces ...)

Complement content mentioning the adverse effects of feeding bottles, dummies sucking and eating complementary foods before 6 months of age in the process of building material information, education and communication about infant feeding.

3. To health facilities

Promote advocacy, dissemination and education on knowledge, skills of breastfeeding and the law provisions to encourage breastfeeding

4. To manufacturing and business facilities of nutrition products for infants

Implement fully and strictly with current regulations in the process of production and business of nutrition products for infants.

Above is the 5-year Review report implementation of Decree No. 21/2006/ND-CP dated 27/02/2006 of trading and using of nutrition products for infants. /.

Recipients:

- -As above;
- Archives: PC.

Annex 6. Inspection Reports from the Department of Health Inspection of MOH (translated into English)

MINISTRY OF HEALTH INSPECTOR

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

Number: / BC-TTrB Hanoi, March 2011

REPORT ON

Inspection results of compliance of Decree No. 21/2006/ND-CP of the Government on Trade and Use of Nutritional Products for Infants in Hanoi, Quang Ninh, Khanh Hoa, and Da Nang

To strengthen the complying of the Decree21/2006/Ne-CP on 27/02/2006 of the Government on trading and using of nutritional products for infants, with the assistance of international organizations in 01/2011, inspector of the Ministry of Health in association with the Departments / Agencies concerned has implemented the inspection and supervision of the complying of the provisions in the Decree 21/2006/ND-CP in Hanoi, Quang Ninh, Khanh Hoa and Da Nang. Results of inspection and supervision are summarized as follows:

I. Inspection and supervision team:

Inspection and supervision team are representatives of the units:

- 1. Ministry of Health inspector;
- 2. Department of Maternal and Child Health;
- 3. Legal Department;
- 4. Department of Food Safety and Hygiene inspector;
- 5. Media and Communications Office, Department of Food Safety and Hygiene;
- 6. Health Department inspector of the inspected provinces and cities.

II. The subjects, contents, methods of inspection and supervision

1. The inspected and supervised localities

The team conducted the inspection and supervision in four provinces, including Hanoi, Quang Ninh, Khanh Hoa, and Da Nang. Total number of inspected units is **32**, in which:

| 1.1. Health facilities: | 19, including: |
|---------------------------------|----------------|
| - Central hospital: | 01 |
| - Provincial and city hospital: | 04 |
| - District hospital: | 07 |
| - Health Care Center: | 03 |
| - Maternity home: | 01 |

- Ward health station: 02- Private hospital: 01

1.2. Trading facilities: 13, including:

- Dairy trading company: 03

- Supermarket: 02

- Dairy Stores: 08

2. Inspection and supervision content

2.1. For health facilities, inspection and supervision content focused:

- Training for medical personnel to the contents of breastfeeding, benefits of breastfeeding, the law provisions on trading and using the nutritional products for infants.
- The organization of propagation and education for mothers on the benefits of breastfeeding; the provision of instructions and consultation on breastfeeding, the use of nutritional products for infants.
- The trading and advertising of nutritional products for infants in the hospital.
- During the inspection and supervision at the health facilities, the team based on the successful breastfeeding conditions issued by Joint Circular No. 10/2006 between the Ministry of Health and other ministries concerned; the complying of interdicts to the heads and physicians, medical personnel in health facilities as prescribed in the Decree 21/2006/ND-CP.

2.2. For trading facilities of nutritional products for infants:

Inspection and supervision of the complying of regulations on food safety and hygiene in the process of importing, trading, advertising of nutritional products for infants with the following contents:

- The security of conditions in the food trading.
- The complying of the regulations on promulgation of standards and labeling of nutritional products for infants.
- The complying of regulations on state inspection of imported food.
- The complying of regulations on advertisements for nutritional products for infants.
- -The complying of the regulations on information, education and communication related to breastfeeding and use of nutritional products for infants
- Other relevant contents prescribed by law.

3. Working process and methods of the inspection and supervision team

- At each locality, the inspection and supervision team worked with the Health Department to gain information from their representatives about their management on trading and using of nutritional products for infants; coordinated with the Health Department to conduct inspection and

supervision in some hospitals at all levels and a number of trading facilities of nutritional products for infants.

- In the process of inspection and supervision at the facilities, the team met the representatives for the report on compliance with the law provisions on trading and using of nutritional products for infants; and checked related documents, examined trading as well as preserving conditions, labeling, advertising for products, communicating with clients; checked in the departments, contacted with medical personnel, new-born mothers and mothers were raising children in the hospitals; made records of inspection and proposed handling measures prescribed by law.

III. Results of inspection and supervision:

1. Local government management of Decree 21/2006/ND-CP

According to the reports and the inspection and supervision results, all of 04 localities have implemented the inspection and supervision of the complying of provisions on trading and using of nutritional products for infants on Decree 21/2006/ND-CP, but still faced some difficulties and limitations:

- The inspection and supervision on Decree 21/2006/ND-CP is not a high concern of local governments.
- Every year, they have implemented inspection and supervision, but not in a position to make a separate topic that was often incorporated into the inspection and supervision of food safety and hygiene.
- The trading and using of nutritional products for infants of people was in a wide range of areas including hospitals, clinics, shops in the market and even in homes while there was a few of the inspection forces with huge volume of works.
- There was a regular rotation between inspectors while the new officials were in state of confusion in the inspection and supervision as well as in handling of violations.
- No control over advertisement on nutritional products for infants due to more sophisticated and increasing advertising.

2. Results of inspection and supervision in health facilities:

In general, the inspected health facilities have implemented 10 conditions of breastfeeding with a concern of provisions in Decree 21/2006/ND-CP:

- + Well complying the interdicts to the heads, physicians, and medical personnel.
- + No detection of medical personnel who sold milk directly in hospitals.
- + Medical personnel working directly in obstetrics and pediatrics were enthusiastic and experienced in propagating and promoting mothers in breastfeeding.
- + Breastfeeding subject was discussed regularly in the training and professional development every week.
- + Well promoting and encouraging mothers in initiating breastfeeding within an hour of birth (except for cases of special consultation)

+ Most health facilities made good instructions for mothers in breastfeeding and maintaining their milk even when they were away from their infants, keeping infants close to their mothers 24 hours a day (except for special cases for separate treatment), encouraging breastfeeding on infants' demand.)

Health facilities' limitations:

- + The deployment of 10 breastfeeding conditions and the complying of Decree 21/2006/ND-CP at some health facilities was not in all levels but almost only focused on the units implementing projects related to breastfeeding or the friendly medical units.
- + There were no widespread and regular training for physicians and medical personnel on the breastfeeding skills and practices, the training was only organized at the Department of Obstetrics, Pediatrics and integrated into other programs that may have their own specialized training for the entire hospital.
- + The consulting on benefits of breastfeeding to pregnant women was mainly held at clinics; most health facilities did not have their own private consultation rooms, no equipment for watching video on breastfeeding propagation.
- + Almost inspected health facilities (except the health facilities of Khanh Hoa and Hanoi Obstetrics Hospital) did not make breastfeeding regulations board, pictures or drawings, etc. hanging in the departments to propagate and encourage breastfeeding.
- + Knowledge and practices of some medical personnel on breastfeeding skills was still confused and incorrect. Interviewed medical personnel have not properly and fully understood the contents of the Decree 21/2006/ND-CP, especially those working in district hospitals, commune health centers and private clinics. Midwives in children's nursing room at Hoan My Hospital used feeding bottles (not spoon) to feed the infants.
- + Dairy traders/suppliers were permitted to hang company logo with its name in the lobby of some health facilities, donate the items with printed their dairy company logo and name (antenatal clinic, benches, plastic chair, pen racks, medical books, propaganda posters, wall calendar, clock, banner, nutrition pyramid, ...). However, a few artifacts were provided by the National Institute of Nutrition including: nutritional counseling tables, infant weight with Vinamilk icon. At the health station in Hai Chau 1 Ward, Hai Chau District, Danang, there were not only objects with milk logos but also brochures and Dumex's workshop invitations in which stated that gifts would be offered to attendants.
- + Milk for infants under 12 months of age, food for infants under 6 months, and feeding bottles with artificial nipples were sold at kiosks in the hospitals (Bai Chay Hospital, Duc Giang District Hospital, Son Tay Town Hospital, and Da Nang Hospital). At Hoan My Da Nang private hospital, the milk company's employees were there to exposure milk to pregnant women, offer gift, sell milk for infants under 12 months and provide telephone number for them to purchase milk).
- + Breastfeeding knowledge of many people were limited: there was a prevalent rate of feeding infants other milk/formula with the viewpoint of there was not enough breast milk from mother, especially in cases of caesarean. Many families did not fully breastfeeding in the first 6

months, did not really believe in the benefits of breast milk, fed children solid/semi-solid foods (milk powder, water) other than breast milk and used feeding bottles, artificial nipples.

3. Results of inspection and supervision in the trading facilities of nutritional products for infants:

Inspection and supervision in the trading facilities of nutritional products for infants noted:

- **In terms of the certificate of FSH eligibility:** Most of the inspected facilities were granted certificates of FSH eligibility, some facilities were making application procedures.

In terms of promulgation on product standards:

- + Most purchased dairy products were promulgated on product standards at the Department of FSH, with full and correct content of labeling regards to the Decree 21 provisions, there were no overdue products and all of them were specified the published certification number of quality standards.
- + A number of stores were purchasing milk imported from retailers without certification number of quality standards (Meiji Milk products originated from Japan, S26 milk originated from Australia).
- + The inspected units importing nutritional products for infants complied with the regulations on state inspection of imported food.

- In terms of the advertisement of products:

- + Some companies advertised dairy products for infants under 12 months old, encouraged the milk purchase by offering the bonus items (vehicles, blankets, pillows, milk, bowl, etc.) when customer purchased a certain number of milk cans.
- + Many dairy company logos and names were hanged, stuck in the stores selling nutritional products for infants; this was a form of threading their ways through law to advertise products (Dumex, Abbott, Mead Johnson, Dutch Lady, Vinamilk, etc.)
- **In terms of product labeling:** The labels of some products were in contravention of regulations:
 - + To have no complying with the dossier of published product standards set by the Department of FSH (Colos Vita Milk).
 - + There was no inclusion of the words: "Attention: Breast milk is the best food ..." or they were less than 2mm, or even there were not enough two of the noted sentences (HIPP herbal tea for children under 6 months old; SimilacIsomal Milk, XO milk, and Dumex Gold).

- + There were pictures of feeding bottles with artificial nipples and uses of comparative language to imply that milk/formula was as good as breast milk (milk powder for infants from 0-12 months old Wakodo Haihai, Barley Tea for children from 1 month old, Organic for children from 06 months old).
- + A number of feeding bottles with artificial nipples were not labeled in Vietnamese or the labels were not complied with the regulations (no Notes required or they were too small).
- + There was a knowledge limitation of the sellers in terms of the regulations on trading and using nutritional products for infants, it also happened with the people regarding to breastfeeding.

IV. Recommendations

1. Recommendations for Ministry of Health:

- Coordinate with other ministries concerned to further manage the trading and using of nutritional products for infants.
- Coordinate with ministries and departments to promote propagating and educating on breastfeeding, to enhance the management of information, advertising on nutritional products for infants, especially on mass media.
- Direct health facilities to comply strictly with the provisions in Decree 21/2006/ND-CP of the Government on trading and using of nutritional products for infants, enhance self- inspection at the units on the complying of Decree 21/2006/ND-CP.
- Plan to counsel the Government in issuing the relevant policy regarding to maternity leave for breastfeeding provisions.
- Complement and modify the Decree 45/2005/ND-CP on handling administrative violations in the field of health for many violations provided in Decree 21/2006/ND-CP, but there were no penalties provisions or fines were too low.
- Complement and modify the Decree 21/2006/ND-CP to suit the current situation of trading and using of nutritional products for infants, enhance a smoother management in localities.
- Dossier for propagating and educating on breastfeeding provided by the Ministry of Health (Breastfeeding Program) has been corrupted; request Breastfeeding Program allocate these dossiers for breastfeeding propagation.

2. Recommendations for Department of Health:

- Frequent direct to the management of the trading and using of nutritional products for infants.
- Increase funds for training and propagation aim to improve the complying of Decree 21/2006/ND-CP.
- Intensify trainings, professional developments on 21/ND-CP Decree for officials involved while prioritizing staff in charge of inspection and supervision.

- Direct health units under its management to comply strictly with the provisions in the Decree 21/2006/ND-CP of the Government on trading and using of nutritional products for infants, enhance self-examination at the units on complying of the Decree 21/2006/ND-CP.
- Intensify inspection and supervision of trading and using of nutritional products for infants and strictly handle of violations.

Receivers:

- TT. Trinh Quan Huan;
- TT. Nguyen Viet Tien;
- Department of Maternal and Child Health;
- Department of Food Safety & Hygiene;
- The Legal Department;
- UNICEF;
- Hanoi Health Department;
- Quang Ninh Health Department;
- Khanh Hoa Health Department;
- Da Nang Health Department;
- Save TTrB.

Chief inspector of Ministry of Health

Tran Quang Trung

Inspection team leaders

Bui Duc Phong

MINISTRY OF HEALTH INSPECTOR

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

TTrB 04/4/2011

Number: / BC-TTrB Hanoi, May 2011

REPORT ON

Inspection results of compliance of Decree No. 21/2006/ND-CP of the Government on Trade and Use of Nutritional Products for Infants

in Dien Bien, Ninh Thuan, An Giang, and Dong Thap

To strengthen the complying of the Decree21/2006/ND-CP on 27/02/2006 of the Government on trading and using of nutritional products for infants, with the assistance of international organizations in 04/2011, inspector of the Ministry of Health in association with the Departments / Agencies concerned has implemented the inspection and supervision of the complying of the provisions in the Decree 21/2006/ND-CP in Dien Bien, Ninh Thuan, An Giang, and Dong Thap. Results of inspection and supervision are summarized as follows:

I. Inspection and supervision team:

Inspection and supervision team are representatives of the units:

- 1. Ministry of Health inspector;
- 2. Department of Maternal and Child Health;
- 3. Legal Department; Ministry of Health
- 4. Institute of Hygiene and Public Health, Ho Chi Minh, the Ministry of Health;
- 5. Department of Food Safety and Hygiene inspector;
- 6. Health Department inspector of the inspected provinces and cities.

II. The subjects, contents, methods of inspection and supervision

1. The inspected and supervised localities

The team conducted the inspection and supervision in four provinces, including Dien Bien, Ninh Thuan, An Giang, and Dong Thap. Total number of inspected units is **43**, in which:

1.1. Health facilities: 23, including:

- Provincial hospital: 04
- District hospital: 08
- Health Care Center of the provinces: 04
- Ward health station: 07

1.2. Trading facilities: 20, including:

- Dairy trading company: 03

- Supermarket: 05

- Dairy Stores: 12

2. Inspection and supervision content

2.1. For health facilities, inspection and supervision content focused on:

- Training for medical personnel to the contents of breastfeeding, benefits of breastfeeding, the law provisions on trading and using the nutritional products for infants.
- The organization of propagation and education for mothers on the benefits of breastfeeding; the provision of instructions and consultation on breastfeeding, the use of nutritional products for infants.
- The trading and advertising of nutritional products for infants in the hospital.
- During the inspection and supervision at the health facilities, the team based on the successful breastfeeding conditions issued by Joint Circular No. 10/2006 between the Ministry of Health and other ministries concerned; the complying of interdicts to the heads and physicians, medical personnel in health facilities as prescribed in the Decree 21/2006/ND-CP.

2.2. For trading facilities of nutritional products for infants:

Inspection and supervision of the compliance of regulations on food safety and hygiene in the process of importing, trading, advertising of nutritional products for infants with the following contents:

- The security of conditions in the food trading.
- The compliance of the regulations on promulgation of standards and labeling of nutritional products for infants.
- The compliance of regulations on state inspection of imported food.
- The compliance of regulations on advertisements for nutritional products for infants.
- -The compliance of the regulations on information, education and communication related to breastfeeding and use of nutritional products for infants.
- Other relevant contents prescribed by law.

3. Working process and methods of the inspection and supervision team

- At each locality, the inspection and supervision team worked with the Health Department to gain information from their representatives about their management on trading and using of nutritional products for infants; coordinated with the Health Department to conduct inspection and

supervision in some hospitals at all levels and a number of trading facilities of nutritional products for infants.

- In the process of inspection and supervision at the facilities, the team met the representatives for the report of the complying of the law provisions on trading and using of nutritional products for infants; and checked related documents, examined trading as well as preserving conditions, labeling, advertising for products, communicating with clients; checked in the departments, contacted with medical personnel, new-born mothers and mothers were raising children in the hospitals; made records of inspection and proposed handling measures prescribed by law.

III. Results of inspection and supervision

1. The management of local government on the decree 21/2006/ND-CP on the trading and using nutritional products for infants.

Health Department of the provinces allocated to the Reproductive Health Centers to implement programs to combat child malnutrition and reproductive health care including breast feeding programs; Reproductive Health Center is a permanent organisation to plan and implement 21/ND-CP

According to reports, annually, reproductive health care centers have fully implemented the activities of breast feeding (directing lower level, training of health personnel, communications, education on knowledge and skills about breast feeding...). However, the activities implemented for breast feeding programs only were integrated into the overall programs to combat child malnutrition. Since the support of the breast feeding project, the activities of breast feeding program were strengthened, they organized trainings and seminars on breast feeding for health personnel in reproductive health care team in the maternity of medical Provincial Children's Hospital, the regional hospitals, district hospitals, and for 100% health personnel of the Health Station communes. Promotional activities, communication, education on knowledge, skills and interests of the breast feeding were strengthened.

According to the reports and the inspection and supervision results, all of 04 localities have implemented the inspection and supervision of the complying of provisions on trading and using of nutritional products for infants on Decree 21/2006/ND-CP, but still faced some difficulties and limitations:

- The inspection and supervision on Decree 21/2006/ND-CP on trading and using of nutritional products for infants was not of high concerns of local governments.
- They have implemented inspection and supervision, but not in a position to make a separate topic that were often incorporated into the inspection and supervision of food safety and hygiene.
- The trading and using of nutritional products for infants of people was in a wide range of areas including hospitals, clinics, shops in the market and even in homes while there was a few of the inspection forces with huge volume of works.

- There was a regular rotation between inspectors while the new officials were in state of confusion in the inspection and supervision as well as in handling of violations.
- No control over advertisement on nutritional products for infants due to more sophisticated and increasing advertising.

2. Results of inspection and supervision in health facilities

In general, the inspected health facilities has implemented 10 conditions of breastfeeding with a concern of provisions in Decree 21/2006/ND-CP:

- + Well complying the interdicts to the heads, physicians, and medical personnel.
- + No detection of medical personnel who sold milk directly in hospitals.
- + Medical personnel working directly in obstetrics and pediatrics were enthusiastic and experienced in propagating and promoting mothers in breastfeeding.
- + Breastfeeding subject was discussed regularly in the training and professional development every week.
- + Well promoting and encouraging mothers in initiating breastfeeding within an hour of birth (except for cases of special consultation)
- + Most health facilities made good instructions for mothers in breastfeeding and maintaining their milk even when they were away from their infants, keeping infants close to their mothers 24 hours a day (except for special cases for separate treatment), encouraging breastfeeding on infants' demand.
- Health facilities' limitations:
- + The deployment of 10 breastfeeding conditions and the complying of Decree 21/2006/ND-CP at some health facilities was not in all levels but almost only focused on the units implementing projects related to breastfeeding or the friendly medical units.
- + There were no widespread and regular training for physicians and medical personnel on the breastfeeding skills and practices, the training was only organised at the Department of Obstetrics, Pediatrics and integrated into other programs that may have their own specialized training for the entire hospital.
- + The consulting on benefits of breastfeeding to pregnant women was mainly held at clinics; most health facilities did not have their own private consultation rooms, no equipment for watching video on breastfeeding propagation.
- + Almost inspected health facilities did not make breastfeeding regulations board, pictures or drawings,... hanging in the departments to propagate and encourage breastfeeding.
- + Knowledge and practices of some medical personnel on breastfeeding skills was still confused and incorrect. Interviewed medical personnel have not properly and fully understood the contents of the Decree 21/2006/ND-CP, especially those working in district hospitals, commune health centers and private clinics.
- + Some mothers did not know how to breastfeed and were not instructed how to breastfeed and milk properly by medical personnel.
- + There were infants fed formula milk and water instead of breast milk.

- + At the canteens of some hospitals, they sold feeding bottle labelled with contents not in compliance with the regulations.
- + Inspection and supervision team detected 01 case over the counter sales of the drug's Hospital Center in An Giang province has been selling Humana attached gloves, hats kids to purchase promotional products (promotional products located in the product box).
- + Knowledge of people was limited in breast feeding: feeding infant with milk powder or water after breastfeeding and using feeding bottles or dummies.

3. Results of inspection and supervision in the trading facilities of nutritional products for infants:

Inspection and supervision in the trading facilities of nutritional products for infants noted:

In terms of the certificate of FSH eligibility: All of the inspected facilities were granted certificates of FSH eligibility.

In terms of origin and promulgation on product standards:

- + Nutritional products for infants were certified about the origination with receipts and the product standards
- + There were no portable milk sold or milk without published product standards.

In terms of the advertisement of products:

- + As reported by the business facilities, the milk companies had a batch of milk advertising and promotion (encouraged the milk purchase by offering the bonus items (vehicles, blankets, pillows, milk, bowl, ...) when customer purchased a certain number of milk cans).
- + In Ninh Thuan, there was a material on nutritional products for infants with the content not complying with the regulations.
- + In VINAFOOD MART Dong Thap supermarket, they gave customer one 40g condensed milk for present when they bought one 400g Dielac Alpha Step 1, 2 (Promotional products are attached on the box of milk products)
- + Many dairy company logos and names were hanged, stuck in the stores selling nutritional products for infants, this was a form of threading their ways through law to advertise products (Dumex, Abbott, Mead Johnson, Dutch Lady, Vinamilk, ...)

In terms of product labeling:

- + All of the nutritional products for infants were being sold with contents labelled in Vietnamese, some feeding bottles with artificial nipples were not labelled in Vietnamese.
- + The inspection checked randomly 85 nutritional products for infants and 24 feeding bottles with artificial nipples, and they found 26 (24%) labels of products were in contravention of regulations.

Some common violations:

- + They had no or not enough the full text content required on the product label.
- + There were pictures, paintings of children under the age of 12 months; images of bottles with artificial nipples on the product label
- + Used of language, images showing the product quality equal to or better than breast milk use the phrase Like mother's milk.
- + There was no specified age appropriate for children to use the product.
- + A number of feeding bottles with artificial nipples were not labeled in Vietnamese or the labels were not complied with the regulations (no Notes required or they were too small).
- + Limited knowledge regarding to the provisions of the trading and the using of nutritional products for infants of sale people of, as well as breastfeeding of mothers.

IV. Recommendations

1. Recommendations for Ministry of Health

- Coordinate with ministries and departments to promote propagating and educating on breastfeeding, to enhance the management of information, advertising on nutritional products for infants, especially on mass media.
- Coordinate with other ministries concerned to further manage the trading and using of nutritional products for infants.
- Direct health facilities to comply strictly with the provisions in Decree 21/2006/ND-CP of the Government on trading and using of nutritional products for infants, enhance self- inspection at the units on the complying of Decree 21/2006/ND-CP.
- Plan to counsel the Government in issuing the relevant policy regarding to maternity leave for breastfeeding provisions.
- Complement and modify the Decree 45/2005/ND-CP on handling administrative violations in the field of health for many violations provided in Decree 21/2006/ND-CP, but there were no penalties provisions or fines were too low.
- Complement and modify the Decree 21/2006/ND-CP to suit the current situation of trading and using of nutritional products for infants, enhance a smoother management in localities.
- Dossier for propagating and educating on breast feeding provided by the Ministry of Health (Breastfeeding Program) have been corrupted; request Breastfeeding Program allocate these dossiers for breastfeeding propagation.

2. Recommendations for Department of Health

- Frequent direct to the management of the trading and using of nutritional products for infants.
- Increase funds for training and propagation aim to improve the compliance of Decree 21/2006/ND-CP.
- Intensify trainings, professional developments on Decree 21/2006/ND-CP for officials involved while prioritising staff in charge of inspection and supervision.
- Direct health units under its management to comply strictly with the provisions in the Decree 21/2006/ND-CP of the Government on trading and using of nutritional products for infants, enhance self-examination at the units on complying of the Decree 21/2006/ND-CP.

- Intensify inspection and supervision of trading and using of nutritional products for infants and strictly handle of violations.

Receivers:

- TT. Trinh Quan Huan;
- TT. Nguyen Viet Tien;
- Department of Maternal and Child Health;
- Department of Food Safety & Hygiene;
- The Legal Department;
- UNICEF;
- Ho Chi Minh Health Department;
- Dien Bien Health Department;
- Ninh Thuan Health Department;
- An Giang Health Department;
- Dong Thap Health Department
- Save TTrB.

Chief inspector of Ministry of Health

Tran Quang Trung

Inspection team leaders

Bui Duc Phong

Annex 7: Number of health facilities assessed and mothers interviewed for monitoring study in the provinces

| Indicators | Tien Giang | Quang Nam | Quang Ngai | Vinh Long | Quang Tri | Quang Binh | Hanoi | Hai Phong | Thanh Hoa | Thai Nguyen | TOTAL |
|---|---------------|--------------|---------------|--------------|--------------|---------------|-------|--------------|--------------|----------------|-------|
| Provincial Hospital | 1 | 3 | 1 | 1 | 2 | 1 | 5 | 5 | 3 | 3 | |
| Retailer (4 retailers around a provincial hospital) | 4 | 12 | 4 | 4 | 8 | 4 | 20 | 20 | 12 | 12 | |
| Mother interviewed (5 mothers/provincial hospital) | 5 | 15 | 5 | 5 | 10 | 5 | 25 | 25 | 15 | 15 | |
| Provincial RHC | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| Retailer (2 retailers around the provincial RHC) | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| Mother interviewed (2 mothers/provincial RHC) | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| District Hospital | 4 | 3 | 4 | 2 | 4 | 3 | 4 | 2 | 3 | 4 | |
| Retailer (2 retailers around a district hospital) | 8 | 6 | 8 | 4 | 8 | 6 | 8 | 4 | 6 | 8 | |
| Mother interviewed (2 mothers/ district hospital) | 8 | 6 | 8 | 4 | 8 | 6 | 8 | 4 | 6 | 8 | |
| District RHC | 0 | 0 | 5 | 0 | 5 | 0 | 3 | 4 | 0 | 0 | |
| Maternity House | | | | | | | 1 | | | 1 | |
| Commune Health Station | 10 | 15 | 12 | 10 | 10 | 12 | 15 | 10 | 15 | | |

| Retailer (1 retailer around a district RHC/Maternity House/Commune Health Station) | 10 | 15 | 17 | 10 | 15 | 12 | 19 | 14 | 15 | 1 | |
|---|----|----|----|----|----|----|----|----|----|---|--|
| Mother interviewed (1 mothers/district RHC or Maternity House or Commune Health Station) | 10 | 15 | 17 | 10 | 15 | 12 | 19 | 14 | 15 | 1 | |
| Total number of medical establishments monitored | | | | | | | | | | | |
| Total number of retailers monitored | | | | | | | | | | | |
| Total number of mothers interviewed | | | | | | | | | | | |

Notes:

Each province estimates <u>number of health establishments</u> monitored (based on A&T's suggestion).

Number of retailers monitored and mother interviewed was subject to A&T's norms: 4 retailers around a provincial hospital; 5 mothers/provincial hospital; 2 retailers around the provincial RHC/district hospital; 2 mothers/provincial RHC or district hospital; 1 retailer around a district RHC/Maternity House/Commune Health Station; and 1 mother/district RHC or Maternity House or Commune Health Station