



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

17 August 2009

**DEPARTMENT CIRCULAR**

No. 2009 - 0228

**SUBJECT: Guidelines for the Monitoring of Milk Code Activities**

**I. RATIONALE**

In the Philippines, the 2003 National Demographic and Health Survey has shown that only 16% of Filipino infants are breastfed exclusively at the age of 4-5 months, leading to under nutrition, which is an underlying cause in 64% of the deaths of children. Malnourished children are less healthy, less intelligent and more vulnerable to infections and illness. Because of this, the Philippines potentially has a tragically and chronically large pool of unhealthy citizens.

The following 2003 data show the gravity of the problems regarding infant and young child feeding in the Philippines:

- 46% of neonates are NOT initiated to breastfeeding within one hour after birth
- 84% of infants are NOT exclusively breastfed at 4-5 months of age
- 50% STOP exclusive breastfeeding at only 3 weeks

One strong explanation for the current health and nutrition situation is that manufacturers and distributors of infant formula and other breastmilk substitutes have taken, over the past twenty (20) years, undue advantage of the loopholes and gaps in the Milk Code to massively penetrate and undermine the breastfeeding in the Philippines. They have conveyed misinformation that undermines breastfeeding while glamorizing infant formula, through false health claims for example, that certain formulations make children geniuses and child prodigies and through the outright peddling of samples in government hospitals and health facilities. Public officials are also manipulated to engage in activities that tend to undermine the importance of breastmilk and breastfeeding through sponsorships, donations and gifts, leading to irreconcilable entanglement and conflicts of interest.

A.O. No. 2006-0012 or The Revised Implementing Rules and Regulations (RIRR) of the Milk Code was promulgated to achieve the relevant constitutional mandates, implement international commitments and provide solutions to the problems identified in scientific and medical studies. The RIRR is not meant to compel women to breastfeed or prohibit or restrict commercial sales of milk substitutes. The RIRR of the Milk Code is meant to ensure that women are provided with accurate and unbiased information to enable them to make an informed choice. This can only be done through regulation of advertisement and promotion of breastmilk substitutes. Particular focus is needed to remove from the medical and public health environment the undue influence brought about by run-away advertisements, sales promotions, donations, sponsorships and other Milk Code activities.

The RIRR seeks to save Filipino children's lives, now and in the future, by regulating manufacturers and distributors of infant formula and other breastmilk substitutes who, over the past twenty (20) years, have taken undue advantage of the loopholes and gaps in the Milk Code and its previous implementing rules to massively undermine breastfeeding in the Philippines

## **II. OBJECTIVE**

In coordination with other agencies involved in the implementation of the Milk Code, this Department Circular aims to set forth the guidelines for monitoring the compliance to E.O. No. 51 and A.O. No. 2006-0012 in the national, regional and provincial levels.

## **III. Composition of the Monitoring Teams** –The Monitoring teams shall be composed of the following:

### **1. National level:**

- National Center for Disease (NCDPC-DOH)
- National Center for Health Facilities and Development (DCHFD-DOH)
- Government/Non-government Organizations/Civil Societies without any conflict of interest with the breastfeeding culture, and/or direct or indirect connection, financial or otherwise, or with commercial interest within the scope of the Code.
- Ad Hoc International Agencies such as the United Nations Children's Emergency Fund (UNICEF) and the World Health Organization (WHO)

### **2. Regional/Provincial/City/Municipal/ Barangay levels** (in collaboration with their respective Local Government Units):

- Center for Health Development Offices
- Provincial Health Offices
- City Health Offices
- Municipal Health Offices/Rural Health Units
- Barangay Health Office
- DOH-accredited GOs/NGOs/Civil Societies

**IV. Functions of the monitoring Teams .** The monitoring teams shall have the following functions:

1. Monitors compliance as well as problems encountered in the implementation of the Milk Code.
2. Verifies reports of violations of the Milk Code;
3. Monitors labels of products within the scope of the Code and marketing practices in various distribution centers;
4. Recommends sanctions or punitive actions for violations of the Milk Code to the Food and Drug Administration and follow-up action/resolution;
5. Submits regular reports on the status of the Milk Code implementation to the Food and Drug Administration.

**V. Continuing Education of Monitoring Teams**

The DOH shall provide continuing education to the Monitoring Team(s). They may seek technical and financial assistance from donor agencies after exhausting all resources.

**VI. Monitoring Activities**

Official members of the Monitoring team(s) are authorized to carry out monitoring activities at any time, or based on specific reports/suggestions from the Food and Drug Administration in their respective jurisdiction.

In particular, the Monitoring team(s) will be furnished by BFAD with copy/ies of the complete set of information related with all applied events, sponsorships and research, advertisements, and promotional materials so that monitoring activities can be scheduled accordingly.

**VII. Partnership and Networking:**

Official Monitoring teams, are encouraged to engage Civil society organizations, consumer groups, religious groups and other agencies, to closely monitor milk code implementation in their area of jurisdiction, and immediately report to the monitoring team of any alleged violation, found during their activity.

The Department may request for the assistance on non-governmental organizations, civil society, and concerned international agencies in order to better monitor the implementation of these rules.

## **VII. Reporting**

1. Members of the Monitoring teams as well as civil society groups should ensure that any report of alleged violation should be supported by:
  - Date and place where violation was found/seen
  - Specific location (health facility, store, TV ad, Radio/TV Channel)
  - For printed matters, get sample or a picture of the violation
  - For radio/TV AD or programs, clearly specific airing time and TV channel or Radio frequency
  - For website based violations. Provide web link
  - For violative products, e.g. mislabeled or misbranded product, a sample shall be purchased and receipt should be obtained and submitted as part of the evidence
  - In no case shall any member of the Monitoring Team resort to unreasonable searches and seizures of suspected violative products and/or advertising or promotional materials.
2. Civil Society organizations should be encouraged to send report of alleged violation to the respective official teams (National or Regional)
3. Monitoring Teams comprised of duly accredited teams from non-governmental organizations, and/or civil society may report their findings to the Office of the Secretary of Health who shall appropriately respond thereto with sufficient dispatch

## **VIII. Reporting Forms and Information**

National and Regional Monitoring teams will use the Monitoring Report forms (attached as Annex "A") to report all alleged violations to the respective Field Regulatory Operations Offices for proper action.

The Reporting Forms shall be made available in FDA and DOH Regional Offices, and in the DOH and FDA websites, to wit: [www.bfad.gov.ph](http://www.bfad.gov.ph) and [www.doh.gov.ph](http://www.doh.gov.ph).

## **IX. Details on how and where to report**

Reports may be submitted at the FDA Central Office at Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City addressed to the Director or to the CHD Regional Offices addressed to the Regional Director.

In the levels of the City Health Offices, Municipal Health Offices/Rural Health Units, Barangay Health Office, etc., reports may be submitted to the CHD Regional offices in any form/format as long as all the basic information listed in VII.1 are provided.

**X. Feedback on action taken by the Food and Drug Administration (FDA)**

To ensure the smooth and effective conduct of all monitoring activities, the Food and Drug Administration, should provide immediate (within 5 working days) feedback on actions taken based on the received reports of alleged violations.

**XI. Documentation**

National and Regional Monitoring teams, should keep proper documentation of all reported alleged violations.

**XII. Repealing Clause**

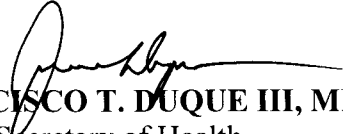
All issuances, rules and regulations or parts thereof inconsistent with these guidelines are hereby modified and/or repealed accordingly.

**XIII. Separability Clause**

If for any reason, any part or provision of these guidelines is declared invalid or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions which shall remain in full force and effect.

**XIV. Effectivity**

This guidelines shall take effect immediately.

  
**FRANCISCO T. DUQUE III, MD, MSc.**  
Secretary of Health

## MONITORING REPORT FORM ON E.O. 51 (MILK CODE)

Mon. No. \_\_\_\_\_

Date/Time : \_\_\_\_\_

Place/location:

1) Type of violation: \_\_\_\_\_

2. Advertising materials

Type of material: (get sample or picture)

- Booklet       Leaflet       Advertisement       Video cassette       mail  
 Audio       Compact disk       Display       Web page       text messages  
 visual       Poster       Billboard       Electronic media       telephone calls  
 Theater       Audio-visual       Others (specify)

3. Where was the material found/observed?

- General Hospital       Maternity       Pediatric hospital       Clinic  
 Doctor's Office       Health centre       Pharmacy       Supermarket  
 Shop       By the roadside       Magazine       Radio  
 Local TV       Cable TV       Junk mail       Cinema  
 Newspaper       Video       Scientific journal       Others (write here)  
 Internet

4. Has any company given sponsorship/fellowships/continuing education and other related researches or other services?  Yes       No

5. Where was the assistance for sponsorship/fellowships/continuing education and other related researches conducted?

- national events  
 regional events  
 local government events  
 with certificate of approval  
 without certificate of approval

materials/activities observed: \_\_\_\_\_  
Others (specify)

6. Who was the recipient of the donation?

- orphanage  
 TV networks  
 government organizations  
 non/government organizations  
 Public officials  
 Others (specify)

7. What is the type of product donated?

- Infant formula,       bottle  
 Follow-on formula       teats  
 Special formula       others (specify)  
 Cereal  
 Fruit/vegetable/meat puree,  
 Sweetened condensed milk

8. What is the purpose of the donation? \_\_\_\_\_

9. Observations made in the hospital/health centers/health facilities?
- presence of medical representatives/visits/decking
  - health personnel receiving samples of milk products and gifts
  - distribution of companies detailing materials
  - product display in the hospital pharmacy
  - contact with mothers
  - speakers from milk companies during mothers class conference/meetings

Other materials/activities observed	Described/remarks
_____	_____
_____	_____

10. Has any company sent promoters to the shop to advise consumers on infant feeding or on particular products?  
 yes  No. If yes, give details : \_\_\_\_\_

11) Is any of the following promotion techniques used to promote sales of infant foods/bottles/teats in this shop? If yes, give details in the box below.

- |   |  |
|---|--|
| <input type="checkbox"/> Discounts to customers | <input type="checkbox"/> Product information                   |
| <input type="checkbox"/> Special displays       | <input type="checkbox"/> Special sales                         |
| <input type="checkbox"/> Coupons                | <input type="checkbox"/> Tie-in-sales (buy one, get two, etc.) |
| <input type="checkbox"/> Samples                | <input type="checkbox"/> Product launch                        |
| <input type="checkbox"/> Gifts with purchase    | <input type="checkbox"/> Shelf-talkers                         |
| <input type="checkbox"/> Posters on display     | <input type="checkbox"/> Other                                 |

12. Does the labels of feeding bottles and teats
- a. carry a photo, drawing or other representation of an infant or young child, or a parent feeding a baby?  Yes  No  
(If YES, please attached photo of offending label)
  - b. contain any other drawing, image or text which idealizes the use of the product?  Yes  No  
If YES, describe \_\_\_\_\_
  - c. promote breastmilk substitutes?  Yes  No  
If YES, describe \_\_\_\_\_
  - d. have text which suggests similarity of the product to the breast or nipple?  Yes  No  
If YES, describe \_\_\_\_\_

13. Does the label indicate the recommended age of user/s?  Yes  No  
If Yes, what is it? ..... Months OR, (other wording) .....

14. Labels of follow-on formula /infant formula  
Does the label:
- a. suggest that a bottle be used for the product?  Yes  No
  - b. carry a photo, drawing or other representation of an infant?  Yes  No  
(If YES, please attach photo of offending label)
  - c. resemble the company's infant formula labels?  Yes  No
  - e. indicate or suggest in any way that this product could be for babies under six months?  Yes  No

**Details and comments:**

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Remarks/Findings/Proposed Action/Action

Taken: \_\_\_\_\_

Monitored by:

\_\_\_\_\_  
(Signature over Printed Name)

\_\_\_\_\_  
**Designation**