

**Violations of the International Code of  
Marketing of Breastmilk Substitutes in Nigeria:  
An analysis of factors influencing the Regulatory  
Authority in Code implementation**

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Violations of the International Code of Marketing of Breastmilk Substitutes in Nigeria: An analysis of factors influencing the Regulatory Authority in Code implementation

A thesis submitted in partial fulfilment of the requirement for the degree of Master of Public Health

by

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Declaration:

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Signature:.....

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## **Dedication**

To the ever-green memory of my dear father  
Christopher Odigwe Nwarache

You were the best. I am eternally grateful for the sweet memories of the years we had together and the many lessons of life you taught me. I hold them all dear and I know you would have been so proud.

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To my beloved husband, my 'honey', Jibola. Thank you for believing in me, supporting my dreams and holding the fort. I love you.

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## **List of Abbreviations**

ANC	Antenatal Care
BFHI	Baby Friendly Hospital Initiative
BMS	Breastmilk substitute(s)
CNLM	Comision Nacional Lactancia Materna
CPC	Consumer Protection Council
CRC	United Nations Convention on the Rights of the Child
CRWC	African Union Charter on the Rights and Welfare of the Child
CSO(s)	Civil Society Organization(s)
DG	Director-General
EBF	Exclusive Breastfeeding
EID	Establishment Inspection Directorate (NAFDAC)
ETB	Nigeria Vision 20:2020-Economic Transformation Blueprint
FCT	Federal Capital Territory (Abuja – Nigeria)
FDB	Food and Drugs Board (Regulatory Authority - Ghana)
FDRPRC	Food, Drugs and Related Products Registration Committee (NAFDAC)
FMF	Federal Ministry of Finance
FMoH	Federal Ministry of Health
FMWA	Federal Ministry of Women Affairs
FY	Fiscal Year
GC	Governing Council (NAFDAC)
GDP	Gross Domestic Product
GINAN	Ghana Infant Nutrition Action Network
GLSI	Global Listing of Supermarket Items

IBFAN	International Baby Food Action Network
IFM(s)	Infant Food Manufacturers/Marketers (includes importers, distributors)
IGR	Internally Generated Revenue(s)
IYC	Infant(s) and Young Child(ren)
IYCF	Infant and Young Child Feeding (Food)
LGA(s)	Local Government Area(s)
MDAs	Ministries, Departments and Agencies
MDG(s)	Millennium Development Goal(s)
MoH	Ministry of Health
NAFDAC	National Agency for Food and Drug Administration and Control (Regulatory Authority - Nigeria)
NARPAD	NAFDAC Registered Products Automated Database
NDHS	Nigeria Demographic and Health Survey(s)
NGO(s)	Non-governmental organization(s)
NIP	Nigeria Vision 20:2020 First National Implementation Plan
NPC	National Planning Commission
NRN	NAFDAC Registration Number
NTC	National Technical Committee on the Code
NTWGH	Nigeria Vision 20:2020 National Technical Working Group on Health
NV20:2020	Nigeria Vision 20:2020
PHC	Primary Health Care
PID	Ports Inspection Directorate (NAFDAC)
R&R	Registration and Regulatory Affairs Directorate (NAFDAC)
SON	Standards Organization of Nigeria
UN	United Nations

UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization

## Glossary

**Breastmilk substitute:** any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose (WHO, 1981). A breastmilk substitute includes any beverage and food marketed as suitable for feeding a baby up to the age of 24 months. Any product which replaces the breastmilk part of the baby's diet either partially or totally is a breastmilk substitute and falls under the scope of the Code (IBFAN/ICDC, 2008).

**Exclusive breastfeeding:** is defined as giving no other food or drink – not even water – except breastmilk. It does, however, allow the infant to receive oral rehydration salts (ORS), drops and syrups (vitamins, minerals and medicines) (WHO, 2008a).

**Legislation:** “the exercise of the power and function of making rules (as laws) that have the force of authority by virtue of their promulgation by an official organ of a state or other organization” (Merriam-Webster Dictionary, 2012).

**NAFDAC Product registration:** is the totality of all integral processes developed to ensure that food, drugs, cosmetics, medical devices, chemicals, detergents and packaged drinks imported, manufactured, exported, advertised, distributed, offered for sale or used in Nigeria are safe, efficacious and of good quality. The registration process requires that products satisfactorily pass through the following regulatory mechanisms (documentation, vetting of product samples, establishment inspection and laboratory evaluation) prior to grant of registration approval, a NAFDAC registration number (NRN) and a certificate of registration valid for five (5) years (Madukwe, 2003).

**Regulation:** “A regulation is a general statement issued by an agency, board, or commission that has the force and effect of law” (Office of Information and Regulatory Affairs, United States General Services Administration, undated).

**Regulatory Capture:** “The body meant to be doing the regulating in practice operates in the interests of those being regulated, not in the public interest” (Mills and Ranson, 2006).

## Abstract

**Background:** Violations of the International Code of Marketing of Breastmilk Substitutes (BMS) in Nigeria by infant food manufacturers/marketers (IFMs).

**Objective:** The thesis aimed at analyzing possible contributory factors and identifying those influencing NAFDAC's regulatory capacity for Code implementation in order to provide recommendations to policy-makers and NAFDAC management.

**Methods:** Literature (document) review was used to gather relevant information. A conceptual framework adapted from Aarons *et al* (2011) was used to analyze possible contributory factors and identify those influencing NAFDAC's Code implementation. Samples of BMS were examined for labelling compliance to the Code and regulations.

**Results:** From the external environment, major factors influencing NAFDAC's Code implementation were identified as weak leadership for policy (Code) implementation, inadequate federal funding, inadequate legislative provisions to suit Nigeria's social framework. Within NAFDAC, major factors identified are ineffective BMS registration, weak capacity for Code monitoring and enforcement, compromise of established Code regulations/policies/procedures probably resulting from 'regulatory capture' by IFMs. Other factors include inadequate numbers of Code-trained personnel and mismatch between professional competencies and assigned tasks.

**Conclusions and Recommendations:** Many factors have contributed to Code violations in Nigeria. Major recommendation to policy-makers: assume leadership for driving the policy process through to policy (Code) implementation by advocacy in relevant quarters for adequate funding. To NAFDAC management: include Code specialists in registration approval committee, mobilize resources for increased and sustained capacity-building of regulatory officers for Code implementation and external stakeholder engagement, establish a Code Centre of Excellence within NAFDAC.

**Key words:** International Code of Marketing of Breastmilk Substitutes (BMS), violations, regulatory authority, regulation, Nigeria.

**Word Count:** 13,096

## **Introduction**

Breastfeeding is a universally acclaimed unparalleled means of ideal feeding for healthy infant growth and development. However, where mothers do not breastfeed, or only breastfeed partly, a justifiable market exists for breastmilk substitutes (BMS). BMS should therefore be accessible but not marketed or distributed by means which may hinder protecting and promoting breastfeeding. This is considering infants' vulnerability in their initial months of life and the risks of improper feeding practices including unwarranted and improper use of BMS. Worldwide, improper feeding practices bring about infant malnutrition, morbidity and mortality. Inappropriate marketing practices for BMS and related products can add to these significant public health problems. The preceding considerations made it clear to the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) that regular marketing practices were improper for BMS. They required special handling. This was the general background that necessitated the development, in 1981, of the International Code of Marketing of Breastmilk Substitutes, which together with subsequent World Health Assembly (WHA) resolutions to update it, are jointly and henceforth referred to as 'the Code' (WHO, 1981). Nigeria is signatory to the Code (Monwuba, 2010).

The Millennium Development Goals (MDGs) 2011 report emphasizes greater prioritization of nutrition in national development for attainment of the MDGs (UN, 2011). Code implementation is recognized in Nigeria's Infant and Young Child Feeding (IYCF) policy as a means of contributing to combating infant and young child (IYC) malnutrition (FMoH, 2005). Exclusive breastfeeding (EBF) of infants during the initial 6 months of life plus timely introduction of safe, adequate and appropriate, complementary foods and micronutrients between 6 and 24 months old are among simple, cost-effective interventions which could significantly decrease undernutrition (UN, 2011). Using a 24-hour recall system, EBF practice in Nigeria is poor at 13% (NPC, 2009a) against 90% which is the universally accepted EBF target (WHO/UNICEF, 2009). The MDG target for infant and under-five mortality rates to be achieved in Nigeria by 2015 is approximately 30/1,000 live-births and 64/1,000 live-births respectively (GFRN, 2010). From the most recent Nigeria Demographic and Health Survey (NDHS) infant mortality rate is 75/1,000 live-births and under-five mortality rate is 157/1,000 live-births (NPC, 2009a) both way behind target. Urgent, speedy and collaborative actions for intervention delivery and scale-up are necessary to attain MDG1 plus other health-related MDGs (UN, 2011). See Appendix 1 for the MDGs.

The National Agency for Food and Drug Administration and Control (NAFDAC) is the regulatory authority mandated to enforce Code compliance

in Nigeria (Akunyili, 2010, p.244). The author, a regulator at NAFDAC in the Registration and Regulatory Affairs Directorate (R&R), has worked 8 years in the Director (R&R)'s office as part of a think-tank for input on policy formulation and regulations drafting in the Standards and Regulations Committee. The last 5 years were spent as Head of Technical Services of Director (R&R)'s office/Head of Global Listing of Supermarket Items (GLSI) of NAFDAC. Some information presented here are accounts from personal work experiences. In 2008, the author's attendance at a conference on 'Adequate Infant Nutrition in Nigeria' ignited a keen interest in NAFDAC's Code implementation. The thesis question is thus 'what are the factors influencing NAFDAC's implementation of the Code in Nigeria?' From study findings, recommendations will be provided to policy-makers and NAFDAC management to inform/support actions for protecting, promoting and supporting breastfeeding in Nigeria through effective Code implementation. It is hoped that recommendations will get 'voice' for the benefit of Nigerian children.

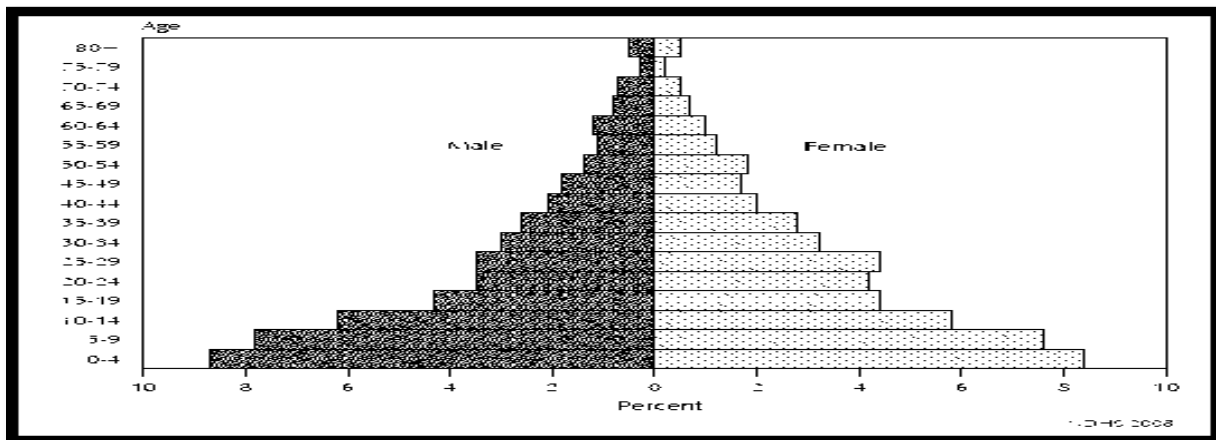
The thesis is set in 7 chapters. Chapter 1 presents country background and Chapter 2 describes the problem, provides justification/rationale, objectives and methodology. Chapter 3 reviews the Code and its evolution in Nigeria. Chapters 4 to 6 present findings, analysis of factors influencing NAFDAC's Code implementation, other countries' experiences and discussion. Chapter 7 draws thesis conclusions and provides recommendations.

## Chapter 1: Background Information

### 1.1. Geography and Population

Nigeria, in West Africa, is Africa's most populous country, spanning a land area of 923,768 km<sup>2</sup>. Census figures for 2006 put Nigeria's population at 140,431,790 with approximated annual growth rate of 2.8% (NPC, 2009a; NBS, 2010). Estimated 2012 population is 166 million. Projected number of births for 2015 is 7 million, representing 63% increase from 4.3 million in 1990 (WHO/UNICEF, 2012). Population is young, approximately 45% under 15 years, with age group 0-4 years constituting the largest population group at 17% (NPC, 2009a) (See figure 1).

**Figure 1: Nigeria: Population Pyramid**



Source: NPC, 2009a

### 1.2. System of Government

Nigeria operates a three-tier federal system of government (NBS, 2010) comprising a Federal Capital Territory (FCT), 36 States and 774 Local Government Areas (LGAs) serving as administrative units. There are 9,572 wards within the LGAs (HERFON, 2006; NPC, 2009a) (Figure 2).

**Figure 2: Map of Nigeria**



Source: <http://www.world-gazetteer.com>



### **1.3. Economy**

Nigeria, though among countries with Africa's highest growth, has high poverty levels with slow progress on several poverty-reducing MDGs (IMF, 2012). Approximately 64.4% subsist on less than \$1.25/day (UNDP, 2011). Wide wealth disparities exist between urban and rural dwellers. Most urbanites, 77%, belong to the two highest wealth quintiles against only 22% of rural dwellers. Women in employment are 59% against 80% of men (NPC, 2009a). Gross Domestic Product (GDP) by Quarter 1 of 2012 was 6.17% against 7.13% recorded in Quarter 1 of 2011. Wholesale and retail trade, a key economic driver, contributed 23.39% to total GDP in Quarter 1 of 2012 increasing marginally from 23.02% in Quarter 1 of 2011 (NBS, 2012a; NBS, 2012b). This is significant as infant food manufacturers/marketers (IFMs) operate in this sphere. Corruption remains widespread in public and private sectors (USAID, 2008).

### **1.4. Literacy**

Literacy levels differ markedly between males and females with 40% of males in the poorest households being literate against 13% of females. About 54% of females are literate, younger women being more literate than their older counterparts with levels ranging from 67% amongst 15-19 year olds to 32% amongst 45-49 year olds. Female literacy levels show a positive urban bias, urbanites being almost twice as likely to be literate (77%) as their rural counterparts (41%) (NPC, 2009a).

### **1.5. Health System**

The health system is decentralized with the federal level responsible for overall policy and tertiary care, States and Local Governments responsible for secondary and primary care respectively. Wards within LGAs are the lowest level of health-care delivery. The health system is complex with varied public and private providers (HERFON, 2006). From FMOH (2000) data cited by HERFON (2006), primary health-care (PHC) facilities were estimated at 20,000 with 7,000 of them operated by the private sector. In 2003, Nigeria had about 2,751 registered pharmacies and 36,000 patent medicine vendors who play a significant role as 'informal' health-care practitioners. Nigeria is among African countries that recorded 2-fold increases in health worker output (doctors, nurses and midwives) from training institutions and at 2008 was above WHO's threshold of 2.3 health workers/1,000 population (Awases *et al*, 2010).

Annual budgetary health allocation is consistently low, for 2012, just 6% of national budget is allocated to health (HERFON, 2012) despite African leaders pledge to allocate a minimum of 15% of national budgets to health in the Abuja Declaration (OAU, 2001). Out-of-pocket expenditure, the largest constituent of health-care finance, accounted for 95% of private expenditure on health for 2010 (WHO, 2010).

## **1.6. Maternal and Child Health**

Maternal mortality ratio is approximately 545/100,000 live-births. Nigeria contributes 11% to global under-five deaths. From 2008 NDHS, under-five mortality is approximately 157/1,000 live-births, infant mortality 75/1,000 live-births and neonatal mortality 40/1,000 live-births. Approximately half of childhood mortality happens in infancy and one-fourth by one-month old. Malnutrition remains challenging with 41% and 23% of under-fives stunted and severely stunted respectively. Among infants under 6 months, 21% are already stunted. Wasting among under-fives is 14% peaking at 20% among 6 to 8 month olds (NPC, 2009a; GFRN, 2010; UNICEF, 2011). This indicates the higher vulnerability of infants to stunting and wasting.

For service utilization, roughly 58% of women obtained antenatal care (ANC) from skilled professionals (doctors, nurses, midwives) in their last pregnancy with 45% making at least four ANC visits. About 35% gave birth in health-care facilities. Skilled professionals assisted 39% of deliveries. Better educated urbanites in higher wealth quintiles have greater likelihood of receiving ANC from skilled professionals and delivering in health-care facilities attended by skilled professionals. Altogether, 42% of women had postnatal care. Vaccination coverage (fully vaccinated) is 23% among 12 to 23 month olds; for first diphtheria, pertussis and tetanus, and oral polio vaccine dose it is 52% and 68% respectively (NPC, 2009a). There is therefore substantial contact between mothers/care-givers and health-care facilities during pregnancy and post-pregnancy.

## **1.7. Water and Sanitation**

Improved drinking water sources are accessible to just 56% of households. Though accessibility is better among urban households, still only 30% access water within their premises (NPC, 2009a). This implies possible water contamination between collection and use. Water treatment is not practiced by majority (85%) of households. Only 27% of households use improved toilet facilities (NPC, 2009a).

## **1.8. Breastfeeding Practices**

The beneficial effects of breastfeeding to mother and child are well acknowledged (Ijarotimi, 2010) (Appendix 1.1). Many Nigerian children are not fed in accordance with WHO/UNICEF recommendations of exclusively breastfeeding infants in the initial 6 months of life, followed by introducing safe and appropriate complementary foods whilst continuing breastfeeding till 24 months or beyond (WHA 2001; WHO 2003; NPC, 2009a).

According to 2008 NDHS, median duration of EBF is short (half-month) despite breastfeeding being a common practice (97% of children under-five are breastfed at some point). Only 13% of children below 6 months are exclusively breastfed, steadily declining as child's age increases to 7% by 4 to 5 months. This is against the 90% EBF target which is generally accepted although no internationally set target exists (WHO/UNICEF, 2009). EBF practice in children below 6 months remains persistently poor, progressively declining from 22% to 17% to 13% in 1999, 2003 and 2008 NDHS respectively. In 84% of children below 6 months there is already early supplementation of breastmilk with BMS (16% with milk, non-milk liquids/juice, 35% complementary foods and 33% plain water) (NPC 2004; NPC 2009a). Early breastmilk supplementation raises the children's risk for diarrhoea and other infections particularly acute respiratory tract infections (HERFON, 2006). The prevailing suboptimal water and sanitation situation (see section 1.7) is significant regarding unhygienic preparation of supplementary foods.

## **1.9. Food and Drug Regulation**

NAFDAC, established by Decree 15 of 1993 (now NAFDAC Act Cap N1 LFN, 2004) as a parastatal under Federal Ministry of Health (FMoH), is the regulatory authority responsible for enforcing Code compliance in Nigeria. NAFDAC is mandated to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals, detergents and packaged drinks. Effectively this means ensuring the safety, efficacy and quality of these products collectively termed regulated products. NAFDAC is empowered to make regulations; these may be used to plug loopholes in principal legislation to enhance effectiveness (Akunyili, 2010). NAFDAC operates in Nigeria's 36 States and the FCT.

### **1.10. National Policies, Legislation and Regulations for Code Implementation**

As a United Nations (UN) Member State, Nigeria has been signatory to all Conventions and Declarations on health matters. This implies commitment to upholding international agreements/resolutions reached on health issues including the Code. The Revised National Health Policy (2004) is anchored on PHC as the main platform for implementation, with overall objective of health system strengthening. The policy aims to improve the health status of Nigerians through achieving the health-related MDGs (FMoH, 2004). Therefore, it is the umbrella policy into which all other health policies should be vertically and horizontally integrated for a strategic fit into the broad national development plan.

Provisions of specific national policies comprise the major frameworks that seek to create an enabling policy environment to achieve optimal nutrition for IYC. They are the National Breastfeeding Policy (1997) which addresses support and spread of EBF (FMWA, 2000; Worugji and Etuk, 2005) and the National Policy on Infant and Young Child Feeding in Nigeria (2005) which addresses optimum IYCF (FMoH, 2005).

The national legislation governing the marketing of BMS is Marketing (Breast-milk Substitutes) Decree 41 enacted 1990 (now Act Cap.M5 LFN 2004) (as amended by Act 22 of 1999) while regulations drawn from it is NAFDAC's Marketing of Infant and Young Children Food and Other Designated Products (Registration, Sales, etc.) Regulations, 2005 (Akunyili 2010, pp. 244, 246). The regulations were made under NAFDAC's Act to circumvent delays in attempting to amend the 1990 BMS legislation (Monwuba 2010).

## **Chapter 2: Problem Statement, Justification, Objectives and Methodology**

### **2.1. Problem Statement/Justification**

#### Code Violations in Nigeria

During World Breastfeeding Week 2007, the Director-General (DG) NAFDAC announced ongoing gross Code violations in Nigeria by IFMs, which have persisted to date as stated by UNICEF. The violations were revealed during a 2005 pilot survey to test monitoring tools developed in readiness for nationwide monitoring of Code compliance. Code Article 11.6 requests yearly communication from UN Member States to the DG (WHO) on national Code implementation efforts. The pilot survey was the beginning of evidence-gathering efforts to assess Nigeria's Code implementation status because globally accepted documentary evidence of code compliance was lacking (WHO, 1981; FRCN, 2007; Monwuba, 2010). The planned nationwide monitoring has not been undertaken to date. However, recent evidence (July 2012) from routine monitoring revealed that IFMs still continue to violate the Code (See monitoring reports in Appendices 4.5/4.6). The spate of ongoing violations, even with national marketing of BMS legislation and regulations in effect, is a problem and calls for analysis of factors influencing NAFDAC's Code implementation. This is necessary because BMS compete with breastfeeding and their improper marketing (Code violations) is a significant factor, often with negative effects on mothers' choice and ability to optimally breastfeed their infants (WHO, 2008b); with attendant ill consequences (Appendix 1.1 details the importance of EBF and the implications of suboptimal breastfeeding).

During World Breastfeeding Week 2012, UNICEF noted the declining EBF practice in Nigeria (from 17% in 2003 to 13% in 2008) and attributed it to poor Code enforcement, among other reasons. The UNICEF Executive Director said if there was more effective promotion of breastfeeding and protection of women from aggressive BMS marketing, more children would survive and thrive, with decreased rates of disease, malnutrition and stunting (Muanya and Chukwu, 2012). Similar linkages between aggressive BMS marketing and low EBF have been articulated. For example, Eregie (2008) suggests that improper BMS marketing by IFMs is possibly contributory to Nigeria's reportedly low EBF levels. These linkages place NAFDAC's regulatory role under scrutiny as effective Code implementation expectedly regulates IFMs' marketing practices. The World Bank also recognizes Code enforcement as a fundamental policy intervention to curb unethical marketing/promotion of commercial BMS (World Bank, 2006).

While there is a paucity of studies investigating Code compliance in Nigeria, one recent study showed that widespread and convincing infant formula advertising significantly affected women's infant-feeding choice towards formula-feeding (Onyechi and Nwabuzor, 2010). Code violations thus ensure that mothers are not afforded the liberty of making optimal infant-feeding choices free from biased information and commercial pressure, only using BMS when medically indicated, thereby improving chances of optimal infant nutrition (WHO, 2008b).

Linkages between Code implementation and child health were recognized in WHA resolution 34.22 (1981) which in adopting the Code stated its conviction that regulating the marketing of BMS (as a component of protecting and promoting infant-feeding) directly and profoundly affects IYC health and is a problem of direct concern to WHO (WHO, 1981). This underscores the international scale of the problem of Code violations (non-compliance). The recently launched 'Zero Hunger Challenge' initiative by the UN Secretary General is a call to all countries to strive towards a future where all people have adequate nutrition. One of its laudable objectives is to end malnutrition in early childhood (UNCSD, 2012). From the foregoing, it is logical to state that one means of contributing to achieving this target is to stem Code violations by protecting, promoting and supporting optimal breastfeeding practices through effective Code implementation.

#### Legal Foundation/Justification

Nigeria is signatory to the 1990 UN Convention on the Rights of the Child (CRC) and the 1990 African Union Charter on the Rights and Welfare of the Child (CRWC), which she ratified in 1991 and 2000 respectively thus making them legally binding international instruments. Both instruments set universal standards/principles for the survival, protection, development and participation of children as human entities with rights (UNICEF, 2010). In article 24, the CRC explicitly states that the child has the right to enjoy the highest attainable standard of health. Commitment to implementation of this right entails government taking measures to ensure that the populace, particularly parents and children, are adequately informed and supported in using basic knowledge on child health and nutrition and the advantages of breastfeeding, amongst others (OHCHR, 2007). The Child's Rights Act (2003), Nigeria's domestication of CRC and CRWC also captures rights of children to health and adequate nutrition (UNICEF, 2010). Breastfeeding is thus a rights issue. Fulfilling these rights includes providing the public protection from breastfeeding misinformation and underscores Member States' legal obligation for Code implementation (IBFAN/ICDC, 2008), essentially mitigating Code violations.

Answers to the thesis question 'what are the factors influencing NAFDAC's implementation of the Code in Nigeria?' are therefore urgent and necessary in recognition of continued Code violations, declining national EBF practice and its ill-consequences for child survival and attainment of health-related MDGs. The MDG target for infant and under-five mortality rates to be achieved in Nigeria by 2015 is approximately 30/1,000 live-births and 64/1,000 live-births respectively (GFRN, 2010). From earlier stated NDHS 2008 figures, Nigeria is way behind target. The thesis aims at discovering influencing factors by analyzing the regulatory service environment, external and internal stakeholders and their contributory roles in Code implementation. Literature search revealed a vast body of knowledge on breastfeeding practices in Nigeria. However, research on NAFDAC's role, being the enforcer of Code compliance and therefore a key contributor in affecting breastfeeding practices, is notably lacking. The author sees this as a knowledge-to-action gap which needs to be urgently addressed to contribute towards achieving MDG4 by 2015.

## **2.2. Objectives**

### **2.2.1. General objective:**

To analyze possible contributory factors and identify those influencing NAFDAC's regulatory capacity for implementation of the Code in order to provide recommendations to policy-makers and NAFDAC management to inform/support action for protecting, promoting and supporting breastfeeding practices in Nigeria through effective Code implementation.

### **2.2.2. Specific objectives:**

- i. To analyze the regulatory service environment and external stakeholders in Code implementation to identify whether they influence NAFDAC's regulatory capacity for Code implementation.
- ii. To analyze NAFDAC's organizational characteristics including regulatory mechanisms to identify whether they influence NAFDAC's regulatory capacity for Code implementation.
- iii. To analyze 'best practices' from other countries to provide a range of perspectives for Code implementation in Nigeria.
- iv. To use the thesis findings to provide recommendations to policy-makers and NAFDAC management in order to inform/support action for protecting, promoting and supporting breastfeeding practices in Nigeria through effective Code implementation.

## **2.3. Methodology**

The analysis of factors influencing NAFDAC's Code implementation relied largely on literature review. This entailed a review of documents including: the Code, IYCF policies, marketing of BMS legislation and NAFDAC regulations on marketing of IYCF. Others reviewed were relevant NAFDAC regulations, registration and post-registration guidelines, NAFDAC internal documents, government reports and national development policies/plans. Samples of BMS were examined for labelling compliance. NAFDAC registered products automated database (NARPAD) was used to authenticate registration status of examined BMS. A gap analysis of national legislation and regulations vis-a-vis the Code was undertaken. These components anchored the thesis combined with the author's personal observations and work experience.

### **2.3.1. Conceptual Framework**

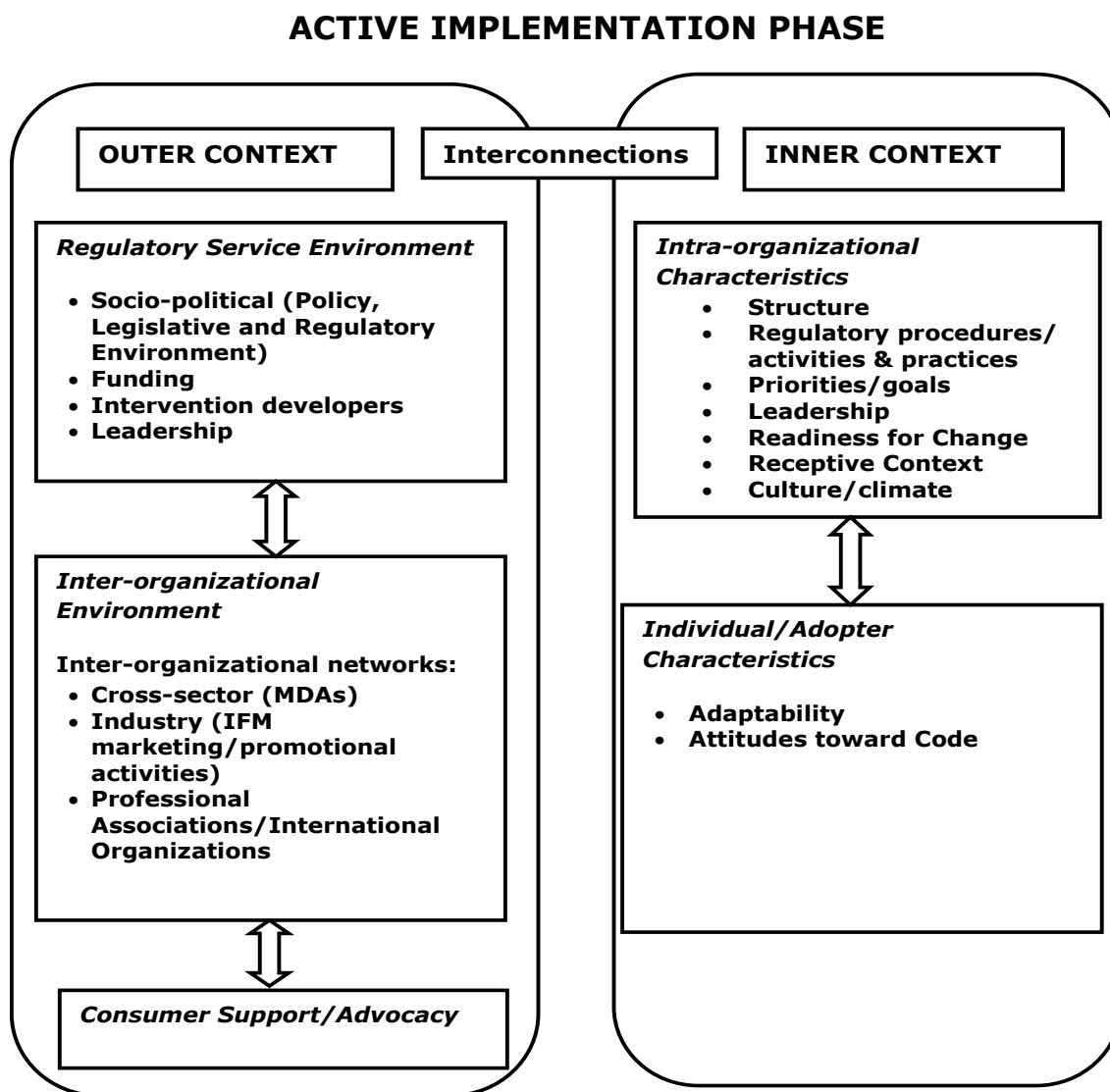
To analyze factors possibly influencing NAFDAC's Code implementation, a conceptual framework adapted from 2 original frameworks of Aarons *et al* (2011) is used. Appendix 2.1 shows the original conceptual frameworks which will be referred to as 'A' and 'B'. These frameworks were chosen because they were designed to suit the analysis of possible factors influencing service implementation in public service sectors generally. Prior to discovering the frameworks the author's search had only yielded frameworks addressing factors affecting breastfeeding practices which is not what the thesis aims to study. Framework 'A' captures broad factors which, in the innovators' opinion, have high likelihood of exerting a major influence on service implementation in public service sectors (Aarons *et al*, 2011). Framework 'B' is expanded into four distinct implementation phases: exploration, adoption decision/preparation, active implementation and sustainment. Components of framework 'A' are then put into each implementation phase of framework 'B'. The distinction into implementation phases is guided by the recognition that some factors may wield greater/different influence in particular phases of the implementation process (Aarons *et al*, 2011) and makes framework 'B' comprehensive and user-friendly for ease of analysis. It enables the user to readily adapt it to analyze a specific implementation phase.

To limit the scope of analysis, this thesis focuses on the 'active implementation phase' while fully appreciating the fact that implementation does not necessarily progress linearly through the phases (Saldana, 2012). This is apparently the phase applicable to NAFDAC since Code implementation is in progress. The 'exploration phase' and 'adoption



decision/preparation phase' are not selected as the decision for NAFDAC to implement the Code has been taken. However, the author realizes that troubleshooting how these 2 phases were implemented could provide further useful insight but would be beyond the scope of this thesis. 'Sustainment phase' is not selected because the author considers it not feasible to analyze this phase without prior analysis of factors influencing active implementation, given the spate of ongoing Code violations. (Figure 3 shows the adapted framework).

**Figure 3: Conceptual Framework of Contributory Factors Influencing NAFDAC's Implementation of the Code**



**Source:** Adapted from Aarons *et al* (2011)

In the adaptation, framework 'A' was used as the main structure (with only 'interconnections' retained in the inter-phase between outer and inner contexts); components of the 'active implementation phase' from framework 'B' were then placed into the 'outer' and 'inner' contexts of this main structure. To guide a systematic/comprehensive analysis, the framework is tailored to the NAFDAC regulatory context. Some adaptations were based on author's working knowledge/experience. In the outer context's 'service environment' (re-named 'regulatory service environment'), 'legislative priorities' is re-named 'policy, legislative and regulatory environment' to encompass these issues in analysis while 'administrative costs' is omitted being beyond the scope of the thesis. 'Funding' is analysed generally; 'contracting arrangements' and 'community-based organizations' are omitted not presently featuring in NAFDAC's Code implementation. The IFMs constitute Code 'inter-organizational networks' so are included while 'contractor associations' are not presently constituent, therefore it is omitted. Issues of 'information sharing' and 'cross-discipline translation' are analysed under 'cross-sector' for brevity. 'Consumer Support/Advocacy' is retained in adapted framework's outer context, though excluded from the 'active implementation phase' of framework 'B'. Justification for this is that food control systems operate under the foundation of safeguarding the consuming public's health and require transparency in development and implementation thus necessitating that all stakeholders participate effectively in decision-making (FAO/WHO, 2003). This implies a central role for consumers and consumer/public interest groups during active implementation. For the inner context's 'intra-organizational characteristics', regulatory functions and leadership are added to suit the regulatory environment; leadership is considered a vital element to steer Code implementation through all stages. 'Innovation-values fit' is removed because the Code is consistent with NAFDAC's role and 'demographics' is also removed being beyond the scope of the thesis. 'Adaptability' and 'attitudes toward Code' are analysed together for brevity.

### **2.3.2. Search Strategy**

This mainly entailed internet searches of varied published articles/reports on the Code and its implementation, reports of Nigerian government, UN organizations, International Baby Food Action Network (IBFAN), other international non-governmental organizations (NGOs). Main search engines used were MEDLINE (PubMed), Science Direct, Ebscohost, Scopus, Google Scholar and Google. Information was also sourced from NAFDAC internal documents/records, textbooks and IBFAN's 2010 publication on Code violations.

**Websites** of relevant Nigerian Ministries, Departments and Agencies (MDAs), WHO, UNICEF, other UN Organizations, World Bank, International Monetary Fund, African Union, IBFAN, other international NGOs, IFMs, and other countries, were accessed.

**Key words** used singly or in combination included: International Code of Marketing of Breastmilk Substitutes, breastmilk substitutes, breastmilk, infant formula, baby milk/food, artificial feeding, BMS Code implementation, regulatory authority, regulation(s)/regulate, legislation, violations, advertising, advertisement, labeling, monitoring, enforcement/enforcing, compliance, infant food manufacturers/marketers, marketing, promotion, infant and young child feeding/food, breastfeeding/exclusive breastfeeding, malnutrition, health facility(ies), health workers, NAFDAC, Nigeria, Ghana.

**Inclusion criteria:** International Code of Marketing of BMS (1981) was included being the thesis foundation. Other relevant documents, published reports/articles were selected from 2000 to 2012. For those on Code implementation this was to capture any new/emerging trends or ideas particularly in IFMs' marketing/promotional practices.

### **2.3.3. Limitations**

Thesis limitations were mainly due to geographical space constraints as qualitative research aspects which would have further enriched the findings were not undertaken. The thesis therefore relied on proxy measures to assess NAFDAC's current readiness for change, receptive context and individual adopter characteristics. Information was also not available from NAFDAC Port offices for Code monitoring activities owing to the closure of the Agency's Port offices nationwide. The author's personal observations were relied on in some instances, not being evidence-based, this introduces the possibility of bias.

## **Chapter 3: The International Code of Marketing of Breastmilk Substitutes**

### **3.1. Historical Background**

Declining global breastfeeding rates came under public scrutiny in the 1960s and 70s. Amid mounting concern that IFMs improper and aggressive BMS marketing was contributing to this decline was the associated global rise in malnutrition, morbidity and mortality among infants and young children (IBFAN/ICDC, 2008). According to Sokol *et al* (2007) citing Wenner (1969), Nigeria's experiences of the 1960s contributed to the Code's advent. They reported Dr. Catherine Wenner, a paediatrician, among the earliest to highlight IFMs' universal and unethical marketing observed in 1960s Nigeria. She wrote of rising trends in IYC malnutrition and sickness owing to bottle-feeding. A landmark meeting on IYCF, convened by WHO/UNICEF in Geneva in October 1979, expressed their concern about declining breastfeeding rates. The meeting had representatives of governments, industry, scientists and NGOs. The final consensus emphasized poor infant-feeding practices and their consequences as largely man-made problems, constituting major barriers to social and economic development in developing and developed nations. It also stressed society's responsibility for breastfeeding promotion and mothers' protection from negative influences. On 21<sup>st</sup> May 1981, WHA's 34<sup>th</sup> session adopted the Code as a recommendation under WHO constitution (IBFAN/ICDC, 2008).

### **3.2. Overview of the Code**

The Code is a compilation of recommendations to regulate marketing practices for BMS, feeding bottles and teats (WHO, 2008b). It aims 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" (WHO, 1981). Code provisions cover labeling and quality of BMS and related products, their promotion to health workers, in health-care systems, to the general public and mothers, infant-feeding information and education, Code implementation and monitoring (WHO, 1981). WHA resolution 34.22 (1981) urged Member States to give full effect to Code provisions in its entirety as a minimum requirement by interpreting it into national laws, regulations or other appropriate measures tailored to prevailing social and legal frameworks (IBFAN/ICDC, 2008). (See appendix 3.1 for Code Articles and appendix 3.2 for WHA resolutions adopted subsequent to the Code).

### 3.3. State of the Code Worldwide

According to IBFAN/ICDC (2009) survey, about 77% of 196 nations surveyed had taken some measures to implement Code provisions since its 1981 adoption. Countries were categorised using the scope of the laws/national measures enacted as the main criterion. Based on this there are 9 categories of countries. Table 1 shows the numbers of countries worldwide in the various IBFAN categories. Appendix 3.3 provides detailed information on criteria for country categories.

<b>Country Category by Measure Taken</b>	<b>1 (Law)</b>	<b>2 (Many Provisions Law)</b>	<b>3 (Few Provisions Law)</b>	<b>4 (Voluntary Code)</b>	<b>5 (Some provisions in other Laws)</b>	<b>6 (Some provisions voluntary)</b>	<b>7 (Measure Drafted)</b>	<b>8 (Being Studied)</b>	<b>9 (No information /No action)</b>
<b>Number of Countries</b>	30	33	42	17	5	23	22	10	14

**Source:** Adapted from: IBFAN/ICDC (2009) State of the Code by Country

### 3.4. Evolution of the Code in Nigeria

Five years after international adoption of the Code, Nigeria, in 1986 came up with her National BMS Code – *Code of Ethics and Professional Standards for Marketing of Breast-milk Substitutes*. Four years after came the national legislation, Decree 41 of 1990. However, none of these 2 national instruments had designated a Code implementing Body/Authority. This meant the continuation of a period of national inaction regarding Code implementation despite having national instruments. Marketing/promotional activities of IFMs went unchecked. IFMs undertook huge media campaigns promoting their BMS nationwide, engaging health workers, directly contacting mothers (Monwuba, 2010).

The Baby Friendly Hospital Initiative (BFHI), jointly launched by WHO and UNICEF in 1991, was to create breastfeeding support centres in recognition of the powerful influence hospitals/maternity units have on new mothers' breastfeeding practice. One criterion for being designated a 'Baby Friendly' facility is prohibiting acceptance of free or low-cost BMS supplies, a Code provision (UNICEF, 2012a). In 1992, BFHI was launched in Nigeria (Ogunlesi *et al*, 2005). The initial successes recorded were said to have been impeded by IFMs' ongoing marketing/promotional activities. This brought forth the realization that no legally designated Authority was actually responsible for Code implementation/enforcement and led to the enactment of amendment Decree 22 of 1999 which mandated NAFDAC to enforce Code compliance in Nigeria (Monwuba, 2010; Sokol *et al*, 2007).

The amendment Decree still had not addressed all loopholes in the original legislation. Additionally, NAFDAC lacked the technical capacity to enforce

Code compliance so the period of national inaction lingered. It took the intervention of a team from UNICEF and BFHI in June 2000 to jolt NAFDAC out of Code inertia. A series of progressive actions followed. The National Technical Committee on the Code (NTC) was established in June 2000 drawing membership from: FMoH, Federal Ministry of Information (Child Rights Bureau), Federal Ministry of Women Affairs (FMWA), Federal Ministry of Justice, Federal Bureau of Statistics, National Primary Healthcare Development Agency, National Committee on Food and Nutrition, UNICEF and WHO with NAFDAC coordinating. Activities took off in earnest from April 2001 under a new NAFDAC management and involved Code trainings. These culminated in the drafting of NAFDAC Regulations on Infant and Young Children Food and other Designated Products (Registration, Sales, etc.) Regulations 2005, and also the development of 12 Code monitoring tools. These monitoring tools are questionnaires and checklists to document incidence (or lack of) of prohibited marketing practices. They were adapted from the IBFAN methodology for monitoring compliance and targeted all likely avenues for tracking violations. These included IFMs, health facilities/health workers, retail outlets, product labels, advertisement materials, among others. During World Breastfeeding Week 2006 the Regulations and monitoring tools were formally launched by the Minister of Health with subsequent dissemination to stakeholders (Akunyili, 2010, pp. 244, 245; Monwuba, 2010; NAFDAC records). It had taken Nigeria 25 years since international Code adoption to arrive at that point. Appendix 3.4 shows Nigeria’s current Code instruments.

Despite being the first among 24 countries comprising West and Central Africa to implement the Code through her 1990 enabling law (Sokol *et al*, 2007), Nigeria presently falls short of being in IBFAN’s category 1, falling instead into category 2 (IBFAN/ICDC, 2009). Table 2 captures the situation around Nigeria showing West and Central African countries by categories of national measures taken for Code implementation.

**Table 2: IBFAN Scale: The Code in 24 West and Central African (UN) Member States**

Country Category by Measure Taken	1 (Law)	2 (Many Provisions Law)	3 (Few Provisions Law)	7 (Measure Drafted)	8 (Being Studied)	9 (No information/No action)
West and Central African Member States	Benin	Burkina Faso	Guinea	Chad	Mauritania	Central African Republic
	Cameroon	Democratic Republic of Congo	Guinea Bissau	People’s Republic of Congo		Equatorial Guinea
	Cape Verde	Mali		Cote D’Ivoire		Liberia
	Gabon	Niger		Sao Tome & Principe		
	Gambia	<b>Nigeria</b>		Sierra Leone		
	Ghana	Senegal		Togo		

**Source:** Adapted from: IBFAN/ICDC (2009) State of the Code by Country

## **Chapter 4: Study Findings: Analysis of Possible Contributory Factors influencing NAFDAC's Code Implementation**

This chapter presents thesis findings using the conceptual framework, in a regulatory context, as a backbone to guide analysis of factors.

### **4.1. Outer Context**

Outer contextual factors comprising the regulatory service environment, inter-organizational environment and consumer support/advocacy are analysed to identify if they influence NAFDAC's Code implementation.

#### **4.1.1. Regulatory Service Environment**

This section focuses on policies, legislation, regulations, funding, intervention developers, leadership, and the extent to which they create an enabling regulatory service environment for effective Code implementation.

#### **Socio-Political (Policy, Legislative and Regulatory Environment)**

##### Policy Environment

Two policies concerning IYCF were reviewed. The National Breastfeeding Policy (1997) was not available online for review. This was attributed to its pre-dating the internet era for official government documents. It was reviewed as presented in a synopsis by Worugji and Etuk (2005). Both policies incorporated the Code's principles and aims, either explicitly or implicitly, as is highlighted below.

- *The National Breastfeeding Policy (1997)*, from Worugji and Etuk (2005) synopsis, addresses some Code provisions without explicitly referring to the Code. The policy prohibits feeding bottles, teats/pacifiers from health facilities and discourages their home use. It discourages BMS use except medically indicated, declaring availability by prescription only. It further prohibits promotion of the mentioned items and states that pregnant women and relevant others should be made aware of the dangers of bottle-feeding. The policy is however explicit in calling for Code-awareness and compliance from health workers, and in its support through disseminating the Code to the public.
- *The National Policy on IYCF (2005)*, unlike the Breastfeeding Policy, makes explicit policy statements on enforcing the Marketing (Breast-milk Substitutes) Act and adherence to regulations, conveying clear Code directives. When BMS is medically indicated for infants, it should be in accordance with Code provisions and available solely on prescription. Health workers should be Code-aware and Code-compliant. The policy covers Code compliance in procuring, managing, distributing, targeting

and using of BMS/other milks during emergency situations. It states that donations of BMS/other milks in emergencies or to orphanages shall be Code-compliant, only to those for whom it is indicated, and for the entire period needed. Specific mention is made of policy support for research on Code implementation (FMoH, 2005).

Collectively, both policies lay the policy foundation to enable Code implementation. The next section analyses whether an enabling legislative and regulatory environment for policy (Code) implementation has been created.

### Legislative and Regulatory Environment

A gap analysis of the national legislation on marketing BMS and NAFDAC regulations on marketing IYCF vis-a-vis the Code was undertaken by the author (using Code provisions as the minimum requirement) to ascertain their conformity to the Code. These national legal instruments were individually reviewed against provisions of the 11 Code articles to identify any gaps. (appendices 3.1, 4.1 and 4.2 for the Code, legislation and regulations).

The analysis revealed several gaps. Neither the legislation nor the regulations met the Code minimum requirement in all aspects. Considered collectively, both documents still fell short of the Code on all articles therefore not meeting the minimum requirement. This corroborates IBFAN's rating of Nigeria in category 2 among countries with not all Code provisions covered by national measures. Of 11 Code articles, legislation met Code provisions on 3, partially on 5 and not at all on 3 articles. The regulations met Code provisions on 5 and partially on 6 articles. (Table 3).

<b>Table 3: Summary Result of Gap Analysis of National Legislation and NAFDAC Regulations (on Marketing of Breastmilk Substitutes) vis-a-vis the Code</b>							
<b>Code Article Numbers</b>	<b>The Code</b> (Title of Articles)	<b>National Legislation</b> Decree 41 Marketing (Breast-milk Substitutes) Act (1990)			<b>NAFDAC Regulations</b> Marketing of IYCF and other Designated Products (2005)		
		<b>Does Legislation meet Code Provisions?</b>			<b>Does Regulation meet Code Provisions?</b>		
		<b>Yes</b>	<b>No</b>	<b>Partially</b>	<b>Yes</b>	<b>No</b>	<b>Partially</b>
<b>Article 1</b>	Aim of the Code	✓			✓		
<b>Article 2</b>	Scope of the Code			✓	✓		
<b>Article 3</b>	Definitions	✓			✓		
<b>Article 4</b>	Information and Education		✓				✓
<b>Article 5</b>	The general public and mothers			✓			✓
<b>Article 6</b>	Health care systems			✓			✓
<b>Article 7</b>	Health workers		✓				✓



<b>Table 3:</b> continued							
<b>Code Article Numbers</b>	<b>The Code</b> (Title of Articles)	<b>National Legislation</b> Decree 41 Marketing (Breast-milk Substitutes) Act (1990)			<b>NAFDAC Regulations</b> Marketing of IYCF and other Designated Products (2005)		
		<b>Does Legislation meet Code Provisions?</b>			<b>Does Regulation meet Code Provisions?</b>		
		<b>Yes</b>	<b>No</b>	<b>Partially</b>	<b>Yes</b>	<b>No</b>	<b>Partially</b>
<b>Article 8</b>	Persons employed by manufacturers and distributors		✓		✓		
<b>Article 9</b>	Labelling			✓			✓
<b>Article 10</b>	Quality	✓			✓		
<b>Article 11</b>	Implementation and Monitoring			✓			✓
<b>Source:</b> Author							

This section is best appreciated with the detailed gap analysis results (Appendix 4.3). It is important to note that the regulations do not supersede the legislation, rather attempts to plug the legislation’s loopholes to bring it more in consonance with the Code (Ejiofor, undated). The gap analysis results provide instances. The scope of products covered (Article 2) was a fundamental flaw in the legislation which had created room for ambiguous interpretation. This loophole was addressed by the regulations’ revised, unambiguous scope of products (Regulation 21). Other loopholes were found concerning information/education and health workers (Articles 4 and 7) both were completely excluded in legislation but now partially addressed by regulations. Responsibilities of marketing personnel (Article 8) were also not covered by legislation but now fully covered by regulation. Regulation 16 makes no provisions for independent Code monitoring as recommended by Code Article 11.4, providing only for IFM self-monitoring. Several ambiguities were also identified in the national legal instruments particularly in Regulation 7.1 being silent on donations of free/low-cost supplies to the healthcare system. Beyond identifying the gaps, the regulations also did not incorporate ‘home-grown’ features specifically tailored to the Nigerian social context. The identified gaps, however, signal that the enabling legislative/regulatory environment for Code implementation is lacking.

## **Funding**

The Federal budget is government’s means of achieving goals set out in the policy documents guiding budget preparation. These policy documents detail government’s vision and current priorities. Presently they are Nigeria Vision

20:2020 (NV20:2020) and government's Transformation Agenda (BOF/FMF, 2012). Considering this, the final report of the NV20:2020-National Technical Working Group on Health (NTWGH), NV20:2020-Economic Transformation Blueprint (ETB) and NV20:2020-First National Implementation Plan (NIP) 2010-2013 were reviewed to ascertain if Code implementation is currently a government priority. The NTWGH report, essentially a summary of government's health aspirations, was incorporated into the ETB from where the NIP was drawn. The Transformation Agenda is drawn from NV20:2020 and NIP (NPC, 2011). Federal budgetary allocation to NAFDAC (through FMoH) for Fiscal Years (FY) 2010 to 2012 (2010 budget proposal was used) were reviewed to discover whether government prioritization of the Code (if ascertained) translated to financial commitment for implementation.

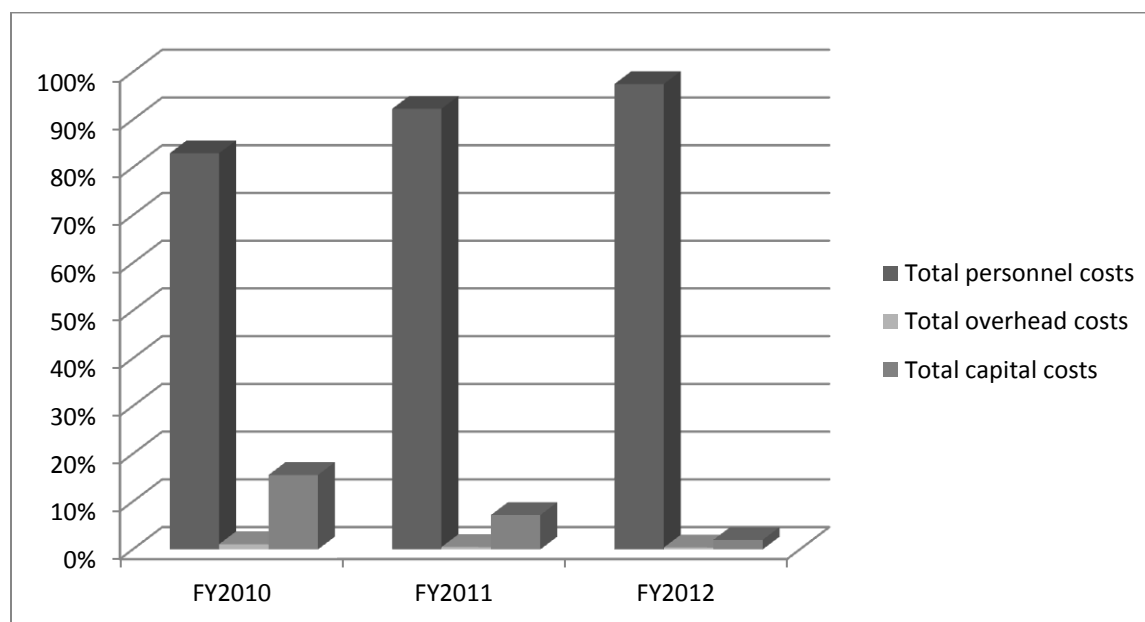
From the review, NTWGH report and ETB both revealed decreasing malnutrition in under-fives to below 20% from 53% by 2015 as one of government's goals. The NIP mentioned improving EBF rates to 50% from the present 13% by 2013 as a goal; the NTWGH highlighted promoting EBF for 6 months as a strategy for achieving the goals (NTWGH, 2009; NPC, 2009b; NPC, 2010). These imply that Code implementation is a government priority since linkages have been recognized between improper BMS marketing (Code implementation) and contribution to infant malnutrition (WHO, 1981) which is positively impacted by EBF.

Federal budgetary allocation to NAFDAC for FY2010 to FY2012 was insufficient to create the required financial environment for Code implementation activities. In FY2010, FY2011 and FY2012, total personnel costs were approximately 83%, 92% and 97.5% of the allocation respectively while overhead costs were 1.1%, 0.5% and 0.4% respectively. (See table 4 and figure 4). The trend observed was progressively increasing personnel costs with correspondingly decreasing overhead costs. This is challenging because the cost of Code implementation (registration, monitoring and enforcing compliance), one of numerous NAFDAC activities, should come from this shrinking overhead cost portion of NAFDAC's allocation. NAFDAC, as a government Agency, should be wholly financed through Federal budget (Akunyili, 2010, p.63) but this is not so. Other financial assistance for Code implementation came from UNICEF in support of trainings/workshops (Monwuba, 2010).

<b>Table 4: Federal Budgetary Allocation to NAFDAC for Fiscal Years 2010, 2011 and 2012</b>						
Line Item	FY2010		FY2011		FY2012	
	Allocation	Federal	Allocation	Federal	Allocation	Federal
	Amount *(#)	%**	Amount (#)	%	Amount (#)	%
Total personnel cost	1,781,100,243	83.3	3,442,980,301	92.3	3,631,627,764	97.5
Total overhead cost	22,727,539	1.1	19,819,459	0.5	15,561,909	0.4
Total recurrent cost	1,803,827,782	84.3	3,462,799,761	92.8	3,647,189,673	97.9
Total capital cost	335,000,000	15.6	267,304,341	7.2	76,000,000	2.0
<b>Total allocation</b>	<b>2,138,827,782</b>		<b>3,730,104,102</b>		<b>3,723,189,673</b>	

**Notes:** \* = Naira (Nigerian local currency). Exchange rate: ₦1 = \$155.00 (BOF/FMF, 2012)  
 \*\* = percentage share of total allocation (total recurrent plus total capital cost make 100%)  
 Total personnel cost and total overhead cost add up to total recurrent cost  
 Total recurrent and total capital cost add up to total allocation  
**Source:** 2010 Budget Proposal [Online]. Available from: <https://commondatastorage.googleapis.com/ckannet-storage/2012-02-20T173148/HEALTH.pdf> [Accessed 12 July 2012].  
 2011 Budget [Online]. Available from: <https://commondatastorage.googleapis.com/ckannet-storage/2012-02-20T181514/Health.pdf> [Accessed 12 July 2012].  
 2012 Budget [Online]. Available from: [http://www.budgetoffice.gov.ng/revision\\_budget/16.%20Summary\\_Health\\_NEW%20xls.xls\\_Revised\\_v3.pdf](http://www.budgetoffice.gov.ng/revision_budget/16.%20Summary_Health_NEW%20xls.xls_Revised_v3.pdf) [Accessed 12 July 2012].

**Figure 4: Graphical Representation of Federal Budgetary Allocation to NAFDAC (Fiscal Years 2010, 2011 and 2012)**



**Source:** Adapted from internet resources mentioned in Table 4

## **Intervention Developers**

Intervention developers are WHO/UNICEF operating through their country offices since these organizations provide global Code leadership/direction. Investigations revealed that UNICEF renders NAFDAC technical and financial support for Code implementation (Monwuba, 2010). No record of WHO involvement was found.

## **Leadership**

FMoH provided leadership for Code issues by formulating required policies. However, providing leadership by adequately resourcing Code implementation and sustaining resource levels for visible impact was lacking. Frequent changes of ministers/leadership at FMoH may be contributory to this. This breeds inconsistencies in policy as successive ministers pursue their unique agendas for achieving health goals. Results revealed a quick succession of 4 Ministers at the FMoH from 2007 to 2011 (NHW, 2011) (Appendix 4.4). This does not augur well either for continuity/completion of their predecessor's agenda or completion of theirs. Leadership was also lacking in provision of technical support, there were no accounts of training/technical support initiated/offered by FMoH on Code implementation. There was a dearth of leadership from civil society organisations (CSOs), professional health associations and other external potential Code advocates who could champion Code implementation with government and the populace. Findings did not reveal any such groups active in championing the cause of Code awareness in Nigeria. These leadership gaps do not make for an enabling Code regulatory service environment.

### **4.1.2. Inter-organizational Environment**

This section deals with the external stakeholders in Code issues and the environment they create for the Code to thrive.

#### **Inter-organizational Networks**

- Cross-sector (Ministries, Departments and Agencies – MDAs)

No cross-sector collaboration was found to exist among MDAs regarding Code implementation beyond meetings of the NTC (Chapter 3, Section 3.5, paragraph 3 details committee membership). From available records the last NTC meeting was held on 24<sup>th</sup> June, 2010 (Annual Report, R&R, 2010).

Feeding bottles and teats/pacifiers (designated products outside NAFDAC's mandate) are within Standards Organization of Nigeria (SON) purview as government's standard setting Body responsible for regulation and control of all items except those mandated to NAFDAC (Akunyili, 2010, p.99). Consumer Protection Council (CPC) is mandated by law to redress unscrupulous consumer exploitation, amongst others (Oluwatola, 2004). Surprisingly, no collaboration exists between NAFDAC and these Agencies on Code implementation; they are not even represented on the NTC.

- Industry (IFM Marketing/Promotional Activities)

Findings showed that several corporations market, import, distribute, and to a small degree, locally manufacture BMS (only Nestle) in Nigeria. Thus majority of BMS is imported. Table 5 shows major IFMs, their Nigerian agents and product brands in Nigeria. They include Nestle, Friesland Foods Holland, Pfizer Nutrition (formerly Wyeth) Ireland, among others.

<b>No.</b>	<b>Name of Manufacturer</b>	<b>Name of Local Representative</b>	<b>Brand(s) of BMS Products</b>
1.	Nestle	Nestle Nigeria Plc	Nestle range of BMS
2.	Friesland Foods Holland	FrieslandCampina WAMCO Nigeria Plc	Friso range of BMS
3.	Pfizer Nutrition (formerly Wyeth Nutritionals) Ireland	Pfizer Global Pharmaceuticals	SMA range of BMS
4.	Abbott Nutrition Ireland	Fareast Mercantile Limited	Similac range of BMS
5.	Nutricia Holland	Fareast Mercantile Plc.	Cow & Gate range of BMS
6.	Fonterra New Zealand	Promasidor Nigeria Limited	Cowbell range of BMS
7.	Nutribio France	Promasidor Nigeria Limited	Cowbell range of BMS
8.	Retail Supermarkets Nigeria (Shoprite)	-	Assorted brands

**Source:** Compiled by Author (from NARPAD/GLSI internal records)

Owing to the long period of Code inertia in Nigeria, IFMs firmly entrenched their marketing/promotional strategies (Monwuba, 2010). Chapter 1, Section 1.5, estimates their potential market size in terms of PHC facilities alone. A UNICEF-sponsored pilot survey to field-test Code monitoring tools was undertaken in 4 zones of Nigeria (Lagos, Onitsha, Kano and Maiduguri) in 2005. Accounts of the results revealed that IFMs were engaged in various

unethical marketing practices such as giving gifts and free BMS samples to health workers and mothers, among others (Table 6). Of IFMs surveyed, 38% engaged in BMS advertising; 75% of the health facilities had entertained promotional visits from BMS marketing personnel (FRCN, 2007; Keri, 2010).

<b>Table 6: Nigeria: Marketing/Promotional Activities of Infant Food Manufacturers/Marketers (Pilot Survey)</b>	
<b>No.</b>	<b>Type of Promotional Activity</b>
1.	Distribution of gifts and free BMS samples to health workers and mothers as incentives for patronage of particular brands
2.	Advertisement of BMS through media houses
3.	Billboard advertisements of BMS in some cities
4.	Distribution of branded growth charts with company names and logos to hospitals
5.	Distribution of leaflets, pamphlets, booklets, posters and T-shirts bearing promotional messages
<b>Source:</b> Adapted from Keri, 2010	

Newer evidence from 2012 showed that the situation remains presently unchanged, in violation of Regulation 16(1) on IFM self-monitoring of marketing practices. Analysis of monitoring reports from 2 locations, Osogbo (small city) and Kaduna (large city), showed IFMs still engaging in Code violations: labelling violations and promotional practices including special shop displays for BMS, distributing promotional items and making direct contact with mothers through delivering lectures (NAFDAC internal records, 2012) (Appendices 4.5 and 4.6). Onyechi and Nwabuzor (2010) confirmed that IFMs still engaged in advertisement of infant formula particularly via television, magazines and posters. Their study revealed that extensive infant formula advertising influenced women's infant-feeding choices considerably, negatively affecting EBF practice.

IFMs sponsor professional health conferences/seminars which present avenues for product promotion. An example was the 'Adequate Infant Nutrition Conference' in December 2008, sponsored by: Nestle Plc., Promasidor, Wyeth Nutrition and Friesland WAMCO (HERFON, 2008). IFMs also organize elaborate new product launches at 5-star hotels, another platform to promote products to health professionals. An example was the 2011 launch of Friso Gold 1 at Lagos Sheraton Hotel. Beyond product promotion, these activities may create conflict of interest (WHA 58.32). NAFDAC, the regulator, attends these events (Personal observations).

Company websites revealed subtle marketing/promotion under the guise of promoting breastfeeding. One example is FrieslandCampina WAMCO (2012) website statements: “despite all the advantages of breastfeeding, you should not feel guilty if you decide to give your baby formula milk. There are good formulas that provide good nutrition and promote growth and development”; “your baby will get all that he needs from breast-milk or an iron fortified infant formula...”. These improper IFM marketing/promotional practices revealed undoubtedly create a negative environment for the Code nationwide.

- Professional Associations/International Organizations

An external stakeholder mapping identified several professional associations and international organizations among stakeholders relevant to Code implementation. (Appendix 4.7). A ‘mini’ external stakeholder analysis was undertaken based on secondary information from online resources, NAFDAC, and authors’ working knowledge and experience of some of the groups. Though a rudimentary, preliminary assessment of the external stakeholder environment, the results were quite revealing. Upon categorization of identified stakeholders based on their degree of power and interest in Code implementation, an interesting matrix emerged with potential Code advocates, particularly the high-power, low-interest groups. Notably, health workers, supposed Code co-implementers, had high-power/low-interest (Appendix 4.8). Besides UNICEF, there was no stakeholder engagement for Code activities beyond attendance at trainings/workshops in some instances.

#### **4.1.3. Consumer Support/Advocacy**

This section also deals with external stakeholders but focuses on their roles for advocacy. From the external stakeholder matrix, local public/consumer interest groups were categorized as ‘high-interest, low-power’ indicative of their potentials as powerful lobby groups/change agents if built up for Code advocacy. From personal work experience, their potentials remain untapped by NAFDAC for Code advocacy, for public awareness campaigns on IYCF and to propagate the Code. Even CPC, the consumers’ watchdog, is ‘low-interest’ and inactive in Code implementation. Successful Code implementation demands contributory efforts from external stakeholders (Orhii, 2010) which was lacking, the supportive environment expected from advocacy was absent.

## **4.2. Inner Context**

Inner contextual factors comprising the intra-organizational characteristics and individual/adopter characteristics will be analysed to identify if they influence NAFDAC's Code implementation.

### **4.2.1. Intra-organizational Characteristics**

This section focuses on NAFDAC organizational factors including Code regulatory processes, and the extent to which they create an enabling environment for effective Code implementation.

#### **Structure**

NAFDAC is headed by a DG who reports to the NAFDAC Governing Council (GC). The Agency has 9 Directorates; 6 technical, 3 service/support directorates. Each Directorate is headed by a Director who reports to the DG (Appendix 4.9 shows NAFDAC's organogram) (Akunyili, 2010). The GC composition is positively skewed towards drug regulatory issues (Appendix 4.10). The last GC was dissolved on 19<sup>th</sup> October 2011 and none has since been inaugurated (NAFDAC internal records).

Relying on observation/knowledge from several years of work experience, NAFDAC structure is a typically bureaucratic civil service setting with strong hierarchy (clear distinction between ranks) and top-down management style. Directives filter down (centralised decision-making) the system with implementers often acting mechanically without understanding the underpinnings of management's directive or importance of public's compliance. Protocol also demands that directives be channelled to regulatory officers according to seniority, irrespective of professional competencies/expertise (Personal observations). The bureaucratic setting negates the ideals of establishing NAFDAC. Its establishment expressed government's desire to more effectively regulate and control food and other regulated products unhindered by bureaucratic obstacles. The then Minister of Health while inaugurating the first GC in 1992 said "NAFDAC as an Agency is being inaugurated today, to give a frontal attack to the health problems arising from foods, chemicals, drugs, medicines and similar regulated products without the inhibition of the civil service setting" (NAFDAC, undated).

Analysis of the directorates showed the technical directorates are structured primarily along functional lines (for example: registration, inspection, enforcement) as opposed to having specialist directorates per product category. For example, there is no Directorate for 'Food and Nutrition' or a



dedicated Code Unit to champion advocacy for, and implementation of, Code issues within NAFDAC.

There exists a strong possibility for lack of cohesion/synergy on Code issues as different Directorates handle different aspects of Code implementation sometimes with overlaps. For example, designated product registration and advertisement monitoring is undertaken by R&R, monitoring and enforcement by Establishment Inspection Directorate (EID) and Enforcement Directorate respectively. Appendix 4.11 shows Directorates, roles in Code implementation and staff strength which stands at 2,174 as at May 2012 (NAFDAC internal records, 2012). Reporting lines are vertical within each Directorate (bottom-up) with no official channels for prompt information dissemination between relevant Directorates because of the hierarchical structure. This presents a challenge for effective Code implementation.

Information available on staff strength of Directorates is not disaggregated by technical or field officers, creating difficulty in determining officers available for regulatory activities, specifically Code implementation. While no evidence has been found of globally recommended number of regulatory personnel/population, information was found for United States Food and Drug Administration (USFDA), also the Chinese and Australian Agencies which will serve as basic comparison (Table 7). When compared, NAFDAC's staff strength/population served can be described as grossly inadequate with a ratio of 1:76,000 against Australia's 1:1,250. This is added to uneven staff distribution across NAFDAC's 36 State offices, 6 zonal offices, 3 special zones and FCT (Abuja). Officers prefer placements in Lagos (operational headquarters) and Abuja (corporate headquarters).

No.	Regulatory Agency	Population served	Staff Strength	Staff strength to Population Ratio
1.	United States Food and Drug Administration (USFDA)	300 million	12,000	1:25,000
2.	Chinese Food and Drug Administration (SFDA)	1.2 billion	70,000	1:17,000
3.	Australian Therapeutic Goods Administration (TGA)	20 million	16,000	1:1,250
4.	Nigeria National Agency for Food and Drug Administration and Control (NAFDAC)	166 million	2,174	1:76,000

**Source:** Adapted from Ojeifo, S. (2012) [Online]. Available from: <http://www.vanguardngr.com/2012/01/how-to-make-nafdac-a-revenue-spinner/> [Accessed 08 August 2012]

## Regulatory Procedures/Activities and Practices

Results are presented stepwise according to the Directorates with a role for Code implementation.

### Registration and Regulatory Affairs Directorate (R&R)

Registration is the entry point for Code implementation going by Section/Regulation 1 of the Legislation/Regulations which state explicitly the mandatory requirement for designated product registration (Appendices 4.1 and 4.2). The Food, Drugs and Related Products Registration Committee (FDRPRC) grants registration approval for products and comprises representation from NAFDAC legal unit and all technical directorates (Akunyili, 2010, p.232). Analysis of registration guidelines and process revealed regulatory activities intended to ensure product safety, quality, wholesomeness and compliance with labelling regulations (documentation, product sample vetting, facility inspection and laboratory analysis) (Madukwe, 2003).

The integrity of the BMS registration process with respect to labelling compliance was assessed by the author. Three brands (4 products) of popular BMS products bearing NAFDAC registration numbers were purchased from retail outlets in Lagos (commercial capital). The selected brands are fairly representative of popular BMS in Nigeria. Nestle NAN was identified by Onyechi and Nwabuzor (2010) as one of the most well known by mothers in Lagos. Products were cross-checked against NARPAD records and confirmed to be genuinely registered products. They were examined for labelling compliance using the Code, national legislation and NAFDAC regulations on marketing of BMS/IYCF. Several labelling violations observed included: illegible information about breastfeeding superiority; using promotional, idealizing logos; 'premiumization' of BMS by making idealizing claims; amongst others. These are suggestive of an ineffective BMS registration process. (Table 8 details the observed violations).

<b>No.</b>	<b>Product Name</b>	<b>Labelling Violation/Remarks</b>
1.	<p><b>*Nestle NAN 1</b> (manufactured by Nestle Nederland)</p> <p>NAFDAC Registration number: 01-0096 Batch number: 12150346AB 21:28 Manufacture date: 3 August 2011</p>	<p>i. Front panel with large, idealizing and promotional logo, a bird feeding her two 'infants' (chicks); mother bird and two baby birds evoking a semblance of mother feeding her children. Contravenes Regulation 15(2) &amp; 15(3) of Marketing of IYCF Regulations 2005.</p> <p>ii. Front panel states that product is "suitable from birth". Until what age? This information is lacking. Regulation states that this information shall be in numeric figures. Contravenes Regulation 15(1)xi of</p>

	<p>Expiry date: 31 August 2013</p>	<p>Marketing of IYCF Regulations 2005.</p> <ul style="list-style-type: none"> <li>iii. Front panel bears "breast-feeding is best for your baby" in small print at the bottom corner (smaller than the print typeset indicating suitability from birth) and with poor contrast of print with background making it obscure. Legislation states that it shall be clearly legible and shall appear conspicuously on the label. Contravenes Regulation 15(1)a of Marketing of IYCF Regulations 2005.</li> <li>iv. Bears information equating the formula to breastmilk: "New Nestle Nan 1 contains 'Protect Start™' a unique combination of protective ingredients; it also helps to activate your baby's natural immune defences in the crucial first months of life". Contravenes WHA 58.32 (2005) and Regulation 20(1) of Pre-packaged Food Labelling Regulations 2005.</li> <li>v. Makes claims because of the addition of **DHA and ***AA "...contribute to the development of brain and vision". Idealising and promotional statement. Contravenes WHA 58.32 (2005) and Regulation 20(1) of Pre-packaged Food Labelling Regulations 2005. An intrinsically deceptive claim which is tantamount to idealising the product as it is impossible that the product offers any added advantage over breastfeeding; conferring a health advantage is a fundamental criterion upon which a product can make a health claim. (IBFAN, 2010).</li> <li>vi. Front panel with conspicuous 'Protect Start' logo insinuating that product confers some protective qualities on infants. Misleading, contravenes WHA 58.32 and Regulation 20(1) of Pre-packaged Food Labelling Regulations 2005.</li> </ul>
2.	<p><b>Nestle NAN 2</b> (manufactured by Nestle France)</p> <p>NAFDAC Registration number: 01-9543 Batch number: 1236080661 01:32 Manufacture date: 24 August 2011 Expiry date: 24 August 2013</p>	<ul style="list-style-type: none"> <li>i. Front panel with conspicuous indication that formula contains DHA. DHA is not listed as an ingredient on nutritional information panel. Contravenes Regulation 15(1)(b)x of Marketing of IYCF Regulations 2005.</li> <li>ii. Front panel with large, idealizing and promotional logo, a bird feeding her two 'infants' (chicks); mother bird and two baby birds evoking a semblance of mother feeding her children. Contravenes Regulation 15(2) &amp; (3) of Marketing of IYCF Regulations 2005.</li> <li>iii. Front panel states that product is suitable "from the 6<sup>th</sup> month"; clearly indicates that it can be offered to the infant upon completion of their 5<sup>th</sup> month as they begin their 6<sup>th</sup> month of life, product claims to be a follow-up formula but is replacing breastmilk in the 6<sup>th</sup> month of infant's life. Contravenes WHA 54.2 (2001) and Regulation 15(1)xi of Marketing of IYCF Regulations 2005.</li> <li>iv. Front panel bears "breast-feeding is best for your</li> </ul>

		<p>baby” in small print at the bottom corner (smaller than the print typeset indicating suitability from the 6<sup>th</sup> month) and with poor contrast of print with background making it obscure. Contravenes Regulation 15(1)a of Marketing of IYCF Regulations 2005.</p> <p>v. Back panel bears information recommending gradual introduction of complementary foods as from the beginning of the 6<sup>th</sup> month of life which breaches the WHO/UNICEF global recommendation of exclusive breastfeeding for 6 months before introducing complementary foods.</p> <p>vi. Makes claims because of the addition of DHA “...contributes to the development of brain and vision”. Idealizing and promotional statement. Contravenes WHA 58.32 (2005) and Regulation 20(1) of Pre-packaged Food Labelling Regulations 2005.</p> <p>vii. Front panel with conspicuous ‘Protect Plus’ logo insinuating conferment of protective qualities to infant. Misleading and in contravention of WHA 58.32 and Regulation 20(1) of Pre-packaged Food Labelling Regulations 2005.</p>
3.	<p><b>Friso Gold 1</b> Infant formula (manufactured by Friesland Foods Holland)</p> <p>NAFDAC Registration number: 01-0459 Batch number: 312283 A 15:43 75 011439 Produced: August 2011 Best Before: August 2013</p>	<p>i. Product makes no statement on the superiority of breastfeeding as required by regulations. Contravenes Regulation 15(1)bxiii of Marketing of IYCF Regulations 2005.</p> <p>ii. Front panel presents the inclusion of DHA and AA in the product in large font size.</p> <p>iii. The words ‘Important Notice’ with the accompanying statement are not clearly legible and conspicuous. Statement reads “breastmilk is the best food for the child...<b>as decreed by the Federal Government of Nigeria</b>”. This carries some level of ambiguity. It leaves room for speculation as to whether the company believes the statement to be true or not.</p> <p>iv. Conveys idealizing and promotional statement about the properties conferred on the product by addition of DHA &amp; AA fatty acids which are valuable for brain development and brain functioning “...which makes Friso Gold 1 a healthy and completely balanced nutritional product”. Misleading and in contravention of WHA 58.32 and Regulation 20(1) of Pre-packaged Food Labelling Regulations 2005.</p>
4.	<p><b>SMA</b> infant formula (manufactured by Wyeth Nutritionals Ireland)</p> <p>NAFDAC Registration number: 01-0431 Batch number: 0C222K07 061795</p>	<p>i. Label does not carry the mandatory statement about breast-milk being the best food for the child as contained in the legislation. Contravenes Section 3(1)b of national legislation.</p>

	Manufactured: 22 February 2010 11:42 Best Before: 21 February 2013	
<p><b>NOTES:</b></p> <ul style="list-style-type: none"> <li>i. Please refer to Section 3 of Marketing (Breast-milk Substitutes) Act and Regulation 15 of Marketing of Infant and Young Children Food and other Designated Product (Registration, Sales etc.) Regulations 2005 in the Appendices for labelling requirements for designated products. NAFDAC - Pre-packaged Food (Labelling) Regulations 2005, Federal Republic of Nigeria Official Gazette (2006) 93(55), pp. B367-372</li> <li>ii. *See Appendix 4.12 for receipts of purchase of infant formula products examined.</li> <li>iii. **DHA (Docosahexaenoic acid), ***AA (Arachidonic acid): both are long-chain polyunsaturated fatty acids (LC-PUFA).</li> </ul> <p><b>Source:</b> Compiled from product label vetting undertaken by author</p>		

On idealizing logos, the author has been present at official NAFDAC deliberations where an IFM (Nestle) claimed that their BMS label ('mother bird and chicks') is a 'universal' presentation therefore cannot feasibly be altered for the Nigerian market and should be registered as presented. From the NAN labels examined, Nestle was apparently obliged with product registration by the regulatory authority. This case is one example of how IFMs use their influence to sway regulatory processes, contrary to prevailing regulations. It is established that in most developing countries, regulators accept inducements from industry to 'look the other way', acting against public interest in furtherance of the interest of the regulated party (Witter *et al*, 2000; Mills and Ranson, 2006). NAFDAC operates within the Nigerian system so is not insulated from the endemic corruption that pervades the society. The labelling 'violations' observed on duly registered BMS products underscore weak aspects of Code regulatory base open to IFM manipulation which will be discussed. Among these are; weak Code knowledge-base, mismatch between Code expertise/specialization and assigned tasks, also susceptibility to IFM power.

#### Establishment Inspection Directorate (EID)

The large scope of EID's work on Code implementation is evident (Appendix 4.11). NAFDAC staff strength has already been roughly assessed as inadequate. This undoubtedly impacts EID's role in Code monitoring, which is just one of several regulatory activities.

#### Ports Inspection Directorate (PID)

Findings revealed Government's removal of NAFDAC from Port operations since October 2011 (Ogbokiri, 2011) effectively excluding Port monitoring

from NAFDAC's Code implementation activities. No PID monitoring report was available for this thesis as Port offices are presently non-operational. However one major finding from earlier PID monitoring activities revealed Code violation regarding product safety and quality. A multinational IFM (Nestle Nigeria) imported nine 40-foot containers of expired skimmed milk powder for manufacture of BMS; expiry dates had been altered which company ascribed as labelling error. The products were destroyed and there was an out-of-court settlement (Akunyili, 2010, p.160).

### Enforcement Directorate

Scant information was available on field activities for Code implementation in all enquiries made to facilitate this thesis. However the prevailing NAFDAC regulatory procedure is that the Directorate investigates cases brought before it for possible prosecution, and undertakes surveillance of shops, factories, warehouses where there is suspicion of illegal manufacture, storage or distribution of regulated products. The Directorate is supported by a permanent squad of armed/investigating police officers for security and cover during operations (NAFDAC, undated). Enforcement therefore has high cost implications. Weak staff strength and budgetary constraints undermine fulfilling enforcement responsibilities and explain the largely reactive approach to enforcement activities which are undertaken mainly on tip-offs (Personal observation). Internally generated revenues (IGR) finance most NAFDAC overhead and capital costs (Akunyili, 2010, p.64). These are revenues raised by NAFDAC from administrative tariffs. Code enforcement is weak judging by inspectors' actions during Osogbo monitoring exercise. Non-compliant products (labels) found at one store were not confiscated; store owner was "briefly enlightened on the Code". Speculation is that those products were NAFDAC-registered hence enforcers felt no justification to confiscate, because similarly non-compliant unregistered products found at another store were confiscated during the same monitoring exercise (Appendix 4.5).

### **Priorities/Goals**

Formulating explicit priorities/goals is crucial to an organization's zeal for their mission and underlying principle (Aarons *et al*, 2011). NAFDAC's vision is 'safeguarding public health' while the mission is 'to safeguard public health by ensuring that only the right quality drugs, food and other regulated products are manufactured, imported, exported, advertised, distributed, sold or used' (NAFDAC, website). The mission statement revealed a striking observation which suggests NAFDAC's priorities towards the

drug/pharmaceutical sector. The changed positioning of 'drugs' before 'food' differs from the traditional listing of NAFDAC regulated products conveyed in the NAFDAC Act, the Agency's name and other official references.

Analysing the composition of NAFDAC GC and leadership (Directors-General) indicates a similar slant towards drug/pharmaceutical sector. The food sector has one GC slot against 4 slots for the pharmaceutical/drug sector and traditionally Directors-General come from a pharmaceutical background. Logically, regardless of NAFDAC regulating 7 product categories, the natural inclination of leadership is prioritization of drug regulatory activities. From personal experience, the huge public outcry over the proliferation of counterfeit drugs is also speculated to contribute to this prioritization.

Review of NAFDAC Strategic Development Plan (2010 – 2015) showed no plan for Code implementation activities. Work-plan for R&R for 2010 and 2011 were also reviewed, none mentioned Code training as required training (unpublished internal documents). From the foregoing, apparently Code implementation (a food/nutrition issue) is not presently a priority issue within NAFDAC. The finding that Code trainings/workshops have been few and far between (sometimes once yearly or none) buttresses this (Appendix 4.13).

## **Leadership**

From personal observations and work experience, leadership for Code implementation is lacking. No champions were identified within NAFDAC who could advocate and mobilize/re-allocate resources from IGR for Code implementation. The benefits of the few Code trainings have not cascaded throughout the Agency as sufficient forums for training other officers have not been provided subsequently. Also Code-trained officers are not strategically deployed (job postings) to guide regulatory decision-making. Actual numbers of Code-trained officers is unclear, however a guesstimate from Appendix 4.13 is that at least 100 officers including all State and Zonal Heads have been trained since 2002.

## **Readiness for Change and Receptive Context**

These concepts are best assessed using qualitative research techniques: questionnaires, focus group discussions, in-depth interviews, among others. This was not achievable due to space constraints. However, as there is not much evidence, the thesis relied on previous events as proxy to analyze NAFDAC's readiness for change and receptive context regarding the Code.

Reports up until 2001 showed a dysfunctional and ineffective NAFDAC. With the same team of regulatory officers under new leadership, the once moribund Agency was revived and evolved into a 'new' NAFDAC (Akunyili, 2010). Chapter 3, Section 3.5, paragraph 3 catalogued activities the 'new' NAFDAC undertook regarding Code implementation. Though few Code trainings were undertaken since 2001, they were non-existent pre-2001 from available information. Going by these, it appears NAFDAC is ready for and receptive to change regarding Code implementation given the right Code leadership.

## **Culture/Climate**

NAFDAC's culture and climate is intertwined with the readiness for change and receptive context which have been shown to thrive under the right leadership. Again qualitative research methods are required for findings in this area. From experience, NAFDAC organizational culture/climate at any point in time mirrors the nature of the leadership and determines the level of commitment to the job. In other words, the presence or absence of exemplary leadership has been shown to be key to NAFDAC's success and is applicable to creating the enabling environment required for Code implementation.

### **4.2.2. Individual Adopter Characteristics**

#### **Adaptability and Attitudes toward Code**

This section also requires qualitative research techniques to assess. This is a limitation of this thesis. It involves the individual/personal characteristics of staff. The proxy assessment used in the earlier section on readiness for change and receptive context is extended here because people make up organizations. It is logical therefore to assume that since NAFDAC has proven receptive to change, by extension it implies that the people who make up NAFDAC are adaptable and have the right attitudes. This has positive implications for adaptability and attitudes toward the Code.

### **4.3. Interconnections**

It is important to analyse the interconnections between outer and inner contexts which underscore the idea that these contexts do not exist in isolation. The external environment created by IFMs' unethical marketing, among others, negatively influences NAFDAC's Code implementation efforts.

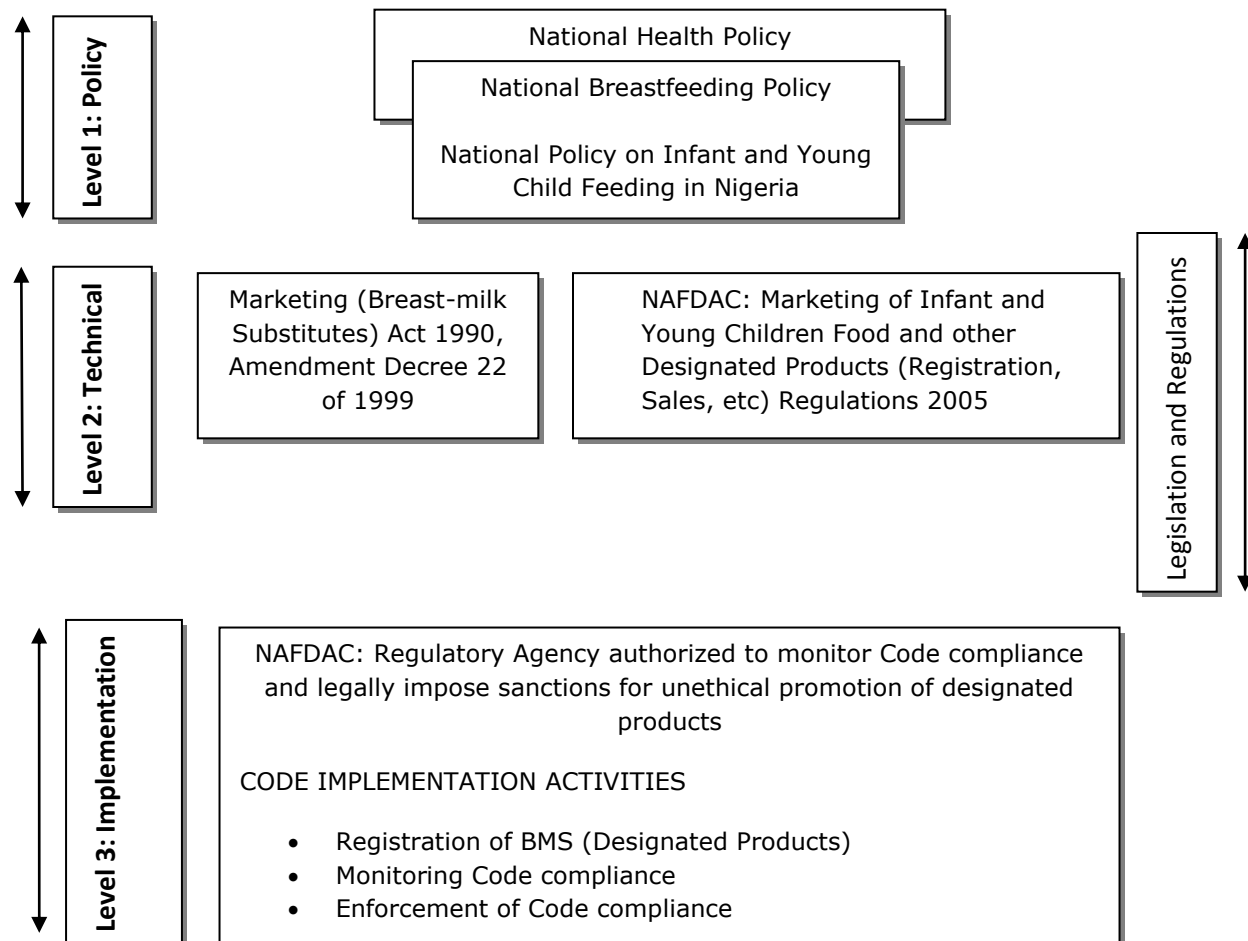


Likewise NAFDAC’s internal environment which fosters regulatory compromise, weak stakeholder engagement and advocacy efforts, among others, negatively influences the external environment resulting in few advocates and ‘enabling’ environment for IFMs’ continued violations.

#### 4.4. Schematic Summary of Findings

To summarize this chapter, a schematic representation is presented to capture the different levels and aspects (identified from thesis findings) in regulation of the marketing of BMS in Nigeria, from policy level to implementation level. (Figure 5).

**Figure 5: Nigeria: Schematic Representation of the Regulation of Marketing of Breastmilk Substitutes**



Source: Author

## **Chapter 5: 'Best Practices' in Code Implementation (Country Experiences)**

This chapter looks at 'best practices' from around the world highlighting different perspectives and approaches to Code implementation.

### **5.1. Outer Context (Regulatory Service Environment)**

In *Botswana*, the regulations incorporate some creative provisions to encompass their unique social framework (ICDC, 2005a). The Marketing of Foods for Infants and Young Children Regulations 2005 is explicit in proscribing practices that create a relationship between IFMs and breastfeeding; it bans health workers from accepting gifts, financial aid, fellowships, research grants, study tours, sponsorships for attending conferences from IFMs, amongst others. There is however a proviso on research activities with written approval from the health research authority. The regulation is also explicit in its designation and role for monitors (independent) in regulations 4 and 5. These should be persons trained on monitoring Code violations and the regulations; they are required to submit monitoring reports to the National Food Control Board. Also all health workers are mandated to keep records of violations within their premises for submission to designated monitors and authorized officers (Board officials) (GOB, 2005).

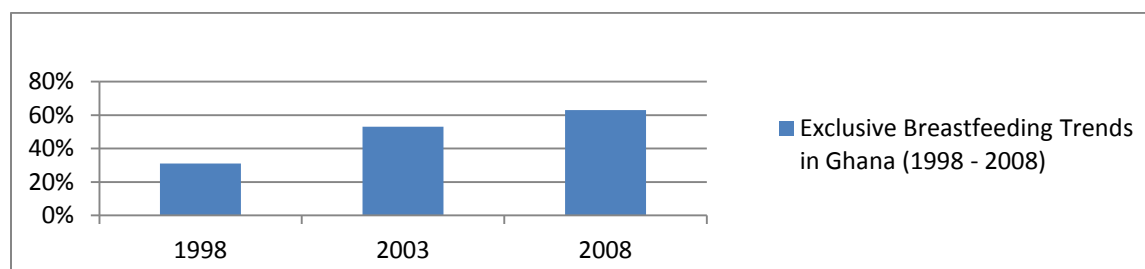
*India* presents a similar, though more stringent, example with Botswana in their Infant Milk Substitutes (IMS) Act 1992 (as amended 2003) in prohibiting IFMs from offering gifts/sponsorships to health workers (without any proviso on research activities). The scope is also widened beyond health workers and includes professional health associations (Jain, 2003; IBFAN/ICDC, 2010). The Act provides for independent monitoring by 4 voluntary organizations (BPNI, 2007). Further, infant formulas are required to bear on the label's central panel, prominent caution on the likely dangers of artificial feeding (UNICEF, 2012b).

Citing ICDC (2000), Alabi *et al* (2007) report that *Ghana's* Breastfeeding Promotion Regulations 2000 LI 1667 is among the strongest national legislations regulating the marketing of BMS, upon independent analysis. Apparently Ghana has maintained this ranking. IBFAN/ICDC (2009) recent categorization of countries according to national Code measures implemented does place these 3 countries (Ghana, Botswana and India) in category 1. These are countries rated highest in implementing most Code provisions as law.

Ghana's Breastfeeding Promotion Regulations 2000 LI 1667 implements all code provisions and relevant WHA resolutions in effect when it was drafted.

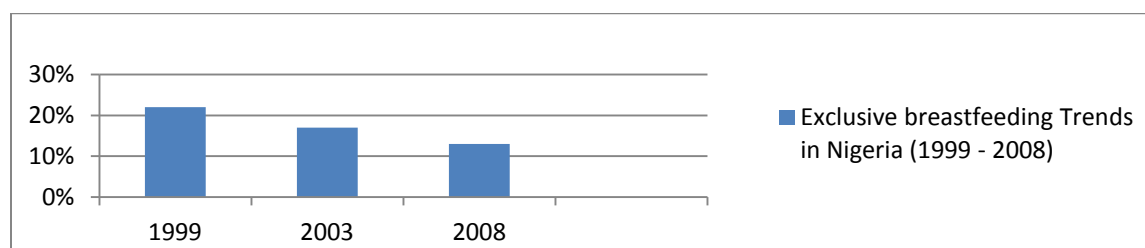
A recent Code monitoring exercise inferred declining sales of infant formula which could be attributable to the regulation's effect on the promotional activities of IFMs (Alabi *et al*, 2007). This could also be related to Ghana's markedly improved EBF levels from 31% in 1998, increasing over 20% to 53% by 2003 and 63% by 2008 (GDHS, 2008; WHO/UNICEF 2012) following the introduction of Breastfeeding Promotion Regulations in 2000. This contrasts with Nigeria which rather showed a downward trend with introduction of regulations in 2005.

**Figure 6: Exclusive Breastfeeding Trends in Ghana (1998 - 2008)**



Source: Adapted from GDHS 2008, WHO/UNICEF 2012

**Figure 7: Exclusive Breastfeeding Trends in Nigeria (1999 - 2008)**



Source: Adapted from NPC 2004, NPC 2009a

## 5.2. Outer Context (Consumer Support/Advocacy)

In *Ghana*, the commitment and activities of an NGO, Ghana Infant Nutrition Action Network (GINAN), in championing the Code, in advocacy and engaging stakeholders was instrumental in keeping Code issues on the national agenda and birthing the national Breastfeeding Promotion Regulations 2000 LI 1667. Beginning in the 1980s with a sensitization campaign for the populace, GINAN persistently provided information, lobbying government, health workers and IFMs (Sokol *et al*, 2007).

Examples from *South Africa* and *Canada* showcase the achievements of advocates/advocacy in foiling attempts by IFMs to influence health workers in infant and young child health through sponsoring professional events. The potential danger is conflicts of interest arising from such sponsorships

highlighted in resolutions WHA 58.32 (2005) and WHA 61.20 (2008) (Appendix 3.2). On 3 occasions (involving Nestle in South Africa, Mead Johnson and Abbott Nutrition in Canada), planned sponsored events for health workers were cancelled due to the vigilance and prompt actions of breastfeeding advocates (ICDC, 2012).

### **5.3. Inner Context (Intra-organizational Characteristics)**

#### **Structure**

In *Ghana*, the Code is enforced by the equivalent of NAFDAC, the Food and Drugs Board (FDB). Structurally the FDB is organized along specialization lines having a stand-alone Food Division (Directorate) with specialized units, a dedicated Food Registration Committee and food post-marketing surveillance unit (FDB, 2012). The Governing Board has balanced representation from the regulated sectors and the consumer/public interest slots are gender-sensitive (See Appendix 5.1 for composition). With this balanced Governing Board and specialization-oriented structural organization, FDB appears well-positioned for informed regulatory decision-making which will also impact Code implementation with voice for all regulated sectors in the Governing Board to guide prioritization.

#### **Regulatory Procedures/Activities and Practices**

##### Monitoring

For effective Code implementation at the national level, it is required that the legislative instruments governing the marketing of breast-milk substitutes provide for monitoring (Sokol *et al*, 2007).

For *Ghana*, instituting an independent monitoring entity has proven invaluable. The National Breastfeeding Promotion Regulations Coordinating Committee (launched in 2004) forwards monitoring reports with recommendations to the FDB which imposes sanctions. The Committee coordinates Code monitoring activities nationwide and independently establishes if and how violations of the regulations are occurring (Sokol *et al*, 2007).

##### Enforcement

*Botswana* not only has strong Code regulations but they are also enforced as is illustrated by the following event. In responding to an IFM request for permission to sponsor a workshop, Ministry of Health (MoH) stated the relevant provisions of the regulations and WHA 58.32 (2005) cautioning company against conflicts of interest. In granting the permission, MoH

resolved that health workers' should not receive IFM sponsorship for attendance and practices which might create a relationship between the IFM and breastfeeding would be disallowed. The IFM cancelled the event thereafter (ICDC, 2007).

In the *Dominican Republic*, Code enforcement is a strong point judging by the actions of the responsible authority, *Comision Nacional Lactancia Materna* (CNLM). They were resolute in their refusal to grant registration for an infant formula product bearing the same brand name as the company's other products. This was to eliminate indirect promotion of the formula under the guise of promoting the other products bearing the same brand name. CNLM mopped-up the products from circulation. Protests by the company to the Ministry of Trade and Industry seeking redress did not weaken CNLM's resolve; the company eventually withdrew and conceded to re-labelling their infant formula range (ICDC, 2010).

Another example is from *Bahrain* on enforcement resulting from advertisement monitoring. Pfizer-Wyeth's advertisement for growing-up milk product was also subtly advertising their infant formula and follow-on formula within the same 'premium' range. Pfizer Bahrain was issued official caution by MoH with photographs of the violating advertisement with a directive to withdraw it within a week or face sanctions. Company responded by defending their violating advertisement as being compliant with Bahraini Decree No. 4 of 1995 on the Control of the Use, Marketing and Promotion of Infant Milk Substitutes. MoH remained resolute issuing Pfizer an ultimatum – 2 weeks within which to comply or face imprisonment and fine for the stipulated time/amount or both penalties. Pfizer complied after 4 days (ICDC, 2012).

In *Bangladesh*, Nestlé's 'mother bird and chicks' logo does not appear on formula labels because the relevant authority enforced the law prohibiting idealizing images (IBFAN/ICDC, 2010). Code enforcement officials at a *Ghana* Port barred access to Nestlé's Lactogen and Nan formula bearing company's 'mother bird and chicks' logo (ICDC, 2005b).

In *Papua New Guinea*, though a country with few provisions law, there is firm control over the sale of feeding bottles, teats, cups and dummies (UNICEF 2012b).

In *Iran*, importation and sale of BMS is undertaken by government and prescriptions are required for sale. Containers mandatorily bear generic labels; pictures or promotional messages are prohibited on labels (UNICEF, 2012b).

These are examples of achievements made when regulators/enforcers stand their ground and strictly enforce the Code.

## Chapter 6: Discussion

This chapter discusses factors considered to influence NAFDAC's Code implementation in Nigeria and uses best practices from other countries, where available, to anchor the discussion which is organized using the outer and inner conceptual framework contexts as guide. The final section discusses the conceptual framework retrospectively.

### 6.1. Influence of Regulatory Service Environment and External Stakeholders on NAFDAC's Code Implementation

For Nigeria, lack of legislative provision for independent Code monitoring is considered a most significant gap as it legally precludes this activity from being undertaken. Ghana has implemented this provision with apparently positive results (Alabi *et al*, 2007) so have Botswana and India (GOB, 2005, BPNI, 2007). Nigeria can emulate Botswana and India in aligning regulations to prevailing national social frameworks (vulnerabilities of the Nigerian context) and provide legislative backing to ban regulators from attending IFM product launches and receiving gifts from IFMs. These activities tend to create possibilities for conflicts of interest, compromising decision-making and adversely affecting Code implementation. Ambiguities identified (such as silence on NAFDAC's position on free/low-cost supplies to the healthcare system - Regulation 7.1) in some aspects of national legislation/regulations present flexibility for speculative interpretation and create more opportunities for Code violations.

Inadequate federal funding to NAFDAC is also a major setback for Code implementation as the Agency grapples with juggling several regulatory activities within the confines of limited funds. This finding illustrates that despite government's commitment in formulating policies that integrate Code provisions, without resourcing the implementation, these policies and the legislative instruments through which they operate might as well be non-existent. This finding is consistent with Sokol *et al* (2007); the implementing authority requires adequate funding to effectively undertake its responsibilities of monitoring and enforcing compliance with national laws. It is unclear from findings how much is allocated for Code implementation, either from federal budget or IGR. However, considering that Code activities are not a NAFDAC priority, whatever is made available is probably inadequate for effective Code implementation. This is apparent from continued Code violations. The regulatory burden on NAFDAC for Code implementation regarding the scope and scale of activities is considered huge. Raising IGR for Code implementation by increasing administrative

tariffs (registration costs for example) is an option for NAFDAC but might have negative consequences on availability/accessibility of designated products for those for whom it is indicated, contrary to the Code's intent (WHO, 1981) as increased costs to IFMs will be borne by the consumer. Ghana's institution of an independent monitoring body presents an option for shifting this cost burden away from the regulatory/implementing authority that may work for Nigeria.

The previous paragraph interconnects with FMOH's leadership from the outer context. FMOH lacks consistent leadership required for taking ownership of the entire policy process and driving policy (Code) implementation to visible outcomes. FMOH leadership is vital for advocacy with Federal Ministry of Finance (FMF), National Planning Commission (NPC), development partners and external stakeholders to rally support for increased funding for policy (Code) implementation. Lack of representation from FMF and NPC in the NTC is considered an FMOH leadership gap and missed opportunity for obtaining their buy-in for Code implementation. Leveraging their power (Appendix 4.8) presents opportunities for high-level representations to the Federal Executive Council (cabinet of ministers) emphasizing linkages between effective Code implementation and improved EBF rates, child survival, achieving MDG4 and national development to elicit support for adequate policy (Code) funding. Also non-membership of SON and CPC in the NTC is a major flaw recalling their potentially vital roles for Code implementation.

The external stakeholder environment is unfavourable. Absence of collaboration between NAFDAC and SON on Code implementation has far-reaching consequences. Feeding bottles, teats/pacifiers are essentially excluded from NAFDAC's Code implementation activities though they are also subject to marketing/promotion like BMS (as NAFDAC has no mandate over these products). Companies, therefore, apparently have liberty to violate the Code on this aspect not covered by regulatory oversight since SON, with the mandate for feeding bottles, teats/pacifiers, is not involved in Code implementation/monitoring. This situation however links with adequate capacity for Code monitoring/enforcement as sanctions can still be placed on violators, regardless. Continual inappropriate marketing activities (advertising) of IFMs negatively influences mothers' infant-feeding choices as highlighted by Onyechi and Nwabuzor (2010). IFM sponsorship of professional health conferences and organizing of new product launches in Nigeria present opportunities for conflicts of interest in Code implementation. Given Nigeria's endemic corruption (USAID, 2008), this aspect is important as NAFDAC regulators attend these functions therefore are vulnerable to regulatory capture on account of conflicts of interest. Botswana has been shown to enforce their regulations on IFM sponsorship (ICDC, 2007). For Nigeria the solution to mitigating regulatory capture may lie in adopting Botswana's example of declining IFM sponsorships to

conferences in addition to banning attendance of product launches and receiving of gifts as inducements from IFMs. India's example of an outright ban (opposed to declining offers of sponsorship) might even work better for the Nigerian context. The benefits of having health workers as effective Code co-implementers cannot be overemphasized for the expected boosts in breastfeeding practices. Negative consequences for mother and child are inherent in health workers' apparently 'low-interest' in Code implementation observed from stakeholder analysis. This is considering their influential role ('high-power') in infant-feeding choices of women they see during ANC, births, post-natal care and vaccinations. These are missed chances for achievable positive impact in proper IYCF from their contributions.

The power of potential advocates is also not leveraged by NAFDAC to positively stimulate the external environment for Code implementation. The untapped power is vast with several identified potential advocates particularly the local public/consumer interest groups, professional health associations, health workers and media (Appendix 4.8). These are missed opportunities as Code champions are considered to have strong leadership roles in situating Code issues constantly in the national consciousness. This is well illustrated by GINAN's achievements in Ghana (Sokol *et al*, 2007). Examples from South Africa and Canada typify strong leadership from vigilant breastfeeding advocates (ICDC, 2012) and can be applied in Nigeria to foil IFMs' unethical marketing. However, it entails strong leadership and commitment from potential advocates to mobilise resources and build-up for Code activities. Also, does NAFDAC have the funds required to leverage these groups? Organize Code trainings, sensitization workshops? A viable option might be to seek financial assistance from UNICEF for advocacy/sensitization programmes, being the development partner that has been supportive of NAFDAC's Code implementation capacity-building.

## **6.2. Influence of NAFDAC's Organizational Characteristics (including regulatory mechanisms) on Code Implementation**

### Structure

With respect to Code regulatory activities, NAFDAC's hierarchical structure where directives are channelled by seniority, not expertise could be considered a leadership gap in failing to use Code expertise already built within NAFDAC to regulatory advantage and is tantamount to poor use of available resources.

### Regulatory Procedures/Activities and Practices

From work experience in R&R, labelling violations on registered BMS products, usually resulted from ineffective product registration where



products with non-compliant labels were registered. Several likely reasons for ineffective BMS registration are discussed. From the Nestle BMS idealizing logo case, one reason could be NAFDAC succumbing to pressure from multinational IFMs to register non-compliant products, meaning foregoing stricter regulation and control of designated products to the detriment of better Code implementation for public health gains. This is tantamount to regulatory capture where the regulatory authority abandons their role of acting in the public interest for the interest of the regulated (Mills and Ranson, 2006, p.526). Bangladesh example refutes Nestlé's claim about the idealizing logo of 'mother bird and chicks' being 'universal' because it has disappeared from formula labels in Bangladesh (IBFAN/ICDC, 2010) but remains on Nigerian labels, making a statement about Nestlé's differential application of Code provisions. Apparently it was not about unchangeable 'universal' labels as claimed but about Nestle finding the regulatory environment conducive to Code violations. This speaks volumes about Nestle and corporate social responsibility in taking advantage of weak national enforcement of Code regulations.

'Street-level bureaucracy' in policy (Code) implementation is another possible reason for ineffective BMS registration with particular reference to labelling lapses ('violations') permitted during registration process. It is speculated that all such Code implementation decisions permitting labelling lapses (registration decision-making) are based on implementers' regulatory discretion and inaccurate interpretation of Regulation 15(2), negating the spirit of the Code. Wong (2007) reviewing Lipsky (1980) on 'street-level bureaucracy' presented Lipsky's views about how policy implementers at the crossroads of responsiveness to clients and proper policy implementation interpret policies according to their discretion. Ghana's FDB with specialist Food Directorate presents possibilities for mitigating wrong interpretations which can be considered for Nigeria. The idea is that such a Directorate would be the natural deployment post for Code-trained officers, the Code being a food/nutrition issue, thereby ensuring that, (as much as possible, barring other confounding issues), interpretations made on Code implementation and BMS registration align with the Code's spirit.

Another challenge enabling the registration of non-compliant BMS products is inadequate numbers of Code-trained personnel, and when available, not assigned Code-related work. Therefore considering the labelling violations revealed on registered BMS products examined, there is a likelihood that regulatory officers thrust with the responsibility of making BMS registration approval decisions lack requisite Code knowledge. According to Sokol *et al* (2007), experiences from West and Central African region revealed that personnel charged with enforcing national Code legislation/measures need to possess a sound knowledge-base of nutrition, infant-feeding and child

survival strategies combined with a thorough understanding of their linkages to the Code. Ineffective BMS registration evidenced from labelling violations on the BMS products examined corroborates those experiences in the mismatch between Code expertise/specialization and assigned duties/roles. Consequently, terming these registered BMS products with labelling lapses as 'violations' becomes difficult since the products were duly registered by NAFDAC in the 'violating' package presentation and the companies hold valid registration licences. Regardless, this should not hamper NAFDAC inspectors/monitors from imposing sanctions on 'violators' when such products are found in circulation, though apparently it does (Appendix 4.5). The implication is that Code violators remain undeterred and continue violations. Ineffective BMS registration calls to question the entire BMS registration approval process and FDRPRC membership. Ghana FDB's dedicated Food Registration Committee presents a possible alternative for mitigating ineffective BMS registration. There is increased likelihood that such a food/nutrition committee will be more knowledgeable on Code issues. Beyond the knowledge-base of regulatory decision-makers, the views expressed by Witter *et al* (2000) and Mills and Ranson (2006) on industry's inducement of regulators might also influence the final registration approval decision-making but this is not established.

Labelling 'violations' on BMS products duly registered by NAFDAC corroborates accounts of power wielded by industry on Code implementation as has been alluded to in several of the country examples. Regrettably, in all the BMS products examined by this thesis, NAFDAC was apparently unable to uphold the provisions of her prevailing regulations (Regulation 15) for labelling of designated products (Appendix 4.2), perhaps buckling under IFM pressure to grant registration approval to non-compliant products. This is unlike the Dominican Republic (ICDC, 2010) where Code implementers stood their ground against the IFM with positive Code implementation outcome.

Monitoring is vital if legislation is to be effective (Sokol *et al*, 2007). The scope and scale of Code monitoring is vast; monitoring all IFMs' marketing practices, monitoring health workers and health-care facilities for complicity with IFMs in Code violations, monitoring product labelling compliance. Given Nigeria's large size/population, estimated numbers of health facilities, pharmacies, health workers and significant wholesale/retail trade, one might begin to appreciate the enormity of NAFDAC's task in Code implementation. Also when matched against inadequate human resources (both in numbers and capacity for Code-implementation) and funds. It becomes obvious that Code regulatory oversight functions overwhelm the Agency and independent Code monitoring as obtains in Ghana (Sokol *et al*, 2007) is required to join forces with NAFDAC. Independent Code monitoring by NGOs fills the vacuum created by governments when Code monitoring is not prioritized (Alabi *et al*, 2007) as has been shown to be NAFDAC's case. Botswana and India with

legislative provisions for independent Code monitors represent a good starting point, workable for Nigeria as regulations drafting falls under NAFDAC purview. Ghana's Monitoring Committee provides useful insight. Being independent, it presumably undertakes monitoring activities unhindered by FDB whose role centres on imposing sanctions (enforcement). Essentially this addresses issues of regulatory capture that could occur during Code monitoring exercises by the regulator. However the challenge with this in Nigeria's context is ensuring the integrity of the independent monitoring committee given the endemic corruption. The effect of NAFDAC's removal from Port monitoring/enforcement activities on the influx of non-compliant BMS may probably go unnoticed. The example of Ghana Port officers (Sokol *et al*, 2007) buttresses the benefits of restricting free Port access considering that most BMS in Nigeria are imported.

Enforcement of legislation is critical for legislation to be useful (Sokol *et al*, 2007). The challenges of Code enforcement are even more than for monitoring being more expensive (requiring police squads) and still plagued by same issues of inadequate personnel and budgetary constraints. Given the amount of NAFDAC regulatory activities competing for IGR weighed against continual IFM violations, possibly internal funding for successful Code enforcement is inadequate to deter IFMs hence the continued violations. However enforcement examples from Botswana and Bahrain reliant on officers' commitment are options for Nigeria and a take-off point which is not capital-intensive. Overall, Ghana's experience with enforcing their BMS regulations is an example for Nigeria to understudy and emulate for its contributions to higher EBF levels.

In closing, various perspectives on Code implementation successes from other countries offer a suite of feasible options for Nigeria for a multi-pronged approach to effective Code implementation.

### **6.3. Conceptual Framework in Retrospect**

It is unclear whether the conceptual framework has been previously validated having just been published in 2011. Nonetheless, the adapted framework proved a practical diagnostic tool for analysis of influencing factors though a shortcoming was observed. The healthcare system is recognized in the Code as a major avenue of IFMs reaching mothers either directly or indirectly through health workers (WHO, 1981). The framework does not allow an analysis of the effect of healthcare systems and health workers on NAFDAC's Code implementation beyond mentioning them regarding IFMs' Code violations and in the external stakeholder analysis. Retrospectively, the author would include healthcare systems/health workers as a factor under 'inter-organizational networks'. Being NAFDAC's natural allies in Code implementation it would be useful to understand, from their perspective, what influences their reactions to IFMs' unethical marketing.

## **Chapter 7: Conclusions and Recommendations**

### **7.1. Conclusions**

The thesis analyzed factors operating in NAFDAC's outer and inner context and identified several as major impediments influencing NAFDAC's regulatory capacity for Code implementation in Nigeria in accordance with legislation/regulations.

In the outer context, national IYCF policies incorporating Code implementation are formulated, however leadership for policy (Code) implementation, funding and the legal platform are inadequate. Besides legislative gaps identified, there were inadequate legislative provisions to suit Nigeria's social framework to guard against regulatory capture by IFMs. Generally, the environment created by external stakeholders, particularly the IFMs, is unfavourable coupled with a dearth of Code champions and advocacy efforts for effective Code implementation.

In the inner context, the major impediments to Code implementation were identified under regulatory procedures/activities and practices with ineffective BMS registration as the foremost influencing factor. BMS products are already non-compliant even before marketing/promotion begins. Weak capacity for proper Code monitoring and enforcement are also major barriers identified. Other factors include compromise of established Code regulations/policies/procedures probably resulting from regulatory capture, inadequate numbers of Code-trained personnel, and mismatch between professional competencies and assigned tasks.

Best practices from other countries did provide some feasible alternatives that can be practiced in Nigeria. Most notable among these is the provision for independent Code monitoring implemented in Ghana since 2004, also in Botswana and India, with the latter two making legal provisions adapted to their country contexts.

### **7.2. Recommendations**

To make positive strides towards achieving effective Code implementation, the following recommendations are proposed to health policy-makers and NAFDAC management, some for the short-term, others long-term.

#### **Government (Policy-makers)**

1. FMoH to take up leadership role to drive the policy process to policy (Code) implementation by initiating and sustaining advocacy efforts with FMF, NPC, development partners and external stakeholders to rally support for increased funding to fully implement IYCF policies (which incorporate Code implementation).

2. FMoH to increase membership of National Technical Committee on the Code to include FMF, NPC, SON, CPC, FMWA and Federal Ministry of Education to create opportunities for more advocacy on Code implementation and secure their collaboration particularly FMF, NPC, SON and CPC.

## **NAFDAC Management**

1. Review FDRPRC membership to include Code specialists at registration approval meetings to mitigate ineffective BMS registration as a first step.
2. Mobilize resources from development partners/international NGOs (UNICEF, WHO, IBFAN, others) through advocacy for increased and sustained capacity-building and training efforts to equip more regulatory officers for Code implementation.
3. Initiate advocacy with external stakeholder groups, particularly those categorised as 'high-power, low-interest' based on preliminary analysis undertaken, to gain their support, cooperation and collaboration as co-complementers of the Code and in propagating it nationwide. This is a short-term measure until research (recommendation 7) reveals clearer stakeholder engagement mechanisms.
4. Special advocacy with local media practitioners to adopt a 'name and shame' strategy and publish information on IFMs' violations in national media. Over 100 are already Code-trained, this is feasible in the short-term.
5. Publish IFMs' violations from NAFDAC Code monitoring exercises in NAFDAC's Consumer Safety Bulletin as a 'name and shame' strategy and means of sensitizing the public about the Code. Short-term and feasible being within NAFDAC's immediate control.
6. Update Regulations to cover identified gaps, align with prevailing national social frameworks (the Nigerian context), that is, provision for independent Code monitoring, among others and thereafter undertake biennial reviews to keep Regulations current with new relevant WHA resolutions or new trends in IFMs' marketing practices observed through monitoring. Expedient and achievable short-term as Regulations were made under NAFDAC's Act.
7. Commission the Planning, Research and Statistics Directorate to commence action research to deepen preliminary external stakeholder analysis to provide a clearer identification of 'allies' and 'threats' to Code implementation to inform stakeholder engagement.
8. Establish a Code Centre of Excellence in NAFDAC to pool Code-trained officers for efficiency in Code implementation and decision-making. This is long-term requiring funding, more Code-trained personnel and support staff.

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## **Appendices**

### **Appendix 1.0: The Millennium Development Goals**

- MDG1:** Eradicate extreme poverty and hunger
- MDG2:** Achieve universal primary education
- MDG3:** Promote gender equality and empower women
- MDG4:** Reduce child mortality
- MDG5:** Improve maternal health
- MDG6:** Combat HIV/AIDS, malaria and other diseases
- MDG7:** Ensure environmental sustainability
- MDG8:** Develop a global partnership for development

**Source:** The Millennium Development Goals Report 2011

## Appendix 1.1: Importance of Breastfeeding

### Q. Why is breastfeeding Important?

Breastfeeding is unparalleled in providing the ideal food for infants. Breast milk is safe, clean and contains antibodies which help protect the infant against many common childhood illnesses.

The protection, promotion and support of breastfeeding rank among the most effective interventions to improve child survival. It is estimated that high coverage of optimal breastfeeding practices could avert 13% of the 10.6 million deaths of children under five years occurring globally every year. Exclusive breastfeeding in the first six months of life is particularly beneficial, and infants who are not breastfed in the first month of life may be as much as 25 times more likely to die than infants who are exclusively breastfed.

Positive effects of breastfeeding on the health of mothers and infants are observed in all settings. Breastfeeding reduces the risk of acute infections such as diarrhoea, pneumonia, ear infection, haemophilus influenza, meningitis and urinary tract infection. It also protects against chronic conditions in the child such as allergies, type I diabetes, ulcerative colitis, and Crohn's disease. Breastfeeding promotes child development and is associated with higher IQ scores in low-birth-weight babies. Breastfeeding during infancy is associated with lower mean blood pressure and total serum cholesterol, and with lower prevalence of type-2 diabetes, overweight and obesity during adolescence and adult life.<sup>2</sup>

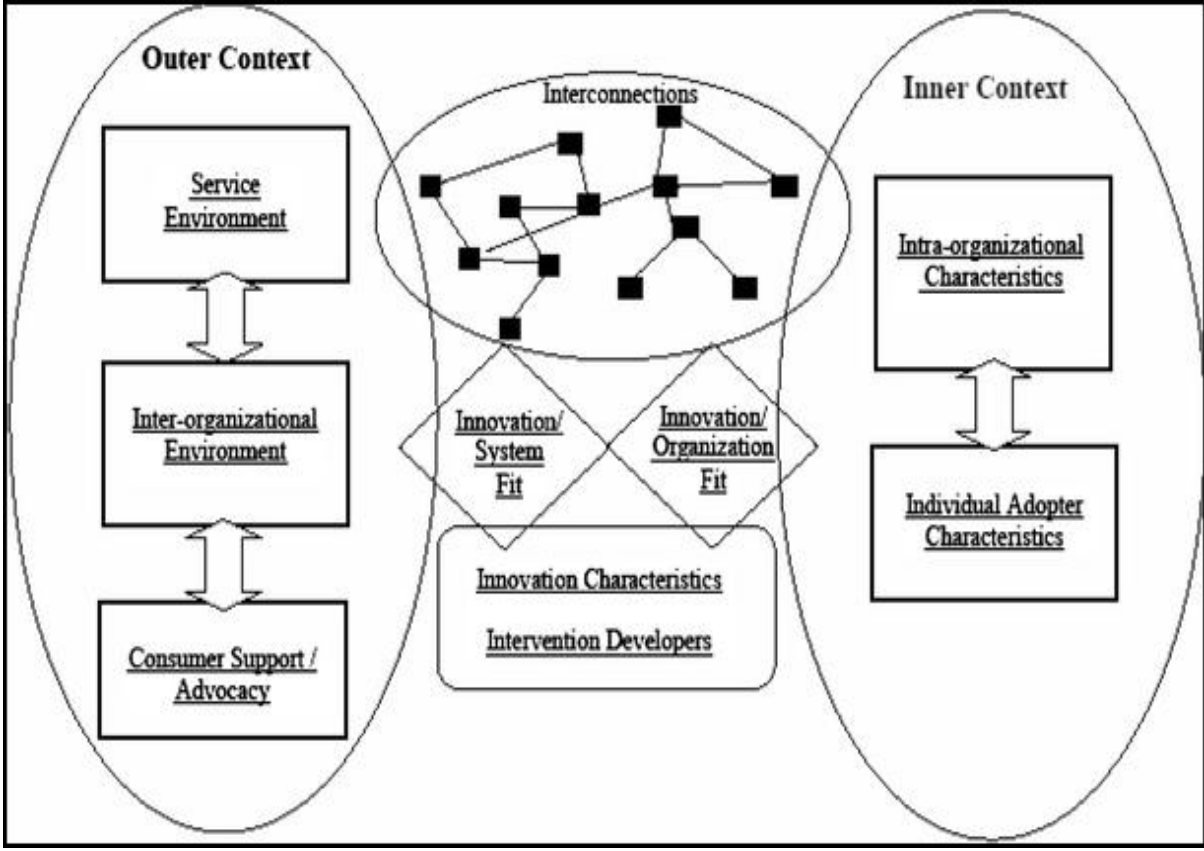
Breastfeeding delays early return of fertility in the mother and reduces her risk of postpartum hemorrhage and breast and ovarian cancer.

Interventions to improve breastfeeding practices are cost-effective and rank among those with the highest cost-benefit ratio. The cost per child is low compared to that for curative interventions.

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**Source:** WHO (2008b) The International code of marketing of breast-milk substitutes: frequently asked questions. [Online]. Available from: [http://whqlibdoc.who.int/publications/2008/9789241594295\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241594295_eng.pdf) [Accessed 17 June 2012].

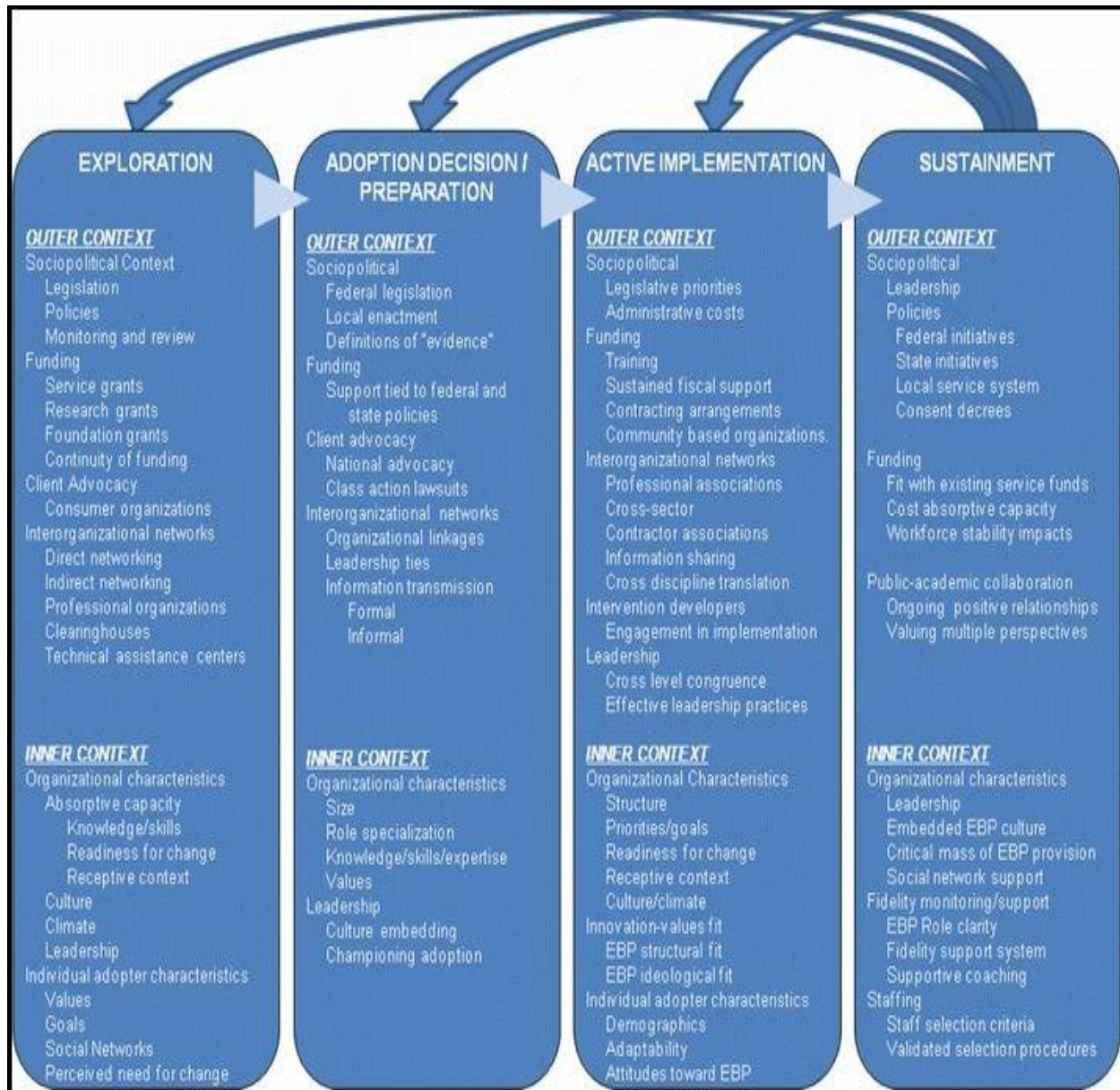
**Appendix 2.1: Original Framework 'A': Conceptual Model of Global Factors Affecting Implementation in Public Service Sectors**



Source: Aarons *et al*, 2011



## Appendix 2.1: Original Framework 'B': Conceptual Model of Implementation Phases and Factors Affecting Implementation in Public Service Sectors



Source: Aarons *et al*, 2011

## **Appendix 3.1: Articles of the International Code of Marketing of Breastmilk Substitutes**

### *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 bottle-fed 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 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	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 to 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 bottle-feeding 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 has 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 breast-milk 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.

**Source:** WHO, 1981



## Appendix 3.2: Summary of WHA Resolutions Adopted Subsequent to the Code

**These recommendations by the Assembly have the same legal status as the Code, clarifying and extending certain provisions. For Code implementation, both Code and resolutions are equally relevant.**

Year	Number	Resolutions
1981	WHA34.22	<ul style="list-style-type: none"> <li>• Code overwhelmingly adopted by WHA, (118 in favour, 1 against, 3 abstentions)</li> <li>• Stresses that adoption and adherence to the Code is a minimum requirement. Member States are urged to implement the Code into national legislation, regulations and other suitable measures.</li> </ul>
1982	WHA35.26	<ul style="list-style-type: none"> <li>• Recognises that commercial promotion of breastmilk substitutes contributes to an increase in artificial feeding and calls for renewed attention to implement and monitor the Code at the national and international levels.</li> </ul>
1984	WHA37.30	<ul style="list-style-type: none"> <li>• Requests the Director-General to work with Member States to implement and monitor the Code and to examine the promotion and use of foods unsuitable for infant and young child feeding.</li> </ul>
1986	WHA39.28	<ul style="list-style-type: none"> <li>• Urges Member States to ensure that small amounts of breastmilk substitutes needed for the minority of infants are made available through normal procurement channels and not through free or subsidized supplies.</li> <li>• Directs attention of Member States to the following: <ol style="list-style-type: none"> <li>1. any food or drink given before complementary feeding is nutritionally required may interfere with breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period.</li> <li>2. practice of providing infants with follow-up milks is "not necessary".</li> </ol> </li> </ul>
1988	WHA41.11	<ul style="list-style-type: none"> <li>• Requests the Director-General to provide legal and technical assistance to Member States in drafting or implementing the Code into national measures.</li> </ul>
1990	WHA43.3	<ul style="list-style-type: none"> <li>• Highlights the WHO/UNICEF statement on "Protecting, promoting and supporting breastfeeding: the special role of maternity services" which led to the Baby-Friendly Hospital Initiative in 1992.</li> <li>• Urges Member States to ensure that the principles and aim of the Code are given full expression in national health and nutrition policy and action.</li> </ul>
1994	WHA47.5	<ul style="list-style-type: none"> <li>• Reiterates earlier calls in 1986, 1990 and 1992 to end</li> </ul>

		<p>“free or low-cost supplies” and extends the ban to all parts of the health care system, effectively superseding the provisions of <i>Art. 6.6</i> of the Code.</p> <ul style="list-style-type: none"> <li>• Provides guidelines on donation of breastmilk substitutes in emergencies.</li> </ul>
1996	WHA49.15	<ul style="list-style-type: none"> <li>• Calls on Member States to ensure that: 1. complementary foods are not marketed for or used to undermine exclusive and sustained breastfeeding; 2. financial support to health professionals does not create conflicts of interest; 3. Code monitoring is carried out in an independent, transparent manner free from commercial interest.</li> </ul>
2001	WHA54.2	<ul style="list-style-type: none"> <li>• Sets global recommendation of “6 months” exclusive breastfeeding, with safe and appropriate complementary foods and continued breastfeeding for up to two years or beyond.</li> </ul>
2002	WHA55.25	<ul style="list-style-type: none"> <li>• Endorses the Global Strategy on Infant and Young Child Feeding which confines the baby food companies’ role to 1. ensure quality of their products and 2. Comply with the Code and subsequent WHA resolutions, as well as national measures.</li> <li>• Recognises role of optimal infant feeding to reduce the risk of obesity.</li> <li>• Alerts that micronutrient interventions should not undermine exclusive breastfeeding.</li> </ul>
2005	WHA58.32	<ul style="list-style-type: none"> <li>• Asks Member States to 1. ensure that nutrition and health claims for breastmilk substitutes are not permitted unless national/regional legislation allows; 2. be aware of the risks of intrinsic contamination of powdered infant formulas and to ensure this information be conveyed through label warnings; 3. ensure that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest.</li> </ul>
2006	WHA59.11	<ul style="list-style-type: none"> <li>• Member States to make sure the response to the HIV pandemic does not include non-Code compliant donations of breastmilk substitutes or the promotion thereof.</li> </ul>
2006	WHA59.21	<ul style="list-style-type: none"> <li>• Commemorates the 25<sup>th</sup> anniversary of the adoption of the Code; welcomes the 2005 Innocenti Declaration and asks WHO to mobilize technical support for Code implementation and monitoring.</li> </ul>
2008	WHA61.20	<p>Urges Member States to:</p> <ul style="list-style-type: none"> <li>• Scale up efforts to monitor and enforce national measures and to avoid conflicts of interest.</li> <li>• Investigate the safe use of donor milk through human milk banks for vulnerable infants, mindful of national laws, cultural and religious beliefs.</li> </ul>

2010	WHA63.14	<ul style="list-style-type: none"> <li>• Member States to implement recommendations to reduce the impact on children of the marketing of 'junk' foods (foods high in saturated fats, trans-fatty acids, free sugars, or salt) by restricting marketing, including in settings where children gather such as schools and to avoid conflicts of interest.</li> </ul>
2010	WHA63.23	<ul style="list-style-type: none"> <li>• Member States to strengthen implementation of the International Code of Marketing of Breastmilk Substitutes and relevant WHA Resolutions, The Global Strategy on Infant and Young Child Feeding, the Baby Friendly Hospital Initiative, Operational Guidance for Emergency Relief Staff and Programme Managers on infant and young child feeding in emergencies.</li> <li>• End to all forms of inappropriate promotion of foods for infants and young children and that nutrition and health claims should not be permitted on these foods .( i.e. claims about IQ, eyesight or protection from infection)</li> </ul>

**Source:** Reproduced from IBFAN (2011). [Online]. Available from: [http://www.ibfan.org/art/WHA\\_resolutions-from-code-essentials.pdf](http://www.ibfan.org/art/WHA_resolutions-from-code-essentials.pdf) [Accessed 13 July 2012]

### Appendix 3.3: Key to Country Categories (IBFAN Scale: The Code in 196 Member States)

1. **Law:** These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing **all or nearly all** provisions of the International Code and subsequent WHA resolutions. Countries with older measures which have not incorporated subsequent WHA resolutions have been downgraded; likewise, laws with narrow scopes have also been downgraded to category 2 or 3.
2. **Many provisions law:** These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing many provisions of the Code and subsequent WHA resolutions. Laws which cover only infant formula have been downgraded to new category 3.
3. **Few provisions law:** These countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing only few of the provisions of the Code or subsequent WHA resolutions.
4. **Voluntary code or policy:** In these countries the government has adopted all or most of the provisions of the Code and subsequent WHA resolutions through a voluntary code, a government policy or other non-binding measure. There are, however, no enforcement mechanisms.
5. **Some provisions in other laws or guidelines applicable to the health sector:** In these countries, the government has i). adopted some provisions of the Code and subsequent WHA resolutions in other laws in particular those pertaining to quality, labeling or consumer protection, or ii). issued directives or guidelines applicable to the health sector.
6. **Some provisions voluntary:** In these countries, the government has adopted some of the provisions of the Code and subsequent WHA resolutions through voluntary measures, official guidelines or other non-binding measures.
7. **Measure drafted, awaiting final approval:** In these countries, a draft law or other draft measure exists to implement all or most of the provisions of the Code and subsequent WHA resolutions, and the draft is pending approval/adoption as a law.
8. **Being studied:** The government in each of these countries is still studying how to best implement the Code and subsequent WHA resolutions.
9. **No information/No action:** Either no information is available regarding Code implementation, or these countries have not taken any steps to implement the Code and subsequent WHA resolutions.

**Source:** IBFAN/ICDC, 2009

### Appendix 3.4: Nigeria: Current National Code Instruments

No.	Name of National Code Instrument	Year	Remarks
1.	Code of Ethics and Professional Standards for Marketing of Breast-milk Substitutes	1986	The National Code
2.	Decree No. 41 - Marketing (Breast-milk Substitutes) Decree 1990	1990	Now an Act known as Cap. M5 Laws of the Federation of Nigeria (LFN) 2004
3.	Decree No. 22 – Marketing (Breast-milk Substitutes) (Amendment) Decree 1999	1999	Cap. M5 Laws of the Federation of Nigeria (LFN) 2004 incorporates the amendment.
4.	NAFDAC – Marketing of Infant and Young Children Food and other Designated Products (Registration, Sales, etc.) Regulations 2005	2005	Made under the NAFDAC enabling Decree No. 15 of 1993 as amended by Decree No. 19 of 1999. This was to forestall anticipated delays of attempting to amend Decree No. 41 of 1990.
<b>Source:</b> Adapted from Monwuba, 2010			

# Appendix 4.1: Marketing (Breast-Milk Substitutes) Act 1990

CAP. M5

*Marketing (Breast-milk Substitutes) Act*

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## CHAPTER M5

### MARKETING (BREAST-MILK SUBSTITUTES) ACT

#### ARRANGEMENT OF SECTIONS

SECTION

1. Prohibition of importation, sale, etc., of breast-milk substitutes.
2. Promoting sale of breast-milk substitute or infant formula.
3. Particulars to be inscribed on container.
4. Prohibition against giving of labels, etc.
5. Publication of advertisement for breast-milk substitute and infant formula.
6. Duty to promote and protect breast-feeding.
7. Prohibition against use of facility of health care delivery system.
8. Prescribed quality.
9. Laboratory analysis.
10. Power to search.
11. Penalties.
12. Forfeiture.
13. Regulations.
14. Interpretation.
15. Short title.

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## CHAPTER M5

### MARKETING (BREAST-MILK SUBSTITUTES) ACT

**An Act to provide for the control of the importation, sale, advertisement, distribution, or offer as sample or gift of breast-milk substitutes or infant formula to members of the public.**

[1990 No. 41.]

[30th December, 1990]

[Commencement.]

#### 1. Prohibition of importation, sale, etc., of breast-milk substitutes

As from the commencement of this Act, no person shall import, sell, display for sale, promote the sale of, distribute or offer as sample or gift to any person or the general public, any breast-milk substitute or infant formula, unless the breast-milk substitute or infant formula has first been registered with the appropriate authority.

**2. Promoting sale of breast-milk substitute or infant formula**

No person shall, for the purpose of promoting or inducing the sale of any breast-milk substitute or infant formula, advertise or give to any person, institution or health facility any bonus sample of a breast-milk substitute or infant formula or any promotion device thereof.

**3. Particulars to be inscribed on container**

(1) No person shall sell, display for sale, consign or deliver any breast-milk substitute or infant formula in a container, unless the container bears a label on which there appears—

- (a) in English language and three main Nigerian languages a true statement of the product as to the following matters, that is—
  - (i) composition;
  - (ii) required storage condition;
  - (iii) batch number; and
  - (iv) expiry date;
- (b) on a label marked on or securely attached to the container the following statement—

“Breast-milk is the best food for the child as it prevents diarrhoea, chest pain and other diseases”.

(2) Any label affixed to any container of a breast-milk substitute or infant formula as required under subsection (1) of this section shall bear directions for use in English language and three main Nigerian languages and such adequate warnings against the health hazards of inappropriate preparation or use.

(3) The statement referred to in subsection (1) of this section shall—

- (a) be clearly legible and shall appear conspicuously and in a permanent position on the label;
- (b) specify the name of either the manufacturer, distributor, packer or labeller of the breast-milk substitute or infant formula; and
- (c) bear an address at which such person carries on business which shall be clearly shown in all notices, advertisements and other publications used by such person in connection with his business as dealer in breast-milk substitute or infant formula.

**4. Prohibition against giving of labels, etc.**

No person shall give with any breast-milk substitute or infant formula sold by him or displayed by him for sale, any label or document, whether attached to or printed on the wrapper or container or not, which bears any word or pictorial device whatsoever suggestive of the superiority of breast-milk substitute or infant formula over breast-milk.

**5. Publication of advertisement for breast-milk substitute and infant formula**

(1) No person shall publish or be a party to the publication of any advertisement for breast-milk substitute or infant formula which makes any claim or suggestion that bottle-feeding is equivalent to breast-feeding.

(2) Any person who contravenes the provisions of this section shall be guilty of an offence and liable on conviction to a fine not exceeding ₦1,000 or to imprisonment for a term not exceeding two years or to both such fine and imprisonment.

(3) No proceedings for an offence under this section shall be taken against any person whose business it is to publish or arrange the publication of advertisement received in the ordinary course of business.

**6. Duty to promote and protect breast-feeding**

It shall be the duty of every governmental, non-governmental or private institution or organisation engaged directly or indirectly in health care delivery to take such measures as may encourage, promote and protect breast-feeding.

**7. Prohibition against use of facility of health care delivery system**

No facility of a health care delivery system shall be used for the purpose of promoting, displaying placards, posters or materials concerning breast-milk substitute or infant formula or other products of like nature.

**8. Prescribed quality**

No person shall manufacture for sale any breast-milk substitute or infant formula, unless the manufacture of such breast-milk substitute or infant formula complies with the standard and quality under the relevant provisions of the Food and Drugs Act relating to that particular product and the applicable standards recommended by the Codex Alimentarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children.

[Cap. F32.]

**9. Laboratory analysis**

(1) Every breast-milk substitute or infant formula intended for sale shall be subjected to a satisfactory laboratory and clinical analysis by the manufacturer or distributor.

(2) Every manufacturer or distributor of a breast-milk substitute or infant formula shall keep a proper record at his place of business of the analysis carried out under subsection (1) of this section.

**10. Power to search**

For the purposes of this Act, a person authorised in writing by the Minister, may at all reasonable times and on production of that authority—

- (a) enter any building or place in which that person has reason to believe there are—
  - (i) any breast-milk substitute or infant formula manufactured or kept for commercial purposes; or



- (ii) any books, documents or papers relating to the manufacturing of breast-milk substitute or infant formula;
- (b) search for any breast-milk substitute or infant formula or any such books, documents or papers in any such building or place;
- (c) examine, count any such breast-milk substitute or infant formula and take extracts from, or make copies of any such books, documents or papers relating thereto.

#### 11. Penalties

(1) Any person who contravenes any of the provisions of this Act shall be guilty of an offence and liable on conviction to a fine not exceeding ₦1,000 or to imprisonment for a term not exceeding two years or to both such fine and imprisonment.

(2) Where an offence under this Act has been committed by a body corporate, every person who at the time of the commission of the offence was a proprietor, director, general manager, secretary or other similar officer, servant or agent of the body corporate (or person purporting to act in any such capacity) shall, as well as the body corporate, be guilty of the offence and may be proceeded against and punished accordingly.

#### 12. Forfeiture

(1) Where any person is convicted of an offence under this Act in relation to any breast-milk substitute or infant formula or container or label, the court shall, in addition to any other penalty it may impose under this Act, order that the breast-milk substitute, infant formula, label or container owned by that person and in respect of which the offence was committed be forfeited to the Federal Government.

(2) Every breast-milk substitute, infant formula, container or label forfeited under subsection (1) of this section shall become the property of the Federal Government and shall be disposed of in such manner as the Minister may direct.

#### 13. Regulations

The Minister may make regulations generally for the purpose of giving effect to the provisions of this Act.

#### 14. Interpretation

In this Act, unless the context otherwise requires—

“advertisement” includes any notice, circular, label, wrapper, invoice or other document, and any public announcement made orally or by any means of producing or transmitting light or sound; and “advertise” shall be construed accordingly;

“appropriate authority” means the National Agency for Food and Drugs Administration and Control;

[1999 No. 22.]

“breast-milk substitute” means any food being marketed or otherwise represented as a partial or total replacement for breast-milk;

“**container**” includes any basket, pail, tray, package or receptacle of any kind, whether open or closed;

“**infant**” means a person under twelve months old;

“**infant formula**” means a breast-milk substitute formulated and adapted to satisfy the normal nutritional requirements of an infant not exceeding twelve months old in accordance with applicable regulations under the Food and Drugs Act;

[1999 No. 22.]

“**label**” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, attached to a container containing breast-milk substitute or infant formula;

“**Minister**” means the Minister charged with responsibility for matters relating to health.

**15. Short title**

This Act may be cited as the Marketing (Breast-Milk Substitutes) Act.

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**CHAPTER M5**

**MARKETING (BREAST-MILK SUBSTITUTES) ACT**

**SUBSIDIARY LEGISLATION**

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*No Subsidiary Legislation*

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# Appendix 4.2: NAFDAC – Marketing of Infant and Young Children Food & Other Designated Products Regulations 2005

Extraordinary



## Federal Republic of Nigeria Official Gazette

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<i>S.I. No.</i>	<i>Short Title</i>	<i>Page</i>
11	NAFDAC—Marketing of Infant and Young Children Food and other Designated Products (Registration, Sales, etc.) Regulations 2005	B 73-81

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Federal Bureau for Food & Drug  
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Regulations & Control  
Division  
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**NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT 1993 (AS AMENDED)**

**Marketing of Infant and Young Children Food and Other Designated Products (Registration, Sales, Etc.) Regulations 2005**

*Commencement : 1st January, 2005*

In exercise of the powers conferred on the Governing Council of The National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 29 of the National Agency for Food and Drug Administration and Control Act 1993 (as amended) and of all the powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Honourable Minister of Health hereby makes the following Regulations -

1.—(1) Every Designated Product manufactured, imported, exported, sold or distributed in Nigeria shall be registered in accordance with the provisions of Marketing Breast Milk Substitute Act of 1990 and these Regulations.

Registration of Designated Product.

(2) Notwithstanding the provisions of subregulation (1) of this Regulation, the manufacture or importation of any Designated Infant Feeding Product as a sample for registration shall be undertaken with the approval of the Agency.

2.—(1) The application for registration of any Designated Product shall be made in such form as may be stipulated from time to time by the Agency.

Application for registration.

(2) An application shall be accompanied by —

- (a) a non refundable fee as may be stipulated by the Agency ;
- (b) samples of the Designated Product as may be stipulated by the Agency ;
- (c) the original certificate of analysis of the Designated Product ;
- (d) evidence of any special labelling of the character, quality and safety of the Designated Product ;
- (e) a copy of certificate of manufacture and sale for the imported Designated Product from the statutory body in the country of origin responsible for the safety of the Designated Product duly authenticated by the Nigeria Mission in that country ;
- (f) the radiation-free test certificate ;
- (g) a copy of Evidence of Trademark ownership ;
- (h) a notarised declaration that the information contained in the Registration form are correct and that all the documents submitted are genuine ;
- (i) a power of attorney or an agreement from the manufacturer signed by a General Manager or Director of the manufacturing company and notarised in the country of manufacture authorizing a Nigerian representative to register the Designated products in Nigeria ; and

Invalidation of certificate of registration.

(f) an undertaking that the Designated Product shall not be advertised.  
(3) The Agency may suspend, withdraw or cancel the certificate of registration of a Designated Product if —

(a) the grounds on which the Designated Products was registered were found to be false or incomplete, or

(b) the circumstances under which the Designated Product was registered no longer exist ; or

(c) any of the conditions or undertaking under which the Designated Product was registered has been contravened; or

(d) the standard of quality, safety or efficacy as stipulated in the documentation for registration is not being complied with; or

(e) the premises in which the Designated Product is imported, processed, manufactured or stored by or on behalf of the holder of the certificate of registration are unsuitable for the importation, processing, manufacturing or storage of the Designated Product ; or

(f) the Designated Product is promoted or advertised.

Information and educational materials on infant feeding

4.—(1) The Agency shall have the responsibility for the control of the production, provision, planning, design, and dissemination of information and educational materials on infant and young child feeding for use by families and those involved in the field of infant and young children health and nutrition.

(2) Information and educational materials whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women, mothers of infants and young children or members of their families shall include clear and appropriate information on all the following points :

(a) the benefits and superiority of breastfeeding ;

(b) how to prepare for and maintain breastfeeding including maternal nutrition ;

(c) the negative effects which the introduction of artificial feeding has on lactation ;

(d) the danger of inappropriate use of designated products and bottle-feeding ; and

(e) the difficulty of returning to breastfeeding after a period of artificial feeding.

Restrictions regarding information, educational materials and equipments.

5.—(1) Information and educational materials shall contain only factual and current information and shall not use any picture or text that encourages artificial feeding or use of bottles for feeding or discourages breast feeding.

(2) Information and educational materials shall be written in English, Hausa, Igbo and Yoruba languages.

(3) Information and educational materials shall not make reference to any brand of Designated Product, but may, contain the name or logo of any manufacturer or distributor of Designated Product, provided the name or logo is not more than 3 per cent of the material outlay.

(4) Any material containing information about the use of Designated Products shall point out the risks that shall arise for the child's health due to these products.

(5) Donation of information and educational materials or equipment by manufacturers or distributors shall be with the approval of the Agency and in accordance with these Regulations.

6.—(1) The health care facility system shall not be used to promote Designated Products, display of such products, placards or posters concerning such products, or for the distribution of materials concerning these items provided by a manufacturer or distributor.

Restrictions on healthcare facility.

(2) Notwithstanding the provisions of sub-regulation (1) of this Regulation, the restrictions prescribed shall not preclude the dissemination of information to Health professionals as provided for in these Regulations.

(3) Feeding with Designated Products, whether manufactured or home prepared, shall be demonstrated by health workers or community workers if necessary and only to the mothers or family members for whom it has been prescribed and the information given shall include a clear explanation of the hazard of improper use.

(4) The head of a health care facility shall—

(a) present to the Agency in writing, a full disclosure of any contribution made by a distributor or manufacturer of Designated Products to the Health Care System or Health Care Workers therein, and

(b) prohibit acceptance into the Health care facility, of gifts in the form of samples of Infants and Young Children Designated Products or supplies of the same or gift of any article which may idealise or promote the use of Designated Products.

7.—(1) Donation, low-price sales or supplies of Designated Products to social welfare institutions shall be accepted with the written approval of the Agency.

Donation to be approved by the Agency.

(2) The supply or donation made under sub-regulation (1) of this Regulation, shall—

(a) only be used or distributed for infants for whom it has been prescribed to be fed on Designated Products ; and

(b) be continued for as long as the infant needs them.

(3) Health workers shall—

(a) encourage and protect breast feeding ; and

(b) make a disclosure to their employers in writing of any contribution made by a distributor or a manufacturer on behalf of the health worker, for fellowship, study tour, research grant, attendance at professional conference or for other similar purposes.

Questions as regards the use of products.

8. And Health professional who has a technical question with regard to the use of products within the scope of these Regulations may, seek information from a manufacturer in writing and the manufacturer shall respond in writing specifically to such professional enquiries, except that, general promotional literature about the Product or Designated Product shall not be included, unless it answers directly the questions asked.

Prohibition of the advertisement or promotion of Designated Products.

9.—(1) No person shall advertise or promote any Designated Product in Nigeria.

(2) No manufacturer, distributor or any other person shall provide directly or indirectly to pregnant women, mothers or members of their immediate families or health workers, samples of products which may promote the use of Designated Products.

Manufacturers to disclose their contributions.

10. Manufacturers or distributor of Designated Products shall, subject to the approval of the Agency, disclose to the institution to which a recipient health worker is affiliated, any contribution made to or on his behalf for fellowship, study tour, research grant, attendance at professional conference, or the like and similar disclosure shall be made by the recipient to his employers.

Prohibition of promotion by manufacturers and distributors.

11.—(1) No manufacturer or distributor shall promote Designated Products within a Health Care Facility or otherwise.

(2) No manufacturer, distributor or retailer of Designated Products under these Regulations shall—

(a) use a system of sales incentive for the marketing personnel, which includes the volume of sales of any of the products under these Regulations for the purpose of the calculation of bonuses;

(b) set quotas specifically for the sale of any of the products under these Regulations; and

(c) have special display of any of the products under these Regulations.

Prohibition of persons employed by manufacturers and distributors.

12. Persons employed in marketing products under these Regulations shall not as part of their responsibilities, perform educational functions in relation to pregnant women, mothers of infants, young children and the general public.

Composition of Designated Products.

13. The composition of Designated Products shall be in accordance with the existing prescribed standard or where such standard do not exist for the particular product, in accordance with any international standard laid down under the directive of Codex Alimentarius Commission.

Prohibition of the sale of unwholesome product.

14. No person shall import, distribute, display for sale or sell Designated Products which :

(a) has in it or upon it any substance which may cause injury to the health of the user when the Designated Product is consumed ; or

(b) consists wholly or in part of any filthy, disgusting, rotten or diseased substance or of any foreign matter, or

(c) is unfit for human consumption ; or

(d) is adulterated, fake, expired or substandard ; or

(e) revalidates any information originally indicated on its label or container by the manufacturer.

15.—(1) In addition to compliance with the Agency Prepackaged Food (Labelling) Regulations 2005, the following shall apply :

What labels and marks on Designated Products shall include, etc.

(a) labels shall be clear, easily readable, printed or firmly attached to the container of the Designated Product ;

(b) the label of the Designated Product shall include :

(i) trade name of the product ;

(ii) name and address of the manufacturer ;

(iii) net content by 'mass/ volume' ;

(iv) county of manufacture ;

(v) batch number ;

(vi) instruction for use ;

(vii) storage condition ;

(viii) date of manufacture ;

(ix) "Best before" date ;

(x) nutritional information ;

(xi) the age after which the product is recommended in numeric figures ;

(xii) the words "important notice" or their equivalent which shall be conspicuous ;

(xiii) a statement of the superiority of breast-feeding ;

(xiv) a statement that the product should be used only on the advice of a health professional as to its use and the proper method of use, provided that such statement shall not appear on feeding bottles, teats pacified complementary food and the like,

(xv) instructions for appropriate preparation and warning against the health hazards of inappropriate preparation, and

(xvi) a statement that Breastmilk is the best food for the child.

(2) The label shall not show any baby, photograph, drawing or other graphic representation to idealise or promote the use of Designated Products.

(3) The use of graphics shall be permitted only for the purpose of illustrating the method of preparation of Designated Products.



Self monitoring by manufacturers and distributors, etc.

16.—(1) Notwithstanding any other measures taken by the Agency with regard to the implementation of these Regulations, manufacturers and distributors of Designated Product shall be responsible for monitoring their practices according to the provisions of these Regulations and for taking steps to ensure that their conduct at every level conforms to these Regulations.

(2) Every manufacturer and distributor of Designated Products shall regularly apprise each member of their marketing personnel of these Regulations and their responsibilities under it.

Offences.

17. A person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction—

(a) in the case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding ₦50,000 or imprisonment and ; fine and

(b) in the case of a body corporate, to a fine not exceeding ₦100,000.

Offences by bodies corporate, etc.

18. Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals, every—

(a) director, manager, secretary or other officer of the body corporate ; or

(b) partner or officer of the firm ; or

(c) trustee of the body concerned ; or

(d) person concerned in the management of the affairs of the association shall be found guilty of that offence and liable to be proceeded against and punished for that offence, in same manner as if he had himself committed the offence, unless it is proved that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

19.—(1) A person convicted of an offence under these regulations shall forfeit to the Federal Government —

(a) any asset or property constituting, or derived from any proceeds the person obtained directly or indirectly, as a result of the offence ; and

(b) any of his property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Forfeiture of Designated Products seized.

20. Any Designated Product seized by the Agency shall be forfeited to the Federal Government and shall be dealt with in such manner as the Minister may from time-to-time determine.

Interpretation.

21. In these Regulations, unless the context otherwise requires —

“advertisement” includes advertising in a publication, by television, internet, radio, film, video or telephone, traditional communication media, by display or signs, bills boards, notices or goods, by exhibition of pictures or models and in any other manner ;

**"Agency"** means National Agency for Food and Drug Administration and Control (NAFDAC);

**"complementary food"** means any food whether manufactured, or locally prepared, suitable as complement to breast milk or infant formula when either becomes insufficient from six months to satisfy the nutritional requirements of an infant as such food is introduced from six months of life;

**"container"** includes every form of packaging of Designated Products for distribution or sale as a retail unit including wrappers;

**"distributor"** means a person, a corporation or any other entity in the public or private sector either distributing or engaged in such business whether wholesale or retail, or marketing any Designated Product and includes any person engaged in the business of providing information, or public relations services in relation to Designated Product;

**"Designated Product"** means —

- (a) infant formula; or
- (b) follow up formula; or
- (c) any product marketed otherwise represented or commonly used for feeding of infants; or
- (d) any product to be fed by use of a feeding bottle; or
- (e) beverages, milk, cereals, and other foods intended for use by infant and young children whether industrially made or occurring naturally; or
- (f) feeding bottles, teats, and pacifiers; or
- (g) products stated to promote breast feeding; and
- (h) such other products as may be specified by the Agency;

**"follow up formula"** means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with the prescribed standard or in the absence of such prescribed standard, in accordance with Codex Alimentarius Standard, and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age;

**"health care facility"** means government, non government or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants, young children and pregnant women, and nurseries or child-care institutions but not including pharmacies;

**"health professional"** means any technical personnel involved in matters of human health, nutrition or both;

**"health worker"** means a person working in a component of such a health care system, whether professional or non-professional, including voluntary unpaid workers;

National Agency For Food & Drug  
Administration and Control  
Affairs Division

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"infant" means a person of not more than twelve months of age ;

"infant formula" means a milk-like product of animal or vegetable origin formulated industrially in accordance with the prescribed standard or in the absence of such prescribed standard, in accordance with Codex Alimentarius Standard, to satisfy the normal nutritional requirements of infants up to six months of age, and adapted to their physiological characteristics and infant formula may also be prepared at home, in which case it is described as "home-prepared";

"label" means any tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, attached, or otherwise appearing on a container of a Designated Product ;

"manufacturer" means a person or corporation or other entity in the public or private sector, engaged in the business of manufacturing of a Designated Product whether directly, through an agent, or a person controlled by or under an agreement ;

"marketing" means any method of introducing or selling a Designated Product, including promotion, distribution, advertising, display on shelves, production, distribution of samples, product public relations and product informational services ;

"Minister" means Minister charged with the responsibility for health ;

"prescribed" means as prescribed by the National Agency For Food and Drug Administration and Control ;

"proceeds" means any property derived or obtained directly or indirectly through the commission of an offence ;

"promote" includes advertising, giving of samples or gifts of Designated Products, or materials or information or decorations related thereto ;

"promotion" means any method of introducing, familiarizing or encouraging a person to purchase a Designated Products ;

"prohibited promotional practice" includes —

- (a) special displays of Designated Products ;
- (b) discount coupons ;
- (c) the selling of Designated Products at a reduced price, unless such reduction in price is intended to be permanent ;
- (d) the distribution of gifts or items of little or no cost, bearing the name or logo of a manufacturer or distributor ;
- (e) the use of printed matter including books, pamphlets, or posters bearing the name, logo, graphic or other representation of a proprietary product or the name or logo of a manufacturer or distributor ;

(f) tie-in sales, extra weight formula etc ; or

(g) in any other manner ;

“sample” means a single or small quantity of Designated Products, provided without cost ; and

“young children” means persons from the age of more than 12 months up to the age of three years.

22. These Regulations may be cited as Marketing of Infant and Young Children Food and other Designated Products (Registration, Sales, Etc.) Regulations 2005. Citation.

MADE at Abuja this 1st day of January, 2005.

DR ANDI NYONG ANDEM  
*Chairman, Governing Council*  
*National Agency for Food and Drug Administration and Control*

### Appendix 4.3: Detailed Results of Gap Analysis of the National Legislation and NAFDAC Regulations (On Marketing of Breastmilk Substitutes) Vis-a-Vis the Code

**Key:**

Art. Code Articles  
 Reg. Regulation  
 WHA World Health Assembly  
 IYCF Infant and Young Children Food  
 BMS Breast-milk substitutes  
 HCF(s) Health care facility(ies)

<b>Code Article Numbers:</b> Titles	<b>The Code</b> (Summary of Provisions of the Articles/WHA resolutions)	<b>National Legislation</b> Decree 41 Marketing (Breast-milk Substitutes) Act (1990)	<b>NAFDAC Regulation</b> Marketing of IYCF and other Designated Products (2005)	<b>Remarks</b>
<b>Article 1:</b> Aim of the Code	Protect and promote breastfeeding by ensuring appropriate marketing and distribution of breast-milk substitutes.	Section 6 particularly expresses the aim and principles of the Code.	All regulations generally express the aim and principles of the Code.	Both instruments ( <b>Legislation</b> and <b>Regulation</b> ) convey the aim and principles of the Code.
<b>Article 2:</b> Scope of the Code	Marketing of, and practices related to marketing of: BMS including infant formula; other milk products, foods and beverages incl. bottle-fed complementary foods, when marketed or represented as partial or total replacement of breast-milk; feeding bottles and teats.	Covers the marketing of, and practices related to the marketing of: BMS or infant formula <b>but not feeding bottles and teats.</b>	Covers the marketing of, and practices related to the marketing of: 'designated products': infant formula, follow-up formula, any product marketed otherwise represented or commonly used for feeding of infants, any product to be fed by use of a feeding bottle, beverage, milk, cereals, and other foods	<b>Legislation</b> Does not cover the entire range of products within the scope of the Code. Creates room for ambiguity in the interpretation of products for which the Code is applicable.  <b>Regulation</b> specifies designated products and leaves room for product additions without necessarily amending the Regulation. More comprehensive than the Code. (Reg. 21)

			intended for use by infant and young children whether industrially made or occurring naturally, feeding bottles, teats and pacifiers, products stated to promote breastfeeding, <b>such other products as may be specified by the Agency.</b>	
<b>Article 3:</b> Definitions	Definitions of terms provided.	Section 14 provides interpretation of terms used.	Reg.21 provides interpretations of terms used.	Both instruments ( <b>Legislation and Regulation</b> ) provide definition of terms.
<b>Article 4:</b> Information and Education	<p><b>Art.4.1</b> Governments should be responsible for ensuring provision of objective and consistent information on IYCF.</p> <p><b>Art.4.2</b> Information and educational materials must explain the benefits/superiority of breastfeeding; maternal nutrition, preparation for and maintenance of breastfeeding; the health hazards associated with bottle feeding; difficulty of reversing decision not to breastfeed; <b>where needed, proper use of</b></p>	<b>Art.4:</b> <b>Information and Education not covered</b>	<p><b>Art.4.1</b> of the Code is adequately covered by Reg.4.1.</p> <p><b>Art.4.2</b> is addressed by Reg.4.2 on most points <b>except for</b> provision of information on the proper use of infant formula where needed.</p> <p><b>Art.4.3</b> i). Regulation (<b>Reg. 5.5</b>) makes no mention that donation should only be <b>at government's request</b>, rather it states that donations shall</p>	<p><b>Legislation</b> Does not address Code article 4.</p> <p><b>Regulation</b> <u>On Art.4.2:</u> Due to not addressing provision of information on the proper use of infant formula where needed, the regulation falls short of the Code provision that such materials should include the social and financial implications and highlighting the health hazards of unnecessary or improper use of infant formula and other BMS.</p> <p><u>On Art.4.3:</u> i). Regulation is less stringent than the</p>

	<p><b>infant formula</b> and the costs of using infant formula.</p> <p><b>Art.4.3</b> i). Donations of informational or educational materials should be made only at the request of government &amp; with written approval of authorized government body.</p> <p><b>Art.4.3</b> ii). Such materials may bear donor company name/logo but no reference to a proprietary product within the scope of the Code.</p>		<p>be with the Agency's approval and in line with the Regulations.</p> <p><b>Art.4.3</b> ii). Adequately covered by Reg.5.3 and goes on to specify that the size of such company name/logo should be no more than 3% of the material outlay.</p>	<p>Code. The spirit of the Code is lost because the regulation implies that donation does not have to be initiated/requested by government; the only requirement is that approval for the donation is sought from government.</p> <p><u>On Art.4.3:</u> ii). More stringent than the Code</p>
<p><b>Article 5:</b> The general public and mothers</p>	<p>No advertising or other form of promotion of products within the scope of the Code to the general public. No free samples of products within the scope of the Code to pregnant women, mothers, or their families.</p> <p><b>Art.5.4</b> Prohibits distributing any gifts of articles or utensils which may promote the use of BMS or bottle-feeding to pregnant women, mothers or infants and young children.</p> <p><b>Art.5.5</b> Marketing</p>	<p>Promotion &amp; advertising provisions are <b>limited to</b> only BMS and infant formula (Section 2; 5.1). Prohibits giving bonus samples of BMS/infant formula to any person, institution or health facility. (Section 2). Excludes other products within the Code's scope in both cases.</p>	<p>Regulation covers the prohibition of advertisement or promotion of products within the scope of the Code. (Reg.9.1). Also covers the Code's prohibition on giving of free samples of products within the scope of the Code to pregnant women, mothers, or their families. It goes beyond the Code &amp; includes health workers. (Reg.9.2).</p> <p><b>Art.5.4</b> is</p>	<p><b>Legislation</b> Less stringent than the Code in not covering all products within the scope of the Code in its relevant sections.</p> <p><b>Regulation</b> More stringent than the Code in some aspects because 'designated' products even make allowance for additional products as the Agency deems fit. Also explicit explanations of 'promotion' &amp; 'prohibited promotional practice' are given in 'Interpretation' section. A loophole is however created in the Regulation's interpretation of</p>

	<p>personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infant and young children.</p>		<p>covered by Reg.6.4b.</p> <p><b>Art.5.5</b> The regulation (in <b>Reg.12</b>) only addresses prohibition of marketing personnel from <b>performing educational functions</b> in relation to pregnant women, mothers of infants, young children and the general public.</p>	<p>'prohibited promotional practice' because it only addresses prohibition on distribution of gifts or low-cost items carrying the company's name/logo and does not address those that could carry only the product's name without company name/logo.</p> <p><b>Reg. 9.2</b> is broader in reach than the Code by including health workers.</p> <p><u>On Art.5.5</u> Another loophole is created in Reg.12 by falling short of addressing <b>all forms of contact</b> of marketing personnel with pregnant women or with mothers of infant and young children – only addresses their performing educational functions.</p>
<p><b>Article 6:</b> Health care systems</p>	<p><b>Art.6.1</b> Appropriate measures to be taken by health authorities to promote the Code's principles and encourage/protect breastfeeding.</p> <p><b>Art.6.2</b> No HCF to be used for promoting infant formula/other products covered by the Code.</p>	<p><b>Section 6</b> addresses Art. 6.1 on health authorities &amp; measures to encourage and protect breastfeeding</p> <p><b>Section 7</b> addresses Arts. 6.2 &amp; 6.3, that is, prohibition of promotion of BMS/infant formula and</p>	<p><b>Reg.6.1</b> adequately covers the provisions of Arts.6.2/6.3 of the Code in</p> <p>Reg.7.1 <b>does not address NAFDAC's position on donations of free or low-cost supplies to the HCFs in view of WHA 47.5 – acceptable or</b></p>	<p><b>Legislation</b> Does not cover all aspects of the Code. Section 2 just gives a broad statement on 'giving' of bonus samples (of BMS or infant formula or any promotional device) to HCF which is not explicit. Arts.6.4/6.5 are not covered.</p> <p><b>Regulation</b> A loophole is present in Reg.7.1 being silent on HCFs; it creates ambiguity &amp;</p>



	<p><b>Art.6.3</b> No HCF to be used for displaying products covered by the Code, i.e. no product displays, placards, posters, or for distributing promotional materials provided by manufacturer/distributor besides those in Art.4.3.</p> <p><b>Art.6.4</b> No use of mother craft nurses or similar company-paid personnel.</p> <p><b>Arts.6.6 &amp; 6.7 now clarified and superseded by WHA 47.5</b> – reiterates earlier calls to <b>end ‘free or low-cost supplies’ – of products within the scope of the Code to all parts of the health care system.</b></p> <p><b>Art.6.8</b> Donations of equipment and materials (excluding educational ones) bearing company name/logo may be made but no reference to any proprietary product within the Code’s scope.</p>	<p><b>other products of like nature</b> in HCFs.</p> <p><b>Section 2</b> addresses prohibition of ‘giving’ of bonus samples of BMS/infant formula/any promotional device to HCF. This is in line with WHA 47.5.</p>	<p><b>not acceptable?</b> It only states that such donations to social welfare institutions shall be with written approval of NAFDAC.</p> <p>On donation of free or low-cost supplies to social welfare institutions, Reg.7.2a uses the word ‘prescribed’ which can be interpreted to give full authority to doctors to prescribe the use of designated products for infants.</p> <p><b>Art.6.8</b> is addressed by <b>Reg.5.5</b> but with the limitation that donations can be originated from the manufacturer without any prior request by the recipient for such items, all that is required is to seek the Agency’s approval.</p>	<p>a possibility of making such donations to HCFs without NAFDAC’s approval. Reg.7.2a is subject to abuse by prescribers (doctors).</p>
<b>Article 7:</b>	<b>Art.7.2</b>	<b>Art.7</b>	<b>Art.7.5</b>	<b>Legislation</b>

<p>Health workers</p>	<p>Product information must be factual and scientific.</p> <p><b>Art.7.3/7.4</b>          Gifts or samples from manufacturers/distributors should neither be offered to nor accepted by health care workers or members of their families for the purpose of promoting products covered by the Code. Samples are only acceptable when required for professional evaluation or research by the institution. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children or their families.</p> <p><b>Art.7.5</b>          Manufacturers/distributors of products covered by the Code should disclose to a recipient health workers institution any contributions made to or on behalf of the recipient for fellowships, study tours, research grants, professional conferences, or</p>	<p>Not covered by Legislation</p>	<p>Reg.10 implies that such disclosures by manufacturers/distributors to institutions should only be made subject to NAFDAC approval.</p> <p><b>Art.7.2</b>          Adequately covered by Reg.5.1.</p>	<p>Art.7 is not covered in the legislation. Lacks guidance on responsibilities of and actions expected of health workers.</p> <p><b>Regulation On Art.7.5</b>          Regulation negates the spirit of the Code if disclosures should only be made to institutions upon NAFDAC approval.</p>
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	the like. Recipients should make similar disclosures.			
<b>Article 8:</b> Persons employed by manufacturers and distributors	<p><b>Art.8.1</b> Volumes of sales of BMS should not be used to calculate bonuses; no sales quotas should be set.</p> <p><b>Art.8.2</b> No educational functions to pregnant women, mothers of infants and young children by marketing personnel.</p>	Not covered by legislation	<p><b>Art. 8.1</b> is adequately covered by Reg.11.2 (a&amp;b).</p> <p><b>Art.8.2</b> is adequately covered by Reg.12.</p>	<p><b>Legislation</b> <b>Art.8</b> is not covered in the legislation.</p> <p><b>Regulation</b> Meets Code provisions</p>
<b>Article 9:</b> Labelling	<p><b>Art.9.2</b> Product labels must be clear, conspicuous with easily readable and understandable message in <b>an appropriate language</b>. Labels should clearly state the superiority of breastfeeding, the need for the advice of a health care worker on the need for use and correct method of use, directions for proper use and a warning about health hazards of improper use. No pictures of infants, other pictures, or text idealizing the use of infant formula on labels.</p> <p><b>Art.9.3</b></p>	Sections 3 & 4 cover some aspects of the Code on labelling.	<b>Reg.15</b> makes no reference that message on designated product container/label should be in an appropriate language.	<p><b>Legislation</b> Does not cover all aspects of the Code. Specific information detailed in Art.9.2 are not all addressed; need to inscribe the words 'important notice', the advice of a health care worker on the need for use and correct method of use. These are in addition to the lapses highlighted for the Regulation except for having adequately addressed the Code provision for use of appropriate language.</p> <p><b>Regulation</b> Less stringent than the Code. Vague and/or silent on some Code provisions. Falls short of the</p>

	<p>Food products which can be modified to meet the requirements of infant formula should bear a warning label that the unmodified product should not be the only nourishment source for the infant. Sweetened condensed milk should not bear instructions on modifying it to be suitable for infant feeding.</p> <p><b>WHA58.32 (2005):</b> Use clear label warnings to convey information on risks of intrinsic contamination of powdered infant formula.</p>			<p>Code provisions regarding easily readable and understandable message on product containers/labels because it does not state the languages to be used. Does not specify that the words 'humanised', 'materialised' or similar words should not be used or that inserts providing further product information are allowed. (Art.9.2).</p> <p>Regulation is silent on Art.9.3 and WHA58.32.</p>
<b>Article 10:</b> Quality	All products should be of a high quality and meet applicable (Codex Alimentarius standards).	<b>Art.10</b> Adequately covered by Sections 8 & 9 which both address Code provisions.	<b>Art.10</b> Adequately covered by Regs.13 & 14 which both address Code provisions.	<b>Legislation</b> Meets the provisions of the Code.  <b>Regulation</b> Meets the provisions of the Code.
<b>Article 11:</b> Implementation and Monitoring	<p><b>Art.11.1</b> See WHO (1981) Code document in Appendix 1.</p> <p><b>Art.11.3</b> Manufacturers and distributors of products covered by the Code to self-monitor their marketing practices.</p> <p><b>Art. 11.4</b> Non-governmental Organizations</p>	<p><b>Art.11.1</b> is addressed by Section 13 regarding making of regulations to give effect to the Code.</p> <p>Arts.11.3, &amp; 11.5 are implicit in Section 6 but not 11.4.</p>	Reg.16 addresses Arts.11.3 and 11.5 but not 11.4.	<p>Article 11 provides general recommendations &amp; guidelines for implementing and monitoring the Code.</p> <p><b>Legislation</b> meets the Code provisions in Arts.11.1, 11.3, &amp; 11.5 but not 11.4 which provides for independent monitoring.</p> <p><b>Regulation</b> meets provisions of</p>

	<p>(NGOs), professional groups, institutions and individuals empowered to independently monitor the Code and inform the relevant government authority.</p> <p><b>Art.11.5</b> Manufacturers and primary distributors to take on the responsibility of adequately informing their marketing personnel of the Code provisions and their responsibilities under the Code.</p>			<p>Arts.11.3 &amp; 11.5. Art.11.4 which makes provision for the role of independent Code monitoring is not addressed.</p>
<b>Source:</b> Author				

**Materials (Resources) Used:** Code articles, Sections of the Act and Regulation provisions adapted from: International Code of Marketing of Breast-milk Substitutes (WHO, 1981); Marketing (Breast-milk Substitutes) Act, 1990; NAFDAC – Marketing of Infant and Young Children Food and Other Designated Products (Registration, Sales, etc.) Regulations, 2005.

#### Appendix 4.4: Nigeria: Federal Ministers of Health (mid 2007 to Date)

No.	Federal Ministers of Health	Tenure of service	Remarks
1.	Adenike Grange	26 <sup>th</sup> July 2007 to 26 <sup>th</sup> March 2008	8 months
2.	Hassan Lawal	April to mid-December 2008	*8 months
3.	Babatunde Osotimehin	17 <sup>th</sup> December 2008 to 17 <sup>th</sup> March 2010	15 months
4.	Christian Onyebuchi Chukwu	April 2010 to 31 <sup>st</sup> May 2011 Reappointed June 2011 – date	13 months (first tenure)
<p>* Minister of Health concurrently with being Minister of Labour as the main portfolio</p> <p><b>Sources:</b> i. Nigeria Health Watch, 2011. Available from: <a href="http://www.nigeriahealthwatch.com/2011/05/four-ministers-in-four-years-can-our.html">http://www.nigeriahealthwatch.com/2011/05/four-ministers-in-four-years-can-our.html</a> [Accessed 13 July 2012]</p> <p>ii. Nighealthminister (FMoHnigeria) on Twitter. Available from: <a href="http://twitter.com/fmohnigeria">http://twitter.com/fmohnigeria</a> [Accessed 13 July 2012]</p> <p>iii. Wikipedia. Available from: <a href="http://en.wikipedia.org/wiki/Babatunde_Osotimehin">http://en.wikipedia.org/wiki/Babatunde_Osotimehin</a> [Accessed 13 July 2012]</p>			

## Appendix 4.5: Monitoring Report 1 (Osogbo)

### NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

#### E. I. D, OFFICE OSOGBO, OSUN STATE.

### REPORT OF SURVEILLANCE ACTIVITIES CARRIED OUT ON THE CODE OF MARKETING OF BREAST MILK SUBSTITUTES

- 1. Preamble:** Monitoring of activities related to the Code of Marketing of Breast Milk Substitutes were carried out at Health Facilities and Supermarkets where Staff of the Hospitals and Nursing Mothers were met and interacted with. Product labels and other materials displayed within the premises were also monitored.
- 2. Date of Surveillance:** 10<sup>th</sup> July, 2012
- 3. NAFDAC Team:** Pharm. (Mrs) Adenuga Y. A. (AD)  
Mrs Sulaiman I. Y. (SRO)  
  
Miss Adeniji B. O. (ROII)

- 4. Findings:** the findings of the team are presented in the following table.

S/N	Date	Name / Address of Facility Visited	Name of Officer Met	Activity	Observation/Code Violation	Remark
1	10 - 07- 2012	Biket Hospital, Off Ikirun Road, Osogbo, Osun State.	Dr A. D. Adenle (Medical Director) Mrs Adenle (Matron)	The Medical Director and Matron of the Hospital were interviewed on whether the representatives of manufacturers of BMS <ol style="list-style-type: none"><li>Visited the facility</li><li>Are allowed to educate mothers</li></ol>	The hospital management informed the inspection team that, a representative of BMS manufacturer once visited their hospital about two years ago and she was referred to public hospitals claiming that they did not have large number of nursing mothers. They also claimed to encourage exclusive breast feeding. They	From the discussion with the management of the hospital indicated that, they were not aware of the International Code of Marketing of Breast Milk

				<p>iii. in the hospital Offer gift items or seminar to staff of the hospital.</p> <p>The materials displayed within the premises were also monitored.</p>	<p>have never received any gift items or invitation for seminar from either the BMS manufacturers or representatives</p>	<p>Substitutes . They were briefly enlightened on the Code.</p>
2	10 - 07- 2012	Unity Supermarket No. 5. Ajewole Shopping Complex, Km 3, Ikirun Road, Osogbo, Osun State	Mrs Faleye Titilayo (Nursing Mother)	<p>She was interviewed using the appropriate BMS monitoring form.</p>	<p>She responded that the</p> <ul style="list-style-type: none"> <li>i. Age of baby is four (4) months.</li> <li>ii. She practises exclusive breast feeding.</li> <li>iii. She intends to introduce infant formula before the baby reaches 6 months because breast milk is no longer sufficient for the baby.</li> <li>iv. She has never come in contact or received any gift items from either the BMS manufacturers or their representatives</li> </ul>	<p>The NAFDAC inspection team advised the mother to breast feed the baby exclusively for six months.</p>
3.	10 - 07- 2012	Unity Supermarket, No. 5, Ajewole Shopping Complex, Km 3, Ikirun Road, Osogbo, Osun State.	Managing Director	<p>The Managing Director in charge of the supermarket was interviewed on whether the representatives of manufacturers of BMS</p> <ul style="list-style-type: none"> <li>i. Visited the facility</li> <li>ii. Offered gift items or sales incentives</li> </ul>	<p>The shop owner informed the inspection team that BMS Companies' representatives have</p> <ul style="list-style-type: none"> <li>i. Not come to the shop for marketing,</li> <li>ii. Not offered any gift items or invited him for seminar.</li> </ul> <p>Labels of ten different brands of infant formula and follow up milk were analysed.</p>	<p>From the discussion had with the shop owner, it was understood that, he has no knowledge of the international code of marketing of breast milk</p>



				<p>iii. Invited him or his staff to seminar.</p> <p>The materials and BMS products displayed within the premises were also monitored.</p>	<p>They all have various kinds of violations. Most notable are various pictorial representations of animals such as elephant (on Friso products) and bear (on Nestle products).</p>	<p>substitutes. He was briefly enlightened on the Codes.</p>
4	10 - 07- 2012	Muslim Hospital, Okefia, Osogbo, Osun State.	Dr Ibitowa Wasiu (Medical Doctor)	<p>The Medical Officer met at the Hospital was interviewed on whether the representatives of manufacturers of BMS</p> <p>i. Visited the facility</p> <p>ii. Are allowed to educate mothers in the hospital</p> <p>iii. Offered gift items or seminar to staff of the hospital.</p> <p>The materials displayed within the premises were also monitored.</p>	<p>The hospital has not received visits from BMS manufacturers or their representatives. He also claimed that mothers were encouraged to practice exclusive breast feeding. The hospital has never received any gift items or invitation for seminar from either the BMS manufacturers or representatives</p>	<p>From the discussion with the doctor of the hospital indicated that, he is not aware of the International Code of Marketing of Breast Milk Substitutes . He was briefly enlightened on the Code.</p>
5	10 - 07- 2012	Muslim Hospital, Okefia, Osogbo, Osun State.	Nursing Mother	<p>She was interviewed using the appropriate BMS monitoring form.</p>	<p>She responded that the</p> <p>i. Age of baby is five (5) months.</p> <p>ii. She practises exclusive breast feeding.</p> <p>iii. She introduced infant milk to her baby but discontinued when the baby could not tolerate it.</p> <p>v. She has never come in</p>	<p>The NAFDAC inspection team advised the mother appropriately.</p>

					contact or received any gift items from either the BMS manufacturers or their representatives	
6	10 - 07- 2012		Nursing Mother	She was interviewed using the appropriate BMS monitoring form.	She responded that the <ul style="list-style-type: none"> <li>vi. Age of baby is six (6) months.</li> <li>vii. She practises exclusive breast feeding.</li> <li>viii. She does not intend to introduce infant formula to her baby.</li> <li>ix. She has never come in contact or received any gift items from either the BMS manufacturers or their representatives</li> </ul>	The NAFDAC inspection team advised the mother appropriately.
7	10 - 07- 2012	Briskol Super Store, Ayetoro, Osogbo, Osun State	Managing Director	The Managing Director of the supermarket was interviewed on whether the representatives of manufacturers of BMS have <ul style="list-style-type: none"> <li>i. Visited the facility</li> <li>ii. Offered gift items or sales incentives</li> <li>iii. Invited her or her staff to any seminar.</li> </ul> The materials and BMS products displayed within the premises were also monitored.	The store had brands of unregistered imported infant formula with various kinds of labelling violations of the code. The shop owner informed the inspection team that, breast milk substitute Companies' representatives have not visited her shop for marketing neither has she been offered any gift items or incentives.	Unregistered BMS products were mopped up from the store. From the discussion had with the shop owner, it was understood that, she had no knowledge of the International Code on the Marketing of Breast Milk Substitutes. She was briefly

						enlightened on the Code.
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**5. Summary of Observations**

- i. The manufacturers of BMS products still violate the Code. Various labelling violations were observed during the surveillance.
- ii. Many health workers are unaware of the Code.
- iii. The mothers interviewed breast fed their babies. They are however unaware of the Code.

**6. Recommendations**

- i. Intensive mass enlightenment on the code should be carried out for all relevant stakeholders.
- ii. Manufacturers of BMS and their representatives may be sanctioned for the various violations of the Code

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Pharm (Mrs.) Y. A. Adenuga

ADi/c EID Osun State

**Source:** NAFDAC internal records, 2012

## Appendix 4.6: Monitoring Report 2 (Kaduna)

### SUMMARY REPORT ON MONITORING : PROMOTION IN SHOPS – FORM 2

/NO	NAME & ADDRESS OF SHOP/PHARMACY	PRODUCTS	OBSERVATIONS/COMMENTS	VIOLATION
1	Kangiwa Trading Investment 16 Isa Kaita Road Shopping Complex, kaduna	Cerelac, Nutrend, NAN, Lactogen 1 & 2, SMA, Peak 123	Shop Owner Informed the group that they get promotional materials yearly such as chairs, bins, baskets.	Promotional materials on Baby Food Products
2	Nana Pharmacy Shop 13/14 Rabah Road	NAN, Cerelac	Nestle Special Display Shelf graded 1,2,3 stages.	Special Display
3	Ishara Pharmacy 1 Mohammed Buhari Road, Kaduna	<i>Lactogen, Cerelac, NAN</i>	Company representatives come frequently to give lectures on the range of baby foods	Lectures on baby food (Direct contact with the Public)
4	Nine Stars Shopping Mall 25 Tafawa Balewa Road, Kaduna	Nestle Baby food products	On Interview, the manager confirmed they get promotional materials when there is a new baby food products from Nestle	Promotional Materials
5	Dalema Supermarket 70 Isa Kaita Road Kaduna	NIL	NIL	NIL

**Source:** NAFDAC internal records, 2012

## Appendix 4.7: External Stakeholder Mapping for Code Implementation

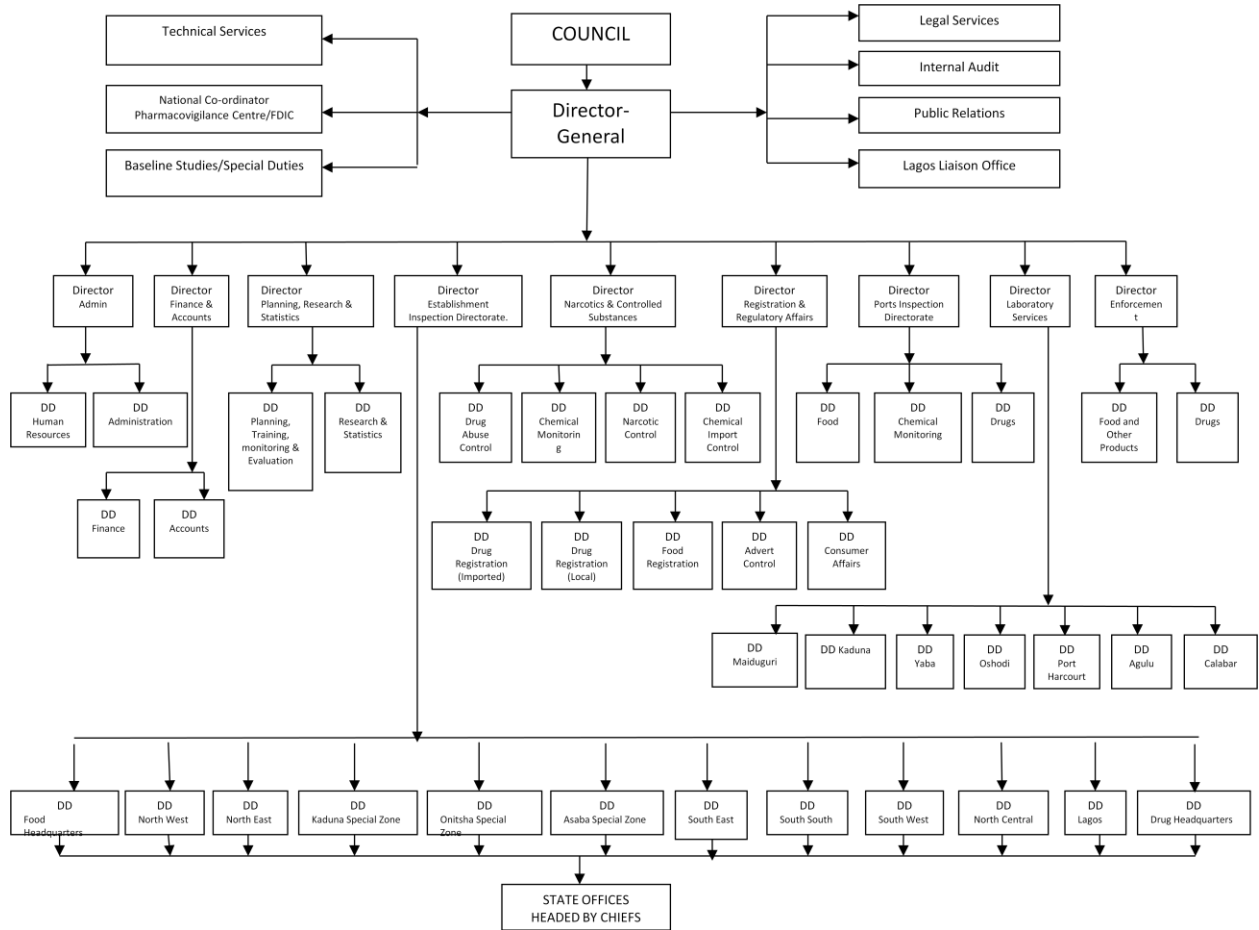
No.	External Stakeholders
1.	Government health policy makers (Federal, State, Local Government levels)
2.	Federal Ministry of Finance (FMF)
3.	National Planning Commission (NPC)
4.	National Primary Healthcare Development Agency (NPHCDA)
5.	Federal Ministry of Information (Child Rights Bureau)
6.	Federal Ministry of Women Affairs (FMWA)
7.	Federal Ministry of Education (FME)
8.	Development Partners (WHO, UNICEF)
9.	Association of Infant Food Marketers
10.	Association of Food, Beverage and Tobacco Employers (AFBTE)
11.	National Association of Supermarket Operators of Nigeria (NASON)
12.	Media Practitioners
13.	Advertising Practitioners Council of Nigeria (APCON)
14.	Health training institutions
15.	Health workers
16.	Hospitals Management Boards
17.	Guild of Medical Directors (Private-for-profit doctors)
18.	Nutrition Society of Nigeria (NSN)
19.	Nigerian Dietetic Association (NDA)
20.	Paediatrics Association of Nigeria (PAN)
21.	Nigerian Society of Neonatal Medicine
22.	Nigerian Medical Association (NMA)
23.	Society of Obstetrics and Gynaecology of Nigeria
24.	Pharmaceutical Society of Nigeria (PSN)
25.	National Association of Nigerian Nurses and Midwives
26.	Nursing and Midwifery Council of Nigeria
27.	Standards Organization of Nigeria (SON)
28.	Consumer Protection Council (CPC)
29.	Public/Consumer Interest groups: Non-Governmental Organizations (NGOs); International NGOs (IBFAN – Africa, Helen Keller International, Global Alliance for Improved Nutrition), Local NGOs (Watiwa Nigeria Limited), Civil Society Organizations (CSOs), Faith-Based Organizations (FBOs)
30.	Child Rights Activists
31.	Parents (particularly mothers)
32.	Crèches and Day-care centres
<b>Source:</b> Compiled by Author	

## Appendix 4.8: External Stakeholder Matrix for Code Implementation

EXTERNAL STAKEHOLDER MATRIX		
<b>Degree of Interest</b>	<b>Degree of Power</b>	
	<b>High</b>	<b>Low</b>
	<b>High</b>	<ul style="list-style-type: none"> <li>Government health policy makers (FMoH)</li> <li>National Primary Healthcare Development Agency (NPHCDA)</li> <li>Federal Ministry of Information (Child Rights Bureau)</li> <li>Federal Ministry of Women Affairs (FMWA)</li> <li>Development Partners (WHO, UNICEF)</li> <li>Association of Infant Food Marketers</li> <li>National Association of Supermarket Operators of Nigeria (NASON)</li> <li>Association of Food, Beverage and Tobacco Employers (AFBTE)</li> </ul>
<b>Low</b>	<ul style="list-style-type: none"> <li>Federal Ministry of Finance (FMF)</li> <li>National Planning Commission (NPC)</li> <li>Federal Ministry of Education (FME)</li> <li>Health Training Institutions</li> <li>Nigerian Medical Association (NMA)</li> <li>Paediatrics Association of Nigeria (PAN)</li> <li>Guild of Medical Directors (Private-for-profit doctors)</li> <li>Society of Obstetrics and Gynaecology of Nigeria</li> <li>Nigerian Society of Neonatal Medicine</li> <li>Hospitals Management Boards</li> <li>Guild of Medical Directors (Private-for-profit doctors)</li> <li>Nursing and Midwifery Council of Nigeria</li> <li>National Association of Nigerian Nurses and Midwives</li> <li>Pharmaceutical Society of Nigeria (PSN)</li> <li>Health workers</li> <li>Standards Organization of Nigeria (SON)</li> <li>Consumer Protection Council (CPC)</li> <li>Media Practitioners</li> <li>Advertising Practitioners Council of Nigeria (APCON)</li> </ul>	<ul style="list-style-type: none"> <li>Parents (particularly mothers)</li> <li>Crèches and Day-care Centres</li> </ul>

**Source:** Author

# Appendix 4.9: National Agency for Food and Drug Administration and Control (NAFDAC) Organogram



Source: NAFDAC internal records

## **Appendix 4.10: Composition of National Agency for Food and Drug Administration and Control (NAFDAC) Governing Council**

### **Establishment of the Governing Council**

- (1) There is hereby established for the Agency, a Governing Council which shall consist of—
- (a) a chairman who shall be appointed by the President on the recommendation of the Minister;
  - (b) the Permanent Secretary of the Federal Ministry of Health or his representative;
  - (c) the Director and Chief Executive of the National Institute for Pharmaceutical Research and Development or his representative;
  - (d) the Director-General of the Standards Organisation of Nigeria or his representative;
  - (e) the chairman of the National Drug Law Enforcement Agency or his representative;
  - (f) the chairman of the Pharmacists Board of Nigeria or his representative;
  - (g) one person to represent the Pharmaceutical Group of the Manufacturers Association of Nigeria;
  - (h) one person to represent the Food Beverages Group of the Manufacturers Association of Nigeria;
  - (i) the Director-General of the Agency; and
  - (j) three other persons to represent public interest to be appointed by the Minister.

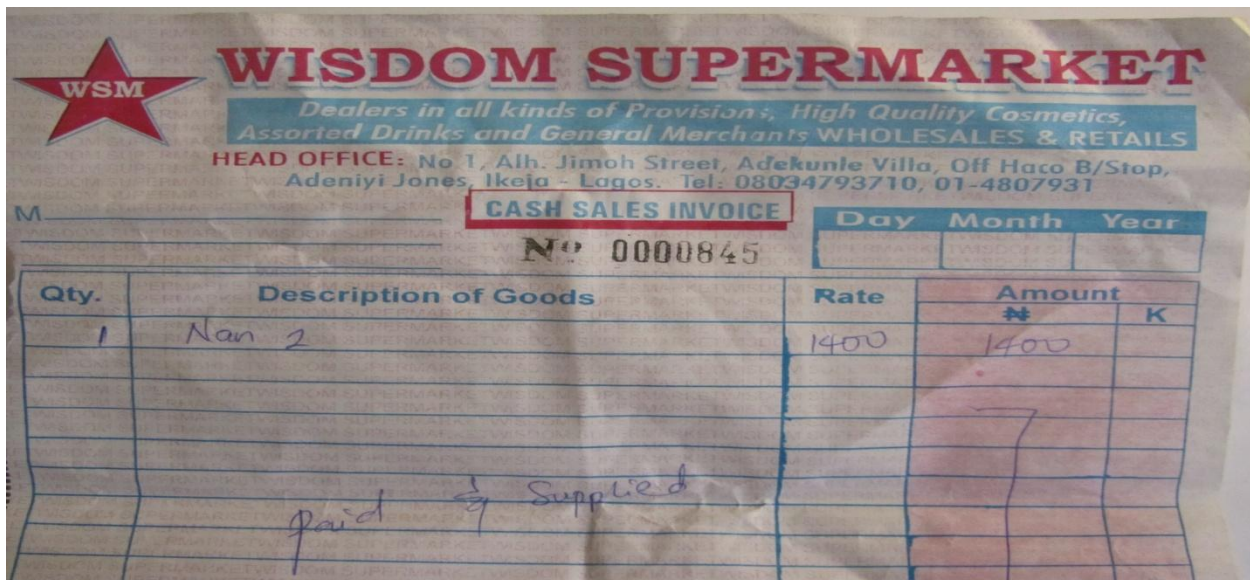
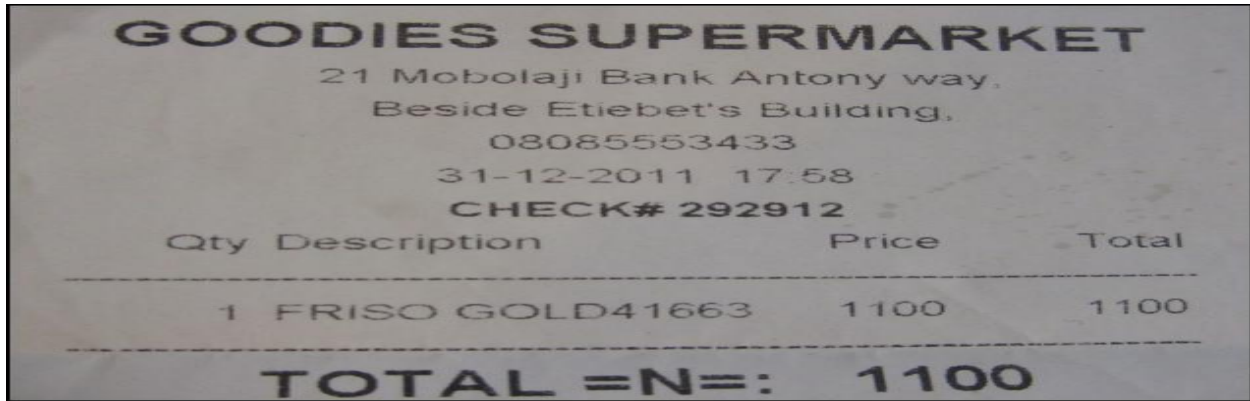
**Source:** NAFDAC Act Cap N1 LFN 2004



## Appendix 4.11: Directorates of NAFDAC, Roles in Code Implementation and Staff Strength

No.	Name of Directorate	Type of Directorate	Role in Code Implementation	Staff Strength
1.	Registration and Regulatory Affairs (R&R)	Technical	<b>Registration</b> of designated products; <b>monitoring of advertisements</b> and <b>post-registration surveillance</b> of designated products in supermarkets and open markets through its Advert Control and Consumer Affairs Units (AC/CA).	143
2.	Establishment Inspection Directorate (EID)	Technical	<b>Monitoring/Surveillance</b> of marketing practices of IFMs, distributors, importers of designated products at health facilities, supermarkets, shops/stores, open markets, retail pharmacies, and with health workers, mothers and their families.	806
3.	Ports Inspection Directorate (PID)	Technical	<b>Monitoring/Surveillance</b> (to detect violations) at *Ports of Entry.	241
4.	Enforcement	Technical	<b>Enforcement</b> of Regulations on designated products	89
5.	Laboratory Services	Technical	Pronounce on <b>quality and safety</b> of designated products. Supports R&R in product registration; supports R&R, EID, PID & Enforcement in pronouncing on the quality and safety of sampled products from monitoring/surveillance activities.	434
6.	Narcotics and Controlled Substances (NCS)	Technical	-	85
7.	Administration and Human Resources (A&HR)	Service/Support	<b>Personnel</b>	41
8.	Finance and Accounts (F&A)	Service/Support	<b>Funds</b>	92
9.	Planning Research and Statistics (PR&S)	Service/Support	-	50
<p><b>NOTES:</b> i. Total staff strength as at May 2012 is 2,174  ii. Director- General's office has 193 staff for the 7 Units  * Suspended as of October 2011 owing to Port Reforms.  <b>Source:</b> Adapted from NAFDAC (A&amp;HR) internal records; NAFDAC Consumer Safety Bulletin (2004), 3(1).</p>				

**Appendix 4.12: Retail Receipts For Purchase of Infant Formula (December 2011)**



**Source:** Lagos (Nigeria) retail stores

### Appendix 4.13: Compilation of Code Trainings/Workshops (2002 to 2011)

No.	Year	Code Training
1.	2002	UNICEF-sponsored training workshop for NAFDAC regulatory officers at Ota, Ogun State, 8 – 12 April, 2002. 62 persons trained including all members of the National Technical Committee on BMS Code.
2.	2003	Two week training of 2 NAFDAC staff, 1 BFHI staff, 1 Child Rights activist at the International Code Documentation Centre (ICDC) Penang, Malaysia
3.	2005	<ul style="list-style-type: none"> <li>i. Pre-survey training of NAFDAC staff and National Technical Committee members for Pilot Survey to field-test Code monitoring tools</li> <li>ii. Training of health workers in 4 zones of Nigeria</li> </ul>
4.	2006	Training of 40 data collectors and 50 Code watchers in Abuja, Nigeria, August 6, 2006
5.	2007	<ul style="list-style-type: none"> <li>i. Training of 50 health workers (doctors and nurses) in Abuja, May 21 – 23, 2007</li> <li>ii. UNICEF-sponsored sensitization workshop for over 100 media practitioners in Lagos and Kaduna, May 14 and 16, 2007</li> <li>iii. Training of Infant Food Manufacturers/Marketers in Nigeria</li> </ul>
6.	2009	UNICEF-sponsored training of NAFDAC Zonal and State Heads on the International Code on Marketing of Breast milk Substitute (BMS) Held on 16 – 18 December, 2009 at Enugu.
7.	2010	<ul style="list-style-type: none"> <li>i. Stakeholders Forum on International Code of Marketing BMS in collaboration with UNICEF for stakeholders, NAFDAC regulatory officers and policy makers from FMoH, 14 December 2010</li> <li>ii. UNICEF-sponsored training-of-Trainers (TOT) workshop on Code monitoring for NAFDAC regulatory officers and policy makers from FMoH in Kaduna, 15 – 17 December 2010</li> </ul>
8.	2011	EID Lagos Special Zone training on the Code, 18 February, 2011.

**Source:** Adapted from Monwuba (2010) with additions from NAFDAC internal records

## **Appendix 5.1: Composition of Ghana Food and Drugs Board (Governing Board)**

### **29. Composition of the Board**

(I) The Board consists of

- (a) the chairman,
- (b) one representative of the Ghana Standards Board,
- (c) one representative of the Food Research Institute,
- (d) the Director of the Fisheries Commission,
- (e) one representative of the Ghana Medical Association,
  
- (j) the Registrar of the Pharmacy Board,
- (g) the head of the Nutrition and Food Science Department, University of Ghana,
- (h) one veterinary surgeon nominated by the Minister responsible for Agriculture,
- (i) the Director, Crop Services Department of the Ministry of Agriculture,
- (j) one representative of the Environmental Protection Agency,
- (k) one practitioner of herbal medicine to be appointed by the President,
- (I) the chief executive of the Board,
- (m) one representative of the Attorney-General or a lawyer of not less than ten years standing, and
- (n) two other persons one of whom is a woman representing consumer interest.

**Source:** P.N.D.C.L. 3058 Food and Drugs Act, 1992 [Online]. Available from: <http://www.epa.gov.gh/ghanalex/acts/Acts/FOOD%20AND%20DRUGS%20BOARD.pdf> [Accessed 22 July 2012].