Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:

_____ _____

Adeniyi Kayode Busari Date

Two Decades of Food Fortification in Nigeria: Situational Analysis

By

Adeniyi Kayode Busari
Master of Public Health

Hubert Department of Global Health

Helena Pachón

Committee Chair

Two Decades of Food Fortification in Nigeria: Situational Analysis

By

Adeniyi Kayode Busari

Bachelor of Surgery, Bachelor of Medicine

Obafemi Awolowo University
2007

Thesis Committee Chair: Helena Pachón, PHD, MPH

An abstract of

A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements for the degree of
Master of Public Health
in Hubert Department of Global Health
April 2013

Abstract

Two Decades of Food Fortification in Nigeria: Situational Analysis

Adeniyi Kayode Busari

Objective: Food fortification has been practiced in Nigeria since 1990; however there is a dearth of published literature that comprehensively reviews Nigeria's food fortification program. This paper aims to address this gap.

Design: A desk review of published and grey literature on food fortification in Nigeria compiled from web searches and institutional archives. Search dates spanned from 1990 to 2013.

Setting: Nigeria.

Subjects: The Nigerian population.

Results: Wheat flour is fortified with vitamins A, B1, B2, B3 and iron. Maize meal, margarine, cooking oil and sugar are fortified with vitamin A. Margarine is also fortified with vitamin D. Salt is fortified with iodine. Vitamin A fortification and salt iodization have been prioritized in Nigeria and have been the focus of impact-evaluation efforts. The salt-iodization program successfully increased iodine content in domestic salt sold in Nigeria from less than 40% to 90%, ten years after implementation. But there is a recent declining trend with only 52% of adequately iodized salt consumed by domestic consumers. Median urinary iodine has persistently been above 130 μg/L since 1999 while total goiter rate decreased from 20% in 1993 to 8% in 2004. Household consumption of vitamin A-fortified foods was less than 20%. The prevalence of vitamin A deficiency has not changed between the pre and post fortification periods.

Conclusion: These findings suggest that salt iodization increased household access to adequate iodine, maintained median urinary excretion at normal level and reduced total goiter rate. Vitamin A fortification had little impact on household access to vitamin A fortified food and the prevalence of vitamin A deficiency. Program challenges include loss of nutrients from inadequate fortification and exposure of fortified food to sunlight by retailers, gaps in regulatory monitoring and unclear quality control procedures by companies. These challenges may reverse achievements of the fortification program and prevent program goals from being accomplished. Addressing these challenges, evaluating the impact of fortification with other nutrients beyond iodine and vitamin A and conducting future research on food fortification will enhance the program and reduce micronutrient deficiencies in Nigeria.

Two Decades of Food Fortification in Nigeria: Situational Analysis

By

Adeniyi Kayode Busari

Bachelor of Surgery, Bachelor of Medicine

Obafemi Awolowo University
2007

A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements for the degree of
Master of Public Health
in Hubert Department of Global Health
April 2013

Acknowledgements

First and foremost, I must thank my thesis advisor, Helena Pachón. Without her support, guidance and advice in every step of this process, this thesis would never have been completed. Thanks for the encouragement and understanding during the course of this thesis. Also my sincere appreciation to Laird Ruth, Sarah Zimmerman, Holly Patrick, Amy Webb Girard and Cynthia Dzingina for the contacts, documents and support provided during this thesis.

Technical support provided by the Global Alliance for Improved Nutrition (GAIN) for the conduct of this project is gratefully acknowledged. In particular, Grant Aaron, Francis Aminu, Magali Leyvraz and Larry Umunna suggested the topic and provided assistance with formulation of the research objectives, gathering the documents that were reviewed, and crafting the recommendations.

Getting through my thesis required more than academic support, I would like to thank Lolade Salaam, Reni Bello, Neto, Nosa, Ibiye, Eso and Danielle for their support and for listening and tolerating me while writing this thesis.

Most importantly, none of this would have happened without my family. My parents, Mr and Mrs. Busari, my brothers Dayo and Segun and my sister Toyin, I am forever grateful for your love and inspiration.

Table of Contents

List of figures and tables

List of Appendices

Background and Literature review

Micronutrient malnutrition

Micronutrient deficiency is widespread globally, especially in developing countries(1). This is attributed to factors such as inadequate feeding, low quality diet, poor food preparation methods, reduced bioavailability and infections(2, 3). Micronutrient deficiency has a significant influence on both the health and productivity of a population(4, 5).

Around 2 billion people suffer from iron deficiency globally(6) and children and pregnant women have the highest risk of anemia with prevalence rates highest in the Western Pacific (90.4%), Southeast Asia (85.1%) and Africa (76.7%)(7). Implications of iron-deficiency anemia and iron deficiency without anemia include increased child and maternal mortality rates and poor cognitive and behavior development. An estimated 5.2 million preschool-aged children have clinical vitamin A deficiency (presence of night blindness) while 190 million preschool-age children are estimated to have vitamin A deficiency using serum retinol measurement of < 0.7 μ mol/l(8). Globally, 9.8 million pregnant women are estimated to have vitamin A deficiency (presence of night blindness) while 19.1 million women have serum retinol < 0.70 μ mol/l. This predisposes children and pregnant women to a higher risk of mortality. Iodine deficiency affects approximately 2 billion people worldwide, leading to impaired brain development in children and goiter and hypothyroidism in adults(9, 10).

Zinc deficiency affects about an estimated 31% of the world population with a range of 4-78% depending on the region (11). Globally, 16% of lower respiratory tract infections, 18% of malaria and 10% of diarrheal diseases are attributed to zinc deficiency,

leading to an estimated 800,000 deaths from these diseases among children under five years(11).

Folate insufficiency in women capable of becoming pregnant is a risk factor for neural tube defects(12). Globally, an estimated 300,000 new cases of neural tube defects occur each year leading to about 41,000 deaths(13, 14). Neural tube defects include spina bifida, anencephaly and encephalocoele. Anencephaly is usually associated with stillbirth, neonatal and post-neonatal deaths while spina bifida and encephalocoele are more frequently associated with infections of the central nervous system, seizures, paralysis of the lower limbs and infant deaths.

Micronutrient deficiencies in Nigeria

Micronutrient deficiencies contribute significantly to the global burden of diseases in the country(15). Iron, vitamin A and iodine deficiency are the three most common forms of micronutrient deficiencies seen and constitute the greatest burden. In 2004, the prevalence of iron deficiency (serum ferritin < 10 ng/ml) nationally, in children under five years was 19.4%(16). This number is slightly lower among mothers, 12.7% (serum ferritin < 12 ng/ml) of whom have iron deficiency. The number rose significantly among pregnant women with 19.9% of pregnant women having iron deficiency (serum ferritin < 12 ng/ml) in 2004. Since serum ferritin is an acute phase reactant, it may be elevated if there is chronic inflammation, infections or malignancy(17) Measuring C-reactive protein can help exclude these diseases, thereby increasing the accuracy of serum ferritin measured. In this survey, C-reactive protein, an inflammation indicator was not measured. The prevalence of anemia (hemoglobin < 120 g/l) in non-pregnant women of reproductive age is 62%(18). It is even higher among pre-school aged children, 76.1% of whom have anemia (serum hemoglobin < 110 g/l). Although the prevalence of anemia was measured in the three agro-ecological zones (Dry Savannah, Moist Savannah and

Humid Forest), it is unclear if it was altitude adjusted. It is important to adjust for difference in serum hemoglobin measurements if the difference in altitude among the three zones is > 1000 feet because prevalence of anemia might be underestimated in high altitude if its not adjusted for(19). The prevalence of (serum retinol concentration < 20 u g/dl) among children aged 6-59 months, pregnant women and mothers is 29.5%, 8.8% ad 4.1% respectively(16). Zinc deficiency (serum zinc < 80 ng/ml) was highest among pregnant women in Nigeria with 43.8% while the prevalence of zinc deficiency was slightly lower among mothers (28.1%) and children under five years (20%)(16).

Introduction of food fortification

Food fortification is the purposeful addition of nutrients to food so that its nutritional value is increased and nutrient deficiencies are prevented or corrected in the consuming population(4, 20). Over several decades, as emphasis shifted from treatment to prevention of micronutrient deficiencies and overall improvement in health status of vulnerable people, strategies and guidelines necessary to follow this trend have also evolved(21). Food fortification is one of the most cost-effective public health strategies that leads to rapid improvement in the micronutrient status of a population(22, 23).

In many Western countries, food fortification programs have been implemented since the early 1900s(24). Switzerland began fortifying salt with iodine in 1923; the United States of America initiated food fortification with salt iodization in 1924; and the United Kingdom started vitamin A fortification of margarine in 1927(25).Canada commenced fortification in the1940s with vitamin B1 fortification of wheat flour(26).

More recently, developing countries have gradually adopted and implemented food fortification policies(27). Due to their unique socioeconomic challenges, these countries have encountered varying levels of success and failure in adopting food fortification programs(27, 28).

Food fortification has increasingly played a major role in providing micronutrients in food and preventing micronutrient deficiencies in developing countries(1, 29). An advantage of fortification is that the food vehicle retains its content and texture after fortification while concurrently reducing and preventing micronutrient deficiencies in the population(30). The major strategies to correct or prevent micronutrient deficiencies include: supplementation, fortification, dietary diversity (education and access), and disease control. The choice of strategy (ies) depends on a number of factors including the degree of deficiency in the population, population subgroups targeted, and the available financial resources to develop and sustain programs. Among these strategies, fortification is widely considered the most cost-effective for reaching large segments of a population without changing food consumption patterns(22, 23).

Types of fortification

There are three main types of food fortification used globally: mass fortification, targeted fortification and market-driven fortification(30). Mass fortification is mandated and regulated by the government of a country at the public health level. Its aim is to ensure food commonly consumed by the general public has adequate nutrients added through the process of fortification. Mass fortification is usually implemented once there is an observed clinical or biochemical micronutrient deficiency or when a risk of deficiency in a general population is identified.

Alternatively, targeted fortification focuses on a specific subset of a population who is at increased risk, such as children or women of childbearing age, to provide the deficient micronutrient in the food regularly consumed by the group(30).For example,

milk is fortified with iron, zinc and copper in Chile for infants up to eighteen months old(31).

Market-driven fortification is a voluntary fortification usually initiated by a food manufacturer to enhance processed foods, such as cereals and beverages, with micronutrients(32). Various concerns have been raised about this mode of fortification despite its benefits at complementing mass fortification programs on a public health level. These concerns range from changing food pattern consumption to inadequate regulation of the processed foods leading to inappropriate amounts of micronutrients consumed by the targeted population(4, 32).

Additionally, there are other types of fortification, which may fall into the above-mentioned categories. These include point-of-use, community and bio-fortification(4). Home fortification is the addition of micronutrient powder such as Sprinkles or lipid nutrient supplements at the point-of-use(33). There are a growing number of programs globally using this means to address micronutrient deficiencies(34). A research conducted in Kenya on the impact of community-based distribution of Sprinkles showed this approach was effective in reducing the prevalence of anemia, iron and vitamin A deficiency in young children(35).

Community fortification is small-scale fortification performed during the milling process by adding sachets of a premix of micronutrients to food in the community(4). This approach has been tested mainly in small studies and pilots to date. A recent study conducted in India to assess the efficacy of community-level fortification of food with a premix fortified with iron and vitamin A in preschool children showed community fortification was effective in reducing the prevalence of anemia, iron deficiency and iron-deficiency anemia(36).

Bio-fortification of staple food focuses on genetic enhancement of plants with micronutrients by combining traditional breeding methods with modern biotechnology(4, 37). A study done in the Philippines to test the efficacy of bio-fortified rice on the iron stores of non-anemic women showed that women who consumed iron bio-fortified rice had significant iron status improvement compared to those who consumed commercially available rice not bio-fortified with iron(38).

Food fortification vehicles and nutrients added

In selecting a food fortification vehicle, certain factors should be considered. For example, population assessment to determine consumption patterns and deficiencies of public health concern has to be conducted, the targeted population being considered, such as women of reproductive age, should consume high amounts of the food vehicle and have a low intake of the nutrients added during fortification for the program to achieve its desired impact(31). Numerous nutrients can be added to different food vehicles during fortification(4). For example, iron is added to wheat flour, maize flour, corn masa flour, pasta, maize meal and salt. Vitamin A is added to commonly consumed food such as milk, margarine, vegetable oil, sugar, wheat flour, pre-cooked maize flour and maize meal while milk, margarine and wheat flour are fortified with vitamin D. Different types of vitamins B are added to food but vitamins B1, B2 and B3 are the three most common vitamins used for fortification. Vitamin B1, B2 and B3 are used to fortify wheat flour, pasta, corn masa flour, pre-cooked maize flour, maize flour and meal. Additionally, vitamin B2 and B3 are added to margarine but vitamin B1 is usually not. Margarine, wheat flour and maize meal are the food vehicles fortified with Vitamin B6 while vitamin B12 is added to wheat and maize flour vitamin Folic acid is added to margarine, wheat flour, maize meal and corn masa flour. Zinc is used for wheat flour and corn masa flour fortification while salt is fortified with iodine and calcium is added to wheat flour.

Global fortification patterns

Several countries have embraced food fortification, and some of these countries have mandatory food fortification policies. Presently, 75 countries require the fortification of wheat flour with iron and/or folic acid(39).

Globally, the percentage of wheat flour fortified industrially increased from 18% to 30% between 2009 and 2012(39). Regionally, between 2004 and 2008, the Americas had the highest wheat fortification percentage-point increase from 90 to 97% followed by 26 to 31% in Africa, 16 to 21% in South East Asia and 3 to 6% in Europe. The lowest wheat fortification was in the Western Pacific region with a 2 to 4% percentage-point increase in wheat fortified being during this period(40).

Progress was made with salt iodization between 1990 and 2001(10). In 2001, more than 43 countries had universal salt iodization, and almost half of the countries with iodine deficiency disorders on a public health scale in 1990 had salt iodization coverage above 50%, and 20 of the countries had greater than 90% coverage(41). A global report revealed that South East Asia has the highest household iodized salt consumption (100%) followed by Africa (98.9%), the Eastern Mediterranean (92.3%), the Western Pacific (88.9%), the Americas (70.4%) and Europe (41%)(42). The country with the highest consumption of household iodized salt, the United States of America, had the lowest proportion of people with insufficient iodine intake, while Europe, with the lowest iodized salt consumption, recorded the highest percentage of people with inadequate iodine intake(42).

Effects of fortification on health outcomes

Fortification has been shown to positively impact nutrition in numerous studies. Evidence indicates that folic acid, iodine and other types of fortification improve health

outcomes(4). The aim of fortifying food with folic acid is to reduce the birth prevalence of neural tube defects and associated morbidity and mortality(43).

Available data suggest mandated folic acid fortification has been successful at doing this in a number of countries(43); ranging from a 31% to 78% reduction in neural tube defects in South Africa and the United States of America(13). Studies also show a reduction ranging between 2% and 76% in the birth prevalence of spina bifida in several countries(44-47). For example, the birth prevalence of spina bifida in Oman was reduced significantly, from 3.06 to 0.29 per 1000 deliveries, within ten years of folic acid fortification of white wheat flour(45). In Chile, fortification of wheat flour with folic acid between 1990 and 2000 also resulted in a 61.7% decrease in the prevalence of anencephaly(48).

Salt iodization helps reduce thyroid size and increase urinary iodine(41). A study in Ivory Coast measured mean thyroid size by ultrasound and urinary iodine concentration six months prior to salt iodization and annually four years post iodization. The results showed an increased urinary iodine from 28-161 μg/L within two years and a 56% decrease in mean thyroid size within four years(49).

Various studies were conducted on the impact of fortification on iron status and anemia. Pre and post fortification levels of serum ferritin measured in different effectiveness studies show percentage increases ranging from 11% to 79% in China, Fiji, Iran and Venezuela(50). Although this clearly demonstrates the effect of fortifying wheat flour with iron, increase in iron status does not occur in all iron fortification of wheat flour. For example, a study in South Africa showed a slight decrease in iron status pre and post fortification of wheat flour(51).

The impact of fortification on anemia status varied among different countries and age groups after flour was fortified with iron. Although lower anemia prevalence was

observed in several countries and age groups, no significant change in anemia status was noted in other countries(52). For example, while Chinese women had lower anemia prevalence after fortification of wheat flour with vitamin A, B1, B2, niacin, folic acid, zinc and iron(53), there was no significant change in anemia status of Iranian women after fortification with iron(54). Additionally, while no significant change was noted in anemia status among pre-school Brazilian children(55), a reduction in prevalence of anemia was observed among Brazilian women(56).

National surveys conducted in 1995 to assess the impact of sugar fortification with vitamin A among pre-school aged children in Guatemala, El Salvador and Honduras between the 1960s and the 1990s showed a reduction in the prevalence of vitamin A deficiency (serum retinol < 20 μg/dl)(57).The prevalence of low serum retinol reduced from 44%, 26% and 40% to <10%, 16% and 13% in El Salvador, Guatemala and Honduras, respectively.

A six-month school-based study was conducted in Nigeria to assess logistical practicality and efficacy of feeding school children with multi-micronutrient beverages fortified with vitamin A, iron and zinc(58). The study revealed that children in the micronutrient group were 53% less likely to have low serum retinol and 36% less likely to have low serum zinc compared to the control group. Also the proportion of anemia, iron deficiency and iron-deficiency anemia decreased in both study groups however the intervention had no significant effect on hemoglobin and iron status.

Monitoring and program evaluation

Studies have been conducted on food fortification effectiveness, but few of these addressed the issue of monitoring and evaluation(30). Monitoring and evaluation plays a vital role in assessing the quality, implementation and impact of the program on the targeted population and helps evaluate program sustainability(4, 27).

Monitoring and evaluation of food programs is divided into two main parts: regulatory and household/individual monitoring and evaluation(4). Regulatory monitoring is used to monitor fortified food (locally produced or imported) and the vitamin and mineral premix added to it. Food control agencies and customs check and assess the imported food and vitamin premix at the point of entry into a country. Regulatory monitoring also includes internal, external and commercial monitoring(4). Internal monitoring encompasses quality control measures implemented by the fortified food producer at the factory. External monitoring is inspection performed at the factory by government officials to ensure producers strictly adhere to standards regulating the fortified food. Commercial monitoring refers to inspection of distributor shops and retailers outlets by government officials to ensure fortified food meets quality standards and safety prior to purchase by the public.

Household/individual monitoring and evaluation is classified into household/individual monitoring and impact evaluation. Household monitoring is used to assess the availability and accessibility of fortified foods to households as well as determine the consistency of the quality of these foods from production to consumption(4). This can be achieved through monitoring provision, which assesses the number of products sold in retail stores; utilization, which is an assessment of the number of fortified food purchased and consumed by households; and coverage, which assesses adequacy and frequency of consumption of the purchased products(4).

Impact evaluation assesses the impact of the fortification over time. Impact evaluation should be done after regulatory monitoring has been properly implemented(4). Planning for impact evaluation should be carried out during the design stage of the program(30). Furthermore, timing of evaluation should depend on the type of fortification(4). For example, it takes approximately 6-9 months to see the effect of iron

fortification on iron status(59), thus, doing an impact evaluation for iron fortification three months after program implementation will give inaccurate findings. The timing of an evaluation also depends on the indicators being monitored. In iodine deficiency, using goiter and urinary iodine as indicators, urinary iodine intake will increase weeks after consumption of iodized salt is started while it takes about 2 years to notice reductions in goiter(4).

A monitoring and evaluation framework by the United States Centers for Disease Control and Prevention (CDC) identified six important steps necessary in monitoring and evaluating a food fortification program(60): ensuring cooperation and active participation of stakeholders such as industry, government officials, and international organizations; providing a detailed description of the monitoring and evaluation program such as activities, inputs, outcomes, goals and developing it into a logical framework; focusing the monitoring and evaluation on specific components of the program that require evaluation; gathering reliable data; performing good data analysis; comparing results to previous data to highlight sections of the program that require improvement; and ensuring stakeholders learn from this experience by communicating the findings and making appropriate recommendations that can further enhance the program.

Background information on Nigeria

Nigeria is the most populous nation in Africa with a population of around 170 million(61, 62). Covering a total area of 923,768 km^2, Nigeria is located in West Africa and borders Niger, Chad, Cameroon and Benin on the north, northeast, east and west, respectively. Nigeria is comprised of 36 states and the capital (Federal Capital Territory), and is grouped into six regions (North Central, North West, North East, South West, South South and South East). The three major tribes are Yoruba, Ibo, and Hausa but there are around other 250 minor tribes and over 200 languages spoken across Nigeria.

Majority of the country's revenue is derived from crude oil exports(61, 62). Globally, it is the 11th largest exporter of crude oil with oil revenue accounting for approximately 95% of foreign exchange revenue, 80% of government budget and about 40% of GDP.

Prior to the discovery of oil in the 1980s, revenue from agricultural sources such as farming and fishing was the largest source for the Nigerian government; it now accounts for 32.5% of GDP. Other segments of the economy contributing to GDP include services such as transport and finance (13.5%) and industries such as mining and construction excluding the petroleum sector, which contributes 2.9% to the GDP (2006).

Industrial production of fortified food

There are 19 industrial mills, (producing > 20 metric tons of wheat and maize per day), fortifying wheat and maize flour in Nigeria(18). Two of these mills (Dangote Flour Mills and Flour Mill of Nigeria) have installed capacity to produce 6000 MT/day of fortified wheat flour(20). All the wheat flour produced in Nigeria is industrially milled(18) and the installed capacity of these mills aids the production of all wheat flour produced in Nigeria in industrial mills(20). In total, about 44,000 MT of wheat flour and 6,724,000 MT of maize flour is produced yearly by the mills(18). The wheat flour is used to produce locally consumed food such as noodles, puddings, bread, and biscuits(20) while the maize flour/meal are mostly used for making tuwo masara(63). About 98% of sugar imported into the country is in raw form and the remaining 2% is imported as refined sugar(64). Two companies (Dangote Sugar and BUA Sugar) have installed capacity to refine 1.44 million MT and 720,000 MT of raw sugar annually(65). The two companies are the major sugar companies in the country with a combined refining capacity of 2.3 million MT of sugar annually. Sugar is mostly consumed as table sugar used in tea, maize millet (pap) meal and garri in Nigeria(63).

Currently, an estimated 52 cooking oil industrial mills exist in Nigeria, with about 25 mills producing > 20 MT of cooking oil per day(20). These mills produce 800,000 MT of vegetable oil (73%) and 300,000 MT is mainly procured from Asia. The largest industrial mill, BUA oil, has installed capacity to produce 500 MT/day of vegetable oil. Most mills have installed capacity to produce between 80-100 MT/day, with 75% of vegetable oil produced in the mills being fortified. Despite the production of fortified cooking oil by the industrial mills, there are numerous traditional vegetable oil industries producing unfortified products such as unfortified palm oil. This results in continuous consumption of unrefined cooking oil by Nigerians. Vegetable oil is mostly used for making soup or stew in Nigeria(63). Furthermore, industrial mills in Nigeria fortify food 10% above the required fortification level but this level of overage may be insufficient with vitamin A fortification of cooking oil(20). There are five major salt companies in Nigeria importing eight different brands of iodized salt with a combined market share of 98%. These companies then repackage the salts in retail sizes of 1 kg, 500 g and 250 g.

Importation and exportation status

Industrial mills in Nigeria import most of their wheat grain, sugar, and crude vegetable oil from North America, Brazil, Malaysia and Indonesia(20, 64, 66). These products are then refined locally, fortified and sold to the public. An estimated 7,795,100 MT of wheat grain, 1,450,000 MT of raw sugar, 300,000 MT of vegetable oil, 687 MT of maize grain, 20 MT of wheat flour, 2567 MT of maize flour, and 100,000 MT of raw refined sugar is imported annually(18, 20, 64, 66). In 2010, Nigeria was the highest importer of US wheat but dropped to the 3rd highest importer in 2012(18).

Nigerian mills export vegetable oil, refined sugar and products derived from wheat such as pasta and noodles to neighboring West African countries(20). Annually,

2884 MT of wheat flour, 82 MT of wheat grain, 10,416 MT of maize grain and 653 MT of maize flour is exported to these neighboring countries(18).

Food fortification legislation and standards

Food legislation is enacted to protect people's health, safeguard against fraud and encourage trade(67). Most countries with food legislation try to adhere to Codex Alimentarius standards and guidelines(68). Food fortification legislation sets the guidelines for the nutrients to be added to fortified food.

The Food and Drug Act Decree 35 was enacted in Nigeria in 1974(69, 70). It serves as the legal framework for food processing, safety and control in Nigeria. The act provides the guideline for the sale of food, drugs and other related items. Additionally, it sets the standard for manufacturing, importing, exporting and labeling of food and drugs in Nigeria.

The National Agency for Food and Drug Administration and Control (NAFDAC) is the government agency responsible for regulating the food and drug industry in Nigeria(71). This includes regulation of food manufacture, importation, exportation, labeling, fortification and distribution of food in Nigeria. The agency was formed in 1993 under the amended Government of Nigeria Act No. 19 of 1993 and the Food and Related Products Act No. 20 of 1999.

Goals and significance

The goal of this thesis was to comprehensively review the food fortification program in Nigeria since inception. Specifically, the program is assessed from a policy, program implementation and impact on micronutrient deficiency point of view. The review and proposed recommendations possess the potential to improve the existing program that can lead to efficient and effective delivery of micronutrients to Nigerians. The report will also provide a general insight into micronutrient deficiencies in the country and impact of fortification on the deficiencies.

Objectives

Specific Objectives of the report include:

1. Review the history of food fortification in Nigeria
2. Assess the current status of food fortification in Nigeria
3. Provide future recommendations for food fortification in Nigeria

Methods

A web search of published literature and grey literature of studies conducted between 1990 and 2013 was done to identify studies on food fortification globally and as it applies to Nigeria. PubMed, Embase, Google Scholar, The Cochrane Library, African Journal of Nutrition were searched for published literature on global food fortification and fortification in Nigeria. Randomized clinical trials, case-control studies, cohort, cross-sectional studies were considered for inclusion in this study. A desktop review of published and unpublished technical reports from government agencies, international organizations and non-governmental organizations was conducted between October 2012 and April 2013 and titles and abstract of studies were reviewed to establish similarity of the study to food fortification in Nigeria. Results of national surveys like the Nigeria Demographic and Health Survey, Nigerian Food Consumption and Nutrition Survey were reviewed. Progress reports was also obtained from websites of government agencies, international organizations and non-governmental organizations: the organizations include Flour Fortification Initiative, Global Alliance for Improved Nutrition, Micronutrient Initiative and Helen Keller International.

Survey instrument

A survey questionnaire was used as the main data collection instrument for fortification in Nigeria. The questionnaire was developed and administered by Global Alliance for Improved Nutrition (GAIN)(72) to twenty stakeholders, which included government agencies, international organizations, non-governmental organizations and industry. The questionnaire is divided into two sections: profile and survey information. The profile contains information such as name of stakeholder's organization, type of organization (government private, non-governmental organization) and contact information of the person representing the organization. The survey part addressed description of food

fortification in Nigeria, purpose of the project and contained questions for stakeholders involved food fortification in Nigeria. The questionnaire was grouped into four main issues: regulatory monitoring by NAFDAC and SON officials, monitoring and impact assessment at household level by officials of the Federal Ministry of Health and other government agencies, production and distribution of fortified food and premix by staff of companies and social marketing and communications of this product by staff of government agencies, industry, non-governmental organizations, international organizations, consumer protection agency and news media. Institutional Review Board approval was not required for this study because it was not a human research study.

Results

Table 1 shows compliance level of port/ factory monitoring of iodized salt by SON and distributor/retailer monitoring of iodized salt by NAFDAC between 2002 and 2009. In the seven-year period, compliance at the port and factory was consistently above 85% with the exception of 2003 when compliance was at 50%. Compliance was even more impressive at the distributors and retail level. Salt iodine content was consistently 97-100% in the seven-year period. Table 2 gives account of national surveys on household access to iodized salt between 2003 and 2008. The surveys are population-based surveys conducted nationally. They indicate a falling trend in household access to iodized salt. Table 3 shows zonal trends in household access to iodized salt in Nigeria. Table 4 shows the number and proportion of people consuming vitamin A fortified food in the five states in the three agro-ecological zones of Nigeria. Less than 20% of all households consume vitamin fortified wheat flour, maize flour, sugar and vegetable oil. Table 5 shows the prevalence of vitamin A deficiency among pre school aged children since 1993. Prevalence rate remain persistently high despite mandatory fortification policy.

Objective 1: History of food fortification in Nigeria

Nigeria initiated efforts to commence food fortification after the World Summit for Children in New York in 1990 where world leaders made a declaration to improve child survival by the year 2000(73). The declaration included increasing immunization coverage, eliminating iodine deficiency disorders and promoting breast-feeding. Food fortification effectively started in 1993 when the Universal Salt Iodization (USI) program was established and mandated by Nigerian Industrial Standard(73). Nigerian Industrial Standard 168:1992 required all food salt either manufactured or imported into Nigeria, to be iodized with 50 ppm potassium iodide prior to packaging. Two years later, the Standard was modified following new evidence indicating the depletion of potassium iodide in food salt sold in USI programs globally. The modified Standard (NIS 168:1994)(74) required that > 50 ppm, > 30 ppm and >15 ppm of potassium iodate be present in food salt at port/factory, distributor/retail and household levels, respectively.

Mandatory fortification of wheat flour, maize meal, sugar and vegetable oil did not begin until 2002 when the Ministry of Industry launched the National Policy on Food and Nutrition(75, 76). The policy was aimed at improving the nutritional status of all Nigerians. In an attempt to achieve the goal of improving nutrition and reducing malnutrition among the people, specific objectives to be achieved by 2010 were highlighted. The objectives include a 30% reduction in moderate and severe malnutrition micronutrient deficiencies and a 50% reduction in micronutrient deficiencies such as vitamin A, iron and iodine deficiency amongst children under five years by 2010.

In 1990, the National Committee on Food and Nutrition was formed under the Ministry of Science and Technology. In 1994, National Planning Commission managed the affairs of the committee after the Ministry was phased out(77). The Committee coordinates food and nutrition policies and programs in conjunction with other agencies

such as the Federal Ministry of Industry (the Standard Organization of Nigeria), National Agency for Food and Drug Administration and Control, and National Primary Health Care Development Agency. The Committee released the National Policy on Food and Nutrition document and the National Plan of Action for Food and Nutrition(75, 77), which serve as a guideline for implementing nutrition policy.

The Nigeria National Fortification Alliance is comprised of professional associations, industry and government agencies(23). The Alliance is a public-private partnership formed in 2002 to encourage better cooperation and coordination among all the fortification stakeholders in the country and minimize the barriers between industry and government agencies. Today, the Alliance is led by the private sector in Nigeria, but was previously coordinated by the National Planning Commission and National Agency for Food and Drug Administration(75).

In Nigeria, fortification has been mandated for wheat flour, maize flour, various cooking oil, sugar, margarine and salt(74). Although foods and beverages such as Blue Band margarine, Dangote pasta, powdered milk and Ovaltine are already fortified with folic acid, the country recently approved fortification of wheat flour with folic acid and zinc(78). It is the only country in Sub-Saharan Africa with a policy requiring vitamin A fortification of four staple foods (wheat and maize flour, sugar and vegetable oil)(79). Standard Organization of Nigeria developed policies to guide the fortification of these foods. According to NIS policy (NIS 121:2000)(74), wheat flour is to be fortified with 30,000 IU/kg of vitamin A, 6.2 mg/kg of vitamin B1, 49.5 mg/kg of niacin, 3.7 mg/kg of riboflavin and 40.7 mg/kg of iron(74). Milled maize flour (NIS 295:2000)(74) is to be fortified with 30,000 IU/kg of vitamin A. The various oils consumed in Nigeria are to be fortified with 20,000 IU/kg of vitamin A. These oils include groundnut oil (NIS 393:2000)(74), which is most commonly consumed. Other types of oil consumed in

Nigeria include palm oil (NIS 230:2000), sunflower oil (NIS 90:2000)(74), coconut oil (NIS 387:2000)(74), palm kernel (NIS 230:2000)(74), soya bean oil (NIS 392:2000)(74), rape seed oil (NIS 394:2000)(74), cotton seed oil (NIS 389:2000)(74), maize oil (NIS 391:2000)(74) and sesame seed oil (NIS 393:2000)(74). Margarine (NIS 243:2000)(74) is fortified with 26,000-33,000 IU/kg of vitamin A and 28,000-33,000 IU/kg of vitamin D. About 98% of sugar consumed by Nigerians, in the form of brown, is imported from Brazil(65). The imported sugar is then refined and fortified locally by sugar mills in Nigeria. Refined white sugar are (NIS 90:2000) and brown sugar (NIS 438:2000(74) are fortified with 25,000 IU/kg of vitamin A. Salt(NIS 168:1994)(73) is fortified with 50 ppm of iodine. The Nigeria Industrial Standard policy does not specify standards for the fortification of this products and Standard is currently being revised to include zinc and folic acid(20).

Industry fortification efforts

Some companies in Nigeria have led fortification implementation in the country. For example, Nestlé in 2012 started fortifying bouillon cubes with iron(80). These bouillon cubes were already been fortified with iodine. Unilever, Dangote and Cadbury have been producing folic acid fortified Blue band margarine, pasta and Bournvita respectively even though folic acid and zinc were recently approved for wheat flour fortification and Standards are currently been revised(78, 81).

Nutrient compounds added during fortification in Nigeria

The food vehicle determines the nutrient compound added to the food(4). Palmitate is the vitamin A compound added to wheat flour, maize flour, vegetable oil, margarine and sugar in Nigeria(74). In Nigeria, potassium iodate is the chemical form of iodine that is used for salt fortification(73) while electrolytic iron is the iron compound

added to wheat flour(20). The Nigerian Industrial Standard does not specify the niacin, thiamine and riboflavin compounds added to wheat flour and maize flour.

Fortification coverage in Nigeria

Following the implementation of the vitamin A fortification policy in 2002, an increase in fortified wheat flour, sugar and vegetable oil was observed(75). By 2004, 70% of sugar, 100% of wheat flour and 55% of vegetable oil sold to consumers was fortified with vitamin A. Nigeria also achieved success with its USI program. In 1999, 97.5% of salt at local retail markets and at iodized salt distribution centers met the required standard of > 30 ppm iodine based on results from the qualitative iodine field kit test(73). This increased to 98.4% in 2003 and peaked at 100% by 2005. In 2005, Nigeria was certified USI-compliant by the Global Network for the Sustained Elimination of Iodine Deficiency Disorders.

Objective 2: Current status of food fortification in Nigeria

Despite the achievements recorded in Nigeria's fortification program, micronutrient deficiency is still a significant global public health issue in the country. For any country to reduce the burden of micronutrient deficiencies, monitoring and assessing the progress and coverage of its fortification program needs to be a key part of its control strategy(49, 60). Although several nutrients are added to food vehicles in Nigeria, most data and reports on monitoring and coverage of Nigeria's fortification program is focused on salt iodization and vitamin A fortification of wheat flour, sugar and cooking oil. There is sparse data or studies on thiamine, vitamin B1 and B2, niacin and iron fortification in the country. A study assessed nicotinamide, pyridoxine, riboflavin and thiamine content of packaged foods (fruit juices, cereal products and dairy products) in Lagos metropolis in 2008(82). HPLC analysis of the samples showed variations in compound content. For instance, while some samples had high concentration of nicotinamide and riboflavin (854.05 μg/ml and 1400 μg/ml) some samples contained no nutrient. The study concluded that mean concentration of these compounds in analyzed food was adequate.

Salt iodization coverage and monitoring in Nigeria

In an effort to reduce the burden of iodine deficiency disorder, Nigeria established its Universal Salt Iodization (USI) program in 1993(73). The program mandated fortification of salts sold in Nigeria, increasing household access to iodized salt from 40% in 1993 to 98% in 1998. In 2001, monitoring and evaluation of the USI program was initiated but lack of retrospective data impeded the monitoring process. Following transition to democracy in 1999, government agencies went through some restructuring and this posed regulatory and monitoring challenges for the USI program. Consequently, the Iodine Deficiency Disorder-Universal Salt Iodization (IDD-USI) taskforce was formed in 2002 to assess effectiveness, monitor coverage and ensure sustainability of the

USI program(73). The taskforce comprises the Federal Ministries of Health (FMoH) Federal Ministries of Education (FMoE), National Primary Health Care Development Agency (NPHCDA), SON, NAFDAC, GAIN, Micronutrient Initiative (MI), salt producers, and UNICEF. These agencies have different tasks at different levels of the USI program. The different levels are the port of entry/border and factory level, distributor and retailer level and household/individual level. After monitoring has been done at each level of the program, the agencies coordinate regularly to maintain an updated national record of salt iodization coverage in the country(83, 84).

Regulatory monitoring of USI program in Nigeria

SON conducts external monitoring of the USI program at the port of entry and factories of salt producers to ensure that iodine content is maintained at > 50 ppm(73). This is done in two ways: an onsite rapid test and a laboratory test on composite samples using titration analysis(73, 84). Records of rapid testing of imported salt at the ports and factories show 90-100% of salt tested has iodine content consistently greater than 50 ppm(Table 1). This result is further validated by titration analysis of the iodine content in composite salt samples performed at SON laboratories in 2002. The composite salt samples tested in SON laboratory had an iodine range between 51-73 ppm.

Port inspections are conducted at the four major ports in Nigeria prior to release of imported salt to the companies. Factory inspections occur at least twice yearly or quarterly depending on the inspector's assessment of compliance level in the company. SON required packaging of salt in 250 g, 500 g and 1 kg of polyethylene bag to ensure iodine content is retained(83, 84). The bags must also display NAFDAC approved numbers indicating compliance with approved standards. Additionally, SON created a logo for consumers to easily identify iodized salt and discourage buying unrefined salt from retailers(83, 84). There are five major salt companies in Nigeria importing iodized

salt in large quantities into the country(73). The imported iodized salts are then repackaged in smaller bags as required by SON. The remaining 2% of salt consumed in Nigeria are produced by local producers or imported from neighboring countries. The companies have quality control and assurance in place to ensure that guidelines and standards of salt fortification are met(73). These companies maintain records such as certificates of shipments of imported iodized salts to ensure that standards for product registration and good manufacturing practices are met. However, some procedures outlined by WHO guidelines for quality control(4) are undocumented or not completed by these companies. For example, the process of storage, production of pre-blend, and salt testing is not detailed in internal monitoring reports from the companies.

The National Agency of Food and Drug Administration (NAFDAC) monitors iodized salt to ensure that salt producers maintain ≥ 30 ppm at the level of the retailers and distributors(73, 84). NAFDAC does an initial primary analysis field test using qualitative iodine test-kits. Salt samples that do not meet the required standard of ≥ 30 ppm of iodine are taken back to NAFDAC laboratories for further tests using titration analysis. An analysis of salt from retail sellers and distributors in 600 local government areas in 2002 and 2003 and 771 local government areas in first six months of 2005(73) indicated that 90-100% of salt samples analyzed had iodine content ≥ 30 ppm(Table 1)(73). Although there were some survey methodology and statistical shortcomings in the 2002 and 2003 surveys, they were adjusted for in the 2005 survey and analysis. NAFDAC has offices in the 36 states of the country and officials have reportedly destroyed 10,000 bags of non-iodized salt found at the distributors and retail shops(73). This may have deterred some of these companies from selling non-iodized salt.

Table 1 Factory, distributor and retail level monitoring of iodized salt by SON and NAFDAC between 2002 and 2009

Year	Factory and port (SON) (% of salt > 50 ppm)	Distributors and retail (NAFDAC) (% of salt > 30 ppm)
2002	N/A	100
2003	50	99.4
2004	N/A	N/A
2005	100	100
2006	97.4	99.9
2007	N/A	97.7
2008	93.9	100
2009	88.5	N/A

SON-Standard Organization of Nigeria, NAFDAC=National Agency for Food and Drug Administration, N/A= Not Available, ppm=Parts per million.
Source: (73, 84)

National assessment of the USI program in Nigeria

The median urinary iodine in school-aged children is the recommended method for assessing iodine status of population (> 100 ug/l indicate adequate iodine intake in school-aged children(85). In 2001, median urinary iodine among children under 5 years ranged between 119 ug/l and 309 ug/l(16). Also, decreased total goiter rates (TGR) were seen in surveys conducted years after USI program implementation in some states in Nigeria(86). Average TGR in the states decreased from 20% in 1993 to 10.6% and 8% in 1998 and 2004 respectively(73, 86, 87). Decline in TGR have also been seen in Cameroon, Benin, Liberia and Tanzania(86). In 2002 and 2005, the Federal Ministry of Education and IDD-USI taskforce monitored household access to iodized salt in Nigeria through two national primary school sample surveys(73, 84). A total of 1256 and 1260 children participated in the 2002 and 2005 survey respectively. In both surveys, 30 primary schools were randomly selected from each of the six zones of the country

totaling 180 primary schools nationally. Seven salt samples, randomly selected from each school, were then tested with iodine field kits. An unstated amount of sub-samples randomly selected were also sent to the NAFDAC labs for iodine testing. Analysis results from the 2002 household survey revealed a range of 84- 95% of the table salt had > 15 ppm iodine in the six regions with an average of 88.5%. The 2005 analysis showed 83-98% of table salt in had iodine content > 15 ppm with an average of 90.5% (Table 2). The 2003 Nigeria Demographic and Health Survey also found similar findings in its survey of iodized salt in the six geographical zones of Nigeria(88). Cooking salt was tested for iodine in 6,752 households representing 94% of total households sampled. About 97% of households who participated in the survey used sufficiently iodized salt (iodine content > 15 ppm). The above analysis suggests significant progress has been made in the USI program.

Table 2 National access (%) to household iodized salt in Nigeria in 2003, 2007 and 2008

Household access to iodized salt	2003 NDHS	MICS 2007	2008 NDHS
Households with salt < 0 ppm	1.7	4.4	3.4
Households with salt < 15 ppm	1	20.7	45.1
Households with no/inadequate iodized salt	2.7	25.1	48.5
Households with adequate iodized salt	97.3	74.9	51.5

NDHS= Nigerian Demographic and Health Survey, MICS= Multiple Indicator Cluster Survey, ppm= parts per million.
Source: (61, 88, 89)

Regional assessment of the USI program in Nigeria

The 2002 and 2005 surveys were also zonally analyzed. The analysis showed that North West zone of Nigeria had the highest proportion of iodized salt in the 2002 survey with 95.2% of salt having adequate iodine followed by the South South (92.9%), North East (90%), South West (85.7%), North Central (84.4%) and South East (82.5%) zones. In the 2005 survey, South West had the highest proportion of iodized salt with 98.6% while

South East still had the lowest proportion of iodized salt with 81%. In fact, the South East experienced a 1.5% decrease from the 2002 analysis.

However two recent surveys, the 2007 MICS and the 2008 NDHS show that access household iodized salt is actually decreasing in Nigeria(61, 89). The MICS survey tested iodine content in cooking salt, in 91% of 25,485 households in the six geo-political zones of the country(89). The survey revealed that 75% of households had adequately iodized salt > 15 ppm while 21% of households had iodized salt < 15 ppm. The 2008 NDHS analyzed salt iodine content in 94% of 32,079 households across the six zones(61). The survey showed that 52% of households had adequately iodized salt (iodine content >15 ppm). These two recent surveys indicate a decline in the proportion of households with adequately iodized salt from the 2005 to 2008. On the average, household access to iodized salt decreased from 88.5% and 90.5% in 2005 to 75% and 50% in the 2007 MICS and 2008 NDHS survey respectively(89). Additionally, a general decline in access to household iodized salt was noted in all six zones of Nigeria. Access to iodized salt in the North Central zone declined from 84.4% and 83.3% in 2002 and 2005 to 75.7% and 54.7% in 2007 and 2008, respectively. The South East zone, which had the lowest proportion of iodized salt with 82.5% in 2002 and 81% in 2005, had 85.9% and 59.7% in 2007 and 2008 respectively. North West dropped from 95.2% and 97.1% in 2002 and 2005 to 75.7% and 54.7% in 2007 and 2008, respectively. From 2002 and 2005 to 2007 and 2008, North East also fell from 90% and 96.7% to 59.2%% and 33.7%, South South declined from 92.9% and 86.2% to 82.2% and 39.8% and, South West declined from 85.7% and 98.6% to 81.4% and 51.1%(Table 3). Although these numbers demonstrate a declining trend in household access to iodized salt in the six-year period, the decline may be due to different methodology used in conducting the survey. The 2002 and 2005 primary school surveys used a simple random survey while a

stratified two-stage cluster sampling was used in the 2007 MICS and 2008 NDHS surveys(84). Salt were also obtained from unbranded sources for testing, which may have resulted in declining level of iodine in salt.

Table 3 Zonal trend of household access to adequately iodized salt (> 15 ppm) in Nigeria between 2002 and 2009

Geo-political zone	2002 NPHCDA/ FMoE(%) (n=1,256)	2005 FMoE (%) (n=1,260)	2007 MICS (%) (n=25,485)	2008 NDHS (%) (n= 32,079)
North Central	84.4	83.3	75.7	56.2
North East	90.0	96.7	59.2	33.7
North West	95.2	97.1	67.8	64.7
South East	85.2	81.0	85.9	56.7
South South	92.9	86.2	82.2	39.9
South West	85.7	98.6	81.4	51.1

NPHCDA= National Primary Healthcare Development Agency, FMoE = Federal Ministry of Education, MICS= Multiple Indicator Cluster Survey, NDHS=Nigeria Demographic and Health Survey. n= number of people surveyed. ppm= parts per million
Source: (61, 73, 89)

In both surveys, three factors showed disparities and impacted household access to iodized salt; residence location, income status and zone of the country(61, 89). People staying in urban areas and individuals with higher incomes use more adequately iodized salt compared to people staying in rural areas and people in lower income quintile. Also North East zone had lower access than other zones of the country in both MICS and NDHS survey. Similarly, a NAFDAC USI report on a population based cross-sectional study using data from the 2007 MICS and the 2008 NDHS also revealed the various factors affecting household access to iodized salt after bivariate and multivariate analysis of the surveys(61, 84, 89). Bivariate level analysis of the 2007 MICS showed that educational status, wealth index, sex of the head of household, and residence location (rural areas), zone of the country (North East) had significant impacts (p-value ≤ 0.05) on household access to adequately iodized salt(84). A bivariate level analysis of the 2008

NDHS(61, 84) survey showed that no formal education, geographical location (North East zone), low-income class, illiteracy and media access (radio) had significant impacts (p-value ≤ 0.05) on household access to inadequate iodized salt.

Multi-level analysis of the 2007 MICS by NAFDAC showed that, low-income segments of the population were 1.7 times more likely to use inadequate or non-iodized salt compared to people that were in high-income groups(84). Persons with no formal education were 1.2 times more likely to use inadequate or non-iodized salt compared to those who received formal education. Additionally, multi-level analysis of the 2008 NDHS survey(61) showed that wealth index, location and inability to listen to radio at least once weekly all contributed to inadequate/lack of access to household iodized salt(84). Furthermore, there was no correlation between the price of salt and household access to iodized salt. Overall, these data suggest that although USI program recorded significant household access and national coverage in the country but access gradually declined over the years. This decline can lead to IDD recurrence as seen in countries such as USSR, Azerbaijan and Guatemala where faltering programs resulted in reappearance of iodine deficiency disorders(49). This can result in adverse consequences for millions of Nigerian children who might be susceptible to cretinism and poor mental development. Thus strategies aimed at increasing household access to iodized salt must consider these factors.

Coverage and monitoring of vitamin A fortification in Nigeria

In 2002, SON mandated the fortification of sugar, wheat flour, and vegetable oil with vitamin A. It was estimated that 70% of sugar, 100% of wheat flour and 55% of vegetable oil would be fortified by 2004(75). However, estimates were not provided for expected margarine by 2004. To effectively assess the coverage and monitor vitamin A fortification, it is imperative to compare trends of prevalence of vitamin A deficiency,

consumption and distribution of vitamin A fortified foods since program implementation(4, 76).

Monitoring

Analysis of fortified wheat flour, vegetable oil, and sugar is done at the borders and factories(20, 76). At the borders, imported products are tested on-site using qualitative analysis. During factory inspections held quarterly, Standard Organization of Nigeria performs an on-site factory analysis on randomly selected samples of wheat flour, vegetable oil and sugar fortified with vitamin A. Additional samples are then taken to SON laboratories for assessment. External monitoring by SON was originally limited because of the lack of high-performance liquid chromatography (HLPC), which was donated by UNICEF to augment SON's quantitative analysis method (icheck Chroma/Fluoro)(20).

NAFDAC monitors wheat flour, vegetable oil and sugar fortification at the distributor and retailer level(20, 76). The agency conducts this test by using HLPC quantitative technique to analyze the fortified wheat flour, sugar and vegetable oil taken from the distributors or retail sellers.

In the 1st and 2nd quarter of 2007, a survey was conducted on vitamin A fortified wheat flour, sugar and vegetable oil produced by companies in each zone of Nigeria(90). Ten companies (four wheat & maize flour, five vegetable oil and one sugar) with 5 major brands were chosen for this survey. Samples were collected in 5 different portions and sent to 3 labs: NAFDAC, SON, Medical Research Council (an independent reference lab in South Africa) labs and 1 retention sample each for manufacturers and NAFDAC was stored for future reference. Analysis revealed that mean vitamin A (average of total vitamin A from the 3 labs) content in sugar and vegetable oil was above mandatory level of 25,000 and 20,000 IU/kg respectively in both quarters(90). However, mean vitamin A

content of wheat flour was below the mandatory level of 30,000 IU/kg in two of the companies in the 1st quarter but above in the 2nd quarter. This was attributed to the companies probably increasing fortification as a result of frequent visit by regulatory agencies. Some concerns were raised about samples tested by NAFDAC, which may not truly reflect the wheat flour and sugar batch produced daily by the industry. This is because NAFDAC officials only take a small sample from the upper part of bag, which is then tested.

There is insufficient information on the internal monitoring procedures performed by industry players involved in vitamin A fortification in Nigeria. Although some companies have quality control procedures, these procedures are not clear. For example, Honeywell Mills have HLPC for quality control of vitamin A fortification wheat flour(20), but it is unclear how often tests are carried out on the wheat flour after fortification. Also, the mode of storing premix is unspecified. Another concern of internal monitoring is the lack of confirmatory analysis on samples tested by NAFDAC officials by the companies. Confirmatory analysis compares results obtained from internal monitoring by companies with results obtained from NAFDAC analysis.

Coverage of vitamin A fortification in Nigeria

A survey was done in 2006 to assess the distribution and consumption of vitamin A fortified sugar, vegetable oil, wheat flour and maize flour in Nigerian households(63, 76). The survey was conducted in 600 households selected from two states in the three agro-ecological zones (Dry Savannah, Moist Savannah and Humid Forest) of the country(63). Vitamin A fortified products consumed by household members was procured from retailers. The survey showed from 676 dietary intakes in five of the six states (one state was excluded due to loss of food samples), 20% consumed fortified vegetable oil, 15% consumed fortified sugar, 14% consumed fortified wheat flour and 6%

consumed fortified maize flour(63). The survey also assessed vitamin A content in wheat flour, maize flour, sugar and vegetable oil from products randomly purchased from retail markets in five states. In 98% of the samples tested, vitamin A content was below the mandatory level of 30,000 IU/kg, 25,000 IU/kg and 20,000 IU/kg respectively with only two states having the required level of vitamin A in vegetable oil.

Another survey conducted in 2006 showed only 80% of flourmill owners, 50% of retail cooking oil producers complied with fortification Standard(91). No sugar importer or bulk cooking oil producer was complying with Standard. The report also showed compliance levels was higher in flourmills because Flour Milling Association collects and sends samples on a monthly basis to an independent lab in London, which analyses the samples. The association then gives feedback to members, whose samples failed to meet required fortification level. Although vegetable oil producers have an association, the association lacks the organizational capacity seen with flourmill producers. Sugar importers and maize millers have no such association making self-regulation difficult. The 2006 data and report show that two majors factors account for low consumption of vitamin A fortified food in Nigerian households: products sold by retailers were inadequately fortified and poor storage and exposure to sunlight by retailers resulted in loss of vitamin A in the products. This may account for a persistently high prevalence rate of vitamin A eight years post fortification.

Table 4 People consuming vitamin A fortified foods, (%) n, in five states across the three agro-ecological zones of Nigeria (March-April 2006)

	Akwa-Ibom	Lagos	Oyo	Nasarawa	Plateau	Total
Vegetable oil	(9.6) 13	(29.6) 40	(10.4) 14	(14.8) 20	(35.6) 48	(20) 135
Sugar	(3.9) 4	(19.6) 20	(5.9) 6	(24.5) 25	(46.1) 47	(15) 102
Wheat flour	(4.3) 4	(47.9) 45	(4.3) 4	(10.6) 10	(33) 31	(14) 94
Maize flour	(0) 0	(0) 0	(0) 0	(24.4) 10	(75.6) 31	(6) 41
Total food consumed	(16.8) 113	(30.5) 206	(25.3) 171	(10.4) 70	(17.2) 116	(55) 676

n=Number

Source: (63)

Evaluation of impact of fortification

The prevalence of vitamin A deficiency from a survey conducted in 1993 in four different zones of Nigeria for children aged 6 months to 5 years showed 28.1% of the children were vitamin A deficient (serum retinol < 20 µ g/dl or 0.7 µ mol/l) and 7% had severe vitamin A deficiency (serum retinol < 10 µ g/dl or 0.35 µ mol/l(76, 92). In a survey of children under 5 years old done in 2001, 29.5% of children suffered from different grades of vitamin A deficiency with 24.8% suffering from vitamin A deficiency (serum retinol < 20 µg/dl) and 4.7% suffering from severe vitamin A deficiency (serum retinol < 10 µg/dl)(16). The two surveys show stable vitamin A deficiency prevalence in the 8-year period. A recent survey in 2009, 7 years after vitamin A fortification was implemented, showed similar prevalence values with 29.5% of children still suffering from vitamin A deficiency (serum retinol < 20 µ g/dl or 0.7 µ mol/l). These data show no changes in prevalence of vitamin A have been observed after implementation of the fortification program and vitamin A deficiency is still a significant public health issue(93)in Nigeria even after fortification.

Table 5: Prevalence of vitamin A deficiency in Nigeria between 1993 and 2009

Year	Proportion of pre-school age children with vitamin A deficiency (serum retinol < 0.7 µ mol/l)	Number of samples (n) tested
1993	28.1	1244
2001	29.5	3099
2009	29.5	3027

Source: (16, 92, 93)

Objective 3: Recommended next steps for food fortification in Nigeria

Although Nigeria is making meaningful progress in its food fortification program, food fortification still needs to be strengthened nationally(76). Prior to making recommendations for food fortification next steps, it is imperative to consider the major obstacles to and challenges of the fortification program.

Institutional/policy

Existing legislation on food fortification in Nigeria mandates food fortification with vitamin A, iron, iodine, vitamin B1, B2 and B3, niacin, thiamine, riboflavin and more recently folic acid and zinc have been approved for fortification(20). Nigerian Industrial Standards need to be generated for zinc and folic acid by SON. SON should also revise the iron compound used for fortification from electrolytic iron to other more bio-available forms of iron such a ferrous fumarate. Additionally, the Standard needs to clearly define roles of each stakeholder in the fortification program especially government agencies to avoid duplication of roles by the various agencies.

Program

There are sparse data or reports on monitoring and evaluation of some nutrients added to food in Nigeria. Nutrients such as iron, vitamin B1 and B2 have received little or no attention in terms of monitoring and impact since fortification was started. Therefore, efforts should be made to monitor and evaluate iron, vitamin B1 and B2 and vitamin B3 being added to food. Of these nutrients, monitoring of iron fortification should be urgently addressed considering the high prevalence rate of iron deficiency seen in children and pregnant women. This can be achieved with collaboration between the government agencies, non-governmental and international organizations. Furthermore, zinc and folic acid fortification, which have been approved for fortification, should be commenced.

A major challenge for Nigeria's fortification program is loss of nutrients in fortified food at the retailer and consumer level. The collaboration among SON, NAFDAC and the industry on monitoring has been successful in sustaining the USI program. However, this effort has not been replicated on the same scale for monitoring of vitamin A fortified foods. Vitamin A fortified wheat, sugar and vegetable oil sold by retailers are openly displayed in the markets and storage conditions are not optimal for nutrient retention in the products(20). Therefore, manufacturers should replace current packaging with airtight opaque packaging in smaller quantities to minimize sunlight exposure. Additionally, retailers should be educated on the importance of sunlight exposure and providing conditions best for storing fortified foods.

It is also imperative to increase the capacity and strengthen these agencies to enhance regulatory monitoring. This can be achieved through increased funding to monitoring agencies, training more inspectors and providing adequate qualitative and quantitative testing kits and well-equipped reference laboratories.

Quality control and assurance procedures implemented by companies fortifying food products in Nigeria are unclear. SON should standardize quality control in these companies. For example, companies should be required to have specific operational procedures such as documenting frequency of routine testing of samples and records of tested samples.

Public awareness of fortified products can be raised through health education. For example, iodized salt logo awareness campaigns targeting people living in both rural and urban areas can be conducted using pamphlets printed in local dialects and mass media, respectively. Additionally, the use of social media should also be explored.

Research

National Fortification Alliance, which is a multi-sectorial collaboration of the food industry, government agencies, academics research facilities, non-governmental organizations, international organizations needs to be strengthened to ensure benefits of Nigeria's food fortification policy are maximized. International UN organizations, NGOs and the private sector can partner with the country to establish a comprehensive country database on food fortification practices in Nigeria. Furthermore, more research studies need to be conducted to effectively measure coverage and program impact of food fortification nationally.

Conclusion

Food fortification employs a unique and cost effective approach to providing nutrients needed by Nigerians and indeed populations around the world. This thesis reviewed data, publications and reports on food fortification in Nigeria including trends over the last two decades As discussed in the recommendations, different stakeholders have different roles in Nigeria's food fortification.

At the institutional/policy level, government should ensure standards for folic acid and zinc are generated. Also, roles of the different government agencies should be clearly defined and these agencies should be further strengthened. In addition, SON should consider replacing electrolytic iron with ferrous fumarate.

At the program level, monitoring and evaluation of iron, vitamin B1, B2 and B3 fortification of wheat flour need to be conducted. Loss of nutrients in fortified food at the retailer and consumer level remains a big issue in the country. Therefore factors such as inadequate fortification, poor storage and exposure of fortified products and gaps in regulatory monitoring should be urgently addressed to increase the impact of the USI and the vitamin A fortification of wheat flour, maize meal, sugar and vegetable oil. A standard quality control operating procedure should be stipulated for all companies fortifying food in Nigeria to ensure food fortification guidelines are adhered to. Health education initiatives can help increase awareness of fortified food products and should be incorporated in program implementation.

At the research level, more studies are required to further assess impact of the fortification program. This can be achieved through collaboration between different stakeholders. International organizations and NGOs should lead this effort and partner with academic institutions, government agencies and food companies to conduct this research.

References

1. Venkatesh Mannar M.G, Sankar R (2004) Micronutrient fortification of foods—Rationale, application and impact. Indian Journal of Pediatrics **71**,997-1002.
2. Jamison DT, Breman JG, Measham AR et al. (2006) Stunting, Wasting, and Micronutrient Deficiency Disorders . Disease control priorities in developing countries. Washington, 551-567
3. Tatala S, Ndossi G, Ash D et al. (2007) Effect of germination of finger millet on nutritional value of foods and effect of food supplement on nutrition and anaemia status in Tanzania children. Tanzania Journal of Health Research **9**,77-786.
4. World Health Organization, FAO (2006) Guidelines on food fortification with micronutrients. Allen L, Dary O, Hurrell R, Horton S, editor. Geneva . 1-331 acessed from http://www.who.int/nutrition/publications/guide_food_fortification_micronutrients.pdf
5. Darnton-Hill I, Webb P, Harvey PWJ et al. (2007) Micronutrient deficiencies and gender: social and economic costs. The American Journal of Clinical Nutrition **81**,1198S-205S.
6. Zimmermann MB, Hurrell RF (2007)Nutritional iron deficiency. The Lancet **370** 511-520.
7. Worldwide prevalence of anaemia 1993-2005: WHO global database on anaemia World Health Organization. 2008.
8. World Health Organization (2009) Global Prevalence of Vitamin A Deficiency in populations at risk 1995–2005: WHO global database on vitamin A deficiency. Geneva, 10-11.
9. de Benoist B, McLean E, Andersson M et al. (2008) Iodine deficiency in 2007: global progress since 2003. Food Nutr Bull **29**,195-202.
10. Andersson M, Karumbunathan V, Zimmermann MB (2012) Global iodine status in 2011 and trends over the past decade. The Journal of Nutrition **4**,744-750.
11. World Health Organization (2007) Reducing Risks, Promoting Healthy Life Available from: http://www.who.int/whr/2002/chapter4/en/index3.html.
12. Prevention of neural tube defects (2007). Available from: http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/neural_tube_defects.pdf.
13. Blencowe H, Cousens S, Modell B et al. (2010) Folic acid to reduce neonatal mortality from neural tube disorders. International Journal of Epidemiology **39**, i110-i21.
14. Botto LD, Moore CA, Khoury MJ et al. (1999) Neural-tube defects. New England Journal of Medicine **341**, 509-519.
15. Ezzati M, Lopez AD, Rodgers A et al. (2002) Selected major risk factors and global and regional burden of disease. The Lancet 360 1347-1360.
16. Maziya DB, Akinyele IO, Oguntona EB et l. (2004) Nigeria Food Consumption and Nutrition Survey 2001-2003. International Institute of Tropical Agriculture , Ibadan. available at http://pdf.usaid.gov/pdf_docs/PNADC880.pdf
17. Baker RD, Greer FR, (2010) Clinical Report—Diagnosis and Prevention of iron Deficiency and iron-Deficiency anemia in infants and young Children (0–3 years of age). Pediatrics **126**, 1043-1050.
18. Flour Fortification Initiative (2012) Nigeria profile . available from: http://www.ffinetwork.org/country_profiles/country.php?record=159.

19. Haemoglobin concentrations for the diagnosis of anaemia and assessment of severity (2011).Vitamin and Mineral Nutrition Information System .available from http://www.who.int/vmnis/indicators/haemoglobin.pdf.
20. Helen Keller International,USAID (2011).Situation analysis on mandatory food fortification in Nigeria.
21. Crane NT, Wilson D, Cook D et al. (1995) Evaluating food fortification options: general principles revisited with folic acid. American Journal of Public Health **85**,660-666.
22. Darnton-Hill I (1998) Overview: Rationale and elements of a successful food-fortification programme. Food Nutr Bull **19**,92-100.
23. Global Alliance for Improved Nutrition (2012) Lessons learned from 10 years of experience in Africa:Sharing experiences in food fortification. available at http://www.gainhealth.org/reports/lessons-learned-10-years-experience-africa-sharing-experiences-food-fortification
24. Fletcher RJ, Bell IP, Lambert JP (2004) Public health aspects of food fortification: a question of balance. Proceedings of the Nutrition Society **63**,605-14.
25. Institue of Medicine (2003) Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification: The National Academies Press, 45-55 available at http://www.nap.edu/openbook.php?record_id=10872
26. Nathoo T, Holmes CP, Ostry A (2005) An analysis of the development of Canadian food fortification policies: the case of vitamin B. Health promotion International **20**,375-382.
27. Darnton-Hill I, Nalubola R (2002) Fortification strategies to meet micronutrient needs: sucesses and failures. Proceedings of the Nutrition Society **61**, 231-41.
28. Mertz W (1997) Food fortification in the United States. Nutrition Reviews. **55**,44-49.
29. Dary O, Mora JO (2002) Food fortification to reduce vitamin A deficiency: International Vitamin A Consultative Group recommendations. The Journal of Nutrition **132**, 2927S-233S.
30. Allen LH (2006) New approaches for designing and evaluating food fortification programs. The Journal of Nutrition **136**,1055-1058.
31. Torrejón CS, Castillo-Duran C, Hertrampf ED et al. (2004) Zinc and iron nutrition in Chilean children fed fortified milk provided by the complementary National Food Program. Nutrition **20**,177-80.
32. Kraemer K, Waelti M, De Pee S et al. (2008) Are low tolerable upper intake levels for vitamin A undermining effective food fortification efforts? Nutrition Reviews **66**,517-25.
33. De-Regil LM, Jefferds MED, Peña-Rosas JP (2012) Point-of-use fortification of foods with micronutrient powders containing iron in children of preschool and school age. The Cochrane Database of Systematic Reviews.
34. Global Alliance for Improved Nutrition (2013) Home fotification. Available from: http://hftag.gainhealth.org.
35. Suchdev PS, Ruth LJ, Woodruff BA et al. (2012) Selling Sprinkles micronutrient powder reduces anemia, iron deficiency, and vitamin A deficiency in young children in Western Kenya: a cluster-randomized controlled trial. The American Journal of Clinical Nutrition **95**,1223-1230.
36. Varma JL, Das S, Sankar R et al. (2007) Community-level micronutrient fortification of a food supplement in India: a controlled trial in preschool children aged 36-66 mo. The American Journal of Clinical Nutrition **85**,1127-1133.

37. Nestel PB, H.E. Meenakshi et al. (2006) Biofortification of staple food crops. The Journal of Nutrition **136**,1064-1067.
38. Haas JD, Beard JL, Murray-Kolb LE et al. (2005) Iron-biofortified rice improves the iron stores of non-anemic Filipino women. The Journal of Nutrition. **135**, 2823-30.
39. Flour Fortification Initiative (2012) Global progress on mandatory wheat flour fortification. acessed at http://www.ffinetwork.org/global_progress/index.php.
40. Maberly G, Grummer-Strawn L, Jefferds M Eet al. (2008) Trends in wheat-flour fortification with folic acid and iron worldwide, 2004 and 2007. MMWR Morb Mortal Wkly Rep **57**,8-10.
41. Delange F, de Benoist B, Pretell E (2001) Iodine deficiency in the world: where do we stand at the turn of the century? Thyroid **11**,437-447.
42. Andersson M, Takkouche B, Egli I et al. (2005) Current global iodine status and progress over the last decade towards the elimination of iodine deficiency. Bulletin of the World Health Organization **83**,518-525.
43. Crider KS, Bailey LB, Berry RJ (2011) Folic acid food fortification—Its history, effect, concerns, and future directions. Nutrients **3**,370-84.
44. Orioli IM, Lima do Nascimento R, López-Camelo JS et al. Effects of folic acid fortification on spina bifida prevalence in Brazil. Birth Defects Research Part A: Clinical and Molecular Teratology **91**,831-5.
45. Alasfoor D, Elsayed M, Mohammed A (1997) Spina bifida and birth outcome before and after fortification of flour with iron and folic acid in Oman. EMHJ **16**, 533-538
46. Williams LJ, Mai CT, Edmonds LD et al. (2002) Prevalence of spina bifida and anencephaly during the transition to mandatory folic acid fortification in the United States. Teratology **66**,33-39.
47. Cortés F, Mellado C, Pardo R et al. (2012) Wheat flour fortification with folic acid: Changes in neural tube defects rates in Chile. American Journal of Medical Genetics Part **158A**, 1885-1890
48. López-Camelo JS, Orioli IM, Dutra MG et al. (2005) Reduction of birth prevalence rates of neural tube defects after folic acid fortification in Chile. American Journal of Medical Genetics Part **135A,1**20-5.
49. Zimmermann MB (2004) Assessing iodine status and monitoring progress of iodized salt programs. The Journal of Nutrition **134**,1673-1677.
50. Flour Fortification Initiative (2013) Effects of Iron-fortification programs on Iron status. acessed at http://www.ffinetwork.org.
51. Modjadji S, Alberts M, Mamabolo R (2008) Folate and iron status of South African non-pregnant rural women of childbearing age, before and after fortification of foods. South African Journal of Clinical Nutrition **20**,89-93.
52. Flour Fortification Initiative. (2013) Effect of Iron Fortificatio Programs on Anemia .accessed at http://www.ffinetwork.org.
53. Huo J, Sun J, Huang J et al. (2012) Effectiveness of fortified flour for enhancement of vitamin and mineral intakes and nutrition status in northwest Chinese villages. Food & Nutrition Bulletin **33**,161-168.
54. Sadighi J, Mohammad K, Sheikholeslam R et al. (2009) Anaemia control lessons from the flour fortification programme. Public Health 123, 794-799.
55. Assunção MC, Santos IS, Barros AJ et al. (2012) Flour fortification with iron has no impact on anaemia in urban Brazilian children. Public Health Nutrition **15**,1796-1801

56. Fujimori E, Sato APS, Szarfarc SC et al. (2011) Anemia in Brazilian pregnant women before and after flour fortification with iron. Revista de Saúde Pública. **45**,1027-1035.
57. Mora J, Dary O, Chinchilla D, Arroyave G (2000) Vitamin A sugar fortification in Central America. Experience and lessons learned. Arlington, VA: MOST/US Agency for International Development.
58. Aaron Grant J, Aliyu R, Flach M et al. (2011) A multi-micronutrient beverage enhances the vitamin A and zinc status of Nigerian primary school-children. The Journal of Nutrition **141**,1565-72.
59. Hurrell R, Ranum P, de Pee S et al. (2010) Revised recommendations for iron fortification of wheat flour and an evaluation of the expected impact of current national wheat flour fortification programs. Food & Nutrition Bulletin **31**,7S-21S.
60. Pena-Rosas JP, Parvanta I, Van Der Haar F et al. (2008) Monitoring and evaluation in flour fortification programs: design and implementation considerations. Nutrition Reviews **66**,148-62.
61. National Planning Commission, ICF Macro (2009) Nigeria Demographic and Health Survey 2008 Abuja 179-180.
62. Central Intelligence Agency (2012) The CIA World Factbook on Nigeria. available at https://www.cia.gov/library/publications/the-world-factbook/geos/ni.html
63. UNICEF (2006) Per capita consumption of vitamin A fortified wheat/maize flour, sugar and vegetable.
64. Rondón M, David M (2012) Sugar Annual. United States Department of Agriculture. available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Sugar%20Annual_Lagos_Nigeria_4-16-2012.pdf
65. Rondon M, David M, Sugar Annual (2012) United States Department of Agriculture. available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Sugar%20Annual_Lagos_Nigeria_4-16-2012.pdf
66. Flake L, David M (2010) Nigeria's Wheat Imports Surge. United States Department of Agriculture. available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Grain%20and%20Feed%20Annual_Lagos_Nigeria_4-13-2010.pdf
67. Orriss GD (1998) Food fortification: Safety and legislation. Food and Nutrition Bulletin **19**,109-16.
68. Standard Organization of Nigeria (2010) Nigerian Industrial Standard. 2010.
69. Anyanwu RC, Jukes DJ (1991) Food systems and food control in Nigeria. Food policy **16**,112-126.
70. Mwalimu C (2009) The Nigerian Legal System: Public Law, New York, U.S.A
71. Service UFA. Nigeria FAIRS Country Report. Agriculture Do; 2008 28th July 2008. Report No.
72. Global Alliance for Improved Nutrition. Appendix B-D. 2010.
73. UNICEF (2005) Universal Salt Iodization in Nigeria:Processes, successes and lessons. available http://www.unicef.org/nigeria/ng_publications_USI_in_Nigeria_Report.pdf
74. Nutriview Special issue (2003) Mandatory food enrichment. available at http://www.sahealthinfo.org/nutrition/nutriview2003special.pdf
75. UNICEF (2006) Nutrition Information Sheet http://www.unicef.org/wcaro/WCARO_Nigeria_Factsheets_Nutrition.pdf

76. National Fortification Alliance, National Agency for Food and Drug Administration and Control (2010) Baseline information on mandatory food fortification program implementation in Nigeria.
77. National Planning Commission(2001) National policy on food and nutrition in Nigeria.
78. Flour Fortification Initiative. (2012) Nigeria Adds Folic Acid to Wheat Flour Fortification Standard. acessed at http://www.ffinetwork.org/about/stay_informed/releases/NigeriaFolicAcid.html.
79. Flour Fortification Intiative Food fortification statement of capabilities. available at http://www.ffinetwork.org/about/stay_informed/releases/NigeriaFolicAcid.html.
80. Nestlé (2012) Nestlé helps address micronutrient deficiency in Africa with new Maggi cube. Available from: http://www.nestle-cwa.com/en/media/NewsAndFeatures/Pages/Iron-fortified-Maggi.aspx.
81. Standard Organization of Nigeria (2010) Nigerian Industrial Standard: Standard for Wheat Flour. Nigeria
82. Anyakora C, Afolami I, Ehianeta T et al. (2008) HPLC analysis of nicotinamide, pyridoxine, riboflavin and thiamin in some selected food products in Nigeria. African Journal of Pharmacy and Pharmacology **2**,029-036.
83. Akunyili D (2007) Achieving and Sustaining Universal Salt Iodization: Doing It Well Through Regulation and Enforcement. Lessons Learned from USI in Nigeria. SCN News **35**,43-47
84. National Agency for Food and Drug Administration, Micronutrient Initiative, Standard Organization of Nigeria (2010) Comprehensive evaluation of USI coverage.
85. WHO I, UNICEF (2007) Assessment of the iodine deficiency disorders and monitoring their elimination. Geneva.
86. Egbuta J, Onyezili, Frank,Vanormelingen (2003) Impact evaluation of efforts to eliminate iodine deficiency disorders in Nigeria. Public Health Nutrition.169-174.
87. UNICEF, MI (2004) Nigeria Damage Assessment Report.
88. National planning Commission, ORC Macro (2004) Nigeria Demographic and Health Survey.
89. National Bureau of Statistics/UNICEF. Nigeria Multiple Indicator Cluster Survey Final Report. ABUJA: 2007 September 2007. Report No.
90. National Agency for Food and Drug Administration/ Micronutrient Initiative/Standard Organization of Nigeria (2007) Sampling and laboratatory analysis of vitamin A fortified foods and iodized salt.
91. Global Alliance for Improved Nutrition (2006) Nigeria Appraisal Mission.
92. Ajaiyeoba A.I (2001) Vitamin A deficiency in Nigerian children. African Journal of Biomedical Research **4**,107-110
93. World Health Organization. Global prevalence of vitamin A deficiency in populations at risk 1995–2005, 2 Geneva

Appendix A – Iodized salt logo

Source: NAFDAC

Appendix B - ASSESSMENT TOOL /GUIDE QUESTIONS FOR KEY STAKEHOLDERS INVOLVED IN CONTROL OF QUALITY AND SAFETY OF FORTIFIED FOOD AND VITAMIN A PREMIX

INFORMATION CHECKLIST REPORT FORMAT
(Please note that these details and this questionnaire remain strictly confidential.)

1. **Name of Organization:**

2 **Nature of Business**

3 **Address/location**

4 **CITY/TOWN**

5 **LGA**

6 **STATE**

7 **PRINCIPAL CONTACT PERSON/NAME?**

8 **CURRENT POSITION/JOB**

8 **TEL** **EMAIL**

National laws to control fortification of foods

1. Is your Agency established under a statutory law by an Act of Parliament with the mandate to ensure that food offered to the public is of desired quality standard?_____ yes _____ no _____
(If yes, please what is the name of this statutory law and the date of enactment_____
_____

If NO, what other legal framework is available for the enforcement of the mandatory fortification?
_____
_____

2. Does this law empower the agency to make regulations and sets the specifications for the levels of retinol in food products? _____ yes _____ no

If YES, who authorizes such regulations?_____
_____

3. Does this law address packaging and labeling requirement in general terms.____ yes _____ no
If NO, are these being addressed through a regulation? _____

4. Is the Agency given broad inspection and investigation powers? _____ yes _____ no

If NO, which agency performs these functions_____
_____

5. Does this law provide for a broad range of penalties for noncompliance (e.g., fines, adverse publicity, license suspension/revocation, removal of product from the market) ____ yes _____ no

If yes, list key penalties against the various noncompliance _____
_____-:

6. Does this law require licensing or registration of product by producers, importers, and retailers respectively?_____ yes _____ no

(If YES, list conditions for registration_____
_____

National regulations

7. has the agency developed regulations which set out the specific standards for food fortification and indicating the appropriate concentration of retinol at production, import, wholesale, retail. and household levels? _____ yes _____ no

(if YES, request for a copy,
if NO, are plans being made to make such regulations_____
_____

8. Does the regulations specify appropriate packaging materials to be used for packaging fortified products (e.g., polypropylene or other non-porous material (lined with high density polyethylene), and establish labeling requirements (e.g., including manufacturer's license number, date of manufacture, lot/batch no., level of retinol in ppm or mg/kg, expiration date)

Packaging _____ yes _____ no; Labeling _____ yes _____ no

List key components for the packaging and label requirements):_____
_____

9. The regulations specify the requirements for storage of fortified food (e.g., avoidance of direct light, excessive heat, moisture, etc.) _____ yes _____ no

List key components for storage requirements):_____
_____

10 Does the regulations require producers and/or importers to engage in routine quality assurance and keep records of QA activities? Producers _____ yes _____ no; Importers _____ yes _____ no

Inspection and enforcement

11. Is this organization authorized by law to inspect the premises of producers' /importers / distributors and enforce legal requirements for fortified foods and carry out laboratory verifications of the quality of fortified products _____ yes _____ no

(If yes, please provide a list of such inspections in the past two years _____
what is the level of compliance?_____
List of penalties for violations in the past one year_____
_____
If No, list main challenges _____

_____

12.Is Vitamin A premix regularly inspected for compliance at point of entry io the country.?
_____ yes _____ no
(If yes, kindly provide a inspection reports indicating level of compliance and penalties for violations in the past two years
_____
_____

If No, please list main challenges):

13. Are the lines of authority for inspectors and enforcement staff clearly defined and understood by all staff at both national and field officers? _____ yes _____ no

If YES, describe the key steps in the procedure for initiating and carrying out inspection and enforcement
actions_____
_____

14. Are the personnel needed to conduct routine and periodic inspections of producers, importers, and retailers of fortified foods adequate and well trained? _____ yes _____ no

If yes, please indicate the number and categories of qualified personnel_____ and indicate type of training received in the past two years_____
_____

If No, indicate desired number of personnel; the number of existing staff and the. types of training desired _____
_____
(Obtain a list of inspection and enforcement personnel, qualifications and training programs)

15. Are samples of fortified foods from routine/periodic monitoring inspections sent to approved laboratories and analyzed in a timely fashion. _____ yes _____ no
(If YES, please indicate the number of such samples analyzed in the past 15months _____
The number of follow-up actions initiated and completed within the same period?_____
_____
If No, please list major challenges hindering routine/periodic monitoring inspections_____
_____

16. Are any of the enforcement actions undertaken by your agency challenged by the court/administrative body setup to hear the action? _____ yes _____ no

(If YES, please give indications of such cases in the past 15months and the proportion of actions overturned
_____
_____

If No, why are there no challenges? _____
_____

17. Do enforcement actions taken by the agency seem to have the effect of deterring noncompliance? _____ yes _____ no

(if yes, show number of industry sanctioned, type of violations and sanctions imposed _____
_____

Laboratory Capacity and capability

18. Do the laboratories of your agency have facilities for the determination of retinol in fortified food, plasma and breast milk samples? _____ yes _____ no
(If YES, List type laboratory instruments/equipment available their cost _____
_____
If No, list main challenges _____
_____

19. For each of the following methods of determining Vit. A, how many samples can your laboratory handle on a weekly basis

Colorimetric determination: _____Nos of tests.
HPLC method: _____Nos of tests
Spectrophotometric method: :_____Nos of tests
Determination of peroxide value: _____Nos of tests

20. Are all instruments currently in good working order? _____yes _____no
(Describe any recurring problems experiences as well as any difficulty in maintaining or repairing equipment):

21. Does the agency ensure that the laboratories are supplied with reliable, basic services, such as clean water, electricity, laboratory wares reagents etc? ___yes _____no

(Describe any problems that exist and what attempts have been made to correct them as ell as any difficulties in correcting):

22. Does the agency ensure that its laboratories obtain sufficient reagents/other consumables needed to perform required test in a timely fashion? _____yes _____no
(If yes, List the key reagents supplied in the past 15 months and their costs _____

_____
_____

If No, list reagents that are not regularly available and reasons for non-availability _____
_____
_____

23. Are there regular and adequate funds for maintenance, repair, or purchase of spare parts for laboratory instruments and equipment? _____yes _____no
If yes, what is the average maintenance cost the past two years? _____2005; _____2006
If No, How much was needed? _____2005; _____2006

<u>Laboratory Quality Assurance</u>

24 Are your laboratory instruments and equipment regularly checked for performance, accuracy, validity, etc? _____yes _____no
(Describe frequency of checks and quality of results obtained):

25. Does the laboratories have well-written detailed standard operating procedures (or manual) for determining retinol in food, serum and breast milk samples? _____yes _____no

26. Are laboratory procedures, results and other key data (e.g. print copies of results of all individual assays run for each method, log of samples received/results obtained,. QC results for each assay, inventory and ordering details, notes on quality of samples sent to the laboratory, evidence that samples are being correctly stores (e.g. refrigerator/freezer temperature charts/ sample database management, etc.) well documented, organized and recorded? ____yes _____no

Staff training, expertise and development

27. Are laboratory staff well trained with adequate skill and expertise to undertake the tasks expected of them? _____yes _____no
(Describe how often training occurs, what is covered, who attends and the level of supervision, etc.)
_____
_____
_____
_____

28 Do laboratory personnel require additional knowledge and skills in order to demonstrate that they can meet expected standards? _____yes _____no
(If yes, please list the training needs for each identified staff category and the approximate
cost_____
_____
_____
_____:

29 Overall comments:

Persons met and documents reviewed

List names, titles/occupations, and location (city or village) of all persons interviewed.

NAME	RANK	DEPARTMENT	EMAIL	TELEPHONE

List all documents reviewed.

Appendix C – ASSESSMENT TOOL/GUIDE QUESTIONS FOR KEY STAKEHOLDERS INVOLVED IN PROJECT MONITORING AND IMPACT ASSESMENT AT THE HOUSEHOLD LEVEL

INFORMATION CHECKLIST AND REPORT FORMAT

1. Has any nationwide population-based health survey been conducted in the past five years?. _____yes _____no
(If yes, please list the types and years each was conducted_____
_____

2 What are the key indicators contained in these survey reports?
_____
_____ _____

3 is there any survey that indicates coverage data for the consumption of fortified foods at the household? _____yes _____no
(If yes, please list the types and years each was conducted
_____
_____

4 Does State and local Ministry of health and Health Departments. District in the local Government areas have developed methods for collection and transporting of food samples to reference laboratories? _____yes _____no

If no, how can sampling and monitoring of fortification program be implemented at the households and retail shops in the communities
_____
_____

5 Does the. State and local government offices have the capacity to monitor the implementation of the fortification program at the local communities and household levels? _____yes _____no

If no, how can the monitoring of fortification program be implemented at the households and retail shops in the communities _____
_____

6. has there any survey to indicates per capital consumption of the fortified foods at the household? _____yes _____no
(If yes, please indicate the years it was conducted and summary of its findings with respect to teach of the food vehicles
_____
_____

7. Overall Comments:

Persons met and documents reviewed

List names, titles/occupations, and location (by city or village) of all persons interviewed
List documents reviewed

Appendix D - ASSESSMENT TOOLS / GUIDE QUESTIONS FOR STAKEHOLDERS INVOLVED WITH THE PRODUCTION AND DISTRIBUTION OF FORTIFIED FOODS AND PREMIX

INFORMATION CHECKLIST AND REPORT FORMAT

1. **Name of Industry:**
1. **Nature of Business**
2. **Address/location**
3. **CITY/TOWN**
4. **LGA**
5. **STATE**
6. **PRINCIPAL CONTACT PERSON** **RANK**
7. **TEL** **EMAIL**

Production capacity and access to fortification materials

1. Please provide the names of products of your industry: _____
2. Are products fortified to meet legal requirements?: ____ yes _____ no

If Yes, state year of commencement, _____

If No, list reasons for noncompliance _____
_____
_____

3. Does your industry produce fortified product on regular basis all year round ? _____ yes _____ no

If yes, state plant outputs for 2005 _____ 2006 _____

If No, list reasons why plant is unable to produce _____

How often in the 2 years did you experience plant shut down, show figures per year):

4. Does the plant has a dedicated production line for fortification of its products? _____ yes _____ no

If Yes, please indicate fortification (mixing) procedure in use? _____batch _____
continuous

Please list key fortification equipment and their costs in use in the plant

5. Does the plant have a functioning fortification department manned with staff? __ yes _____ no

If Yes, how many staff members involved and what are their responsibilities? _____
_____

6. Does the plant currently have adequate supply of good quality premix for its fortification program on a sustainable basis? _____ yes _____ no

If yes, list the source(s) and describe key quality characteristics (color, smell, free flowing ability, form and
concentration of retinol and cost. _____
_____

If No, please list key challenges experienced with premix supply_____
_____

7. Please list key micronutrients and their concentrations in the premix supply to your factory_____
_____

8. Are you aware of Government incentives to industries to sustain the mandatory vitamin A fortification program?. _____ yes _____ no

If YES, list these incentives _____
_____
_____
If NO, List the incentives you will like Government to put in place _____
_____

9. Does the industry have any strategic plan(s) to ensure that fortification is sustained? ____ yes _____ no
If YES, please outline the plans: _____

If No, why ?:_____

10. Are the marketing objectives for the consumption of fortified products being met? ___ yes___ no
(IF NO, why?:_____

11. What arrangements /plans does the industry have (both institutional and household)to promote consumers preference for fortified products? _____
_____

Awareness and commitment to national fortification program

12. Is your organization aware of the activities of The National Fortification Alliance (NFA)? __ yes _____ no
If YES, how many times has your organization been represented at it's meetings? _____

13. Is the operation of the NFA truly represents Public-Private partnership _____ yes _____ no
(If NO, why? and please suggest how it's operations can be improved :_____
_____
_____

14. Are the plant personnel including your distributors aware of Vitamin A Deficiencies (VAD), its consequences on children, pregnant and lactating women in the population, and the importance of vitamin A fortified products?

_____ yes	consequences of VAD	____yes importance of Vit. A
_____ no	consequences of VAD	_____Non importance of Vit. A

15. Does your industry marketing plans define the target audience(s) and channels in both rural and urban areas? _____ yes _____ no
If NO, what are the plans to improve marketing strategies?_____
_____

16. Has the fortification of the product significantly affected consumer demand for the product. _____ yes _____ no
(If Yes positively Negatively

17. Is your industry a member of any umbrella Association which has mechanism for self regulation and sanctions of members incase of violations of mutual code of practice? ____yes _____no
If YES, what is the name of the association and year of joining? List key sanctions against violation of association codes or ethics_____
_____
_____
If No, list reasons for not joining _____
_____

Laboratory and quality assurance practices

18. Does the plant have laboratory facility for routine tests on products _____ yes _____ no
(If yes, what tests are carried out per day/shift, type of test(s) carried out and methods employed for each): _____

If No, how is the quality of product verified _____
_____

19. Does the plant have access to adequate supply of laboratory reagents/other laboratory consumables in order to perform required tests in a timely fashion.? _____ yes _____ no
(If NO, what are your challenges that prevents your access ? : _____
_____

20 Are your laboratory personnel qualified, adequate number and possess adequate levels of training and expertise to undertake the tasks expected of them?.
_____ yes qualified ____yes adequate number _____yes training programs
_____ No qualified ____No adequate number _____No training programs
(Obtain a list of laboratory staff, qualifications and training programs)

21. Are routine product test performed during production and results recorded and available for inspection? _____ yes _____ no
(If yes, what tests and how often they carryout the test procedures; etc. _____
If NO, what are the obstacles?: _____
_____
_____

22. Review of production QA records reveals that random product testing confirms presence of adequate amounts of retinol in product currently being processed. _____ yes _____ no

23. Does your organization routinely inspect equipment for fortification and replace worn-out parts (e.g. spray nozzles) as recommended by the manufacture.
_____ yes _____ no
(If yes, how often?_____

24. Is routine testing of fortificant (Vitamin A premix) being performed and results recorded and available for inspection? _____ yes _____ no

(If NO,give reasons why this is so._____

25 Are fortified products properly packaged according to legal requirements?
_____ yes _____ no
(If NO, Comment generally on these inadequacies. _____
_____

26. Do labels on packages contain adequate information (e.g., name of producers, lot/batch no., logo for fortification, level of fortification mg/kg, expiry date, and other information required by regulations)._____ yes _____ no
(If NO, list observed deviations _____
_____

27. Are fortified products stored properly before they are distributed (e.g., no exposure to excess heat, direct light, moisture, no excess storage time, etc.). _____ yes _____ no
(Describe typical storage conditions and time and show proportion of those visited that store fortified product
properly_____
_____

Industry perspective on the Government regulations, inspection and enforcement procedures

28. Does your organization believes the inspections, enforcement and sanctioning process provided by law /regulatory agencies are fair and effective?. _____ yes _____ no

If NO, list areas for improvements: _____
_____

29. Does your organization have any collaborative arrangement with any government regulatory laboratories for the testing of your product as part of your routine quality assurance processes?
_____yes _____ no
(If yes which laboratories? How often?
If No; list reasons):

30 The Global Alliance for Improved Nutrition (GAIN) has a partnership arrangement with industry
involved with mandatory food fortification which is designed to reduce malnutrition through the use of food fortification to improve the health and nutrition of populations at risk; will your organization be interested in this partnership arrangement ? _____ yes _____ no

4.1.7 Persons met and documents reviewed

List names, titles/occupations. And location (by city or village) of all persons interviewed:

NAME	RANK	DEPARTMENT	EMAIL	TELEPHONE

List all documents reviewed: