

Manual for Monitoring Fortified Foods in Liberia

Guidelines for Inspectors





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1. Introduction

Chronic malnutrition and micronutrient deficiencies persist in Liberia as outlined by the 2011 Micronutrient Deficiency Survey. As a result, the nation is at risk of losing significant individual and national economic potential not to mention premature death and disability. Food fortification, or the addition of essential vitamins and minerals to commonly consumed staple food products, has been deemed one of the most cost-effective means of addressing this form of malnutrition that exists today. In order to support the Government of Liberia in its fight against this malady, in 2010 the National Fortification Alliance (NFA), lead by the Ministries of Health and Social Welfare and Commerce and Industry, was established.

The importance of food-based activities aimed at addressing micronutrient malnutrition remains a global priority. Food fortification as an intervention has been deemed as one of the most relevant modes of action. Advantages of food fortification relative to other interventions have been widely noted including time to implement and demonstrate impact (Austin et al., 1981; Arroyave, 1987; INACG, 1990; Mannar, 1991; Nestel, 1993).

There are several key steps in the implementation of a food fortification program:

- Identification of the need for nutritional intervention on behalf of a population or a sub-group and required levels of fortification;
- The identification of a suitable carrier and appropriate fortificants to be added;
- Determination of the technologies used in the fortification process;
- An effective quality control and quality assurance system to ensure implementation is happening as outlined;
- A mechanism to determine whether the nutritional objectives of the program are being met.

In 2010, Liberia adopted a set of food standards from Nigeria, which were revised in 2013 to include mandatory fortification for foods widely consumed by Liberians, namely: wheat flour, cooking oil, salt, and sugar. The identified food vehicles have to be available nationwide or, at least, in the specific geographical areas targeted by the program. In practice, this means that the product must be available to purchase from local retail stores or outlets that are accessible to the targeted segments of the population. Additionally, fortified products have to be purchased by the target families, and consumed with sufficient frequency and appropriate amounts by the targeted individuals. Throughout this process, that is to say, from the factory to the retail stores, and right up until the time of consumption by targeted individuals, it is vital that the product maintains its expected quality.

In order to ensure that the planned impact is achieved, a program's performance status must be monitored; this is best accomplished through a system of continuous data collection at key delivery points. The importance of having a well-planned monitoring and evaluation system cannot be over-emphasized.

The goal of this series of Inspection Manuals is to ensure such a data collection and monitoring system for Liberia's fortification program is implemented as effectively as



possible and individual roles and responsibilities are clearly defined. The Manuals have been designed specifically for Liberia's established food inspection system as it relates to sampling and testing fortified foods. The Manuals are broken down into five different sections for ease of use and understanding. Each identified inspector will be formally trained between 2014 and 2015 by the National Standards Laboratory using these manuals enabling inspectors to hold domestic staple food producers and importers to the country's mandatory program of fortification compliance starting in July 2014. Such a monitoring system will help to ensure the country reaches its full nutritional and economic potential as a result of the program.

Part I: Includes general information relevant for all inspectors to have a clear overview and understanding of food fortification and general inspection and monitoring processes. It is important that inspectors involved with the food fortification program understand these underlining concepts in addition to understanding how such a system should be designed in a way whereby the information provided is used effectively for decision-making and for overall program management.

Part 2 - 4: Includes detailed processes relevant for different levels of inspection (i.e. Production, Commercial, and Port / Border). Inspectors will receive the part relevant for their respective work.

Part 5: Includes the National Standards Laboratory's Quantitative Compliance and Assessment guideline to ensure all those working at the Laboratory are aware of what they have to do and how to do it.

The goal of this training is to enable inspectors to effectively monitor fortified foods throughout the country, in addition to:

- Providing inspectors with a comprehensive reference tool for the inspection of fortified foods in Liberia;
- Assisting in the training of inspectors on respective roles and functions in the food fortification program;
- Ensuring inspection is carried out under uniformed and standardized procedures;
- Enhancing effective and up-to-date monitoring and QA/QC activities;
- Equipping inspectors with the practical knowledge and experience on the use of rapid test kits.

2. General framework for Monitoring

There are two general components to monitoring a fortification program: 1) ensuring the premix (vitamin and mineral mix purchased for the addition to the identified staple food) is of sufficient quality and 2) ensuring the produced and / or imported food complies with the stated national standard at point of production, at border, and at market.



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All foods and premix must have a Certificate of Quality when they enter Liberia. The Ministry of Finance Customs inspectors ensure that this is the case when foods enter at the port, airport, or the borders.

In cases where the fortified food is produced within Liberia itself (currently only Premier Milling Corporation), regular internal monitoring processes take place. Imported foods are again checked to ensure that relevant certificates exist. Inspectors audit the quality of the foods through random sampling. Production facilities are inspected through the standards inspectors of the Ministry of Commerce and Industry to ensure the standards are adhered to. These foods will eventually reach retail stores and households and will be inspected again for quality by relevant assigned inspectors.

Therefore inspections take place on three levels:

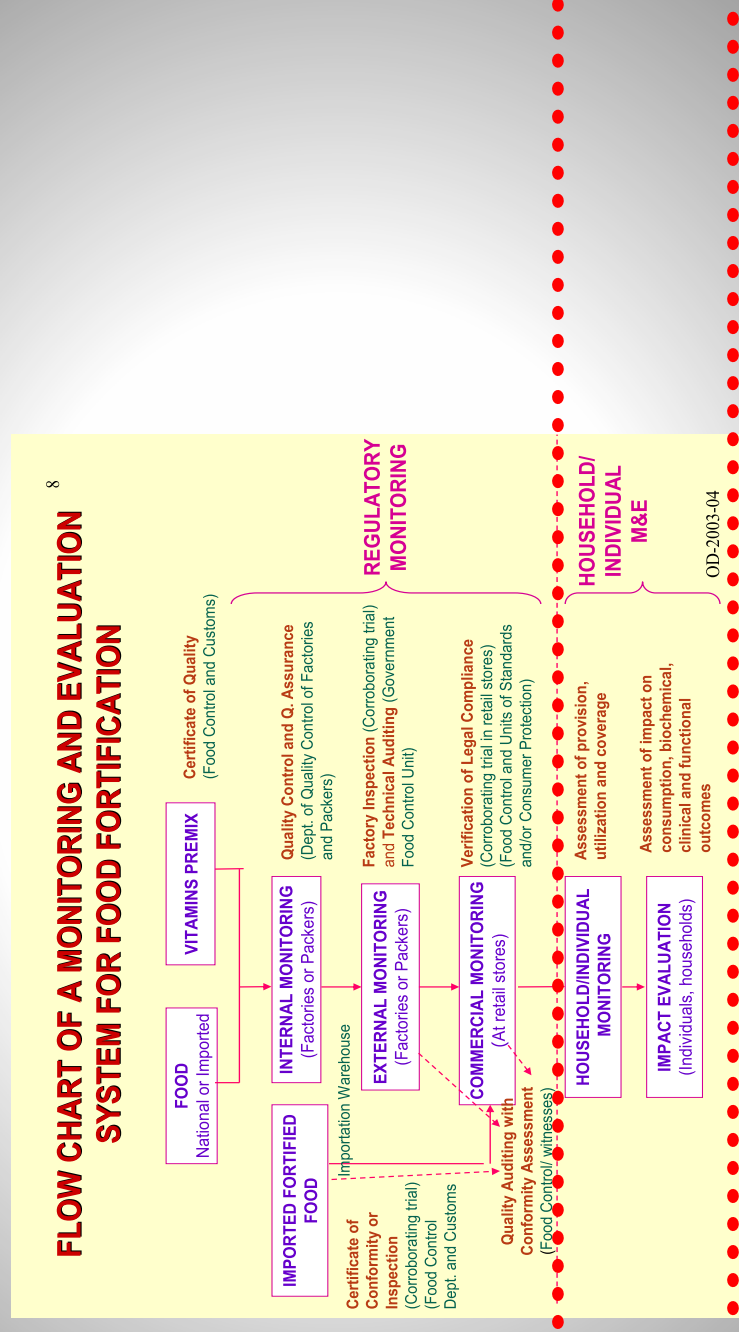
1. Borders and Ports
2. Production
3. Commercial / Market

A schematic representation of a model monitoring and evaluation system for a fortification program is pictured below. For the purpose of these manuals, focus will be placed on regulatory monitoring.



Diagram 1: Fortified Food Monitoring Model

Fortified Food Monitoring





Quality Assurance and Quality Control

Monitoring by inspectors is essential to assure that producers and importers are complying with the approved technical standards. Awareness that their product might be checked at any time usually provides producers with a strong motivational force to carry out an acceptable production process with the appropriate QA/QC procedures. The quality control procedures will typically consist of *taking samples of the fortified food, either by batch or in a continuous manner depending on the system of production, and determining their micronutrient content*. It is important to take and analyze samples routinely in order to verify and keep track of whether the technical standards are being met.

1. **Technical Auditing:** The performance and the records of the producer's quality assurance procedures must be inspected carefully. Imported products should be treated in a similar manner to locally produced foods, only instead of checking the producers' documented QA/QC procedures, the Certificate of Conformity provided by the country of origin should be examined. Food control authorities can corroborate compliance of the technical standards in samples of the imported shipments. **Quality Control results must be carefully recorded in the appropriate forms.**
2. **Inspection:** Inspectors must confirm that technical specifications for the product are being met at factories, packaging sites and points of entry into the country.
3. **Sampling:** Random samples must be taken from the products and tested on a regular basis. On the spot inspections that ensure the presence of vitamin A in oil and sugar will be done by the inspectors using the BASF kits. Spot iron tests for flour will be conducted as available. The National Standards Laboratory will test the level of micronutrients in the foods quantitatively. All samples should contain the fortificant; at least 80% of samples from factories, importation sites and warehouses should present the Legal Minimum amount, and less than 20% of samples should have a micronutrient content that is above but always near the Maximum Tolerable Level. If this is found not to be the case, then more frequent visits to the factory to carry out technical auditing and inspection will be required.

3. Inspection Processes in Liberia

In order to ensure consistency and a clear structure, this section clarifies the responsibilities in the inspection process of food fortification and defines the procedure involved. All inspection processes should follow this procedure, regardless of the industry, manufacturer, or importer being inspected. Generally, all inspections must be unannounced.

The following Ministries and agencies are charged under the law with inspecting fortified foods and ensuring compliance with standards and regulations:



- The MoHSW has an Environmental Health Technician (EHT) in each county that is a member of the County Health Team and in charge of food safety at county and district level, including markets and households. Each EHT will be responsible for testing fortified food brands at the market level. Counties with import sites are manned by Port Health Officers that work closely with the Customs officials in monitoring foods imported into the country. The Port Health Officers will be responsible for testing fortified foods at import sites and will advise Custom Officers on whether the foods will be allowed into the country or not.
- The MoCI, through their Standards Officers, is responsible for inspecting local industry and manufacturers in cooperation with the MoHSW;
- The Customs Department of the Ministry of Finance (MoF), through their Customs Officers, is responsible for inspecting the ports of entry and border points in cooperation with the MoHSW;
- The Ministry of Justice (MoJ) is responsible for the implementation of non-compliance procedures;
- BIVAC inspectors are responsible for pre-and post-shipment inspections at the multiple ports of entry.

There are three levels of inspection: imports (Port of Monrovia and other border entry points), local industry, and markets. The breakdown of inspector responsibilities, flow of collected data and samples, and frequency of inspections are as follows:



Market Inspections at County and District Level

Market and Commercial inspections at County and District levels

Inspectors

*Environmental Health Technicians (EHT),
MoHSW*

EHT responsibilities

1. Every quarter, composite samples for each staple food brand (oil, sugar, flour, and salt) are collected.
2. Random qualitative tests are conducted on oil and sugar brand samples using BASF test kits. Iodine spot test kits are used for salt.
3. Results are recorded in appropriate forms

EHT transfers samples and forms to Food Safety Coordinator (FSC)

The EHTs transfers completed forms and samples for quantitative testing to the CHT Food Safety Coordinator each quarter via airplane or road. Transfer of samples must happen within 24 hrs of collection.

FSC transfers samples and forms to NSL

The FSC transfers completed forms and samples for quantitative testing to NSL each quarter. Transfer of samples must happen within 24 hrs of collection.



Frequency

Wholesalers and retailers should be inspected at least once per quarter.

Inspection Procedure

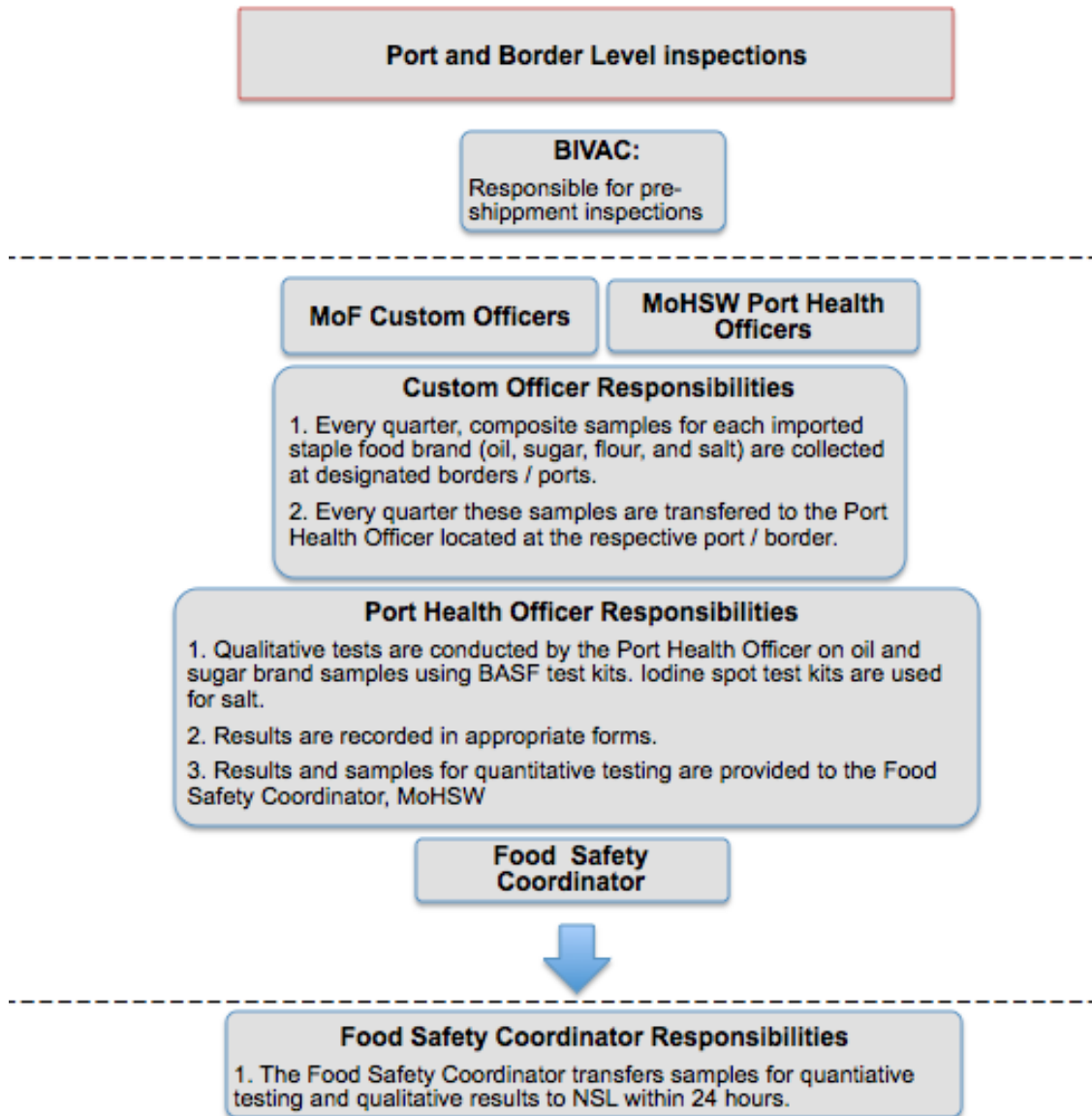
Inspections at the market level collected by MoHSW inspectors should include the following:

- The monitoring cycle should be conducted every three months and be based on a breakdown by counties (see sample collection table below).
- Inspectors should decide on the practical number of samples to be inspected qualitatively in their county. This inspection will include assessment of label information, packaging and other details as outlined in *Manual¹ for Monitoring Fortified Foods at Commercial level*.
- Inspectors shall sample as widely as possible in their area of jurisdiction. If for example, a county is divided into four divisions of equal populations, sample numbers should be close to reflect the population distribution
- Monitoring shall include as many varieties and brands of product as possible and the brand names should be noted during the exercise.
- All inspectors are to ensure that all wheat flour, cooking oil, salt, and sugar packaging includes the ENRICHED logo. The presence of the logo should be noted on the checklists.
- The National Standards Laboratory must advise on the total number of samples they can test quantitatively so results are provided on time when samples are submitted.
- Samples should be transported to the NSL in opaque, airtight containers within 24 hours.
- Sampling for every quarter should be done over a period of time and sampling in different areas of the county will be done at different times.
- Tests at market level shall include qualitative tests as the first method of choice. Samples that are positive to the qualitative testing shall be grouped (by brand name) to make one composite sample of the brand for the area. The composite samples are sent to the National Standards Laboratory or they are tested in the county if iChecks are available. Due to the nature of reagents used for some qualitative tests, the following should still be done in a laboratory. The County Water Laboratories would serve as ideal sites for such test to be conducted:
 - Qualitative test for sugar - with color reagents
 - Qualitative test for oil - with color reagents
 - Qualitative test for iron - iron spot test
 - Qualitative test for iodine in salt can be done on site with rapid test kits
- It is important to keep track of the brand performance and at least one composite sample of the brand should be sent to the NSL for quantitative testing.

¹ <http://www.a2zproject.org/node/74>



Port and Border Level Inspections



Frequency

The contents of all containers/products attempting to cross the border must be tested on a quarterly basis, through the selection of random samples by lot/batch/brand. On-the-spot qualitative tests must be conducted to determine whether or not the product can enter into the country. If a positive qualitative test is obtained, the product can cross the border. If a negative qualitative test is obtained, the product will be prohibited from entering the country. Documented review is important to confirm that the product is fortified according to specifications.



Inspection Procedure

Inspections at points of entry for **imported foods** collected by MoHSW, MoF, and BIVAC inspectors should include the following:

- All consignments will be reviewed in terms of documentation for import and the CoA or Certificate of Conformity (CoC) that accompanies the import documentation. The CoA must provide evidence of fortification in line with Liberia Standards.
- Appropriate product packaging will be ensured to preserve fortificants levels in accordance with the standard levels. As outlined above, appropriate product packaging includes a label of nutrition facts and airtight packaging.
- All products designated as fortified should bare the ENRICHED logo in accordance with the logo guidelines.
- The required fortification should be verified as completed by the producers / manufacturers of the imported food products.
- Samples must be drawn randomly to determine PRESENCE of the added nutrients (qualitative/spot test) and then tested quantitatively to confirm that the product is imported with nutrient levels within the “market range”. It is important to establish that the product is fortified before transporting to NSL for quantitative testing (see sample collection table below). BASF test kits can be used for qualitatively determining if vitamin A is present in sugar and oil. Other equivalent testing methods can be used in its place.
- Samples should be transported to the NSL in opaque, airtight containers within 24 hours.
- Officers must note the brand name of consignments that comply and record in appropriate forms – examples and details provided in the ECSA Manual for Monitoring at Import sites²
- If the iCheck is available, quantitative testing can be conducted at import sites otherwise the samples should be sent to the National Standards Laboratory for determining the level of an indicator nutrient (e.g. vitamin A for oil and sugar, iron for flour and iodine for salt). WYD iodine checkers are appropriate for quantitative iodine testing at the border following testing with a rapid test kit.

² <http://www.a2zproject.org/node/74>



Industry Level Inspections

Industry Level Inspections

Inspectors

Standards Officer, MoCI

Standards Officer Responsibilities

1. Every quarter, composite samples for each domestically produced staple food product are collected.
2. If a qualitative testing method exists, they are conducted.
3. Results are recorded in appropriate forms.

Standards Officer transfers samples and forms to Standards Director, MoCI

This happens each quarter via airplane or road. Transfer of samples must happen within 24 hrs of collection.

Standards Director transfers forms to NSL

Samples and results are then transferred to the NSL for quantitative testing.

This happens each quarter via airplane or road. Transfer of samples must happen within 24 hrs of collection.

Frequency

- All producers in the country must be inspected at least three times per year by MoCI inspectors. For new facilities that become established, testing should be done once a month for the first three or four months.
- All importers and re-packagers within the country must be inspected at least three times per year.
- Inspections following the initial inspection cycle may be limited to industries and importers that have a history of non-compliance. However, all industries must be inspected once a year regardless of compliance.



Inspection Procedure

Raw product inspections should be done according to normal procedures, while inspections and auditing at production and repackaging facilities should examine the following:

- Raw products before fortification (currently including salt, wheat flour, cooking oil, and sugar) to ensure basic hygiene and Good Manufacturing Practice (GMP) parameters and standards are met.
- The fortificant premix to ensure it is stored properly (cool, dry places away from direct sunlight), not expired, that adequate amounts are in stock, and that the Certificate of Analysis (COA) is present and indicates appropriate fortificants and levels according to the Liberian standard for fortification.
- The fortified food product to ensure it meets Liberia's national standards through both qualitative and quantitative tests.
- Production processes of local manufacturers or producers to ensure that the fortificants are mixed with the food vehicle in the appropriate manner. This will vary depending on the product being fortified. Adequate dosing, proper and thorough mixing, proper handling and storage, and proper record keeping (premix used vs. product produced) should be verified.
- General QA practices and record keeping including sample collection, production procedures, and equipment maintenance. This includes ensuring appropriate hygiene levels.
- Appropriate product packaging to ensure that the fortificants levels claimed are in accordance with the standard levels. In the same manner, the storage areas and practices must be inspected. Manufacturers of processed foods or food products shall include on the label a statement of "nutrition facts" indicating the nutrient(s) and the quantities of said nutrients added in the food. Proper packaging for fortified products includes the use of opaque (where possible) and airtight materials to avoid unnecessary nutrient degradation during transport and storage on the market.
- Product nutrient labeling with usage of the ENRICHED logo in accordance with the logo guidelines.



The National Standards Laboratory

National Standards Laboratory

Receives samples every quarter from:

1. Food Safety Coordinator, MoHSW
2. Standards Director, MoCI

NSL Responsibilities:

1. Tests all composite samples quantitatively using iChecks
2. Inputs quantitative data and qualitative data from submitted forms into the Monitoring Tool
3. Reports results to NFA Secretariat and GAIN on a quarterly basis
4. Issues National Fortification Logo to importers and producers after application and conformity have been confirmed
5. Conducts refresher training for inspectors on sampling and monitoring procedures as needed
6. Follows outlined procedures in the case of non-compliance
7. After third warning to non-compliant producer or importer, NSL reports event to Ministry of Justice. MoJ

4. Random Sampling Procedures

The actual number of samples to be submitted by each county is determined by a consultative process with Country Environmental Officers who know the distribution of the population and can provide realistic number of samples that can be inspected during every quarter. No samples should be collected if there is no capacity to test qualitatively or quantitatively.

The table below provides number of samples to be tested quantitatively at the National Standard Laboratory or using the iCheck at county level. *Through consultations with inspectors, sample collection numbers established make sure that at least one representative sample of each brand is sent for testing from each county.* Where the population is large, two or three representative samples of the same brand can be sent to the laboratory depending on the area sampled.

If 3 brands are recognized at country level, each county will have to send 3 representative samples for quantitative testing or conduct tests using the iCheck. Where some known samples are not available during sampling, duplicate samples of the same brand can be sent. The objective is to get indicative compliance of brands at county level and national level.



Number of samples to be tested quantitatively – number based on ensuring at least each brand is represented from each county

County	Population	% of population	Samples to test at NSL				Capital
			# OIL	# FLOUR	# SUGAR	# SALT	
			40	50	30	90	
Number of recognized brands			3 Brands	4 Brands	2 Brands	5 Brands	
Bomi	82,036	2%	3	4	2	5	Tubmanburg
Bong	328,919	9%	4	5	4	10	Gbarnga
Gbarpolu	83,758	2%	3	4	2	5	Bopolu
Grand Bassa	224,839	6%	3	4	2	5	Buchanan
Grand Cape Mount	129,055	4%	3	4	2	5	Robertsport
Grand Gedeh	126,146	4%	3	3	2	5	Zwedru
Grand Kru	57,106	2%	3	4	2	5	Barclayville
Lofa	270,114	8%	3	4	2	10	Voinjama
Margibi	199,689	6%	3	4	2	5	Kakata
Maryland	136,404	4%	3	4	2	3	Harper
Montserrado	1,144,806	33%	10	12	8	20	Bensonville
Nimba	468,088	13%	6	8	4	10	Sanniquellie
Rivercess	65,862	2%	3	4	2	5	Cestos City
River Gee	67,318	2%	3	4	2	5	Fish Town
Sinoe	104,932	3%	3	4	2	5	Greenville
15 counties	3,489,072	100%	95	122	70	193	



Table 1: Standard Levels

Nutrient	Fortificant Compound	Level of Addition	Tolerable analytical range at factories and borders		Border / Production Average	Claim level at the market	Market Range	Household Range	Fortification Cost	Price of Unfortified Food	Price Increase	Cost per Person consuming daily the serving size	Serving size per capita
			Min	Max									
		mg / kg	mg/kg		mg / kg	mg / kg	mg / kg	mg / kg	USD / MT	USD / kg	%	USD / year	g / day
Salt													
Iodine	Potassium Iodate	45	40	60	50	40	30-60	15-60					
Refined Oil													
Vitamin A	Retinyl Palmitate	20	17.4	22.6	20	20	15.2-22.6	12.2-22.6	5.10	0.50	1.02%	0.093	45g
Wheat Flour													
Thiamine (B1)	Thiamine mononitrate	8.5	5.1	13.3	9.2	8.5	4.8-13.3	4.3-13.3	6.99	1.58	0.44%	0.234	57g
Riboflavin (B2)	Riboflavin	5	3.1	8.1	5.6	5	3.0-8.1	2.8-8.1					
Niacin (B3)	Niacinamide Ferrous	59	38.1	99.9	69	59	35-99.9	34.3-99.9					
Iron	fumarate	60	47	91	69	60	47-91	47-91					
	NaFeEDTA	40											



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Folic Acid	Folic acid	2.6	1.6	4.2	2.9	2.6	1.5-4.2	1.4-4.2	
Zinc	Zinc oxide	95	70	136	103	95	70-136	70-136	
Vitamin B12	Vitamin B12	0.04	0.02	0.058	0.04	0.04	0.020-0.058	0.020-0.058	
Sugar									
Vitamin A	Vitamin A								
Palmitate	Palmitate								
Vitamin A (water disp.)	Vitamin A (water disp.)	15	8	22	15	15	6.0-22	4.0-22	10.50
									0.78
									1.50%
									0.11
									14-16g



Annex 1: Definitions

Effectiveness refers to the impact of an intervention in practice. Compared to efficacy, the effectiveness of a fortification program will be limited by factors such as non- or low consumption of the fortified food.

Efficacy refers to the capacity of an intervention such as fortification to achieve the desired impact under ideal circumstances. This usually refers to experimental, well-supervised intervention trials.

Essential micronutrient refers to any micronutrient, which is needed for growth and development and the maintenance of healthy life that is normally consumed as a constituent of food and cannot be synthesized in adequate amounts by the body.

Evaluation refers to the assessment of the effectiveness and impact of the program on the targeted population. The aim of an evaluation is to provide evidence that the program is achieving its nutritional goals.

Fortification is the practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health.

Legal Minimum Level (LML) is the minimum amount of micronutrient that a fortified food must contain according to national regulations and standards. This value is estimated by adding the intrinsic content of a micronutrient in the food to the selected level of fortification.

Mass fortification refers to the addition of micronutrients to foods commonly consumed by the general public, such as cereals, condiments and milk.

Maximum Tolerable Level (MTL) is the maximum micronutrient content that a fortified food can present as it is established in food law, in order to minimize the risk of excess intake. It should coincide or be lower than the safety limit.

Minimum Fortification Level (MFL) is the level calculated by reducing the Feasible Fortification Level by three standards deviations (or coefficients of variation) of the fortification process, in order that the average coincides or is lower than the calculated Feasible Fortification Level.

Monitoring refers to the continuous collection and review of information on program implementation activities for the purposes of identifying problems (such as non-compliance) and taking corrective actions so that the program fulfills its stated objectives.



Nutritional equivalence is achieved when an essential nutrient is added to a product that is designed to resemble a common food in appearance, texture, flavor and odor in amounts such that the substitute product has a similar nutritive value, in terms of the amount and bioavailability of the added essential nutrient.

Nutrient requirement refers to the lowest continuing intake level of a nutrient that will maintain a defined level of nutrition in an individual for a given criterion of nutritional adequacy.

Processed foods are those in which food raw materials have been treated industrially so as to preserve them. Some may be formulated by mixing several different ingredients.

A *premix* is a mixture of a micronutrient(s) and another ingredient, often the same food that is to be fortified, that is added to the food vehicle to improve the distribution of the micronutrient mix within the food matrix and to reduce the separation (segregation) between the food and micronutrient particles.

Quality assurance (QA) refers to the implementation of planned and systematic activities necessary to ensure that products or services meet quality standards. The performance of quality assurance can be expressed numerically as the results of quality control exercises.

Quality control (QC) refers to the techniques and assessments used to document compliance of the product with established technical standards, through the use of objective and measurable indicators.

Restoration is the addition of essential nutrients to foods to restore amounts originally present in the natural product, but unavoidably lost during processing (such as milling), storage or handling.

Safety limit is the greatest amount of a micronutrient that can be safely added to specific foods. It considers the UL for the nutrient and the 95th percentile of consumption of a food, and makes allowances for the fact that the nutrient is also consumed in unfortified foods, and may be lost during storage and distribution, and/or cooking.

Targeted fortification refers to the fortification of foods designed for specific population subgroups, such as complementary weaning foods for infants.

The *technological limit* is the maximum level of micronutrient addition that does not change the organoleptic or physical properties of the food.

The *Tolerable Upper Intake Level (UL)* is to the highest average daily nutrient intake level unlikely to pose risk of adverse health effects to almost all (97.5%) apparently healthy individuals in an age- and sex-specific population group.