Manual for Regulatory Monitoring of Fortified Foods

November, 2015

Contents

ACRONYMS

CAC/GL	-	Codex Alimentarius Commission Guideline
COA	-	Certificate of Analysis
ECSA	-	East Central and Southern Africa
GAIN	-	Global Alliance for Improving Nutrition
GMP	-	Good Manufacturing Practices
KSCN	-	Potassium Thiocyanate
MOH	-	Ministry of Health
MOLG	-	Ministry of Local Government
NaFeEDTA	-	Sodium Iron Ethylene Diamine Tetraacetic
NDA	-	National Drug Authority
QA	-	Quality Assurance
QC	-	Quality Control
SPRING	-	Strengthening Partnership Results and Innovation in Nutrition Globally
TFA	-	Triflouracetic Acid
UNBS	-	Uganda National Bureau of Standards
UNICEF	-	United Nation International Children Emergency Fund
URA	-	Uganda Revenue Authority
USAID	-	United States Agency for International Development
US-EAS	-	Uganda Standard East Africa Standard

ACKNOWLEDGEMENTS

The GAIN supported food fortification project supported the development and publishing of the manual for regulatory monitoring of fortified foods in Uganda. That manual was originally based on the manual for monitoring of fortified foods (Quality Assurance/Quality Control QA/QC) published by the East Central and Southern African Health Community Secretariat, (ECSA) under the A2Z the USAID micronutrient and child blindness project.

This manual for regulatory monitoring of fortified foods in Uganda has been reviewed and published with support from USAID/SPRING. The Ministry of Health and UNBS acknowledge the financial support from the USAID/SPRING.

The MOH and UNBS also acknowledge the input of the various stakeholders who contributed to the development of this manual.

Scope

This manual describes procedures for carrying out the quality assurance and quality control of fortified foods by the relevant government regulatory bodies.

To assure the safety and quality of fortified foods produced, imported and sold on the Ugandan market, the various government agencies carry out monitoring, control and regulatory activities at varying levels. These activities include: - technical auditing and inspection of processing factories, inspection of fortified food products at ports of entry, and commercial inspection of fortified foods.

The Uganda National Bureau of Standards (UNBS) is mandated among others to formulate and enforce national standards to assure the safety and quality of products, including food products, produced and sold on the Ugandan market (UNBS Act, Cap 327).

Regulatory monitoring derives authority from the following: UNBS Act Public health act, Local government, Cap 327, Food and drugs act, The Uganda National Bureau of **Standards (Import Inspection** and Clearance) **Regulations**, 2002, UNBS Imports Inspection and Clearance Regulations of 2015 and requires all imported products whose standard specifications were declared compulsory to be inspected for conformity to the relevant standards before release onto the domestic market. NDA act, Food fortification regulation, US 28 EAS 39, EAS 38 CAC/GL1, CAC/GL2 CAC/GL23, US EAS767, US EAS768 and US EAS769.

While executing its role, the UNBS, collaborates with other government institutions as mentioned below:

a) The Ministry of Health (MOH) is the parent ministry that monitors the implementation and enforcement of the Food and Drugs (Food Fortification) Regulations, 2005.

b) Health inspectors under the Ministry of Health and the Ministry of Local Government (MoLG) are mandated under the public health act (Cap 281) and the food and drugs act (Cap 278) to carry out inspection at factory, entry ports and markets for foods.

c) Uganda Revenue Authority (URA) collaborates with the MOH, UNBS and NDA in the area of import inspection to ensure that only products (fortified foods, fortificants and fortification mixes) compliant to the national standards and regulations are allowed into the country.

d) NDA is mandated to assure the safety and quality of drugs (including fortificants and fortification mixes) produced, imported, and marketed in the country.

This manual is divided into three parts:

- Technical auditing and inspection of fortified foods manufacturing factories
- Inspection of fortified foods at importation sites
- Inspection of fortified foods at market level.

PART I:

TECHNICAL INSPECTION OF FACTORIES

Introduction

Technical inspection activities carried out at fortifying industries and mills are part of the enforcement activities performed by the regulatory agencies to ensure that fortified foods meet the nutrient quality as well as the safety specifications established in regulations. During the technical audits, the performance of quality assurance and control activities done by the producer is examined. Then, the conformity of the fortified food with technical specifications is established through sampling and analysis of food samples taken from the factory. Samples of premix are also taken to verify the authenticity of the Certificate of Analysis (COA) provided by the supplier.

This manual presents steps for carrying out technical inspection in establishments that fortify food. The Food Control Authority in the country is responsible for carrying out the auditing and inspection activities of fortified foods, in coordination with other government bodies involved in the enforcement of food fortification regulations.

Since technical inspections are based on checking the producer's records, the listed objectives measured by indicators and criteria of success are based on the similar objectives used for the QA/QC system. The manual also includes the people responsible for each stage. Legal actions to be taken such as warnings and impounding of goods may be applied when non-compliance occurs are as indicated in the food fortification regulation.

Results of auditing and inspection activities should be consolidated regularly with a minimum of twice a year in order to determine the degree of success in fulfilling the fortification goals, obstacles to overcome and actions to be taken. It is recommended that an annual report be prepared and published where data from external monitoring are presented graphically to describe the status of the

Fortification program in the country, along with information from other food control or surveillance activities.

This part of the manual consists of the following sections:

- Planning inspection visits
- Technical inspection visits and
- Sampling for confirming conformity of the products for fortified maize, fortified wheat flour and fortified oil/fat.

1 Planning inspection visits

1.1 Objectives

The purpose of planning inspection visits is to ensure that:

- Resources to visit the factories and mills regularly are allocated. The visits should be made at least twice a year.
- Inspectors receive appropriate training on the fortification process and sampling in order to perform the auditing and inspection activities.

1.2 Responsibility

The supervisor of Food Control Inspectors is responsible for achieving the objectives and submitting the monitoring plan to the Head of the Food Control Authority.

1.3 Procedure

1.3.1 Plan, budget and schedule

a) Based on the total number of factories and mills that should be visited, plan at least two yearly visits to each mill.

b) Estimate the financial resources that will be needed considering:

- Personnel
- Transportation and fuel
- Approximate number of samples to be analyzed and cost
- Consider other expenses such as approximate number of extra-visits

Take into consideration the competence of the inspectors regarding the fortification process in the factories and mills, the Quality Assurance and Control (QA/QC) performed by the factory/mill, and auditing and sampling activities during the visits to factories. Planned training may be necessary on regular basis to

b) Ensure continued competence of inspectors. Annual training programmes may be used based on needs assessment.

c) Provide a report to the Head of Food Control Unit on the plan, schedule including dates of visits, period of analysis of samples, report writing and estimated budget to carry out the plan.

1.3.2 Defining actions to be taken

Define the actions to be taken when non-compliance is found during a visit. These actions might include warnings and legal actions which should be considered within the legal framework of the Food Control regulations and will depend on the level of non compliance.

Non compliance may be considered minor, major or critical.

The following actions may be taken:

- When the non-compliance is minor, technical advice should be provided on areas that need improvement and follow up with more frequent visit.

- When a major non-compliance is found during a visit, a letter should be sent to the factory stating the issues identified and the need to correct the issue(s). The factory should submit clearly stated corrective actions with timelines of completion of corrective action. The inspectors should assess implementation of corrective actions during the follow up visit, which may take place ahead of schedule if the identified limitations were considered serious.

- If the factory has not taken any action to solve the problem or if there is proof that the non compliance is intentional, action should be taken against the factory as provided for in the regulations for food fortification.

- If corrective measures are in process of being implemented, or new unrelated findings that require redress are identified, continue providing technical support and conduct more frequent follow up visits.

1.3.3 Records and Reporting

The person in charge of the inspection visits should keep records of:

- The plan, schedule and estimated budget.
- Factory information such as location, management and products
- Inspection reports, corrective action reports, and results of product analyses.

This information has to be reported to the *Head of the Food Control Authority*.

2 Technical inspection visits

2.1 Objectives

The purpose is to verify that the fortifying factory and mill has implemented and continues to apply a program for:

- Compliance with required good manufacturing practices and other relevant systems.
- Quality assurance of premix receipt, storage and issue
- Quality assurance of the food fortification process
- Quality control of the fortified food

The Inspector should visit the premises and plan to spend sufficient time to make detailed examination of processes and verify documentation. The visit should be made with the view to assist the factory perform better and the frequency of the visits may be scaled down or scaled up depending on the performance of the factory. Where possible, and when the fortification program is new, the visits should be done on a monthly basis and be scaled down depending on the success of the fortification in the factory. Once the operation is working smoothly, two visits per year may be sufficient.

2.1.1Responsibility

The personnel directly responsible for achieving these objectives are the *Inspectors*. They shall communicate their findings to the supervisor. The *Supervisor* is responsible for sending the reports to the factories and mills. The *supervisor* should also report every three months to the *Head of the Food Control Authority* and any other government body involved in the enforcement of fortified foods.

2.2 Procedure (Food Inspectors)

2.2.1 Preparation for the /inspection

The inspector should adequately prepare for the inspection. This will depend on whether the inspection is a follow up of previous inspection findings or a new / first time inspection. The inspector should ensure he is familiar with the process to be inspected. The preparation will include review of available information at the factory, the structure or set up of the factory and the functions involved. An inspector should notify the factory of the pending inspection in time. Where an impromptu inspection is planned such notification will not be done.

2.2.2 Opening session

Start the inspection with an opening session where the General/Factory Manager or Production Manager, Quality Assurance and Control Department Manager and Laboratory Manager are present. Explain briefly the purpose and approximate duration of the inspection and explain that this will be carried out through reviewing of written procedures, records, personnel interviews, observation of the fortification process and taking some samples. Record attendance during the session in Table **B-1.**

2.2.3 Technical inspection

Begin the technical inspection with the aid of the checklist presented in **Table B-2, section A**. As the inspection takes place, record any non-compliance found in **Table B-2, section C**.

Also review the non-compliances found during the last visit and the recommendations made. Assess the corrective actions and record the findings in **Table B-2, section B.**

2.2.4 Inspection

At the end of the inspection, take product samples for inspection by corroborating trials (refer to Section C – Inspection by Corroborating Trials).

Take a sample of the undiluted premix or fortificants currently used for fortification, from the original container of the supplier. Write down the type of iron used in the premix for flours as labelled on the box or the Fact Sheet, as well as information of other nutrients. Use **Table B-2, cell D.**

2.2.5 Preliminary report

Plan to dedicate from 15 to 30 minutes to finish the preliminary report on the major findings during the inspection. In the report, provide comments about the adequate performance of the quality assurance and control procedures, opportunities for improvement and non-compliances if any (use **Table B-3**).

2.2.6 Closing session

Conclude the inspection with a closing meeting to be attended by those present during the opening meeting where possible. Check again in **Table B-1** the names of those attending. Explain the major findings as stated in the prepared preliminary report. If non-compliances are found inform the management about the actions to be taken.

Leave a copy of the report with the Quality Assurance Manager.

2.2.7 Samples transport

a) Pack the samples in suitable tight containers, and transport the samples appropriately, protecting them from exposure to heat, humidity and direct sun light.

b) As soon as the inspectors arrive to their headquarters, they must give the

samples to the Supervisor of Inspectors, who will in turn send them to the Food Control National Laboratory.

2.3 Records and reporting (Supervisor of Food Inspectors)

Once results from the laboratory are received and analyzed by the Head of Inspectors, send a final report to the General Manager of the establishment with some interpretation of results.

If any non-compliance is found, enclose a letter stating the points that shall be corrected before the next visit.

3 Inspection by corroborating trials for maize flour

3.1 Objectives and Accountability

The purpose of the corroborating trials is to ensure that:

a) All flour samples contain the legal range level as specified in the standards. For example:

	Total iron	Iron.From NaFeEDTA	Vitamin.A (Retinylpalmitate)
• Whole maize flour	>40 mg/kg	> 5 mg/kg	> 0.2 mg/kg
• Refined flour	21-41mg/kg	10-30mg/kg	0.5-1.4mg/kg

b) 80% samples contain the factory recommended levels, for example:

	Total iron	Iron. from NaFeEDTA	Vitamin A (Retinyl palmitate)
• Whole maize flour	40-60 mg/kg	5-15 mg/kg	0.3–0.7 mg/kg
• Refined flour	31±10	20±10	1±0.4

c) All premix and fortification mixes samples comply with the specifications established in the standard of the premix.

3.2 Responsibility

Inspectors are directly responsible for taking the samples at the factories and mills and delivering the samples to the laboratory whereas the *National Food Control Laboratory* is responsible for analysing them. The Supervisor of the food inspectors coordinates the activity, from checking the records of the inspection visits, receiving and analyzing the laboratory results, and preparing and sending the reports.

3.3 Procedure for Sampling (by Food Control Inspectors)

3.3.1 Fortification Premix

Take a 30-g sample of the premix that is being used for fortification at the factory during the time of Inspection. Seal the sample in a sample bag and label it with the details of the premix including the name of the mill, name of the manufacturer, vitamin A and iron content indicated, expiry date and date of sample collection.

3.3.2 Daily composite samples of fortified maize flour

a) Before the inspection visit ends, go to the laboratory and check that "daily composite samples" for the last 30 working days are appropriately stored.

b) Choose three daily composite samples at random. In **Table B-2**, write down the production date, estimated iron level, and any other information provided on the sample ID.

3.3.3 Samples from production or storage warehouse

Take two more samples per type of flour either from the flour being produced that day or from the storage warehouse.

3.3.4 Samples from production

a) In the packaging area, randomly take one scoop (~ 100-150 g) of flour from different bags, before they are weighed and sealed.

b) Repeat above step until about 1.0 kg sample has been collected.

c) Sampling for next 1 kg begins after letting 20 sacks to pass and then begin scooping the 100-150 g to make the new sample.

3.3.5 Samples from storage warehouse

Select one stack of sacks at random to take one sample per stack. Ask the support of the warehouse operators to move the flour sacks to get the samples.

One sample is composed of eight 200 g-portions taken from eight different bags along the stack. Try to obtain the samples from all accessible sides of the stack, taking the bags out, opening them, and taking the flour samples

3.3.6 Sample homogenization and labelling

a) Homogenize the samples taken and divide each one of them into three portions. Prepare 500-g replicates of each sample.

b) Pack the samples in dark containers and close them tightly.

c) Label each sample with the following information:

- name of the factory
- product brand
- date of inspection
- lot number
- sample ID or number

d) The three portions are divided as follows: one for reference kept by the maize mill laboratory, one for reference sent to the Food Control Authority and one is sent to the National Food Control Laboratory.

e) On return to the office, hand in the /inspection forms and the samples to the Supervisor.

3.4 Records and Reporting (Supervisor of Inspectors)

a) The Head of the Food Control Authority shall receive the samples and the report from the inspection visits. The undiluted premix samples shall be sent to the National Food Control Laboratory or to a reliable laboratory to determine the type and amount of iron that was used. Likewise, samples of fortified maize flour shall be sent to the laboratory to determine the content of iron and vitamin A using a quantitative assay.

b) When results from the National Food Control Laboratory are received, these are compared with the producer's semi-quantitative records. Remember that the results used to calculate the estimated average were obtained using a semi-quantitative method, whereas the National Laboratory uses quantitative methods and therefore, some variation between the two results is expected. However, if results differ greatly, for example, iron level reported quantitatively was less than the legal range 21 mg/kg and the daily estimated average was greater then, the cause of such discrepancy should be investigated.

c) Record the results from the laboratory in the corresponding section E of **Table B-2**.

d) Analyze the results and complete the report. Prepare letters for the inspected factories.

e) Prepare a consolidated report every 6 months and submit it to the Head of the Food Control Authority. These reports shall also be forwarded to the National Coordinating Committee of the Fortification Programs in the country.

4 Sampling for confirmation of conformity of wheat flour

4.1 Objectives and Accountability

The purpose of the corroborating trials is to ensure that:

a) All flour samples contain the legal minimum level as specified in the standards. The following requirements apply for wheat flour:

	Total iron	Vitamin A (retinol)
• Whole wheat flour	> 40 mg/kg	> 1 mg/kg
• Refined flour	>20 mg/kg	0.5-1.4 mg/kg

b) 80% samples contain the factory recommended levels. The following requirements apply for wheat flour:

	Total iron	Vitamin A (retinol)
• Whole wheat flour	60-100 mg/kg	2-4 mg/kg
• Refined flour	30±10 mg/kg	1.0±0.4mg/kg

c) All premix samples comply with the specifications established for premix in the wheat flour standard (US EAS 767:2012).

4.2 Responsibility

Inspectors are directly responsible for taking the samples at the wheat mills whereas the *Food Control National Laboratory* is responsible for analyzing them. The *Supervisor* of the food control inspectors coordinates the activity, from checking the records of the inspection visits, receiving and analyzing the laboratory results, and preparing and sending the reports.

4.3 Procedure (Food Control Inspectors)

4.3.1 Daily composite samples

a) Before the inspection visit is finished, go to the laboratory and check that "daily composite samples" for the last 30 working days are adequately stored.

b) Choose three daily composite samples at random. In **Table B-2**, write down the production date, estimated iron level, and any other information labelled in the sample ID.

4.3.2 Samples from production or storage warehouse

Take two more samples per type of flour either from the wheat flour being produced that day or from the storage warehouse.

4.3.3 Samples from production

a) In the packaging area, take one scoop (~ 100-150 g) of wheat flour from different bags, before they are weighed and sealed.

b) Repeat step (4) until about 1.0 kg sample has been collected.

c) For collection of other samples, let 20 sacks pass and then take the new sample.

4.3.4 Samples from storage warehouse

a) Select one stack of sacks at random to take one sample per stack. Ask the support of the warehouse operators to move the flour sacks to get the samples.

b) One sample is composed of eight 200 g-portions taken from eight different bags along the stack. Try to obtain the samples from all accessible sides of the stack, taking the bags out, opening them, taking the flour samples

4.3.5 Homogenization of sample

Homogenize the samples taken and divide each one of them into three portions. Prepare 500-g replicates of each sample.

4.3.6 Sample packaging

Pack the samples in dark containers and close them tightly.

4.3.7 Labelling of samples

a) Label each sample with the following information:

i) name of the factory

ii) date of inspection

iii) lot number

iv) sample ID or number

b) The three portions are divided as follows: one for reference kept by the wheat mill laboratory, one for reference sent to the Food Control Authority and one is sent to the National Food Control Laboratory.

c) Hand in the inspection forms and the samples to the Supervisor of Food Inspectors.

4.4 Records and Reporting

a) Receive the samples and the report from the inspection visit. Send the undiluted premix samples to the National Food Control Laboratory, or to a laboratory which has been confirmed that reports reliable results, to determine the type and amount of iron that was used. Likewise, send the samples of fortified wheat flour to determine the content of iron and vitamin A using quantitative assays.

b) When results from the National Food Control Laboratory are received, these are compared with the producer's records. Remember that the results used to

calculate the estimated average were obtained using a semi-quantitative method, while the National Laboratory uses a quantitative method. Therefore, some variation between the two results is expected. However, if results differ greatly, for example, iron level reported quantitatively was below the legal range and the daily estimated average was greater than 40mg/kg, the cause of such discrepancy should be investigated.

c) Record the results from the laboratory in the corresponding section of Table B-2.

d) Analyze the results and complete the report. Prepare letters for the inspected factories.

e) Prepare a consolidated report every 6 months and submit it to the Head of the Food Control Authority. These reports may also be forwarded to the National Coordinating Committee of the Fortification Programs.

5 Sampling for confirmation of conformity of oil/fat

5.1 Objectives

The purpose of the corroborating trials is to assure that: All oil samples lie within the legal range (20 - 40mg/kg) of vitamin A as specified in the standard (US EAS 769:2012). 80% samples lie within the factory recommended levels of 30 - 40 mg/kg of vitamin A. The vitamin A compound sample complies with the specifications established for it.

5.2 Responsibility

Inspectors are directly responsible for taking the samples at the oil factories whereas the *Food Control National Laboratory* is responsible for analysing them. The *Supervisor* of the food inspectors coordinates the activity, from checking the records of the inspections, receiving and analyzing the laboratory results, and preparing and sending the reports. The *Supervisor* should prepare a consolidated report every six months about the activities accomplished and actions taken, and send it to the *Head of the Food Control Authority* and any other governmental body involved in the enforcement of fortified foods.

5.3 Procedure (Food Inspectors)

Ensure appropriate sampling bags are available for transporting and storage of samples. Light proof (opaque) containers should be used.

5.3.1 Vitamin A compound

Take a 30-g sample of the vitamin A compound that is being used for fortification at the factory during the time of Inspection. Label it with the name of the manufacturer, claimed vitamin A content, and date.

5.3.2 Daily composite samples

Before the inspection is finished, go to the laboratory and check that "daily composite samples" for the last 30 working days are adequately stored.

Choose three daily composite samples at random. In **Table B-2**, write down the production date, estimated vitamin A level, and any other information labelled in the sample ID.

5.3.3 Samples from production or storage warehouse

a) Take two more samples from the oil being produced that day or from the storage warehouse. In the packaging area, randomly select 8 retail-size bottles or 2 middle or large size cans. From the small bottles take 100-mL of oil and transfer to a 1-L container. If samples come from larger bottles or cans, take 0.5 Litre from each one of them.

b) Mix the samples well. Repeat the same process for other samples.

c) Take a sample of UNFORTIFIED OIL. This sample may be used by the laboratory as the blank.

5.3.4 Homogenization and labelling

a) Divide each composite sample into three portions. Pack the samples in opaque containers and close them tightly.

b) Label the triplicates of each sample with the following information: name of the factory; product brand; date of inspection; lot number; and sample ID or number, if any.

c) The three portions are divided as follows: one for reference to the oil factory, one for reference to the Food Control Authority and one is sent to the National Food Control Laboratory.

d) Transport samples with the minimum exposure to heat, humidity and light.

Upon arrival at your office, hand in the inspection forms and the samples to your supervisor.

5.4 Records and Reporting (Supervisor of Inspectors)

a) Receive the samples and the report from the inspection visit. Send the samples identified with a correlative number (do not send original information) to a Reference Laboratory.

b) When results from the National Food Control Laboratory are received, record the results from the laboratory in the corresponding section of **Table B-2.** Remember that factory may have used a semi-quantitative method, and hence some variation might exist with the results of the laboratory, but discrepancy should not be too large.

c) Analyze the results and complete the report. Prepare letters for the inspected factories.

d) Prepare a consolidated report every 6-months and submit it to the Head of the Food Control Authority. These reports may also be forwarded to the National Coordinating Committee of the Fortification Programs.

FORTIFIED FOOD PRODUCTS - INSPECTION-Table B-1

TECHNICAL INSPECTION MEETING ATTENDANCE REGISTER

Name of establishment:

Physical address:

Date: **Time:**

NAME	POSITION	SIGNATURE	Opening	Closing

FORTIFIED FOOD - INSPECTION-TABLE B-2

CHECKLIST OF TECHNICAL INSPECTION OF FACTORIES AND MILLS

Inspection registry #:	Date:	Inspector Name:
Factory name:		
Address:		
Telephone:	Fax:	e-mail:

A. ASPECTS	YES	NO	N/A	A. ASPECTS	YES	NO	N/A
1. Basic GMPs and GHPs				**3. Food fortification process**			
Facilities and structures				3.1 Premix/**fortificant** dilution (if applicable)			
Raw material sourcing and handling				3.1.1 Homogeneity assessed			
Storage				3.1.2 Adequate storage and handling			
Processing				3.2 Records of feeder performance are available			
Personnel hygiene				3.3 Premix/**fortificant** level in feeder adequate during visit			
Cleaning and sanitation				3.4 Records of product produced/premix/**fortificant** used up to date			
Pest control				3.5 Food samples taken for analysis during every shift			
Waste management				3.6 Corrective actions taken when			
1.3 Written procedures or instructions for:				3.6.1 Ratio product produced/premix/**fortificant** is not right			
1.3.1 Receipt and storage of premix				3.6.2 Nutrient content above below minimum			
1.3.2 Premix dilution (if applicable)				**4. Fortified food product**			

1.3.3 Feeder verification				4.1 Records of product samples analyzed using			
1.3.4 Sampling of fortified food for QC				4.1.1 Spot test for iron			
1.3.5 Iron spot test for maize flour				4.1.2 Quantitative methodIron (external lab.)			
1.3.6 Iron spot test for wheat flour							
1.3.7 Spot test for retinol in oil							
2. Micronutrient premix/fortificant				4.1.3 Quantitative method Vit. A (external lab.)			
2.1 Premix/**fortificant** inventory is up to date				4.2 Daily composite samples are prepared			
2.2 Certificate of Analysis is received per lot				4.3 Last 30 samples are stored and available			
2.3 **Premix/fortificant** is stored under adequate conditions				4.4 Labelling meets specifications			
2.4 "First-in, first-out" system used				4.5 Fortified food is stored appropriately			
2.5 Premix/**fortificant** is handled well in fortification site				4.6 "First-in, first-out" system applied to dispatch			

B. ACTIONS TAKEN FOLLOWING RECOMMENDATIONS OF LAST TECHNICAL INSPECTION VISIT

Recommendations	Corrective actions taken	Assessment of corrective action[1]		
		(√)	(x)	Comments

C. NEW RECOMMENDATIONS

Non-compliances:	Suggestions for Improvement:
	D. TYPE OF IRON IN PREMIX:

[1] (√) = Adequate; (x) = Not adequate

E. LIST OF SAMPLES TAKEN FOR CORROBORATING TESTS							
Composite samples ID	Factory estimation [Iron]	Factory estimation [Vit. A] (mg/kg)	Lab. Results from inspection[2]		ID Other samples	Lab. Results from inspection[2]	
			[Iron] (mg/kg)	[Vit.A](mg/kg)		[Iron] (mg/kg)	[Vit.A](mg/kg)
Inspector (Name)					**Signature**		**Date**

2 Results from Food Control National Laboratory or an external laboratory

FORTIFIED FOOD PRODUCT - INSPECTION-TABLE B-3

TECHNICAL INSPECTION PRELIMINARY REPORT

Inspection Registry #:	Date of Inspection:
Establishment name:	Establishment representative:
Address:	Telephone:

PRELIMINARY REPORT

1. Areas visited

☐ Production ☐ Packaging ☐ Fortification site ☐ Laboratory

☐ Warehouse ☐ Raw material warehouse ☐ Other:

2.Observations (Areas found complying/conforming)

2. **Non-compliances.** List the non-compliances found	
3. **Areas for improvement**	
Inspector:	**Received by** (Establishment **representative):**
Signature:	**Signature:**
Date:	**Date:**

PART II: INSPECTION OF FORTIFIED FOODS AT IMPORTATION SITES

Introduction

The purpose of this section of the manual is to provide enforcement officers at importation sites with a tool for assessing the extent to which importers of fortified foods comply with local regulations related to specific foods. This is to make sure that specified foods are not imported and distributed to consumers if they are not fortified appropriately. The process mainly involves collecting food samples and reviewing documentation and declarations on food labels. This is achieved by reviewing the Certificate of Conformity or Analysis (COA) accompanying imported food batches as well as collecting samples at ports of entry and testing them qualitatively on site.

Composite samples of the month are prepared during inspection and sent out for quantitative tests at reliable laboratories. The purpose of the quantitative tests is to confirm the decision taken at the importation site based on qualitative tests. If anomalies are identified through the quantitative testing, the results provide a basis for alerting border officials on which failing brands need more scrutiny.

The procedures described in this section of the manual are applicable for the following foods:

- Oil/fat/fats
- Sugar
- Salt
- Wheat flour
- Maize flour

These procedures are divided in three categories namely;

a) Checking for the presence of key micronutrients for authorizing entry

b) Checking for labelling compliance to the national standards and the regulations on food fortification

c) Documenting compliance in terms of micronutrient content through laboratory testing

1 Checking for the Presence of Key Micronutrients for Authorizing Entry

1.1 Objectives

The purpose for assessing the minimum requirements prior to authorizing entry is:

a) To ensure that the imported products are accompanied by adequate documentation to certify that national standards and regulations are being fulfilled.

b) To ensure that the products are labelled in accordance with national standards.

c) To confirm that the food complies with fortification conditions based on the presence of one or more key micronutrients.

1.2 Responsibility

Officials from the customs office in conjunction with the Uganda National Bureau of Standards, Local Government, (or any other mandated institution) should perform the task of collecting samples, reviewing documentation, reviewing labels and testing them qualitatively before the food can be allowed into the distribution chain within the country.

1.3 Procedures

1.3.1 Reviewing the Certificate of Conformity or Certificate of Analysis and Labelling

The food inspector and customs official shall perform the following duties:

a) Review the documents that usually certify the safety of the imported product. Examine the Certificate of Conformity or Analysis, issued by a government authority or an officially recognized body from the country of

origin, which would declare (supported by laboratory analysis) that the food is fortified and in accordance with regulations established in the importer country.

b) Examine the packaging and the labelling to make sure that it indicates the name of product (and brand), batch number, list of ingredients country of origin and manufacturer. The food must comply with the General standards for Labelling of pre-packaged foods (US EAS 38), as well as the labelling requirements established in the standards for fortified foods such as micronutrient levels and the food fortification regulations. Inspectors should also look out for false health claims that may be contrary to set national standards (US EAS 804 and US EAS 805). They should record data in the Inspection Form (Table A-1).

1.3.2 Confirming the presence of indicator micronutrients

a) From each brand and truck (or consignment) which ever is appropriate, randomly collect 3 samples (50 grams or 50 milliliters per sample) of imported fortified food. Collect samples based on brand names and perform appropriate qualitative tests corresponding to the food using methods described in **Section C**. Record results in Inspection **Table A-1**.

b) All samples should test positive for the indicator micronutrient.

c) If importer disagrees with the results, collect 3 new samples and perform the test again.

1.3.3 Taking decisions to authorize

a) If samples fail packaging, qualitative test or fail to comply in terms of proper documentation, labelling requirements, the affected brand should not be allowed to enter the country and shall be re-exported or destroyed at the cost of the importer in accordance with recommended procedures and applicable regulations.

b) If documentation is correct, and samples show the presence of the key micronutrient, authorize importation and proceed with the preparation of a composite sample as described below.

1.3.4 Preparation of monthly composite samples for quantitative testing

a) Take three samples of 25 g (or 25 mL) each from each brand and truck (or consignment) that has been accepted and place in a 250 g (or 250 mL) containers labelled with the name of the brand imported into the country. Write the date of sampling on the container.

b) Positive samples of the same brand that arrive in subsequent consignments are to be combined by adding them to the appropriate container for that brand. Do not forget to write the corresponding date of each and every consignment added to the composite sample. Once the container is full, close and store it. Use new containers for additional samples and always keep samples in a dark, dry and cool place.

c) Once a month, send the composite samples collected to a reliable laboratory protecting the samples from exposure to heat, humidity and light. Send all the samples that have been collected during the period, regardless of the containers being full or not. Package them well and check that they are well labelled.

1.3.5 Actions for brands whose composite samples fail quantitative tests

a) In the case of laboratory reports of brands containing below minimum levels of the indicator micronutrient, inspectors at the border will be notified immediately and the brand name put on its Black List for closer scrutiny of subsequent consignments. A letter shall be sent by the Office of Importation to importer(s) advising them of the new status of their brand. This warning letter will state that any shipments arriving after the issuing of the letter will be sampled for immediate quantitative analysis, over and above normal sampling

for qualitative tests and document review, and the importer will cover the cost of this quantitative analysis. These quantitative analyses in this case will be done before consignments are released.

b) The Inspector shall randomly collect three 250-g single samples per truck and send to the laboratory with the instruction that the analysis should be done urgently and report submitted to the Office of importation. Importer should cover the cost of shipment and analysis.

c) If a brand on the Black List passes the qualitative test, it shall be allowed entry and bonded by customs officials pending successful laboratory results for authorizing release. When the sample is cleared the brand shall be allowed entry however the brand will remain on the black list until 3 subsequent consecutive consignments are found to comply. However if a brand on the Black List fails qualitative tests it shall be denied entry as in step see (6) above.

1.4 Records and Reporting

In all cases, the inspector shall duly complete inspection form (Inspection **Table A-1**) relating to import inspection and forward samples for testing at the Food Control Laboratory or any reliable laboratory. Results of qualitative analysis should be kept by the food control institution at the importation sites. Border inspectors should submit a report (Table B-1) to the central offices, as well as the food fortification committee, every month indicating the dates, brands, amounts, and actions taken.

2 Documenting compliance with the micronutrient content through laboratory testing

2.1 Objectives

The purpose of documenting compliance in terms of micronutrient content is:

a) To provide documented evidence that imported brands comply with national regulations and standards based on laboratory reports of quantitative tests performed on samples of imported foods.

b) To provide a basis for issuing specific quality improvement recommendations to importers.

c) To inform the officials at importation sites of failing brands that deserve more stringent examination.

2.2 Responsibility

This task is a combined responsibility of the food laboratory, the Head of the Food Control Division and Importation Office, and the supervisors of inspectors at the importation sites.

2.3 Procedures

2.3.1 Receipt of Composite Samples

a) The food control laboratory must record the receipt of the composite samples sent by the official at the importation points, number them and record the date.

b) Store samples in cool, dry and dark places.

2.3.2 Quantitative Determination of Micronutrients

Mix the samples very well, and then determine the content of key micronutrients depending on the type of sample (vitamin A for oil/fat and sugar,

vitamin A and iron for wheat and maize flour, e.g.), using quantitative tests provided in the Manual for Laboratory Methods.

2.4 Records and Reporting

a) The Head of the Food Laboratory shall submit a report to the Office of Importation and the supervisor of inspectors at the corresponding importation site.

b) Whenever a sample fails the quantitative test by containing less than the legal minimum or more than legal maximum, the Office of Importation should immediately send to the importer a warning letter for attention and immediate action. The letter should state that new consignments arriving after the date of the warning letter will be subjected to immediate quantitative testing even if it passes the qualitative test before the consignment can be released.

c) When the brand fails the quantitative test described in step 5, a letter shall be sent to all importation sites advising them to quarantine all new consignments until the laboratory results confirm that technical requirements are complied. This special treatment shall end on instruction from the laboratory confirming compliance.

d) The Head of the Food Control Unit in charge of inspection of the imported foods shall prepare a consolidated report every 6 months with all the results based on the type of food, and indicating brands, country of origin, amount imported, micronutrient tested and the corresponding analytical results, and actions taken. The report should be submitted to the central offices, as well as the food fortification committee.

3 Qualitative tests

3.1 Vitamin A in Oil/fat

This method for testing vitamin A uses corrosive reagents and so tests need to be conducted in protected areas and with proper handling. The test must only be performed by adequately trained personnel.

3.1.1 Reagents and chemicals

Reagents described in these methods are of analytical grade unless otherwise specified.

- **Chromogenic solutions**
- **Trifluoroacetic acid (TFA) Solution:** It is prepared by dissolving 15 mL of TFA in 60 mL of dichloromethane. Store in a brown bottle in a cool environment. When properly stored, the solution has been found to be stable for up to 4 months.

3.1.2 Equipment

- Pasteur pipettes and pipette bulbs
- Test tubes
- Pipette 5 mL
- Vortex Mixer

3.1.3 Procedure and interpretation

In a test tube, place 0.5 mL oil/fat (3 drops of oil/fat), then add 3 mL of the chromogenic reagent (TFA). Mix as quickly as possible and observe the formation of a blue color. The blue color shows the presence of vitamin A.

3.1.4 Handling of remnant reagents

Discard residual chromogenic reagent, including that mixed with the oil/fat, into a labelled glass bottle containing dissolved sodium bicarbonate, slowly adding

the reagent to the bottle. Clearly mark the bottle "Organic Waste" and indicate the date. After the bottle is filled, send it to the laboratory to be discarded appropriately as other organic waste material.

3.2 Vitamin A in Sugar

This method for testing vitamin A uses corrosive reagents and so tests need to be conducted in protected areas and with proper handling. The test must only be performed by adequately trained personnel.

3.2.1 Reagents and chemicals

Reagents described in these methods are of analytical grade unless otherwise specified.

3.2.2 Chromogenic solutions

Trifluoroacetic acid (TFA) Solution: It is prepared by dissolving 15 mL of TFA in 60 mL of dichloromethane. Store is a brown bottle is a cool environment. When properly stored, the solution is stable for up to 4 months.

Alternatively, the following solution could be used:

Trichloroacetic acid/Dichloromethane/acetic anhydride: Dissolve 30.0 g trichloroacetic acid in 60 dichloromethane. To dissolve completely, warm up the mixture in a water bath at 50°C stirring constantly. Add 2 mL of acetic anhydride and store in a dark bottle with glass stopper.

3.2.3 Equipment

- Pasteur pipettes and pipette bulbs
- Test tubes
- Pipette 1 mL
- Vortex Mixer

3.2.4 Procedure and interpretation

In a test tube, place 1 gram of sugar measured by volume using a calibrated spoon. Add 2 mL of hot distilled water and dissolve the sugar. Then add 1 mL of the chromogenic reagent. Mix as quickly as in the vortex mixer and observe the formation of a blue color. The blue color shows the presence of vitamin A.

3.2.5 Handling of remnant reagents

Discard residual chromogenic reagent, including that mixed with the sugar, into a labelled glass bottle containing dissolved sodium bicarbonate, slowly adding the reagent to the bottle. Clearly mark the bottle "Organic Waste" and indicate the date. After the bottle is filled, send it to the laboratory to be discarded appropriately as other organic waste material.

3.3 Iodine in Salt

3.3.1 Reagents and chemicals

Rapid Test kits (RTKs) for iodate and iodide in salt are commercially available from MBI Chemicals in India and are procured through UNICEF, or any other supplier. Use the appropriate one (there is a kit for salt fortified with iodate, and another for iodide).

The test kits have a life span of 18 months but when opened, the solutions are effective for a maximum of 6 months. It is important when using iodine test kits to take into account the type of iodine compound (iodate or iodide) that was added to the salt in order to use the correct kit. The use of potassium iodide is discouraged but there could manufacturers who use it especially for refined salts, and inspectors need to be aware of this possibility.

3.3.2 Procedure and interpretation

Place the salt on a clean dry test plate or surface and moisten the salt by dropping the test solution onto the salt. If iodine is present in the salt, a blue color is developed where the solution is dropped.

If a color is not developed, add the confirming solution (re-test) over the wet spot (alkaline salts require of this reagent). If the blue/purple color does not appear, it means that the salt lacks iodine from iodate.

It should be noted that the test kit for iodate will give a negative answer if the salt was iodized with iodide.

Note: Although some kits include a scale of color to approximate the content of iodine in the salt, do not use it for reporting levels. The kit is unreliable for giving quantitative results; it is only useful for detecting the presence of iodine in salt.

3.4 Iron in Fortified Wheat and Fortified Maize Flours

3.4.1 Reagents and chemicals

- **Solution A** (2 N-HCl): To a 500 ml beaker, add 100 ml distilled water. Then pour slowly 17 ml of concentrated HCl, and finally 83 mL more of water.
- **Solution B** (10% Potassium Thiocyanate): Dissolve 10 g of KSCN in 100 ml distilled water.
- **Working Solution (1:1 Solution A: Solution B):** Prior to testing, mix 10 mL Solution A and 10 mL Solution B
- **H_2O_2-3%** (requiredonly when iron is as elemental iron or as a ferrous salt). Add 5 ml concentrated H_2O_2 (30%) to 45 ml distilled water. Prepare daily and discard after finishing the analysis.

3.4.2 Material

- Magnet
- Filter paper Whatman # 1
- Manual sieve.
- Watch glass.
- Pasteur pipettes and pipette bulbs

3.4.3 Procedure for determining elemental iron (e.g. electrolytic, reduced iron and others)

Take a clean magnet and insert it into a 1-kg sample of flour.

Move it thoroughly inside the sample and then take it out.

The presence of electrolytic or reduced iron is shown by the presence of small iron metal particles on the magnet.

3.4.4 Procedure for determining the presence of iron from NaFeEDTA (mostly used for maize flour fortification)

a) Place a filter paper over a watch glass.

b) Wet the surface of the filter paper with the working solution prepared as described above. Let the liquid penetrate the paper.

c) Using a hand sieve, sift portion of the flour sample in order to load a thin layer over the entire wet area. Scrape off any excess flour.

d) Add a little more of the acidic solution of potassium thiocyanate over the flour. Let it stand for a few minutes for the reaction to occur.

e) Red color spots indicate the presence of a ferric salt, such as the one present in NaFeEDTA.

3.4.5 Procedure for determining iron from other sources

a) Place the filter paper over the watch glass

b) Wet the surface of the filter paper with the working solution prepared as described above. Let the liquid penetrate the paper.

c) Using a hand sieve, sift portion of the flour sample in order to load a thin layer over the entire wet area. Scrape off any excess flour.

d) Add a little more of the acidic solution of potassium thiocyanate over the flour.

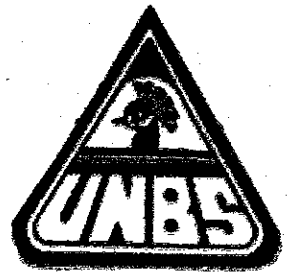
e) Add small amounts of the H_2O_2-solution to wet the whole surface. Let it stand for a few minutes for the reaction to occur.

f) Red color spots indicate the presence of added iron from any source. (Note: If the result for electrolytic or reduced iron was negative with the magnet test, then it is likely that iron comes from an iron salt).

3.4.6 Interpretation

Number and distribution of spots are indicative of the iron level of the sample. Use samples with known amounts of the same type of iron that is expected to make a comparative assessment. [Note: Unfortified flours may develop a red color due to inherent iron but this will appear one big red/pink patch and not in the form dots or spots].

The appropriate type of iron will depend on the local standard for fortification. However, current ECSA recommendations promote the use of iron EDTA for maize flour fortification and ferrous fumarate for wheat flour fortification. A number of countries use electrolytic iron for wheat flour. The inspectors need to be aware of what type of iron to expect as per standard of the country.



INSPECTION OF FORTIFIED FOODS AT IMPORTATION SITES – TABLE A-1
IMPORT INSPECTION / SAMPLING FORM

DATE: _____ **BORDER POST/BOND** _____ _____

Inspector Name:		Supplier Address:	**Batch Numbers and Size (MT):**
Product/Variety of Food	**Brand:**		
Applicable standard:			**Certificate of Conformity:**
Country of Origin:			**Container no:** **Vessel no:** **Truck no:**

Custom Entry Number:	Importer : Name and Address:

Product Examination

LABELING INFORMATION[1]

	Adequate	Inadequate	Comments
Name of product			
Brand Name			
Manufacturer			
Nutrient declaration			SPECIFY NUTRIENTS :
Expiry Date			
List of Ingredients			
Lot/Batch Number			
Presence of nutrient			Based on qualitative test on representative samples per lot/ brand and per truck (consignment)

1 Mark with a tick (√) in the *adequate or inadequate* boxes where appropriate.

Action:	
Importer's /representative signature:	
Inspector's signature:	

MONTHLY REPORT OF INSPECTION AT IMPORTATION SITES- TABLE B-1

Date	Product (Food Type)	Brand	Country of origin	Amount (MT)	Tested Micronutrient	Qualitative Test (+ or -)	Action Taken

PART III: INSPECTION OF FORTIFIED FOODS AT MARKET LEVEL

Introduction

Inspection at market level is the verification of legal compliance of fortified foods sold in retail supermarkets, markets, grocery stores, and wholesale stores. It also includes inspection at bakeries as a convenient sampling site for fortified foods namely salt, sugar, flour and oil. This monitoring allows for the detection in the market of brands that are not approved by the Ministry of Health or do not comply with local fortification regulations. It also helps to confirm whether brands that have previously been inspected are indeed fulfilling the requirements as claimed by inspectors during the external monitoring process.

When non-compliance is observed in certain brands, this type of monitoring provides a warning signal to indicate that the quality control and quality assurance procedures are not adequate in the factories, and that the visits by inspectors for auditing purposes and inspection are failing in enforcement. In such a situation there is need for increased frequency of audit visits to the factories producing the failing brands. Furthermore, commercial monitoring serves as an education tool since food inspectors are able to inform the retailers about the existence of the fortification program, the benefits of fortification, their role as retailers and their rights as consumers.

Monitoring at market level is the responsibility of the Food Control authorities, in cooperation with other governmental bodies in charge of enforcing these regulations such as government officials from ministries of Trade, Industry, Local government and Finance. Monitoring at this level should also involve municipal inspectors and other local officials in carrying out inspection visits and taking of samples in their respective areas. Food Control authorities are responsible for preparing the Sampling Plan and providing the technical training to carry out the inspections.

This section of the manual describes the procedures for carrying out the inspection visits at any retail store selling fortified foods such as sugar, salt, wheat flour, maize meal and oil. It also describes those responsible for each stage. As any enforcement procedure carried out by a governmental body, warning and legal actions that are to be given when non-compliances are observed need to be defined and applied when necessary.

Results of monitoring at market level activities should be consolidated in reports to be issued twice a year. The reports assist defining the degree of success in fulfilling the fortification goals and spells out obstacles that need to be overcome and actions to be taken. It is further recommended that an annual report be prepared and published where data is presented graphically to describe the status of the fortification program in the country, along with information from other general food control or surveillance activities.

This section of the manual is divided into two sections:

- Planning monitoring at market level visits
- Conducting inspection visits at retail shops, wholesale stores and bakeries.

1 Planning monitoring at market level visits

1.1 Objectives

The purpose of planning for monitoring at market level visits is to ensure that:

a) Resources to conduct the visits at retail, whole sale and bakery stores around the country throughout the year are allocated.

b) Inspectors receive appropriate training on how to assess the compliance of fortified foods in the field.

1.2 Responsibility

The *supervisor of Food Control inspectors* is responsible for achieving these objectives and submitting the monitoring plan to the *Head of the Food Control Authority*.

1.3 Procedure

The supervisor of the Food Control inspectors will perform the following tasks;

1.3.1 Plan, budget and schedule

a) Plan at least one visit a year to each region based on the total number of districts in the country. Seven regions namely; west Nile, northern, eastern, south eastern, south western, mid western and central should be used. Frequency and intensity of sampling depends on the population density, amount of food sold in the region, and risk factors such as location close to the borders with other countries where the food is not fortified. Bakeries may be included as a convenient sampling place.

b) Estimate the financial resources that will be needed considering:

- Personnel
- Transportation and fuel
- Approximate number of samples to be purchased and analyzed and the cost

c) Materials including sample containers and brochures or leaflets

d) Report to the Head of Food Control Authority on the plan, schedule and estimated budget to carry out the yearly activities.

e) Ensure cooperation and coordination among the governmental parties involved in the enforcement of regulations as this is important in order to perform the exercise effectively and make efficient use of resources. It is recommended that Municipal/district health inspectors be included during commercial monitoring activities in areas under their jurisdiction.

1.3.2 Prepare educational materials and training for the inspectors

a) Prepare brochures or leaflets with information on the general labeling requirements for food in general (e.g. requirements for the use of the fortification logo, name and address of supplier, expiration date, net weight, and others) as well as specific information on labelling of fortified foods particularly sugar, salt, wheat flour, maize meal and oil.
b) Plan a training workshop for the inspectors on how to conduct the inspection visits to wholesale and retail stores and bakeries, and how to take samples and record the information during the visits.
c) Prepare a list of brands of fortified food per food vehicle. This list should be updated every 3 months or more frequently if needed.

1.3.3 Define actions to be taken

Define the actions to be taken when non-compliance is found during a visit. These actions might include warning letters and legal actions which should be considered within the legal framework of the Food Control work. The following actions are suggested:

Retailer, wholesaler or bakery:

a) At the retail and wholesale level, when a brand is claimed to be fortified but it is not on the list of fortified foods known to be marketed in the country, the product shall be investigated. If it is confirmed that the brand or product is not fortified, the brand or product should be confiscated.

b) Bakeries producing fortified bread shall prepare bread and other foods derived from wheat flour, using at least 60 percent fortified wheat flour. If less than 60% of flour used in a bakery is unfortified, the brand or product should be handled according to the regulation

- If a product is expired or shows signs of spoiling or non-hygienic conditions, the product should be quarantined and the case reported to the local Food Control Division to take the proper action.
- Micronutrient testing is not carried out at this level; the food samples would be sent by the supervisor of the local food inspection to the central Food Control Authority office together with the report forms.

Actions taken by the central Food Control Authorities

When a brand does not meet the minimum legal requirements (micronutrient content, labelling and packaging) depicted in the fortification regulations, a warning letter shall be sent to the factory, packaging plant or importer responsible for the brand. Sampling priority should be given to these brands in future visits. Extra visits to the factories might be considered within the external monitoring activities.

- If the brands belonging to a specific factory consistently fail to comply with the legal minimum, the Food Control authorities should consider organizing a visit for comprehensive audit and if there is proof that non-compliance is intentional, they should apply the prescribed legal actions, which may include the banning of the brand.

1.4 Records and Reporting

The *supervisor of the Food Control inspectors* should keep records of the plan, schedule and estimated budget. The information is to be reported to the *Head of the Food Control Authority*.

2 Conducting inspection visits to retail, wholesale stores and bakeries

2.1 Objectives

The purpose of the inspection visits to retail, wholesale stores and bakeries is to ensure that:

a) Fortified foods comply with the requirements established in the national standard and that products bearing the food fortification logo have been approved by the Food Control authority.

b) Fortified food items sold on the market or used in bakeries comply with national criteria for micronutrient fortification. Specifically the fortified food should satisfy the following:

Fortified food	Presence *(All samples tested must show presence of indicator micronutrient)*	Levels *(80% of samples of each brand comply with the legal minimum and maximum tolerable levels of micronutrients)*
Oil	Vitamin A (Retinol)	Retinol: 20-40mg/kg
Sugar	Vitamin A (Retinol)	Retinol: 15-30 mg/kg
Wheat flour	Vitamin A (Retinol) and Iron	Iron: >20mg/kg Retinol:0.5-1.4 mg/kg
Maize meal	Vitamin A (Retinol) and Iron	Iron: 21-41mg/kg Retinol: 0.5-1.4 mg/kg
Salt	Iodine	Iodine: 20-60 mg/kg

2.2 Responsibility

The *Food Control Authority inspectors* or *municipal/district health inspectors* are responsible for checking compliance of packaging and labelling, and for taking samples of the foods for analysis. They should report on the results of their visits to their *supervisor*. The *supervisor* is then responsible for sending samples to the central office, and for consolidating the reports on the findings and reporting every month to the *Head of the Food Control Authority*. In turn, the Food Control Authority should prepare consolidated reports every 6 months and send to other government and auxiliary bodies, such as the National Food Fortification Alliance, involved in the supervision of the food fortification programs.

2.3 Procedure

2.3.1 Visits by Inspectors

a) When inspectors arrive in the villages, towns or cities, they should visit the most popular grocery stores, markets or supermarkets, bakeries and distribution centres, where people buy their supplies. Inspectors should buy samples in a manner similar as consumers would.

b) Inspectors should enter the store and show their credentials identifying them as inspectors of the Food Control authorities when inspecting bakeries and big distribution point. They should follow on with a brief explanation about the purpose of the visit.

c) They should record the name and address of the store, date of visit, name and address (town, village, district, others), in **Table B-1**.

d) Inspectors should be able to identify the approved brands sold in the store and using **Table B-1** they should record product name, manufacturer, packer or importer, use of the fortification logo, the expiration date and lot number if specified, the inspector should check handling conditions of the product.

e) Choose a sealed package of about **0.2 kg** or **0.2 L** of each brand of each fortified food in the store. If the food is not available in such quantities, take the nearest larger retail-size presentation. If packages are much smaller, collect sufficient packages to make up the specified weight ;(e.g. 2 packages of 100 g).

f) If the food is sold by weight or volume from large sacks or a barrel, take approximately 0.2 kg or 0.2 L sample from this food product. Ensure that the sack or the barrel is new, otherwise there is no guarantee that the product inside corresponds to the factory name in the container.

g) Pack the samples inside a box and transport them to the local Food Control office[4], which in turn sends copies of report and the samples to the Food Control Authority headquarters every month.

2.3.2 Labelling samples and sending them to the laboratory for analysis

Upon arrival at the Food Control headquarters, the person in charge of the food fortification programs should split each package of sample taken in to two. Label each sample using the appropriate code given and send one replicate of each sample to an appropriate laboratory, together with the original report from the local office. Keep the other replicate as reference until the results from the laboratory are received and acceptable.

2.3.3 Analysis of the samples

a) Upon receipt of the samples, the laboratory should first detect the presence of the key micronutrients in all samples using qualitative tests.

b) Composite samples based in brand are then prepared by mixing equal amounts (approximately 100 g or 100 mL) of the single positive samples. Up

[4]Local food control office could be the regional office of the National Bureau Of Standards or any other food control agency

to 5 single samples may be mixed in the same composite sample. Quantitative determinations are then carried out for key micronutrients.

c) The laboratory prepares reports that include the total number of samples per brand, the number and percentage of positive samples per each micronutrient tested qualitatively, and the number of composite samples per brand that contained the following micronutrient levels: below the legal range, within the legal range, above the upper tolerable level (see **Table B-2** for an example).

d) Laboratory reports are sent to the responsible authority of the food fortification programs in the Food Control headquarters, and the supervisor of food control in the corresponding local office.

2.4 Records and reporting

Every 6 months, the Food Control Authority should prepare a consolidated report from the commercial monitoring, broken down by brand, presenting the percentage of samples showing the presence of the nutrient, below the legal range, within the legal range, and above the upper tolerable level, as well as any action taken when failures were detected. These reports should also be forwarded to the National Food Fortification Committee, as well as the supervisors of food inspectors in all the local offices.

MONITORING-TABLE B-1 - LABELING OF FORTIFIED FOOD BRANDS AND COLLECTION OF SAMPLES IN RETAIL STORES AND BAKERIES

Date: **District./Region:**					**Inspector's name:**				
Place (village/town/neighbourhood/city):					**Inspector's institution:**				
Store Owner:									
Store Name:									
Address:									
Tel/mobile phone number									
Sample No.	**Type of food**	**Brand**			LABELING INFORMATION				**REMARKS**
			Fort. Logo	**Name of Manufacturer**	**Lot #**	**Exp. date**	**Storage instructions**	**Health/Nutritional Claims**	

COMMERCIAL MONITORING-TABLE B-2–SUMMARY OF MICRONUTRIENT LABORATORYANALYSIS RESULTS OF FORTIFIED FOODS FROM THE MARKET

Date:	Region: District:
Inspector Name:	Address:

Food	Brand	Micronutrient Tested	Number of Samples Tested	Single Positive Samples		Number of Composite Samples		
				#	%	min	min - t Max	Tol. Max

Report Date: Name: Signature: