



East, Central and Southern African  
Health Community

# **MANUAL FOR EXTERNAL MONITORING OF FORTIFIED MAIZE FLOUR**

**(Technical Auditing and Inspection)**

FIRST EDITION – 2007



**EAST, CENTRAL AND SOUTHERN HEALTH  
COMMUNITY (ECSA-HC)**

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## ***Foreword***

Over the last five years, the East, Central and Southern African Health Community (ECSA-HC) has continued to undertake advocacy and technical assistance to assist member countries to embrace and scale up Food Fortification initiatives as a key strategy to reduce micronutrient malnutrition in the region.

ECSA has been working with partners in direct response to resolutions of the Conference of Health Ministers to scale up Food Fortification initiatives as a critical plank in fighting the devastating effects of micronutrient malnutrition among populations of member states. ECSA partners in the Regional Food Fortification Initiative include the A2Z Project, USAID, UNICEF, Micronutrient Initiative (MI), and ICCIDD, among others.

Part of the outcome of the intensified collaborative initiative, is a series of fortification guidelines developed to guide the Industry during the fortification process of staple foods and provide government food inspectors a reference point in enforcing the standards.

Similarly, food control manuals have been developed for the Industry and the Government to provide technical reference resources that cover the entire fortification process to ensure that the fortified foods are safe and adequately fortified with the required fortificants.

This manual is part of a series of manuals on food fortification and is meant to directly contribute to the overall effort to strengthen food fortification in the region.

It is our hope that the use of this manual will help strengthen food control activities in our countries in order to deliver safe and quality fortified foods to the ECSA population.

Steven Shongwe  
Executive Secretary

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The manual is as a result of joint work by distinguished food fortification experts in developing countries. During the drafting of this manual, consultations with senior officers from food control departments of the ECSA member states were made and input incorporated.

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ECSA is deeply thankful to the above authors for preparing this manual.

## ***Disclaimer***

*The content of this manual can be adapted to suit country specific contexts. In such a case, the content of the resulting document will be the sole responsibility of the organization adapting the manual and will not represent the views of the authors and that of the ECSA-HC.*

*The Use of the content of this manual should be duly acknowledged.*

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## ***MANUAL FOR EXTERNAL MONITORING OF FORTIFIED MAIZE FLOUR (Technical Auditing and Inspection)***

Technical auditing and inspection activities are carried out at maize mills as part of the enforcement activities performed by the government in order to ensure that fortified maize flour meets the nutrient quality and safety specifications established in regulations. During the technical audits, the performance of quality assurance and quality control activities conducted by the producer is examined. The conformity of the fortified food with technical specifications is determined through sampling and chemical analysis of flour samples collected from the factory. Samples of premix are also taken to verify the validity of the Certificate of Analysis (COA) provided by the supplier.

This manual presents steps for carrying out technical auditing and inspection in maize mills. 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 audits are based on checking the producer's records, the objectives which are measured by indicators and criteria of success are based on similar objectives used for the QA/QC system. The manual also describes the people responsible for each stage. As any enforcement procedure carried out by a government body, the warnings and legal actions to be taken when non-compliance occurs should be defined and applied where necessary.

Results of auditing and inspection activities should be consolidated twice a year in order to determine the degree of success in fulfilling the fortification goals identify obstacles to overcome and propose actions to be taken. It is recommended that an annual report be prepared and published where data from this external monitoring is presented graphically to describe the status of the maize flour fortification program in the country, along with information from other food control or surveillance activities.

The sections included in this manual are:

- Planning inspection visits
- Technical auditing and inspection visits
- Inspection by corroborating trials

## **A. PLANNING INSPECTION VISITS**

### **I. Objectives and Accountability**

The purpose of planning inspection visits is to ensure that:

- Resources to visit the maize mills at least two times a year are allocated.
- Inspectors receive appropriate training on the fortification process and sampling in order to perform the auditing and inspection activities.

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*.

### **II. Procedure**

The supervisor of inspectors shall perform the following duties

#### **a. Plan, budget and schedule**

1. Based on the total number of maize mills that should be visited, plan at least two yearly visits to each mill.
2. 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
3. Plan a training workshop for the inspectors regarding the fortification process in the maize mills, the Quality Assurance and Control (QA/QC) performed by the mill, and auditing and sampling activities during the visits to factories.
4. Provide a report to the Head of Food Control Authority on the plan, schedule and estimated budget to carry out the whole plan.



## ***b. Defining actions to be taken***

5. Clearly 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. The following actions are suggested:

- When a minor non-compliance is found, technical advice should be provided to the production personnel on areas that need improvement and follow up with more frequent visits.
- 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 food control authority should then conduct a comprehensive audit visit and submit immediately, clearly stated corrective actions specifying a time frame.

During the next visit, they should assess implementation of corrective actions. The follow up visit, which may take place ahead of schedule if the identified limitations are considered serious.

- If the factory is found to have not taken any action to solve the problem or if there is proof that the noncompliance is intentional, action should be taken against the factory and this could vary from a written warning to legal action such as a fine.
- 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.

## ***III. Records and Reporting***

The person in charge of the inspection visits should keep records of the plan, schedule and estimated budget. This information has to be reported to the *Head of the Food Control Authority*.

## **B. TECHNICAL AUDITING AND INSPECTION VISITS**

### **I. Objectives and Accountability**

The purpose of the technical auditing and inspections visits is to verify that the maize mill has implemented and continues to apply a program for:

- Quality assurance of premix receipt, storage and distribution
- Quality assurance of the maize flour fortification process
- Quality control of the fortified maize flour

The Inspector should visit the premises and plan to spend an hour or two 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.

The people directly responsible for achieving these objectives are the *Food Control Authority* inspectors, who should pass on the results of the visits to their *Supervisor*. The *Supervisor* is responsible of preparing the reports to the maize mills and reporting every three months to the *Head of the Food Control Authority* and any other government body involved in the enforcement of fortified foods.

### **II. Procedure (Food Inspectors)**

#### **a. Opening session**

1. Start the visit with an opening session where the General Manager, Factory or Production Manager, Quality Assurance and Control

Department Manager and Laboratory Manager are present. Explain briefly the purpose and approximate duration of the visit 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 names of attendants during the session in **Table B-1**.

**b. Technical audit**

2. Begin the technical audit with the aid of the checklist presented in **Table B-2, section A**. As the audit takes place, record any non-compliance found in **Table B-2, section C**.
3. 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**.

**c. Inspection**

4. At the end of the audit, take five samples for inspection by corroborating trials (refer to Section C –Inspection by Corroborating Trials).
5. Take a sample of the undiluted premix (50 g) currently used for fortification, from the original container of the supplier. Write down the type of iron used in the premix as labeled on the box or the Fact Sheet, as well as information of other nutrients. Use **Table B-2, cell D**.

**d. Preliminary report**

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

**e. Closing session**

7. Finish the visit with a closing session to be attended by those present during the opening session. 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 general management about the necessary actions to be taken.
8. Leave a copy of the report with the Quality Assurance Manager.

**f. Samples transport**

9. Pack the samples in suitable tight containers, and transport the samples appropriately, protecting from exposure to heat, humidity and direct sun light.
10. 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.

**III. Records and reporting** (Supervisor of Food Inspectors)

1. Once results from the laboratory are received and analyzed by the Head of Inspectors, send a final report to the General Manager of the maize flour mill with some interpretation of results and suggestions for corrective action where necessary.
2. If non-compliance is found, enclose a warning letter stating the points that shall be corrected before the next visit.

## C. INSPECTION BY CORROBORATING TRIALS

### I. Objectives and Accountability

The purpose of the corroborating trials is to ensure that:

- All flour samples (including single samples) contain added iron and vitamin A, which are used as the micronutrient “indicators”:

	<u>Iron Spots (qualitative test)</u>	<u>Vitamin A (retinol)</u>
• Whole maize flour	Present	Present
• Refined flour	Present	Present

- 80% of them (composite samples) satisfy regulatory requirements with an average close to the specified factory addition level, for example:

	<u>Only added iron</u>	<u>Total Iron</u>	<u>Vitamin A (retinol)</u>
• Whole maize meal	5 – 15 mg/kg	30 - 50 mg/kg	0.2-1.0 mg/kg
• Refined maize flour	5 – 15 mg/kg	15 - 30 mg/kg	0.2-1.0 mg/kg
• Factory Addition Level	10 mg/kg	10 mg/kg	0.5 mg/kg

- All premix samples comply with the specifications established in the standard for the premix. *Inspectors* are directly responsible of taking the samples at the maize mills whereas the *National Food Control Laboratory* is responsible for analyzing them. The *Supervisor* of the food inspectors coordinates the activities, from checking the records of the auditing visits, receiving and analyzing the laboratory results as well as preparing and sending the reports. The same officer should prepare a consolidated report every three months about the activities accomplished and actions taken, and send it to the *Head of the Food Control Authority*.

### II. Procedure for Sampling (by Food Control Inspectors)

#### a. Fortification Premix

- Take a 50-g sample of the premix that is being used for fortification at the factory during the time of inspection. Label it with the name of the mill, name of the manufacturer, vitamin A and iron content indicated, and date of sample collection.

#### b. Daily composite samples

- Before the inspection visit ends, go to the laboratory and check that “daily composite samples” for the last 30 working days are appropriately stored.
- 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 identification.

**c. Samples from production or storage warehouse**

4. Take two more samples per type of flour either from the maize flour being **produced that day** or from the **storage** warehouse.  
*Samples from production* i. In the packaging area, the inspector should take 500 g of maize flour from any bag before weighing and sealing.
  - (ii) Repeat step (i) every 10 minutes until 8 samples have been collected. Ask personnel of the mill to help for the verification of the presence of iron in each sample, using the spot-test method.
  - (iii) Mix equal amounts of each of the 8 samples to produce a **composite sample from production**.

**Samples from storage warehouse**

- (iv) Collect 8 samples from stores warehouse by selecting bags at random. Collect 500 g from each bag and mix well the 8 samples to produce a **composite sample from store**. Ask for the support of the warehouse operators to move the flour bags around to get the samples.
- (v) Ask personnel of the mill to help for the verification of the presence of iron in each sample.
- (vi) Combine and mix well the 8 samples to produce a **composite sample from store**.

**d. Homogenization and labeling Samples**

4. Homogenize all the five samples taken and divide each one of them into three portions of 500 g.
5. Pack the samples in dark containers and close them tightly. The configuration of samples collected during the inspection is as follows
  - (i) 3 samples, in duplicates, from daily samples kept for the month
  - (ii) 1 sample, in duplicate, collected from production of the day
  - (iii) 1 sample, in duplicate, collected from stored maize flour in warehouse store
  - (iv) 1 sample of the fortificant/premix used on the day of the visit
6. Label each sample with the following information:
  - name of the factory
  - date of inspection
  - lot number
  - sample ID or sample number
7. The three 500-g portions prepared in (5) above are divided as follows:
  1. One sample kept for reference by the maize mill laboratory

2. One sample sent to the Food Control Authority to be kept for reference
  3. One sample sent to the National Food Control Laboratory for quantitative testing.
8. The inspector shall hand in the auditing/inspection forms and the samples collected to the Supervisor of Food Inspectors.

### **III. Records and Reporting (Supervisor of Inspectors)**

#### ***The Supervisor of the Inspectors shall***

1. Receive the samples and the report from the auditing/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, the content of vitamin A should also be determined using a quantitative assay, as well as any other micronutrient that is used eventually for confirmation.
2. Record the results from the laboratory in the corresponding section E of **Table B-2**.
3. When results from the National Food Control Laboratory are received, these are compared with the producer's records. Remember that the results from the mill 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 less than the legal minimum and the daily estimated average was greater than 20 mg/kg, the cause of such discrepancy should be investigated.
4. Analyze the results and complete the report. The analytical results for ALL five samples should be randomly distributed within acceptable range as defined above (in Section C.I.) irrespective of whether they are samples from production of the day, from storage warehouse or from composite samples of the month. Any significant discrepancy between samples collected during inspection and those stored as daily composite samples should be a cause for concern and should be investigated during next inspection visit. Prepare letters to advise the visited factories of the problem.
5. 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.

**FORTIFIED MAIZE FLOUR - AUDITS AND INSPECTION-TABLE B-1  
BRIEFING SESSIONS - TECHNICAL AUDIT AND INSPECTION VISITS**

Date: \_\_\_\_\_

Time: \_\_\_\_\_

Maize mill: \_\_\_\_\_

Address: \_\_\_\_\_

Inspector: \_\_\_\_\_

NAME	POSITION	SIGNATURE	Opening	Closing



**FORTIFIED MAIZE FLOUR - AUDITS AND INSPECTION-TABLE B-2  
CHECKLIST OF TECHNICAL AUDIT AND INSPECTION VISIT TO MAIZE MILLS**

Inspection registry #:		Date:			Inspector Name:			
Maize Mill name:								
Address:								
Telephone:			Fax:			e-mail:		
<b>A. ASPECTS</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>A. ASPECTS</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	
<b>1. Cleaning and sanitation:</b>				<b>3. Maize flour fortification</b>				
1.1.1 Production area				3.1 Premix dilution (if applicable)				
1.1.2 Packaging area				3.1.1 Homogeneity assessed				
1.1.3 Warehouse				3.1.2 Adequate storage and handling				
1.1.4 Staff facilities and toilettes				3.2 Records of feeder performance are available				
1.2 Personnel				3.3 Premix level in feeder adequate during visit				
1.2.1 Hygiene as required in regulations				3.4 Records of flour produced/premix used up to date				
1.2.2 Wearing protective clothing				3.5 Flour samples taken for analysis during every shift				
1.2.3 Trained in the tasks they perform				3.6 Corrective actions taken when				
1.3 Written procedures or instructions for:				3.6.1 Ratio maize produced/premix is not right				
1.3.1 Receipt and storage of premix				3.6.2 Iron content above factory minimum				
1.3.2 Premix dilution (if applicable)				<b>4. Fortified maize flour</b>				
1.3.3 Feeder verification				4.1 Records of flour samples analyzed using				
1.3.4 Sampling of maize flour for QC				4.1.1 Spot test for iron				
1.3.5 Iron spot test for maize flour				4.1.2 Quantitative method Iron (external lab.)				
<b>2. Micronutrient premix</b>				4.1.3 Quantitative method Vit. A (external lab.)				
2.1 Premix 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 is stored under adequate conditions				4.4 Labeling meets specifications				
2.4 "First-in, first-out" system used				4.5 Fortified maize flour is stored appropriately				
2.5 Premix is handled well in fortification site				4.6 "First-in, first-out" system applied to dispatch				

B. ACTIONS TAKEN FOLLOWING RECOMMENDATIONS OF LAST TECHNICAL AUDITING AND INSPECTION VISIT						
Recommendations	Corrective actions taken			Assessment of corrective action <sup>1</sup>		
				(√)	(x)	Comments
C. NEW RECOMMENDATIONS						
Non-compliances:				Suggestions for Improvement:		
				D. TYPE OF IRON IN PREMIX:		
E. LIST OF SAMPLES TAKEN FOR CORROBORATING TESTS						
Composite samples ID	Factory estimation [Iron] (mg/kg)	Lab. Results from inspection <sup>2</sup>		ID Other samples	Lab. Results from inspection <sup>2</sup>	
		[Iron] (mg/kg)	[Vit.A](mg/kg)		[Iron] (mg/kg)	[Vit.A](mg/kg)
Inspector (Name)				Signature		Date
Supervisor (Name)				Signature		Date

Out \_\_\_\_\_

<sup>1</sup> (√) = Adequate; (x) = Not adequate

<sup>2</sup> Results from Food Control National Laboratory or a reliable one

**FORTIFIED MAIZE FLOUR - AUDITS AND INSPECTION-TABLE B-3**  
**PRELIMINARY REPORT - TECHNICAL AUDIT AND INSPECTION VISITS**

Inspection Registry #:	Date of Inspection:
Mill name:	Mill representative:
Address:	Telephone:
<b>PRELIMINARY REPORT</b>	
<b>1. Areas visited</b>	
<input type="checkbox"/> Production	<input type="checkbox"/> Packaging
<input type="checkbox"/> Maize warehouse	<input type="checkbox"/> Raw material warehouse
<input type="checkbox"/> Fortification site	<input type="checkbox"/> Laboratory
<input type="checkbox"/> Other:	
<b>2. Non-compliances. List the non-compliances found</b>	<b>3. Suggestions for improvement</b>
Inspector:	Received by (Mill representative):
Signature:	Signature:
Date:	Date:
Supervisor of Inspectors (Name and Signature)	Date



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FROM THE AMERICAN PEOPLE

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