



East, Central and Southern African
Health Community

MANUAL FOR EXTERNAL MONITORING OF FORTIFIED WHEAT FLOUR

(Technical Auditing and Inspection)

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**EAST, CENTRAL AND SOUTHERN HEALTH
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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 strategy 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
ECSA Health Community

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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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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 WHEAT FLOUR

(Technical Auditing and Inspection)

Technical auditing and inspection activities carried out at wheat mills are part of the enforcement activities performed by the government to ensure that wheat flour meets the nutrient quality as well as the safety specifications established in standards and regulations. During the technical audits, the performance of quality assurance and control activities done by the producer is verified. Then, the conformity of the fortified flour with the technical specifications is corroborated through sampling and chemical analysis of samples taken at the factory. Samples of the micronutrient premix are also taken to confirm certainty of the Certificate of Analysis (COA) provided by the supplier.

This manual presents the steps to carry out the technical auditing and inspection in wheat mills. The Food Control Authority in the country is responsible to carry out the auditing and inspection activities of fortified foods, in coordination with other governmental bodies involved in the enforcement of food fortification regulations.

Since the technical audits are based on checking the producer's records, the listed objectives measured by indicators and criteria of success are based on the ones used for the QA/QC system. The manual also includes the persons mainly responsible for each stage. As any enforcement procedure carried out by a governmental body, warning and legal actions to be taken when non-compliances are found should be defined and applied when necessary.

Results of auditing and inspection activities should be consolidated twice a year and determine the degree of fulfillment of the fortification goals, obstacles to overcome and actions to be taken. It is recommended to prepare and publish an annual report where data from external monitoring are presented graphically to divulge the situation of the fortification program in the country, along with information from other food control or surveillance activities such as commercial monitoring or household surveillance.

The sections included in this manual are:

- Planning inspection visits
- Technical auditing 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 wheat mills at least two times a year are allocated.
- Inspectors receive appropriate training on the fortification process and sampling to perform the auditing and inspection activities.

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

II. Procedure

a. Plan, budget and schedule

1. Based on the total number of wheat mills that should be visited plan at least two yearly visits to each mill, plus a few additional visits to those factories that require it.
2. Estimate the financial resources that will be needed considering:
 - Personnel
 - Transportation and fuel
 - Approximate number of samples to be analyzed and cost
 - Other such as approximate number of extra-visits and additional samples to be analyzed
3. Report to the Head of Food Control Authority the plan, schedule and estimated budget to carry out the plan.
4. Plan a training workshop for the inspectors about the fortification process in the wheat mills, the Quality Assurance and Control (QA/QC) performed by the mill, and auditing and sampling activities during the visit to the factory.

b. Defining actions to be taken

5. 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 the non-compliance is minor, technical advice should be provided on areas that need improvement and follow up with more frequent visit.
- When 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 conduct a comprehensive audit visit and submit clearly stated corrective actions with a time frame. Assess implementation of corrective actions during the following 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 incompliance is intentional, action should be taken against the factory and could vary from warning to legal action such as a fine.
- If corrective measures are in process of being implemented, or new unrelated findings to be improved 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 wheat mill has implemented and continuously apply a program for the:

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

The achievement of these objectives is the responsibility of the *Food Control Authority Inspectors*, who should inform the results of the visits to their *supervisor*. The *supervisor* is responsible of preparing the reports to the wheat mills and reporting every six months to the *Head of the Food Control Authority* and any other governmental body involved in the enforcement of fortified foods regulations.

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 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 in 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 the inspection by corroborating trials (refer to **section C**).
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 in the box or the Fact Sheet, as well as information of the other nutrients. Use **Table B-2, cell E**.

d. Preliminary report

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

e. Closing session

7. Finish the visit with a closing session with the same attendants to the opening session. Check in **Table B-1** the attendants. Explain the major findings presented in the report previously prepared. If non-compliances were found inform the general management about the actions to be taken.
8. Leave a copy of the report to the Quality Assurance Manager.

f. Samples transport

9. Pack the samples in suitable and tight containers, and transport them protected against 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 send them to the Food Control National Laboratory.

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

1. Once results from the laboratory are received and analyzed, send a final report to the Quality Assurance Manager of the wheat flour mill. Interpretation of results and suggestions should be included.
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 wheat flour	Present	Present
• Refined wheat 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 wheat flour	5 – 45 mg/kg	40 - 100 mg/kg	1.0 - 3.0 mg/kg
• Refined wheat flour	30 – 50 mg/kg	40 - 60 mg/kg	1.0 - 3.0 mg/kg
• Factory Addition Level	25 mg/kg	40 mg/kg	2.0 mg/kg

- All premix samples comply with the specifications established for premix in the specific standard.

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

II. Procedure (Food Control Inspectors)

a. Fortification Premix

1. 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, micronutrient content, especially vitamin A and iron that are used and micronutrient “indicators”, and dates of expiration and sample collection.

b. Daily composite samples

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

c. Samples from production or storage warehouse (Inspector)

4. Take two more samples per type of flour either from the wheat 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 wheat flour from any bag before weighing and sealing or any appropriate retail size package.
- (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 well all the 8 samples to produce a **composite sample from production**.

Samples from storage warehouse

- (iv) Collect 8 samples from stored flour in the warehouses by selecting bags at random. Ask the support of the warehouse operators to move the flour sacks to get the samples. Collect 500 g from each bag.
- (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

5. Homogenize all the five samples taken and divide each one of them into three portions of 500 g.
6. Pack the samples in dark containers and close them tightly. The sample configuration 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 wheat flour in the warehouses
 - (iv) 1 sample of the fortified premix used on the day of the visit
7. Label each sample with the following information:
 - name of the factory
 - date of inspection
 - lot number
 - sample ID or sample number
8. The three 500-g portions are divided as follows:
 1. One sample kept for reference by the wheat mill laboratory
 2. One sample Food Control Authority to be kept for reference
 3. One sample sent to the National Food Control Laboratory for quantitative testing.
9. The inspector shall hand in the auditing/inspection forms and the samples collected to the Supervisor of Food Inspectors.

III. Records and Reporting

1. The supervisor of the food inspectors shall receive the samples and the report from the auditing/inspection visit. Supervisor shall send the undiluted premix samples to the National Food Control Laboratory, or any reliable laboratory to determine the type and amount of iron that was used. Sample of fortified wheat flour will be sent to determine the content of iron and vitamin A using quantitative assays, as well as any other micronutrient that is used eventually for confirmation.

2. 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 60 mg/kg, the cause of such discrepancy should be investigated.
3. Record the results from the laboratory in Section D of **Table B-2**.
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 may also be forwarded to the National Coordinating Committee of the Fortification Programs.

FORTIFIED WHEAT FLOUR - AUDITS AND INSPECTION-TABLE B-1
TECHNICAL AUDIT AND INSPECTION VISIT SESSIONS

Date: _____

Time: _____

Wheat mill: _____

Address: _____

Inspector: _____

NAME	POSITION	SIGNATURE	Opening	Closing

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

Inspection registry:		Date:		Inspector			
Wheat Mill name:							
Address:							
Telephone:	Fax:		e-mail:				
A. ASPECTS	YES	NO	N/A	A. ASPECTS	YES	NO	N/A
1.1. Cleaning and sanitation:				3. Wheat flour fortification			
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 in 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 wheat 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)				4. Fortified wheat flour			
1.3.3 Feeder verification				4.1 Records of flour samples analyzed using			
1.3.4 Sampling of wheat flour for QC				4.1.1 Spot test for iron			
1.3.5 Iron spot test for wheat flour				4.1.2 Quantitative method Iron (external lab.)			
2. Micronutrient premix				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				4.5 Fortified wheat flour is stored adequately			
2.5 Premix is handled well in fortification site				4.6 "First-in, first-out" system applied to dispatch			

B. Actions taken from recommendations of last technical auditing and inspection visit						
Recommendations		Corrective actions taken			Assessment of corrective action ¹	
				(√)	(x)	Comments
C. New Recommendations						
Non-compliances:				Suggestions for Improvement:		
				E. Type of Iron in Premix:		
D. List of samples taken for corroborating tests						
ID Composite samples	Factory estimation [Iron] (mg/kg)	Results from inspection ² (mg/kg)		ID Other samples	Results from inspection ² (mg/kg)	
		[Iron]	[Vit.A]		[Iron]	[Vit.A]
Inspector (Name)		Signature			Date	
Supervisor (Name)		Signature			Date	

¹ (√) = Adequate; (x) = Not adequate

² Results from Food Control National Laboratory or a reliable one



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