



East, Central and Southern African
Health Community

MANUAL FOR INTERNAL MONITORING OF FORTIFIED MAIZE FLOUR

FIRST EDITION – 2007



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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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Acknowledgement

This Manual has been developed by the ECSA Health Community Secretariat with technical and financial assistance from the Academy for Educational Development through A2Z: The USAID Micronutrient and Child Blindness Project (GHS-A- 00-05-00012).

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 INTERNAL MONITORING OF MAIZE FLOUR (Quality Assurance and Quality Control, QA/QC)

Maize flour producers and importers are responsible of complying with the regulations regarding maize flour fortification in the country. Fortification of maize flour with vitamins and minerals requires the implementation of quality control and assurance activities to ensure that the fortified flour meets the requirements established in standards and regulations.

Quality assurance and quality control program (QA/QC) for maize flour fortification does not require the establishment of a new process in the maize mills, but only to incorporate those aspects that are specific to flour fortification into the ongoing QA/QC procedures. In any case, it requires the support and commitment of management to provide the human and financial resources to implement the new procedures, and sustain them at an acceptable level.

This manual describes the steps to be carried out to ensure quality of maize flour fortified with vitamins and minerals. In general, this manual covers the receipt and inspection of the premix, the maize flour fortification process and quality control of the fortified maize flour. The manual also includes an iron spot test for confirming that the flour is being fortified with a premix containing that nutrient. Analysis of iron is relatively easy and less costly than the methods for determining vitamins in flour. Analytical methods for determining quantitatively vitamins and minerals can be found in the literature and the mill should seek a reliable external laboratory to analyze the samples. The fulfillment of these activities needs the participation of personnel from the Warehouse, Production, and Quality Control and Quality Assurance departments.

The different sections on the process and quality control of the product describe the objectives measured by indicators and criteria of success as well as responsible people. As in any QA/QC system, identifying the causes of noncompliance, implementing corrective and preventive actions is indispensable and so is the keeping of updated records of the activities performed. National Health inspectors shall visit the maize mills at different times throughout the year to carry out technical audits and inspection of the fortification process and product. This work by government personnel is mainly based on the review of records kept by the producer and so it is important to keep in mind that “what has not been recorded has not been done”.

The following sections are included in this manual:

- Quality assurance of premix and flour bags - receipt, storage and delivery
- Quality assurance of the maize flour fortification process
- Quality control of the fortified maize flour
- Spot-test for determining added iron in fortified maize flour

A. QUALITY ASSURANCE OF PREMIX AND FLOUR BAGS - RECEIPT, STORAGE AND DELIVERY

I. Objectives and Accountability

The objectives of the quality assurance of premix receipt, storage and delivery are to ensure that:

- The factory always has enough supply of premix in properly labeled bags for at least two months of production.
- Vitamins and mineral premix meets the specifications established for flour fortification in the country such as lot number, expiry date and it contains the micronutrient levels declared on the label and as presented in the Certificate of Analysis for lot.
- The premix is stored under suitable conditions and it is used on the “first-in, first-out” (FIFO) basis.

Personnel directly responsible for this activity are the *Warehouse manager* and the *Head of the Quality Control Department*, who should inform the *Production Manager* periodically, upon receipt of premix or whenever internal checks are done.

II. Procedure

a. Receipt and Storage (Warehouse)

1. Every time a new shipment of vitamins and mineral premix is received, check that it is in accordance with the quantity and type indicated in the purchase order. Use **Table A1** to record information. Check that the boxes are not damaged and they are properly labeled. The following information should be included: name of manufacturer and address, lot number, production and expiry dates, list of ingredients using the chemical names, micronutrient content and net weight.
2. Check that the results of analysis in the Certificate of Analysis correspond to the lot number of the premix delivered to the factory. The certificate should report results for every micronutrient in the premix. Results for moisture, granulometry and other parameters may also be included in the certificate by the manufacturer in describing the quality of the premix to the client.
3. In addition to the Certificate of Analysis, a Specifications or Fact Sheet should be included with each shipment. This sheet should contain the following information: Name and address of manufacturer, contact information, lot number, recommended addition rate of the premix to flour, levels of micronutrients added at the recommended addition rate, handling instructions and safety precautions.
4. If the lot meets the specifications accept it, record the quantity of premix received in **Table A-1**. When a box is damaged to harm the integrity of the premix, contact the supplier to return it and have it replaced.

5. Store the premix on top of palletes, made of a suitable material¹, in a cool dry place, separated from potential contaminants. Arrange the stacks to deliver premix on a “first-in, first-out” basis.

b. Delivery (To the Fortification Section)

6. When premix is dispatched to the fortification section in the plant, record the date of dispatch and name of the person who is receiving the order, as shown in **Table A-2**. Keep the inventory records up to date and record in separate rows when quantities are “received” or “dispatched”.
7. Send a copy of the control form to the Quality Control Department and the Factory Manager every week.

c. Bag Receipt (warehouse)

8. When the orders of new bags are received from the suppliers, check that the label is appropriate and complies with the specification. Record the amount received, and keep daily track of the balance.

III. Records and Reporting

The responsible warehouse should:

- Send the Certificates of Analysis and the Specifications/Fact sheet to the Quality Control Department
- Keep a copy of the Specifications/Fact sheet for the handling and storage instructions
- Keep all records up to date

The records should be periodically reviewed by personnel of the Quality Control Department. Weekly reports should be sent to the Production Manager and the Quality Control department.

¹ If wooden palletes are used, handling and proper storage of them must be assured in order to prevent pest infestation and contamination of the food.

B. QUALITY ASSURANCE OF THE MAIZE FLOUR FORTIFICATION PROCESS

I. Objectives and Accountability

The purpose of the Quality Assurance of the maize flour fortification process is to ensure that:

- The premix is always available and properly added to the unfortified maize flour.
- Feeder is working properly and the amount of premix discharged is in accordance with the flow of maize flour.
- The ratio of maize flour produced to premix used is close to the theoretical ratio calculated.

Personnel directly responsible for this component are the *production personnel* assigned to the area where fortification is taking place, with supervision by the *Quality Assurance Department*, and daily or weekly reporting to the *Production Manager*.

II. Procedures

a. Premix dilution (if applicable)

1. Depending on the type of feeder installed in the wheat mill, it may be necessary to dilute the premix prior to its use. If this is the case, validate the mixing procedure² to verify the homogeneity of the final premix. For this, take ten independent samples at random from a batch of diluted premix.
2. Send the samples to an external laboratory to determine their iron content quantitatively.
3. Calculate the coefficient of variation³ and this **should be less than 10%**.
4. The amount of premix to add to maize flour in g/M.T. will be calculated multiplying the amount expressed in the Fact Sheet from the premix manufacturer by the dilution factor used for preparing the diluted premix in the mill.

² Validation of the mixing procedure should be done before the diluted premix is used in the mill, and any time the mixing conditions are changed.

³ $CV (\%) = (Average/Standard\ Deviation) \times 100$

b. Steps to follow at the beginning of the shift

5. Check that there is enough premix in the fortification plant to use during the shift and that the premix container is properly closed.
6. When a new box is opened check that the premix is free of lumps, there is no physical contamination, and that the color is not different from previous batches. If a problem is found, contact the Production Manager.
7. If the feeder does not automatically adjust itself when flour flow changes, prepare a reference table with the amount of premix the feeder has to discharge at different flow rates of the flour. This table should be available for the operators in charge of checking the feeder flow and preferably be displayed in the fortification section.
8. **Feeder verification**⁴: To verify the performance of the feeder, collect the amount of premix the feeder discharges in one minute. Repeat this step three times.
9. Weigh the three portions collected and calculate the average, standard deviation and coefficient of variation (CV)⁵ of the collected masses. If the **CV is higher than 5%**, take another portion for one minute and calculate the average again.
10. Compare the amount of premix discharged by the feeder expressed in (g/min) to the theoretical amount that should be added according to the current flow of flour in the mill.
11. If the amount discharged does not coincide with the theoretical one, adjust the feeder and repeat steps 8 to 10 again to verify the adjustment. Record results in **Table B-1**. Keep the records up to date and ready to show them to the Quality Control Department when required.

⁴ Check the feeder at least once every shift or as needed during the day.

⁵ CV (%) = Average/Standard Deviation x 100

c. Steps to follow during the shift

12. Check that the feeder is loaded with enough premix and that it is working properly⁶.
13. Take 500 g samples of flour every hour, and check using the iron-spot test (see **Section D**) that the micronutrient premix is being delivered.
14. Report any abnormality to the Production Manager.

d. End of the shift

15. Record in **Table B-2** the amount of flour produced and the quantity of premix used during the shift.
16. Calculate the ratio flour produced to premix used and record the ratio in **Table B-2**.
17. Report this information to the Production Manager and the data should always be available to show to the Quality Assurance Department when requested.
18. Prepare a composite flour sample, mixing all the hourly samples of the shift. Label it with the date, hours of shift, and batch numbers if applicable. Send the shift composite sample to the laboratory.

III. Records and Reporting

The *Production Manager* should keep updated information and file records of the premix dilution done, feeder verification conducted, amounts of flour produced and amounts of premix used, as well as description of actions taken during production to keep the fortification process performing as expected. *Quality Assurance Department* verifies them amount of flour produced and amount of premix used from the production records and a copy of these should be kept along with the quality control records.

⁶ It is recommended to install electrical interlocking systems to stop the feeder automatically when the flour flow stops, in order to avoid premix waste and over fortification.

C. QUALITY CONTROL OF FORTIFIED MAIZE FLOUR

I. Objectives and Accountability

The purpose of the Quality Control of the fortified maize flour is to ensure that:

- Content and spot density for iron in the maize flour samples are comparable to those of standard maize flour samples containing the average level of added iron expected at the factory⁷ (e.g. 10 mg/kg iron from added NaFeEDTA to unfortified flour).
- 80% of all samples fortified with iron and vitamin A comply with regulatory levels and the average is close to the addition level at the factory based on quantitative methods. For example for maize flour in the ECSA countries:

	<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

- Fortified maize flour is packaged in new and properly labeled packaging materials as required by relevant national or international regulations for General Labeling of Prepackaged Foods and maize flour fortification.

Quality Control Department has direct responsibility of this component, and should send daily reports to the *Production*

Manager.

⁷Based on ECSA 2007 guidelines for wheat flour fortification.

II. Procedures

A. Supervision and sampling (by personnel from Quality Control Department)

1. Personnel from this section should make unannounced visits to the fortification place to check that the feeder has been calibrated; it contains the adequate premix and is working properly. Sign in **Table B-1** and **B-2** to record the completion of the supervision exercise.
2. Ensure that personnel in the packaging site are taking 500 g samples of the fortified flour every hour to be used for preparing shift composite samples, and that the spot-test for iron is being used for confirming that the premix is being delivered. The composite samples must be labeled with the day and shift of the sample.

B. Using the Iron spot test

3. In the laboratory, mix well the shift composite sample and take about 250g to carry out the “*Iron Spot Test*” with semi-quantitative purposes, which are based on the density of spots in comparison with controls with known amounts of added iron (See **section D** for the method).
4. Record results from the spot tests in **Table C-1** by marking an “x” in the appropriate box to express the concentration ranges: 0-10 mg/kg, 10-15 mg/kg, 15-20 mg/kg, 20-25 mg/kg and >25 mg/kg.
5. Prepare a daily composite sample by mixing 500 grams of each of the shift samples. Mix well. Determine the content of iron in the composite of the day using the method in Section D and record results in **Table C-1** under *Daily Comp*. Store the remnant of the daily composite sample in an air-tight and opaque container, and identify it with the brand name and date. Keep this sample in the sample-store room for up to a month.

C. Corrective actions

6. If abnormalities are found, discuss immediately with the Production Supervisor and determine measures to correct them.

III. Records and Reporting

The Quality Control Manager shall:

1. Complete **Table C-1** with the data provided by the production supervisor as recorded in **Table B-2**.
2. Calculate the ratio of maize flour produced/premix used.
3. Record all the required information in **Table C-1**, and send a copy to the Production Manager on a daily basis. 4. Select randomly two daily-composite samples and send to an external reference laboratory for the quantitative determination of iron and vitamin A. The frequency of this analysis will depend on factory tonnage as follows:
 - (i) if production is less than 20 MT per day, take 2 samples every 6 months.
 - (ii) for production 20-50 MT, test 2 samples every 3 months and
 - (iii) for production above 50 MT, test 2 composite samples every month.
5. Once the report from the external laboratory is received, record the results in the corresponding sectors in **Table C-1**. Compare the results recorded on that day with the laboratory data, and if discrepancies exist identify the reason, and apply corrective measures that are necessary.
6. Send reports to the *General Manager* that include the overall performance of the fortification process, results from the external laboratory, problems found and corrective or preventive actions taken.

D. SPOT TEST FOR DETERMINING ADDED IRON (NaFeEDTA) IN FORTIFIED MAIZE FLOUR

I. References

AOAC Methods. 12 ed. Ferrous salts. Official Final Action (7.74).

AACC Method 40-40. Iron –Qualitative Method. First approval 5-5-60; reviewed 10-27-82.

II. Principle

Ferric iron, in an acidic medium, reacts with a solution of potassium thiocyanate (KSCN) to form an insoluble red pigment. Other types of iron, such as ferrous iron and elemental iron can also produce this reaction, once they are oxidized to the ferric form using hydrogen peroxide.

III. Materials

A. Filter paper Whatman # 1

B. Manual sieve.

C. Watch glass.

IV. Reagents

A. HCl–2 N. 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.

B. Potassium Thiocyanate-10%. Dissolve 10 g of KSCN in 100 ml water. Previous to use, mix 10 mL of this solution with 10 mL of HCl-2 N.

V. Procedure

1. Place the filter paper over the watch glass.

2. Wet the surface of the filter paper with the solution of potassium thiocyanate. Let the liquid penetrate the paper fibers.

3. Using a hand sieve, sift portion of the flour sample in order to load a thin layer over the entire wet area. Take out any excess.

4. 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.

5. Red color spots indicate the presence of a ferric salt, such as NaFeEDTA.

VI. Interpretation

E. Number and density of spots are indicative of the iron level in the sample. Use flour controls with known amounts of the same type of iron that is added to the flour to make a comparative coarse assessment of the range of the iron content in the samples.

FORTIFIED MAIZE FLOUR-TABLE A-1

INSPECTION FORM FOR INCOMING

VITAMINS AND MINERAL PREMIX

Product: Vitamins and mineral premix	Purchase order #:
Manufacturer:	
Inspected by:	Date:
SPECIFICATIONS	OBSERVATIONS
Quantity:	
Integrity of boxes <input type="checkbox"/>	
Lot number <input type="checkbox"/>	
Production date <input type="checkbox"/>	
Expiry date <input type="checkbox"/>	
Micronutrient levels in label <input type="checkbox"/>	
Certificate of Analysis (results for every micronutrient) <input type="checkbox"/>	
Other	
Accepted <input type="checkbox"/>	Rejected <input type="checkbox"/>
REASONS FOR REJECTION/ACTION TAKEN	
Reviewed by:	Date:

FORTIFIED MAIZE FLOUR-TABLE A-2
VITAMINS AND IRON PREMIX INVENTORY CONTROL LOG

Page No. _____

DATE	TIME	RECEIVED			DISPATCHED		BALANCE (C) ¹ (C) = (A) – (B)	OBSERVATIONS/ QA-Review (Name and Signature)
		QUANTITY (kg) (A)	LOT ID	EXP. ² DATE	QUANTITY (kg) (B)	LOT ID		

Date of reporting: _____

Signature: _____

¹ When premix is received, C= previous C + Received A but when premix is dispatched C= previous C – dispatched B.

² Expiry date

MAIZE FLOUR FORTIFICATION-TABLE B-1

FEEDER FLOW CONTROL FOR FORTIFIED MAIZE FLOUR³

Feeder location:		Page No.	
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DATE	SHIFT (TIME)	PRODN RATE (MT/Hour)	THEORETIC FEEDER FLOW (g/min) ⁴	FEEDER FLOW (g/min)					ADJUSTED (YES/NO)	RESPONSIBLE	OBSERVATIONS/ QA- Review (Name and Signature)
				1	2	3	Avg.	CV			

³ This table should be kept near to the feeder site. Once a sheet is full, it should be sent to the Quality Assurance Department.

⁴ Feeder flow (g/min) = MT/hour x 100/6

MAIZE FLOUR FORTIFICATION-TABLE B-2
PRODUCTION LOG OF FORTIFIED MAIZE FLOUR

Production line:				Page No.	
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SHIFT (TIME) & DATE	FLOUR PRODUCED		PREMIX USED (kg) (B)	FLOUR/ PREMIX RATIO (A/B)	RESPONSIBLE	OBSERVATIONS/ QC-Review (Name and signature)
	(MT) (A)	LOT ID				

FORTIFIED MAIZE FLOUR- TABLE C-1

PRODUCTION AND QUALITY CONTROL

LOG FOR FORTIFIED MAIZE FLOUR

5

SHIFT (Hour)	MAIZE FLOUR PRODUCED (M.T.)	PREMIX USED (kg)	RATIO MAIZE FLOUR/ PREMIX	NOTES
DAILY TOTAL				
TOTAL TO DATE				

COMPOSITE SAMPLE IDENTIFICATION:	DATE:
	Results from External Laboratory ⁶ :
	[Vitamin A] (mg/kg) =
	[Total Iron] (mg/kg) =
Responsible:	Signature:

[Iron] from NaFeEDTA

GRAPHIC REPRESENTATION

		6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	Daily Comp.	
More than 25 mg/kg	> 25																						
Between 20 to 25 mg/kg	20-25																						
Between 15 to 20 mg/kg	15-20																						
Between 10 to 15 mg/kg	10-15																						
Less than 10 mg/kg	< 10																						
Not detected	ND																						
		6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25		
						0	1	2	3	4	5	6	7	8	9	0	1	2	3	4			
		Time of day (hour)																					

⁵ Table is based on Log-form from Los Tarros Sugar Refinery, S.A. in Guatemala.

⁶ Results from external laboratory will be available once a month, not on a daily basis.



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The publication of this manual is made possible by the generous support of the American people through the US Agency for International Development (USAID), through the Academy for Educational Development, A2Z: The USAID Micronutrient and Child Blindness Project (GHS-A-00-05-00012) and the East, Central and Southern African Health Community (ECSA). The content of this document is the responsibility of the authors and does not necessarily reflect the opinion of USAID or the government of the United States