



East, Central and Southern African
Health Community

MANUAL FOR INTERNAL MONITORING OF FORTIFIED WHEAT FLOUR

(Quality Assurance and Quality Control, QA/QC)

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

Wheat flour producers and importers are responsible of complying with the standards and regulations regarding wheat flour fortification in the country. Fortification of wheat 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 regulations and standards. Quality assurance and quality control program (QA/QC) for wheat flour fortification does not require the implementation of a new program in wheat mills, but only to incorporate into the ongoing QA/QC procedures those aspects that are specific to flour fortification. In any case, it requires the support and commitment of the general management to provide the human and financial resources to implement the new activities, and maintain their acceptable performance.

This manual describes the steps to be carried out to assure quality of wheat flour fortified with vitamins and minerals. In general, they cover the receipt and inspection of the premix, the wheat flour fortification process, and quality control of the fortified wheat flour. The manual also includes a spot-test method to determine iron in wheat flour, since it has been used as the micronutrient indicator for timely verification that the micronutrient premix is being incorporated to the flour in the mill. Analysis of iron is relatively easy and less costly than the methods to determine vitamins in flour. Analytical methods to determine vitamins can be found in the literature and the mill should seek a reliable external laboratory to analyze the samples. The fulfillment of the activities of internal monitoring needs of the coordinated participation of personnel from the Warehouse, Production, and Quality Control and Quality Assurance departments.

Each stage of the process and quality control of the product includes listing of objectives measured by indicators and criteria of success, and the main responsible persons. As any other QA/QC system, identifying the causes of noncompliance with the purpose of implementing corrective and preventive actions is indispensable. National health authorities visit the wheat mills throughout the year to carry out technical audits and inspection of the fortification process and product. The government activities are mainly based on checking the producer's records. Therefore, 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 receipt, storage and delivery
- Quality assurance of wheat flour fortification process
- Quality control of the fortified wheat flour
- Spot-test for determination of added iron in fortified wheat 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 in the label as verified in the Certificate of Analysis per lot.
- The premix is stored under suitable conditions and it is used on the “first-in, first-out” (FIFO) basis. Persons directly responsible for this activity are the *Warehouse manager* and the *Head of the Quality Control Department*, who should inform the *Plant Manager* periodically, upon reception of premix or whenever internal checks of storage conditions are done.

II. Procedure

a. Reception 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. Check that the boxes are not damaged and they are properly labeled, i.e. the following information is included: name of manufacturer and address, lot number, expiry date, list of ingredients using the chemical names, micronutrient content and net weight.
2. Check that the results of 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 order to ensure 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. **Table A-1** presents a form to record inspection of the incoming premix. If the lot meets the specifications accept it, record the quantity of premix received. When a box is damaged and this might harm the integrity of the premix, contact the supplier to return and replace it.
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 (warehouse)

6. When premix is dispatched for flour fortification, 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.
7. Send a copy of the log form every week to the Quality Control Department and the Production Manager.

c. Bag Receipt (warehouse)

8. When the order of new bags is received check that label is adequate and complies with the specification. Record amount, and keep daily track of the balance.

III. Records and Reporting

Warehouse responsible should:

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

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 WHEAT FLOUR FORTIFICATION PROCESS

I. Objectives and Accountability

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

- ❖ Premix is continuous and properly added to the unfortified wheat flour.
- ❖ Feeder is working properly and the amount of premix discharged is in accordance with the flow of wheat flour.
- ❖ Ratio of wheat flour produced/premix used is close to the theoretical ratio calculated.

Persons directly responsible for this component are the *production personnel* assigned to the area where fortification is taken 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 batch of diluted premix.
2. Send the samples to an external laboratory to determine their iron content quantitatively.
3. Calculate the coefficient of variation³. This should be less than 10%.
4. The amount of premix to add to wheat 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. In order to avoid lumping during premix dilution, it is recommended to prepare only the amount to be used for 12 working hours.

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) x 100

b. Beginning of the shift

5. Check that there is enough amount of premix to use during the shift and that the premix container is properly closed.

When a new box is opened, check that the premix is free of lumps, any physical contamination and that the color is not different from other batches. If a problem is found, contact the production manager.

7. If the feeder does not automatically adjust when flour flow changes, prepare a table with the amount of premix the feeder has to discharge at different flour flows. This table should be available for the operators in charge of checking the feeder.
8. *Feeder verification*⁴: Collect the amount of premix the feeder discharges in one minute. Repeat this step three times.
9. Weigh the three portions and calculate the average, standard deviation and coefficient of variation (CV)⁵. If the coefficient of variation 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 flour flow 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. During the shift

12. Check that the feeder is loaded with enough premix and it is working properly⁶.
13. Take 500 g samples of flour every hour, mix well, 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 (identification of the package material and remove bags).
16. Calculate the ratio flour produced/premix used. Record the ratio in **Table B-2**. Report to the production manager. Data should always be ready to show to the Quality Assurance Department when requested.
17. 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 and file the records of the premix dilution, feeder verification, confirmation that flour is fortified, 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 the 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 ones.

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 WHEAT FLOUR

I. Objectives and Accountability

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

- Content and spot density for iron in the flour samples are comparable to those of standard wheat flour samples containing the average level of added iron expected at the factory⁷ (e.g. 40 mg/kg iron from added iron fumarate to refined flour).
- If quantitative tests are used, 80% of samples should comply with the iron and vitamin A specifications during production, and the average should be nearly to the one expected. For example for refined flour in the ECSA countries:

	Only added Iron	Total Iron	Vitamin A (retinol)
• 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

- Fortified wheat flour is packaged in new and properly labeled packaging materials as required in the relevant national or international regulations for General Labeling of Prepackaged Foods and the Wheat Flour Fortification Regulations. *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. Make unannounced visits to the fortification place for checking that the feeder has been calibrated, it contains a proper level of premix and it is working properly. Sign the **Table B-1** and **B-2** to record completion of this supervision.
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. 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 in **Table C-1** expressed in ranges: 0-30 mg/kg, 30-40 mg/kg, 40-50 mg/kg, 50-60 mg/kg and >60 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 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 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 the measures to be implemented to correct them.

III. Records and Reporting

1. Complete **Table C-1** with the data provided by the production supervisor recorded in **Table B-2**.
2. Calculate the ratio wheat flour produced/premix used.
3. Record all the needed information in **Table C-1**, and send daily a copy to the production manager.
4. At least once a month, select randomly two daily-composite samples and send to an external reference laboratory for the quantitative determination of iron and vitamin A.
5. Once the report from the external laboratory is received, record the results in the corresponding **Table C-1**. Compare the results with your own data, and if incompatibility is found look for the reason, and apply corrective measures as needed.
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 IN FORTIFIED WHEAT 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 daily use, mix 10 mL of this solution with 10 mL of HCl-2 N.

C. H₂O₂-3% (only when iron is as elemental iron or as a ferrous salt). Add 5 ml concentrated H₂O₂ (30%) to 45 ml distilled water. Prepare daily. Discard after finishing the analysis.

V. Procedure for determining iron from NaFeEDTA

1. Place the filter paper over the watch glass. Wet the surface of the filter paper with the solution of potassium thiocyanate. Let the liquid penetrate the paper fibers.

2. Using a hand sieve, sift portion of the flour sample in order to load a think layer over the entire wet area. Take out any excess.
3. 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.
4. Red color spots indicate the presence of a ferric salt, such as NaFeEDTA.

VI. Procedure for determining iron from other sources

1. Place the filter paper over the watch glass. Wet the surface of the filter paper with the solution of potassium thiocyanate. Let the liquid penetrate the paper fibers.
2. Using a hand sieve, sift portion of the flour sample in order to load a think layer over the entire wet area. Take out any excess.
3. Add a little more of the acidic solution of potassium thiocyanate over the flour.
4. Add small amounts of the H₂O₂-solution. Let it stand for a few minutes for the reaction to occur.
5. Red color spots indicate the presence of added iron from any source.

VII. Interpretation

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 WHEAT 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 <input type="checkbox"/> (results for every micronutrient)	
Other	
Accepted <input type="checkbox"/>	Rejected <input type="checkbox"/>
REASONS FOR REJECTION/ACTIONS TAKEN	
Revised by:	Date:

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

Page No. _____

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

Date of reporting: _____

Signature: _____

¹ Expiry date _____

**WHEAT FLOUR FORTIFICATION-TABLE B-1
FEEDER FLOW CONTROL FOR FORTIFIED WHEAT FLOUR¹**

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

¹ This table should be kept near to the feeder site. Once a sheet is full, it should be sent to the Quality Assurance Department.
² Feeder flow (g/min) = MT/hour × 100/6

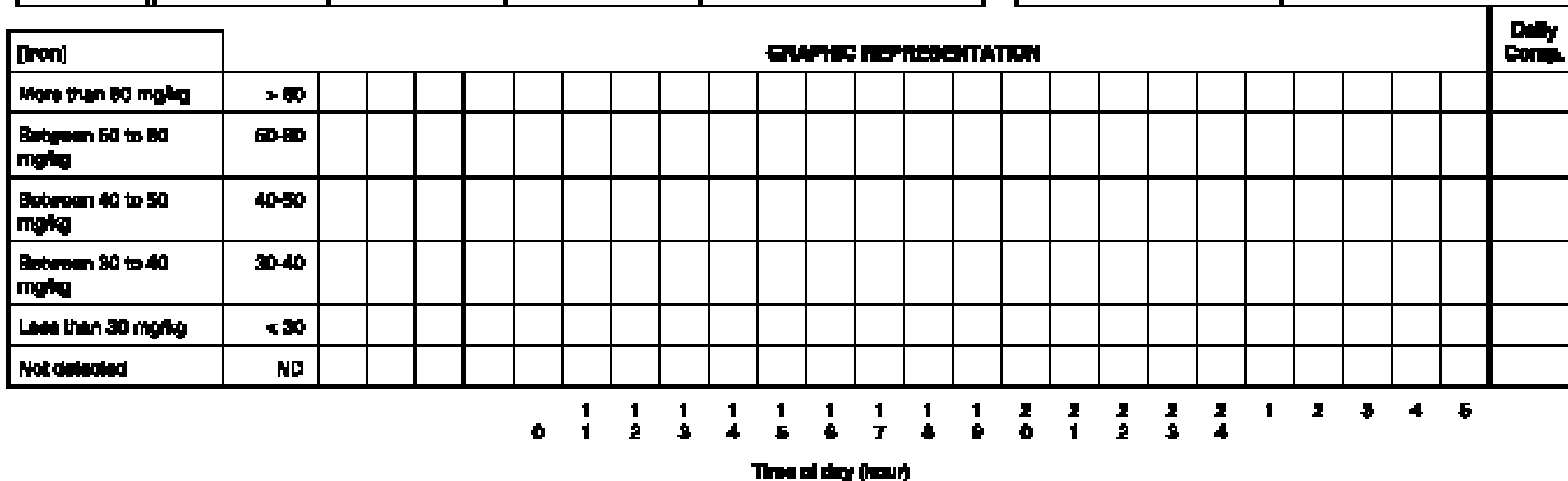
**WHEAT FLOUR FORTIFICATION-TABLE B-2
PRODUCTION LOG OF FORTIFIED WHEAT FLOUR**

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

**FORTIFIED WHEAT FLOUR- TABLE G-1
PRODUCTION AND QUALITY CONTROL LOG FOR FORTIFIED WHEAT FLOUR¹**

SHIFT (Hour)	WHEAT FLOUR PRODUCED (M.T.)	PREMIX USED (kg)	WHEAT FLOUR/ PREMIX	NOTES	COMMENTS:	DATE:
						Results from External Laboratory ² :
						[Vitamin A] (mg/kg) =
						[Total Iron] (mg/kg) =
DAILY TOTAL					Responsible:	Signature:
TOTAL TO DATE						



¹ Table is based on Log-form from Los Tance Sugar Refinery, S.A. in Guatemala.
² Results from external laboratory will be available once a month, not on a daily basis.



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