



East, Central and Southern African
Health Community



MANUAL FOR EXTERNAL MONITORING OF SUGAR FORTIFICATION WITH VITAMIN A AT FORTIFICATION SITES

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 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.

LIST OF CONTENTS

A. Planning inspection visits	2
B. Technical Auditing visits.....	4
C. Inspection by corroborating trials	6

LIST OF TABLES

Fortified Sugar - Audits and Inspection-Table B-1	9
Technical Audit and Inspection Visit Sessions	9
Fortified Sugar - Audits And Inspection-Table B-2	10
Checklist of Technical Audit and Inspection Visit to sugar factories.....	10
Fortified Sugar - Audits And Inspection-Table B-3	11
Technical Audit and Inspection Preliminary Report.....	11

MANUAL FOR EXTERNAL MONITORING OF SUGAR FORTIFICATION WITH VITAMIN A AT FORTIFICATION SITES

(Technical Auditing and Inspection)

Technical auditing and inspection activities carried out at fortification sites are part of the enforcement activities performed by the government to ensure sugar meets the nutrient quality as well as the safety specifications established in regulations. In the technical auditing, the performance of quality assurance and control activities carried out by the producer is confirmed. This action is known as auditing. Then, the conformity of the fortified food with the technical specifications is verified through sampling and chemical analysis of sugar samples taken during the visit. The latter task is identified as the inspection.

This manual presents the steps to carry out the technical auditing and inspection in sugar factories or packaging centers. 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 suggests the main persons responsible for each stage. As any enforcement procedure carried out a governmental body, warning and legal actions to be taken when non-compliance is found should be defined and applied when necessary.

Results of auditing and inspection activities should be consolidated at the end of the 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 is presented graphically to divulge the situation of the sugar fortification program in the country with other government bodies, Non Governmental Organizations (NGO's), international organizations and civil society in general.

The sections included in the manual are:

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

A separately manual about chemical assays includes the methods used for vitamin A determination in sugar.

A. PLANNING INSPECTION VISITS

I. Objectives and Accountability

The purpose of planning inspection visits is to ensure that:

- Resources to visit every sugar factory at least two times a year are allocated.
- The visits are scheduled according to the harvest season when sugar is being fortified.
- Inspectors receive appropriate training on the fortification process and sampling to perform the auditing and inspection.

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. Plan at least two visits to each factory during the harvest season months, as well as additional visits when non-compliance are found.
2. Estimate the financial resources that will be needed considering:
 - Personnel
 - Transportation and fuel
 - Approximate number of samples to be analyzed and cost
 - Other issues such as approximate number of extra-visits
3. Report to the Head of Food Control Unit the plan, schedule and estimated budget to carry out the plan.
4. Plan a training workshop for the inspectors on the fortification process in the sugar factories, including knowledge about the Quality Assurance and Control (QA/QC) performed by the factory, and auditing and sampling activities during the visit to the factory.

b. Defining actions to be taken

1. Define the actions to be taken when non-compliance is found during a visit. These actions might include formal warnings to legal actions and they should be considered within the legal framework of the food control work.

The following actions are suggested:

- When a major non-compliance is found during a visit, a warning letter is sent to the factory stating the need to correct it. Assess implementation of corrective actions during the next visit, which may take place ahead of schedule if the identified limitations were considered as serious.
- If the factory has not taken any action to solve the problem, the food control authorities might consider to organize a comprehensive audit visit or, if there is proof that the non-compliance is intentional, to apply a legal action such as a fine.
- If corrective measures are in process of being implemented, or new unrelated factors to be improved are identified, another warning letter might be issued before considering comprehensive auditing or applying sanctions.

III. Records and Reporting

The person in charge of supervising 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 VISITS

I. Objectives and Accountability

The purpose of the technical auditing and inspections visits is to verify that the factory has implemented and continuously applies a program for the:

- Quality assurance of premix receipt, storage and delivery
- Quality assurance of the sugar fortification process
- Quality control of the fortified sugar

Those directly responsible to achieve these objectives are the *Food Control Authority inspectors*, who should inform the results of the visits to their *Supervisor*. The *Supervisor* is responsible for preparing the reports to the sugar factories 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.

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 to 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 of fortified sugar for inspection by corroborating trials (see **section C**).
5. Take a sample of the undiluted premix (50g) currently used for fortification, from the original container of the supplier. Write down the type of Vitamin A used in the premix as labeled in the container or the Fact Sheet. 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-compliances, 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-compliance is found inform the general management about the actions to be taken.
8. Leave a copy of the preliminary report (**Table B-3**) to the General Manager.

f. Samples handling

9. As soon as the inspectors arrive to their headquarters, 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 Inspectors)

1. Once results from the laboratory are received and analyzed, send a final report to the General Manager of the factory or the fortification center. Interpretation of results and suggestions should be included.
2. If non-compliances were 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 inspection by corroborating trials is to ensure that:

- All sugar samples contain vitamin A based on qualitative assays.
- 80% samples contain vitamin A levels within regulatory levels (e.g. **2-15 mg/kg**¹) and the average concentration is close to the factory addition level (e.g. **7.5-8.0 mg/kg**).

Inspectors are directly responsible for collecting the samples at the sugar factories whereas the *Food Control National Laboratory* is responsible of analyzing them. The *Supervisor* of the food 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 Inspectors)

a. Daily composite samples

1. 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.
2. Choose three daily composite samples at random. In **Table B-2, section D**, write down the production date, estimated retinol level, and any other information labeled in the sample identification.

¹ Based on ECSA 2007 Guidelines

b. Samples from production or storage warehouse

3. Take two more samples one from the sugar being produced that day and another from the storage warehouse. *Samples from production*
 - (i) In the packaging area, the inspector should take 500 g of fortified sugar from any bag before weighing and sealing or any sealed retail package.
 - (ii) Repeat step (i) every 10 minutes until 8 samples have been collected.
 - (iii) With the help of the factory personnel, verify that all single samples show the presence of vitamin A using a qualitative test.

- (iv) Mix well the 8 samples to produce a **composite sample from production**.

Samples from storage warehouse

- (v) 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 the support of the warehouse operators to move the sugar bags to get the samples.
- (vi) Try to obtain the samples from all accessible sides of the stack, taking the bags out, opening them, taking the sugar samples.
- (vii) With the help of the factory personnel, verify that all single samples show the presence of vitamin A using a qualitative test.

(c) Homogenization and labeling

4. Homogenize the samples taken, using a sample splitter if available. Prepare three 500-g replicates of each sample. One replicate is sealed and left in the factory.
3. 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 samples, in duplicate, collected from stored sugar in warehouse stores
 - (iv) 1 sample of the fortified premix used on the day of the visit
4. Label each sample with the following information:
 - Name of the factory
 - Nate of inspection
 - Lot number
 - Sample ID or sample number
5. The three 500-g portions are divided as follows:
 1. One sample kept for reference by the sugar mill laboratory
 2. One sample for the Food Control Authority to be kept for reference
 3. One sample sent to the National Food Control Laboratory for quantitative testing.
 6. 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 Food Inspectors)

1. Receive the samples and the report from the auditing/inspection visit. Send one set of the samples to the National Food Control Laboratory, or a laboratory which has been confirmed that reports reliable results, to determine the content of vitamin A using a quantitative assay (see the specific manual of laboratory methods).
2. When results from the National Food Control Laboratory are obtained, these are compared with the producer's records. Remember that the results from the factory might be originated using a semi-quantitative method, whereas the National Laboratory used a quantitative method. Therefore, some variation between the two results is expected. However, if results differ greatly, for example, vitamin A level reported quantitatively was less than the legal minimum and the daily estimated average was around 12-15 mg/kg, the cause of such discrepancy should be investigated.
3. Record the vitamin A estimated average in the corresponding **Table B-2, section D**.
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 3 months and submit it to the Head of the Food Control Authority. These reports may also be forwarded to the National Co-ordinating Committee of the Fortification Programs.

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

Date: _____

Time: _____

Sugar factory: _____

Address: _____

Inspector: _____

NAME	POSITION	SIGNATURE	Opening	Closing

FORTIFIED SUGAR - AUDITS AND INSPECTION-TABLE B-2
CHECKLIST OF TECHNICAL AUDIT AND INSPECTION VISIT TO SUGAR FACTORIES

Inspection registry:		Date:		Inspector Name:			
Sugar factory name:							
Address:							
Telephone:		Fax:		e-mail:			
A. ASPECTS	YES	NO	N/A	A. ASPECTS	YES	NO	N/A
1.1. Cleaning and sanitation:				3. Sugar fortification with vitamin A			
1.1.1 Production area				3.1 Feeder flow is verified at least every shift			
1.1.2 Packaging area				3.2 Records of feeder verification are available			
1.1.3 Warehouse				3.3 Feeder is adjusted when needed			
1.1.4 Staff facilities and toilets				3.4 Premix level in feeder was adequate during visit			
1.2 Personnel				3.5 Evidence of maintenance of the feeder			
1.2.1 Hygiene as required in regulations				3.6 Records of sugar/premix up to date			
1.2.2 Wearing protective clothing				3.7 Sugar samples taken for analysis per shift			
1.2.3 Trained in the tasks they perform				3.8 Corrective actions taken when			
1.3 Written procedures or instructions for:				3.8.1 Ratio sugar/premix is not right			
1.3.1 Receipt and storage of premix				3.8.2 Results show retinol < 5 mg/kg			
1.3.2 Feeder verification				4. Quality of fortified sugar			
1.3.3 Sampling of sugar for QC				4.1 Records of sugar samples analyzed using			
1.3.4 Vitamin A assay for fortified sugar				4.1.1 Semi-quantitative method			
2. Vitamin A premix				4.1.2 Quantitative method (internal lab.)			
2.1 Premix inventory is up to date				4.1.3 Quantitative method (external lab.)			
2.2 Stored under adequate conditions				4.2 Daily composite samples are prepared			
2.3 "First in, first-out" system				4.3 Last 30 samples are stored and available			
2.4 Adequately delivered to fortification site				4.4 Labeling meets specifications			
2.5 Verification of retinol levels in premix				4.5 Fortified sugar is stored adequately			
				4.6 "First-in, first-out" system applied to dispatch			

**FORTIFIED SUGAR - AUDITS AND INSPECTION-TABLEB-3
TECHNICAL AUDIT AND INSPECTION PRELIMINARY REPORT**

Inspection registry:		Date of inspection:	
Sugar factory name:		Sugar factory representative:	
Address:		Telephone:	
PRELIMINARY REPORT			
1. Areas visited			
<input type="checkbox"/> Production	<input type="checkbox"/> Packaging	<input type="checkbox"/> Fortification site	<input type="checkbox"/> Laboratory
<input type="checkbox"/> Sugar warehouse	<input type="checkbox"/> Raw material warehouse	<input type="checkbox"/> Other:	
2. No n-com pliances. List the non-compliances found		3. Sug gestions fo r im provement	
Inspector:		Received by (Sugar factory representative):	
Signature:		Signature:	
Date:		Date:	
Supervisor (Name and Signatu re)		Date	

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 Vitamin Fortificant:		
D. List of samples taken for corroborating tests					
ID Composite-Samples	Estimated average [Vit. A] (mg/kg)	Results from inspection [Vit. A] (mg/kg) ²	ID Other Samples	Estimated average [Vit. A] (mg/kg)	Results from inspection [Vit. A] (mg/kg) ²
				-	
				-	
				-	
Inspector (Name)		Signature			Date
Supervisor (Name)		Signature			Date

¹ (√) = Adequate; (x) = Not adequate

² Results from the Food Control Laboratory or a reliable one.



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