



East, Central and Southern African
Health Community

MANUAL FOR EXTERNAL MONITORING OF OIL FORTIFIED WITH VITAMIN A

(Technical Auditing and Inspection)



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

Plot 157 Oloirien, Njiro Road
P.O. Box 1009
Arusha, Tanzania
Telephone: +255 27 250 8362 / 3; 250 4106
Fax: +255 27 254125 / 250 8292
Email: regsec@ecsa.or.tz
Website: www.ecsa.or.tz

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
ECSA Health Community

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

About the Authors

Phillip Makhumula:

A Malawian food fortification consultant with experience in Africa and Central Asia.

Monica Guamuch:

A Guatemalan food fortification consultant with experience in Latin American and the Caribbean.

Omar Dary (PhD):

The Food Fortification Specialist of A2Z: The USAID Micronutrient and Child Blindness Project.

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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 OIL - AUDITS AND INSPECTION-TABLE B-1.....	9
TECHNICAL AUDIT AND INSPECTION VISIT SESSIONS.....	9
FORTIFIED OIL - AUDITS AND INSPECTION-TABLE B-2.....	10
CHECKLIST OF TECHNICAL AUDIT AND INSPECTION VISIT TO OIL FACTORIES.....	10
FORTIFIED OIL - AUDITS AND INSPECTION-TABLE B-3.....	12
TECHNICAL AUDIT AND INSPECTION PRELIMINARY REPORT.....	12

MANUAL FOR EXTERNAL MONITORING OF OIL FORTIFIED WITH VITAMIN A

(Technical Auditing and Inspection)

Technical auditing and inspection activities carried out at oil factories are part of the enforcement activities performed by the government to ensure that fortified oil meets the nutrient quality as well as the safety specifications established in regulations. During the technical audits, the performance of quality assurance (QA) and control (QC) activities done by the producer are verified. Then, the conformity of the fortified food with the technical specifications is confirmed through sampling and chemical analysis of oil samples taken at the factory. Samples of the vitamin A compound are also taken to verify certainty of the Certificate of Analysis (COA) given by the supplier.

The fortification of oil in a country follows specific guidelines as set out in the national standards and monitored by regulatory bodies in that country. These regulatory bodies may include the Bureau of Standards, the Ministry of Health Food Inspectorate, Customs officials and Ministry of Trade Inspectors. Each body plays a distinct role with the overall objective of ensuring that the consumer is provided with fortified oil that is safe and adequately fortified. The compliance of the fortification specifications belongs to the individual factory through their QC and QA procedure. The procedures at the factory level are to be transparent with proper documentation on which external inspectors can base their assessment of compliance, because the process of ensuring that the oil is adequately fortified cannot be left to the industry alone.

Results of auditing and inspection activities should be consolidated two times 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 is presented graphically to divulge the situation of the fortification program in the country, along with information from other food control or surveillance activities.

This manual presents the steps to carry out the technical auditing and inspection in oil factories. 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 oil factories at least three 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 these 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 oil factories that should be visited plan at least three visits to each factory per year.
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 about the fortification process in the oil factories, 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

Define the actions to be taken when non-compliance is found during a visit. These actions will vary from advice on areas of requiring improvement, warnings, to legal actions. These should be considered within the legal framework of the Food Control work. The following actions are suggested:

1. When the non-compliance is minor, technical advice should be provided on areas that need improvement follow up with more frequent visit.
2. 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.
3. 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.
4. If corrective measures are in process of being implemented, or new unrelated factors 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 VISITS

I. Objectives and Accountability

The purpose of the technical auditing visits is to verify **that the oil factories have implemented and continuously apply** a program for the:

- Quality assurance of the vitamin A compound receipt, storage and delivery
- Quality assurance of the oil fortification process
- Quality control of fortified oil

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 is a new program, the visits should be done on a monthly basis and be scaled down depending on the success of the fortification in the factory.

The people directly responsible for achieve 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 oil 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. Inquire from them if there are problems that they are experiencing with their fortification program. Record name 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**. As the audit takes place, record any non-compliance found in **Table B-3**.

c. Inspection

3. At the end of the audit, take five oil samples for the inspection by corroborating trials (refer to section C).
4. Take a sample of the vitamin A compound currently used for fortification, from the original container of the supplier.

d. Preliminary report

5. 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

6. Finish the visit with a closing session. Check in **Table B-1** the attendants. Explain the major findings presented in the report previously prepared. If non-compliances are found inform the general management about the actions to be taken.
7. Leave a copy of the preliminary report (**Table B-3**) to the General Manager.

f. Samples analysis

8. As soon as the inspectors arrive to the headquarters, they should give filled forms and the samples to the supervisor of inspectors to send to the Food Control National Laboratory.

III. Records and reporting (Supervisor of Food Inspectors)

1. Once results from the laboratory are received and interpreted, send a final report to the General Manager of the oil factory. Conclusions 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 assure that:
- All samples indicate the presence of vitamin A based on qualitative tests.
- 80% of samples contain vitamin A within specified regulatory levels of **10-45 mg/kg**¹ and the average concentration is close to the target addition level of 30mg/kg at the factory.
- The vitamin A compound sample complies with the specifications established for it.

Inspectors are directly responsible for taking the samples at the oil factories whereas the *Food Control National Laboratory* is responsible for 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 officer 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* and any other governmental body involved in the enforcement of fortified foods.

II. Procedure for Sampling (Food Inspectors)

a. Vitamin A compound

1. Take a 30-g sample of the vitamin A compound that is being used for fortification at the factory during the time of Inspection. Label it with the name of the manufacturer, claimed vitamin A content, and date.

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 vitamin A level, and any other information labeled in the sample ID.

¹ Based on ECSA 2007 guidelines

c. Samples from production or storage warehouse

4. Take two more samples, one from the oil being *produced that day* and the second from **storage** warehouse.

Samples from production

- (i) In the packaging area, the inspector should collect one bottle of oil from production. Collect one retail-size bottle or at least 0.5litres before packaging and sealing.
- (ii) Repeat step (i) every 10 minutes until 8 samples have been collected.
- (iii) Mix equal amounts of oil (200mL or 200g) of each of the 8 samples and mix well to produce a **composite sample from production**.

Samples from storage warehouse

- (iv) Collect 8 samples from stores warehouse by selecting retail size bottles from boxes at random. Collect at least 200g (or 200mL) from each bottle and mix well the 8 samples to produce a **composite sample from storage warehouse**. Ask the support of the warehouse operators to move the boxes or containers to get the samples.
- (v) Try to obtain the samples at random and where retail packs are not available collect 200g from available containers.

5. Take a sample of UNFORTIFIED OIL. This sample may be used by the laboratory as the blank

d. Homogenization and labeling

6. Divide all **composite samples** into three portions of 0.5 liters. Pack the samples in dark containers and close them tightly.

7. Label the triplicates of each sample with the following information:

- (i) Name of the factory;
- (ii) Product brand;
- (iii) Date of inspection;
- (iv) Lot number; and
- (v) Sample ID or number if any.

8. The three portions are divided as follows:
 - (i) 1 sample kept at the factory for reference
 - (ii) 1 sample sent to the Food Control Authority for reference
 - (iii) 1 sample is sent to the National Food Control Laboratory for quantitative testing.
9. Transport samples with the minimum exposure to heat, humidity and light. On arrival at your office, hand in the auditing/inspection forms and the samples to your supervisor.

III. Records and Reporting (Supervisor of Inspectors)

1. Receive the samples and the report from the auditing/inspection visit. Send the samples identified with a code number (do not send original information) to a Reference Laboratory.
2. When results from the National Food Control Laboratory are received, record the results from the laboratory in the corresponding section of **Table B-2**. Remember that factory may have used a semi-quantitative method, and hence some variation might exist with the results of the laboratory, but discrepancy should not be too large.
3. 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 with the problem.
4. Prepare a consolidate 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 OIL - AUDITS AND INSPECTION-TABLE B-1
TECHNICAL AUDIT AND INSPECTION VISIT SESSIONS**

Date: _____

Time: _____

Oil factory: _____

Address: _____

Inspector: _____

NAME	POSITION	SIGNATURE	Opening	Closing

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

Inspection registry:		Date:		Inspector			
Oil factory name:	Name:						
Address:							
Telephone:		Fax:		e-mail:			
A. ASPECTS	YES	NO	N/A	A. ASPECTS	YES	NO	N/A
1.1. Cleaning and sanitation:				3. Oil fortification process			
1.1.1 Production area				3.1 Premix preparation			
1.1.2 Packaging area				3.1.1 Homogeneity assessed.			
1.1.3 Warehouse				3.1.2 Storage and handling adequate			
1.1.4 Staff facilities and toilettes				3.2 Records of premix preparation updated			
1.2 Personnel				3.3 Equipment is routinely checked			
1.2.1 Hygiene as required in regulations				3.4 Records of oil produced/premix up-dated			
1.2.2 Wearing protective clothing				3.5 Oils amples 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 for oil fortification:				3.6.1 Ratio oil produced/premix is not right			
1.3.1 Receipt and storage of vit. A				3.6.2 VitA in compliance with specifications			
1.3.2 Preparation of premix.				4. Fortified oil			
1.3.3 Recording of information				4.1 Records of oil samples analyzed using			
1.3.4 Sampling of oil for QC				4.1.1 Semi-quantitative test			
1.3.5 Test for retinol in oil				4.1.2 Quantitative method (external lab.)			
2. Vitamin A compound				4.1.3 Vit A compound (external lab.)			
2.1 Inventory is up to date				4.2 Daily composite samples are prepared			
2.2 Sufficient for the following 3 months				4.3 Last 30 samples are stored and available			
2.3 Certified of Analysis is received per lot				4.4 Labeling meets specifications			
2.4 Storage is adequate				4.5 Fortified oil is stored appropriately			
2.5 "First-in, first-out" (expiration) system				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 Vitamin A in Premix:		
D. List of samples taken for corroborating tests						
ID Composite-Samples	[Vit.A] (mg/kg) Factory result	[Vit. A] (mg/kg) Results from Inspection	ID Other Samples	[Vit. A] (mg/kg) Results from Inspection	Vit. A Compound Claimed level (g/kg)	[Vit. A] (g/kg) Results from inspection
Inspector (Name)		Signature			Date	
Supervisor (Name)		Signature			Date	

? (√) = Adequate; (x) = Not adequate

FORTIFIED OIL - AUDITS AND INSPECTION-TABLE B-3
TECHNICAL AUDIT AND INSPECTION PRELIMINARY REPORT

Inspection registry:	Date of inspection:		
Oil factory name:	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"/> Oil warehouse	<input type="checkbox"/> Raw material warehouse	<input type="checkbox"/> Other:	
2. Non-compliances. List the non-compliances found		3. Suggestions for improvement	
Inspector:		Received by (Factory representative):	
Signature:		Signature:	
Date:		Date:	
Supervisor (Name and Signature)		Date	



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FROM THE AMERICAN PEOPLE

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