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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

Acknowledgement

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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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MANUAL FOR EXTERNAL MONITORING OF FORTIFIED SALT
(Technical Auditing and Inspection)

Technical auditing and inspection activities carried out at salt factories are part of the enforcement activities performed by the government to ensure that salt 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 food with the technical specifications is confirmed through sampling and chemical analysis of salt samples taken at the factory. Samples of the iodine compound are also taken to verify 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 salt factories. The methods recommended to be used to analyze samples quantitatively appear in the laboratory manual. The Food Control Authority in the country is responsible to carry out the auditing and inspection activities of fortified salt, 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 people mainly responsible for each stage of the whole process. As any enforcement procedure carried out by a governmental body, warning and legal actions to be taken when non-compliances is noted 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 is presented graphically to divulge the situation of the fortification program in the country, along with information from other food control or surveillance activities.

The sections included in this manual are:

- Planning inspection visits
- Technical auditing and inspection 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 salt factories 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 salt factories that should be visited plan at least two 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 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 salt factory, 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 warnings and legal actions which should be considered within the legal framework of the Food Control work.The following actions are suggested:

- When major non-compliance is found during a visit, a warning letter is sent to the factory stating the need to correct them. Assess implementation of corrective actions during a following visit, which may take place ahead of schedule if the identified limitations were considered serious.

- If in the following visit, 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 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 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. and Accountability

The purpose of the technical auditing and inspection visits are to verify that the salt factory has implemented and continuously apply a program for the:

- Quality assurance of iodine compound receipt, storage and delivery
- Quality assurance of salt fortification process
- Quality control of the fortified salt

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 for preparing the reports to the salt 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 for management which should include the General Manager, Factory or Production Manager, Quality assurance and control department Manager and Laboratory Manager. 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**. 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 salt samples for inspection by corroborating trials (refer to section C).

4. Take a sample of the iodine compound (25 g) 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-compliance if any (use **Table B- 3**).

e. Closing session

6. Finish the visit with a closing session with the same attendants to the opening session. Check in **Table B-1** the attendants present at the closing session. Explain the major findings presented in the report previously prepared. If non-compliances are found inform the management about the actions to be taken.

7. Leave a copy of the report for the General Manager.

f. Samples analysis

8. As soon as the inspectors arrive at their headquarters, give the samples to the Supervisor of Inspectors to be sent to the Food Control National Laboratory.

III. Records and reporting (Supervisor of Food Inspectors)

Once results from the laboratory are received and analyzed, send a final report to the General Manager of the fortification site. Interpretation of results and suggestions should be included. If non-compliance is found, enclose a warning letter stating the points that should 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 salt samples contain iodine based on qualitative methods such as the Rapid Test Kit.
- 80% of samples contain iodine levels according to factory levels (e.g. **30-60 mg/kg**[1] and the average concentration is close to the target addition at the factory (e.g. **45 mg/kg**).
- All fortificant samples comply with the specifications established in the standard of the premix *Inspectors* are directly responsible of taking the samples at the salt 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**, write down the production date, estimated iodine level, and any other information labeled in the sample ID.

[1] Based on ECSA 2007 guidelines.

b. Samples from production or storage warehouse

3. Take two more samples per brand from the salt being produced that day and from the storage warehouse.

Samples from production

(i) In the packaging area, the inspector should collect 500g of fortified salt or any similar retail size package from the production line.

(ii) Repeat step (i) every 10 minutes until 8 samples have been collected.

(iii) Test each sample for the presence of iodine using a qualitative test (e.g. RTK).

(iv) Mix equal amounts of salt (500g) of each of the 8 samples and mix well to produce a **composite sample from production**.

Samples from storage warehouse

(v) Collect 8 samples from stores warehouse by selecting retail size bags or collect 500 g of salt from large bags. Test each sample for the presence of iodine.

(vi) Mix well 500 g of each one of the 8 samples to produce a **composite sample from storage warehouse**. Ask the support of the warehouse operators to move the bags around to collect the samples.

(vii) Try to obtain the samples as randomly as possible.

c. Homogenization and labeling

4. Homogenize the composite samples. Then, divide each one of them into three portions. Prepare 500-g replicates of each sample.

5. Pack the samples in dark containers and close them tightly.

6. Label each sample with the following information:

- Name of the factory
- Date of inspection
- Lot number
- Sample ID or number
- Type of iodine compound (iodate or iodide)
- 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) 1sample is sent to the National Food Control Laboratory for quantitative testing.

– 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.

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III. Records and Reporting (Supervisors of Inspectors)

- Receive the samples and the report from the auditing/inspection visit. Send the iodine compound samples to a regulatory laboratory to determine the type of iodine that was used. Likewise, send the samples of fortified salt to determine the content of iodine using a quantitative assay.

- Record the results from the laboratory in the corresponding section of **Table B-2.**

- 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.

- 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 Coordinating Committee of the Fortification Programs.

FORTIFIED SALT - AUDITS AND INSPECTION-TABLE B-1

TECHNICAL AUDIT AND INSPECTION VISIT SESSIONS

Date: _____ **Time:** _____

Oil factory: _____ **Address:** _____

Inspector: _____

NAME	POSITION	SIGNATURE	Opening	Closing

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

Inspection registry:		Date:		Inspector	
Mill name:					
Address:					
Telephone:	Fax:			e-mail:	

ASPECTS	YES	NO	N/A	ASPECTS	YES	NO	N/A
1.1. Cleaning and sanitation:				**3. Salt fortification**			
1.1.1 Production area				3.1 Premix preparation			
1.1.2 Packaging area				3.1.1 Storage and handling adequate			
1.1.3 Warehouse				3.2 Records of feeder/sprayer performance are available			
1.1.4 Staff facilities and toilettes				3.3 Premix level in feeder adequate during visit			
1.2 Personnel				3.4 Records of salt produced/premix used up to date			
1.2.1 Hygiene as required in regulations				3.5 Salt samples taken for analysis in every shift			
1.2.2 Wearing protective clothing				3.6 Corrective actions taken when			
1.2.3 Trained in the tasks they perform				3.6.1 Ratio salt produced/premix is not right			
1.3 Written procedures or instructions for:				3.6.2 Results show iodine < 40 mg/kg			
1.3.1 Receipt and storage of premix							
1.3.2 Premix dilution (if applicable)				**4. Fortified salt**			
1.3.3 Feeder verification				4.1 Records of salt samples analyzed using			
1.3.4 Sampling of salt for QC				4.1.1 Internal test			
1.3.5 Iodine test for salt				4.1.2 External laboratory			
2. Micronutrient premix				4.2 Daily composite samples are prepared			
2.1 Iodine compound inventory is up to date				4.3 Last 30 samples are stored and available			
2.2 Certificate of Analysis is received per lot				4.4 Labeling meets specifications			
2.3 Iodine compound is stored adequately				4.5 Fortified salt is stored adequately			
2.4 “First-in, first-out” system							
2.5 Iodine compound is handled well							

B. ACTIONS TAKEN FOLLOWING 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:
	D. TYPE OF IRON IN PREMIX:

E. LIST OF SAMPLES TAKEN FOR CORROBORATING TESTS						
Composite samples ID	Factory estimation [Iron] (mg/kg)	Lab. Results from inspection[2]		ID Other samples	Lab. Results from inspection[2]	
		[Iron] (mg/kg)	[Vit.A](mg/kg)		[Iron] (mg/kg)	[Vit.A](mg/kg)

Inspector (Name)	**Signature**	**Date**
Supervisor (Name)	**Signature**	**Date**

Out ———————————

[1] (√) = Adequat e; (x) = Not adequate

[2] Results from Food Control National Laboratory or a reliable one

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

Inspection registry:	Date of inspection:
Factory name:	Factory representative:
Address:	Telephone:

PRELIMINARY REPORT

1. Areas visited

☐ Production ☐ Packaging ☐ Fortification site ☐ Laboratory

☐ Salt warehouse ☐ Raw material warehouse ☐ 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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