

MANUAL FOR REGULATORY/EXTERNAL MONITORING OF FORTIFIED WHEAT FLOUR (Technical Auditing and Inspection)

Introduction

Technical auditing and inspection activities carried out at wheat flour mills are part of government enforcement to ensure that wheat flour meets the nutrient quality and safety specifications established in the Pure Food (Food Control) Regulations.

The Environmental Health Division (EHD) in the Ministry of Health and Medical Services (MHMS) is responsible for carrying out regulatory/external auditing and inspection activities of fortified foods produced in the Solomon Islands (i.e. wheat flour).

Overview

This manual presents the steps for EHD to carry out external technical auditing and inspection in wheat flour mills.

During a technical audit, a mill's Quality Assurance and Quality Control (QA/QC) activities are assessed. The conformity of the fortified flour with national standards is also assessed via chemical analysis of samples taken at the mill.

The main focus of technical audits and inspection is on checking a mill's records and internal QA/QC system. A secondary focus is laboratory testing of composite samples, to check that iron content of fortified flour meets national standards.

Results of regulatory/external auditing and inspection activities should be considered to determine the degree of fulfilment of fortification program goals, obstacles to overcome and actions to be taken. Warnings and legal action should be taken when non-compliance is found.

The sections included in this manual are:

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Acknowledgement

This manual draws on the manual developed by the East, Central and Southern African Health Community Secretariat in 2007.

Disclaimer

Comparable external monitoring manuals will need to be created in the event of domestic production of fortified rice and salt.

A. PLANNING INSPECTION VISITS

I. Objectives and Accountability

The purpose of planning inspection visits is to ensure that:

- Resources are allocated to visit wheat flour mills at least annually.
- Inspectors receive appropriate training on the fortification process and sampling to perform the auditing and inspection activities.

The *supervisor of Food Safety inspectors* is responsible for achieving the objectives and reporting the plan to the Head of EHD, MHMS.

II. Procedure

a. Plan, budget and schedule

1. Plan and schedule at least an annual visit to each wheat flour mill, plus additional visits as necessary according to EHD's risk framework. It is recommended that three visits be conducted during the first year of fortification. An annual visit can be conducted after the first year.
2. Estimate the financial resources that will be needed considering:
 - Personnel
 - Transportation and fuel
 - Approximate number of samples to be analysed.
3. Report the plan to the Head of EHD.
4. Plan a training workshop for the inspectors about the fortification process in the wheat flour mills, the internal Quality Assurance and Quality Control (QA/QC) performed by the mill, and the external auditing and sampling activities to be undertaken during the visit to the mill.

b. Defining actions to be taken

5. Define the actions to be taken when non-compliance is found during a visit. These actions might include warnings and legal actions that should be considered within the legal framework of the Pure Food Act 1996 and Pure Food (Food Control) Regulations 2010. The following actions are suggested:
 - When the non-compliance is minor, technical advice should be provided on areas that need improvement. An additional visit should be scheduled to confirm that the areas of non-compliance have been appropriately addressed.
 - When major non-compliance is found during a visit, a letter should be sent to the mill stating the issues identified and the need to correct the issue(s). EHD should conduct a comprehensive audit visit and submit clearly stated corrective actions and a timeframe to address these. Schedule another visit to assess implementation of corrective actions.
 - If the mill has not taken any action to solve the problem or if there is proof that non-compliance is intentional, action should be taken against the factory and could include financial and prison penalties, as outlined in the Pure Food Act 1996.
 - If corrective measures are still in the process of being implemented, or EHD identifies further issues for correction, 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 needs to be reported to the Director of EHD.

B. TECHNICAL AUDITING AND INSPECTION VISITS

I. Objectives and Accountability

The purpose of the regulatory/external technical auditing and inspections visits is to verify that the wheat flour mill has implemented and continuously applied a program for the:

- Quality assurance of premix receipt, storage and distribution.
- Quality assurance of wheat flour fortification process.
- Quality control of the fortified wheat flour.

The achievement of these objectives is the responsibility of the *Food Safety Inspector*, who should inform the results of the visits to their *supervisor*. The *Food Safety Inspector* is responsible for preparing the reports for the wheat flour mill.

II. Procedure (Food Safety Inspectors)

a. Opening session

1. Start the visit with an opening session with the General Manager, Factory/Production Manager and QA/QC Department Manager. Explain the purpose and approximate duration of the visit. Explain that it will be carried out by reviewing written procedures, records, personnel interviews, observation of the fortification process and taking 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, 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 a composite sample for inspection by laboratory analysis (**refer to section C**). This will be made up of samples from production and from the store room.
5. Write down the type of iron used in the premix as labelled in the box or the fact sheet, as well as information of the other nutrients. **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 i.e. comments on the adequate performance of the QA/QC procedures, opportunities to improve and any non-compliance (**use Table B-3**).

e. Closing session

7. Finish the visit with a closing session with the same attendants in the opening session. Explain the major findings presented in the report. If cases of non-compliance were found, inform the General Manager of the next steps and actions that need to be taken.
8. Leave a copy of the preliminary report with the Quality Assurance Manager.

f. Samples transport

9. Pack the samples in suitable and tight containers, and transport them protected against exposure to heat, humidity and direct sun light.
10. The *Food Safety Inspectors* must provide the sample for laboratory testing to the Public Health Laboratory straight away.

III. Records and reporting (*supervisor of Food Safety Inspectors*)

1. Once results from the laboratory are received and analysed, send a final report to the mill's Quality Assurance Manager. This should include interpretation of results and recommendations for improvement, if necessary.
2. If non-compliance is found, enclose a warning letter stating the points that need to be corrected before the next visit.

C. INSPECTION BY LABORATORY ANALYSIS

I. Objectives and Accountability

The purpose of the laboratory analysis is to ensure that:

- Flour samples contain the correct amount of iron, which is used as the micronutrient indicator.

Food Safety Inspectors are responsible for taking the samples at the wheat flour mills. The Public Health Laboratory is responsible for analysing them. The *supervisor* of the *Food Safety Inspectors* coordinates the activity, from checking the records of the auditing visits, receiving and analysing the laboratory results, and preparing and sending the reports. The *supervisor* should prepare a report annually on activities and findings, for sending to the Head of EHD and the Food Fortification National Committee (via the Committee's Secretariat in the Nutrition Unit).

II. Procedure (Food Safety Inspectors)

a. Samples from production

1. From the packaging line, take 500g of wheat flour from any bag before weighing and sealing.
2. Repeat step (1) every five minutes until five samples have been collected. Ask personnel of the mill to verify the presence of iron in each sample, using the iron spot test method.
3. Mix well the five samples.
4. Take 1kg of this mixed sample for a composite sample from production. Use this in step (c.).

b. Samples from sample store room

5. Check that the mill has at least one composite sample made up of flour milled during the previous quarter (three months) of production. This should be clearly labelled with dates of production, and stored appropriately. It should weigh at least 2kg.
6. Take the quarterly composite sample from the last quarter from the store room. Take 1kg of this for a composite sample from storage. Use this in step (c.).
7. In **Table B-2** write down the production week (dates), and any other information labelled in the composite sample identification.
8. Check that the mill is keeping weekly and monthly samples to create its composite quarterly sample.

c. Homogenization and labelling

9. Combine the composite sample from production and the composite sample from storage to create a homogenous sample. Mix well.
10. Divide the homogenous sample into three equally sized portions (about 666g each).
11. Pack the samples in dark containers and close them tightly.
12. Label each sample with the following information:
 - Name of the factory.
 - Date of inspection.
 - Lot number.
 - Sample ID or sample number.
13. Allocate the three portions as follows:
 - One sample kept for reference by the mill.
 - One sample kept for reference by EHD.
 - One sample sent to the Public Health Laboratory for quantitative testing.

14. On return to MHMS, the inspector will provide the auditing/inspection forms and the samples collected to the supervisor of *Food Safety Inspectors*.

III. Records and Reporting

1. The supervisor of the *Food Safety Inspectors* will receive the samples (2) and the report from the auditing/inspection visit. One sample will be sent to the Public Health Laboratory to determine the content of iron using quantitative assays. One sample will be retained for MHMS records.
2. When results from the Public Health Laboratory are received, compare these with the mill's records. Remember that the mill's records will be for different flour samples, so some variation between the two results can be expected.
3. Record the results from the laboratory in Section D of **Table B-2**.
4. Analyse the results and report to the Director of EHD. Check that the iron levels meet the minimum fortification requirements in the Pure Food (Food Control) Regulations i.e. 60mg/kg if electrolytic iron has been used or 45mg/kg if ferrous fumarate has been used. Check that the mill's records of its laboratory testing show that its flour contains the minimum levels of iron (as above) and folic acid i.e. 2mg/kg.
5. Advise the mill of the findings of the laboratory analysis and the need for any corrective action.
6. Include the findings from laboratory analysis in the annual report submitted to the Director of EHD and the Food Fortification National Committee.

Table B-1: Technical Audit and Inspection Visit Sessions

Date/Time: _____

Mill: _____

Inspector: _____

Name	Position	Signature	Opening	Closing

Table B-2: Checklist of Technical Audit and Inspection Visit

Date/Time: _____

Mill: _____

Inspector: _____

A. Aspects	Yes	No	N/A	A. Aspects	Yes	No	N/A
1. Cleaning and sanitation				5. Wheat flour fortification process			
1.1 Production area				5.1 Records of feeder performance available			
1.2 Packaging area				5.2 Premix level in feeder adequate during visit			
1.3 Warehouse				5.3 Records of production & premix use up to date			
1.4 Staff facilities and toilets				5.4 Flour samples taken for iron spot test every day			
1.5 Surroundings				5.5 Corrective actions taken when:			
2. Personnel				5.5.1 Ratio wheat flour produced/premix is not right			
2.1 Hygiene				6. Fortified wheat flour			
2.2 Wearing protective clothing				6.1 Records of flour samples analysed using			
2.3 Trained in tasks they perform				6.1.1 Iron spot test			
3. Written procedures or instructions for				6.1.2 Quantitative method for iron (external lab)			
3.1 Receipt and storage of premix				6.1.3 Quantitative method for folic acid (external lab)			
3.2 Feeder verification				6.2 Weekly flour samples stored			
3.3 Sampling of wheat flour for QC				6.3 Composite monthly flour samples stored			
3.4 Iron spot test for wheat flour				6.4 Last quarterly composite sample stored & available			
4. Micronutrient premix				6.5 Labelling meets national standards			
4.1 Premix inventory is up to date				6.6 Fortified flour is stored adequately			
4.2 Certificate of Analysis (CoA) received				6.7 "First-in, first-out" system applied to dispatch			
4.3 CoA complies with national standard							
4.4 Premix appropriately stored							
4.5 "First-in, first-out" system							
4.5 Pre-mix is handled well							

B. Actions taken from recommendations of last technical auditing and inspection visit			
Recommendations	Corrective action taken	Assessment of corrective action	
		Yes/No	Comments
C. New recommendations			
Non-compliances	Suggestions for improvement		
D. List of samples taken for external laboratory tests			
ID composite samples for last quarter	External lab tests (mg/kg) [iron]	Mill results from its own external lab tests for the last quarter (mg/kg) [iron] and [folic acid]	
E. Type of Iron in Pre-mix			

Inspector (Name and signature): _____

Supervisor (Name and signature): _____

Table B-3: Technical Audit and Inspection Preliminary Report

Inspection registry:		Date of inspection:	
Mill name:		Mill representative:	
Address:		Telephone:	
Preliminary Report			
1. Areas visited			
Production: Y/N	Packaging: Y/N	Fortification site: Y/N	Laboratory: Y/N
Wheat warehouse: Y/N	Raw material warehouse: Y/N	Other:	
2. Non-compliances. List the non-compliances found		3. Suggestions for improvement	
Inspector: Signature: Date:		Received by (mill representative): Signature: Date:	
Supervisor: Signature: Date:			