



Palestinian Ministry of Health

Inspection Manual for Monitoring Salt and Flour Fortification



Directorate General for Primary Health Care
Environmental Health Department
2010

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A2Z: The USAID Micronutrient and Child Blindness Project consolidate, build, and expand on USAID's long-term investment in micronutrients, child survival, and nutrition. A2Z takes proven interventions to scale, introduces innovation, expands services, and builds sustainable programs to increase the use of key micronutrient and blindness interventions to improve child and maternal health.

A2Z provides technical assistance to the Palestinian Authority to increase the provision of essential micronutrients in the Palestinian diet, thereby reducing the risk of micronutrient deficiencies. ANERA implements A2Z activities in close cooperation with the Palestinian Ministry of Health (MOH).

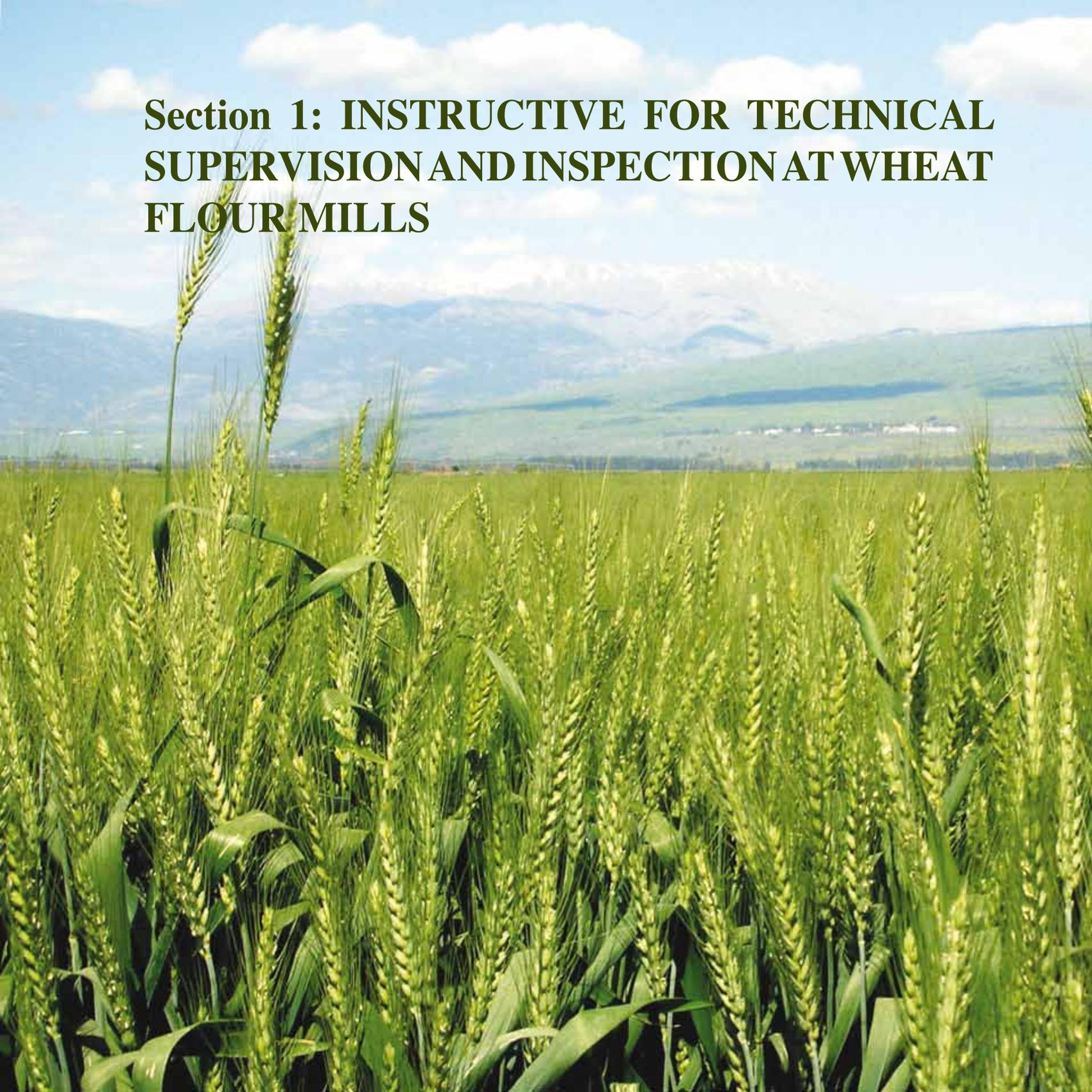


Acknowledgments

This instructive was prepared based on the Monitoring Fortified Foods Manual prepared by the Technical committee for Monitoring Fortified Foods/ Palestinian National Authority and the Manual for External Monitoring of Fortified Wheat Flour (Technical Auditing and Inspection) as well as and the Manual for Commercial Inspection of Fortified Foods., ECSA Health Community Secretariat/A2Z/Project: The USAID Micronutrient and Child Blindness Project.

It was reviewed and adapted according to the recommendations of the Environmental Health Department of the Ministry of Health/Palestinian Authority.

**Section 1: INSTRUCTIVE FOR TECHNICAL
SUPERVISION AND INSPECTION AT WHEAT
FLOUR MILLS**



INSTRUCTIVE FOR TECHNICAL SUPERVISION AND INSPECTION AT WHEAT FLOUR MILLS

Technical supervision and inspection activities carried out at wheat mills are part of the enforcement activities performed by the Food Control Authorities to ensure that wheat flour 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 flour with the technical specifications is corroborated through sampling and chemical analysis of samples taken at the factory. Samples of the micronutrient premix



are also taken to confirm certainty of the Certificate of Analysis (COA) provided by the supplier.

This manual presents the steps to carry out the technical supervision and inspection in wheat mills. It also includes the persons mainly responsible for each stage. The inspectors inform the mill representative when the findings indicate that there is a need for improvement in order to comply with the specifications and standards.

Results of technical supervision and inspection activities should be consolidated quarterly 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 from external monitoring are presented graphically to divulge the situation of the fortification program, along with information from other food control or surveillance activities such as commercial monitoring or household surveillance.

A. INSPECTION VISITS

I. Objectives and Accountability

The purpose of the inspection visits is to verify that the wheat mill has implemented and continuously apply procedures for the:

- Premix receipt, storage and distribution.
- Wheat flour fortification process
- checking the iron content in fortified wheat flour using the spot test

The achievement of these objectives is the responsibility of the Environmental Health Department Inspectors who should inform the results of the visits to their supervisor. The supervisor is responsible of preparing the reports to the wheat mills and reporting quarterly to the Head of the Environmental Health Department/Ministry of Health.

II. Procedure (Environmental Health Inspectors)

a. Contact with the General Manager or mill representative

1. As soon as the inspector arrives to the mill, contact the General Manager or mill representative to explain briefly the purpose of the visit.

Inspection procedure

2. Begin the technical audit with the aid of the checklist presented in Table A-1, section A. As the audit takes place, record any non-compliance, observation or comment in Table A-1, section B.
3. A brief explanation of the points to be checked is presented below. The main topics to be reviewed are focused on fortification of wheat flour, but remember that any factory should implement cleaning and sanitation aspects to provide a safe and well fortified product. The mill must comply with the requirements established in the Health Standard Conditions for Food Institutions (pending release date) and refer to this Standard for further reference on food safety.
4. Explanation of aspects included in the checklist

ASPECTS	EXPLANATION
Cleaning and sanitation:	
<ol style="list-style-type: none"> 1. Production area 2. Packaging area 3. Wheat reception and warehouse 4. Staff facilities and toilettes 	<p>Cleaning and sanitation practices take place in each area in order to produce a safe product. The mills should take actions towards implementing these aspects and Environmental Health inspectors shall verify the progress since the last visit. For further explanation refer to the Health Standard Conditions for Food Institutions.</p>
Personnel	
<ol style="list-style-type: none"> 1. Hygiene practices are required to personnel 2. Wearing protective clothing 3. Trained in the tasks they perform 	<p>Personnel must follow hygiene practices such as washing hands, use of jewelry, protective clothing including beard and mustache nets.</p>
Micronutrient premix	
<ol style="list-style-type: none"> 1. Premix inventory is up to date 2. Certificate of Analysis is received/lot 3. Premix is stored under adequate conditions 4. Handling:“First-in, first-out” system 5. Premix is handled well in fortification site 	<p>The mill shall have premix in enough quantities to fortify the flour production. This premix should be handled in an appropriate way (following the first in-first out system) and stored in a warehouse separated from chemicals and avoid cross contamination. Every lot of premix shall be received with a Certificate of Analysis and packaging should be appropriate. Premix formula must be compatible with the one approved by the Pharmaceutical Products Monitoring and Registration Department/Ministry of Health.</p>
Wheat flour fortification	
<ol style="list-style-type: none"> 1. Premix dilution (if applicable) <ol style="list-style-type: none"> 1.1 Homogeneity assessed 1.2 Adequate storage and handling 	<p>precision of their feeders. The mill should ensure that the dilution is homogeneous in order to avoid variation that might affect fortification results. The diluted premix should be stored in a tightly closed container that does not affect the stability of micronutrients and prevent it from gaining moisture.</p>

ASPECTS	EXPLANATION
2. Records of feeder performance are available 3. Premix level in feeder adequate during visit	Feeder should be checked periodically to ensure that it contains adequate levels of premix and avoid it runs out of premix unnoticeable. The operators should check that is discharging the adequate amount of premix according to the flow of wheat.
4. Records of flour produced/premix used up to date 5. Flour samples taken for analysis in every shift	Every relevant action must be recorded as part of quality assurance program, for inspectors reference, for traceability and monitoring of performance of fortification, among other reasons.
6. Corrective actions taken when 6.1 Ratio flour produced/premix is not right 6.2 Iron content above factory minimum	The mill should keep records of corrective actions taken when it is suspected that there is a problem with the fortification process. These corrective actions might include investigation of the problem such as verifying the feeder, check calculations of ratio of wheat flour produced/premix used.
Fortified wheat flour	
1. Records of flour samples analyzed using	Records of analysis should be kept.
2. Daily composite samples are prepared	Composite samples are prepared and stored as indicated in the quality assurance/quality control manual. These samples are stored for one month.
3. Labeling meets specifications	Flour meets the specifications established in regulations.
4. Fortified wheat flour is stored adequately 5. “First-in, first-out” system applied to dispatch	Verified through visit to the warehouse and mill records.

b. Inspection

5. At the end of the visit, take five samples for the inspection by corroborating trials (refer to section B).

c. Preliminary inspection report

6. Plan to dedicate from 15 to 30 minutes to finish the preliminary inspection report on the major findings during the visit. (Use Table A-2).
7. If there is something wrong, record it in Table A-2, section 2. Finish the report and inform the mill the aspects that must be changed to improve and comply with the standards.
8. Meet the representative of the mill or the person appointed to accompany through the visit. Explain the major findings presented in the report previously prepared.
9. Leave a copy of the report to the mill representative.

d. Samples transport

10. Pack the samples in plastic bags and close them tightly. Seal them and transport them protected against exposure to heat, humidity and direct sun light.
11. As soon as the inspectors arrive to their headquarters, they must give the samples to the Supervisor of Inspectors, who will send them to the Central Public Health Laboratory.



III. Records and reporting (Supervisor of Environmental Health Inspectors)

1. Once results from the laboratory are received and analyzed, send a final report to the Quality Assurance Manager of the wheat flour mill, stating clearly whether the samples taken comply with the specifications in the Standard.
2. Results shall be entered in the EHD database to prepare the quarterly report.

B. INSPECTION BY CORROBORATING TRIALS

I. Objectives and Accountability

The purpose of the corroborating trials is to ensure that:

- All flour samples (including single samples) contain added iron and vitamin A, which are used as the micronutrient “indicators”:

	Iron Spot Test (qualitative test)	Vitamin A (retinol)
Refined wheat flour	Present	Present

- 80% of them (composite samples) satisfy regulatory requirements specified in the Wheat Flour Fortification Standard.
- All premix samples comply with the specifications established for premix.

II. Procedure (Environmental Health Inspectors)

a. Fortification Premix

1. In the case that Environmental Health Department is assigned the responsibility for premix inspection at the flour mills then: Take a 50-g sample of the premix that is being used for fortification at the factory during the time of Inspection. Label it with the name of the mill, name of the manufacturer, micronutrient content, especially vitamin A and iron that are used and micronutrient “indicators”, and dates of expiration and sample collection.

Inspectors are directly responsible of taking the samples at the wheat mills whereas the Central Public Health Laboratory is responsible of analyzing them. The Supervisor of the Environmental Health 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 Environmental Health Department.

b. Samples from production or storage warehouse (Inspector)

Every month take at least one sample from production and one from the warehouse following the procedure explained below:



- **Samples from production**

- i. In the packaging area, the inspector should take 500 g of wheat flour from any bag before weighing and sealing or any appropriate retail size package.
- ii. Mix well all the 5 samples to produce a composite sample from production.

- **Samples from storage warehouse**

- iii. Collect 5 single samples from stored flour in the warehouses, from the same brand and the same type of flour¹, by selecting bags at random. Ask the support of the warehouse operators to move the flour sacks to get the samples. Collect 500 g from each bag.
- iv. If possible, ask personnel of the mill to help for the verification of the presence of iron in each single sample.
- v. Combine and mix well the 5 samples to produce a composite sample from storage.

c. Homogenization and labeling

1. Homogenize all the five samples taken and divide each one of them into two portions of 500 g.
2. Pack the samples in dark containers and close them tightly. The sample configuration is as follows
 - i. 1 sample collected from production of the day
 - ii. 1 sample collected from stored wheat flour in the warehouses
 - iii. 1 sample of the fortified premix used on the day of the visit (if EHD is assigned the responsibility to inspect premix at the mill).

¹ Composite samples should be prepared from the same brand and the same type of flour, for example: all purpose, for bread, etc.

3. Label each sample using a non-erasable marker with the following information:
 - name of the factory
 - date of inspection
 - lot number
 - Code assigned by Environmental Health Department
4. The inspector shall hand in to the Supervisor of Environmental Health Department, the inspection forms, as well as the samples collected.

III. Records and Reporting

1. The supervisor of the food inspectors shall receive the samples and the report from the auditing/inspection visit. Supervisor shall send the undiluted premix samples to the Central Public Health Laboratory, or any reliable laboratory to determine the type and amount of iron that was used. Sample of fortified wheat flour will be sent to determine the content of iron and vitamin A using quantitative assays, as well as any other micronutrient that is used eventually for confirmation.
2. Analyze the results and complete the report. Prepare letters to advise the visited factories of the problem.
3. Prepare a consolidated report monthly and submit it to the Head of the Environmental Health Department, who will forward it to the Director of Primary Health Care/Ministry of Health.

FORTIFIED WHEAT FLOUR - SUPERVISION AND INSPECTION-TABLE A-1 CHECKLIST OF TECHNICAL SUPERVISION AND INSPECTION VISIT TO WHEAT MILLS

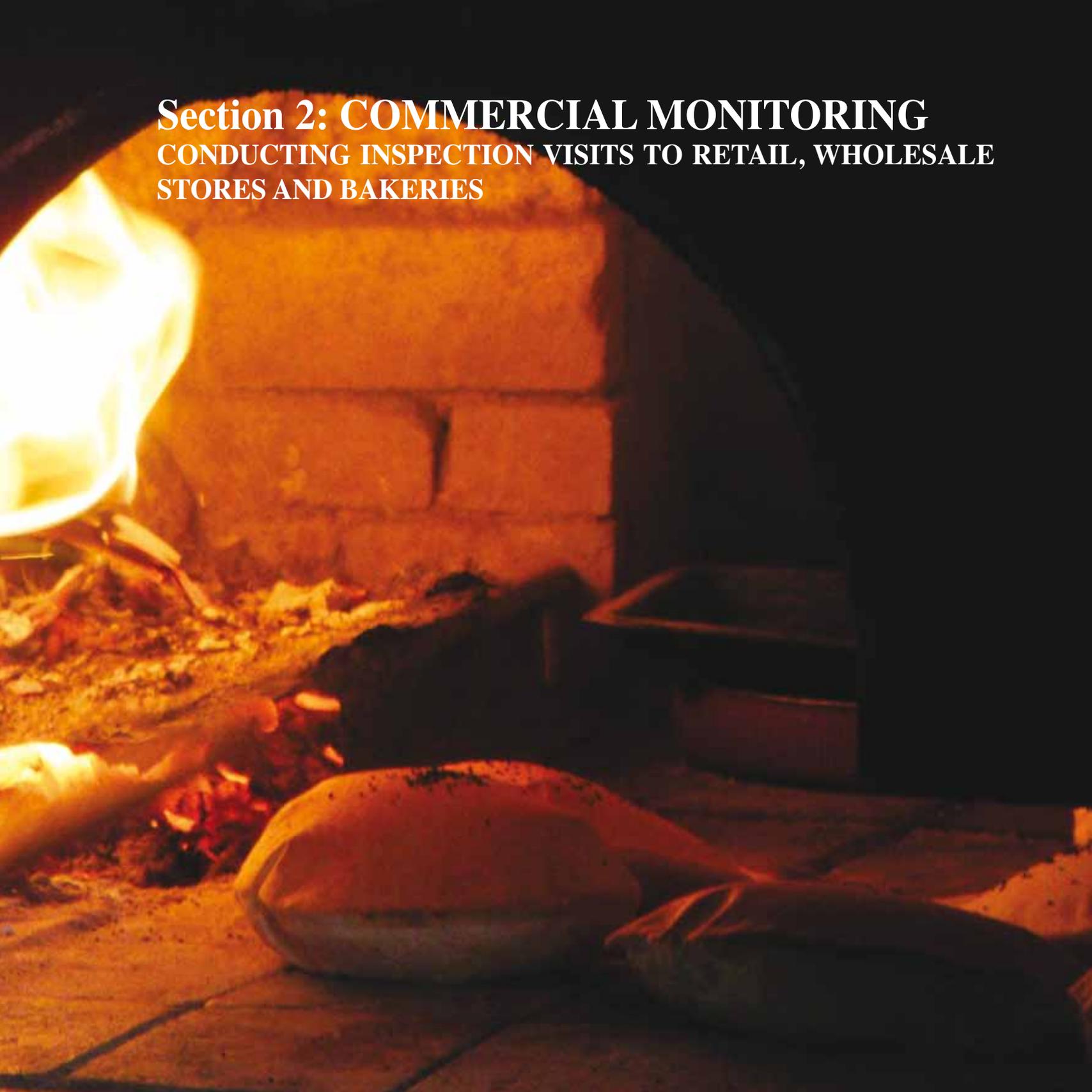
Date:	Time:	Inspectors Names:		
Wheat Mill name:				
Address:				
Telephone:			E-mail address:	
ASPECTS	Compliance	Partial Compliance	NO compliance	COMMENTS
Cleaning and sanitation:				
1. Production area				
2. Packaging area				
3. Grain reception and warehouse				
4. Staff facilities and toilettes				
Personnel				
1. Hygiene as required in regulations				
2. Wearing protective clothing				
3. Trained in the tasks they perform				
Micronutrient premix				
1. Premix inventory is up to date				
2. Certificate of Analysis is received/lot				
3. Premix is stored under adequate conditions				
4. Handling: "First-in, first-out" system				
5. Premix is handled well in fortification site				
Page 1/2				

ASPECTS	Compliance	Partial Compliance	NO compliance	COMMENTS
Wheat flour fortification:				
1. Premix dilution (if applicable)				
2. Records of feeder performance are available				
3. Premix level in feeder adequate during visit				
4. Records of flour produced/ premix used up to date				
5. Flour samples taken for analysis in every shift				
6. Corrective actions taken when				
6.1 Ratio wheat produced/ premix is not right				
6.2 Iron content above factory minimum				
Fortified wheat flour				
1. Records of flour samples analyzed using spot test for iron				
2. Labeling meets specifications				
3. Fortified wheat flour is stored adequately				
4. "First-in, first-out" system applied to dispatch				
B. Type of Iron in Premix:				
Inspector (Name)	Signature		Date	
Supervisor (Name)	Signature		Date	
Page 2/2				

FORTIFIED WHEAT FLOUR - SUPERVISION AND INSPECTION-TABLE A-2 TECHNICAL SUPERVISION AND INSPECTION PRELIMINARY REPORT

Inspection registry:.....	Date of inspection:.....
Mill name:.....	Mill representative:.....
Address:.....	Telephone:.....
PRELIMINARY REPORT	
1. Areas visited (check the box corresponding to the areas that were visited during the inspection)	
<input type="checkbox"/> Production	<input type="checkbox"/> Packaging
<input type="checkbox"/> site	<input type="checkbox"/> Laboratory
<input type="checkbox"/> Fortification	
Wheat warehouse	Raw material warehouse Other (specify):
2. Main findings. Write the aspects that need improvement in order to comply with the specifications and the standards.	
1. 2. 3. 4. 5.	
Inspector 1:	Received by (Mill representative):
Inspector 2:	
Signature(1)	Signature:
Signature(2)	
Date:	Date:
Supervisor (Name and Signature):	
Date	

**Section 2: COMMERCIAL MONITORING
CONDUCTING INSPECTION VISITS TO RETAIL, WHOLESALE
STORES AND BAKERIES**



COMMERCIAL MONITORING

CONDUCTING INSPECTION VISITS TO RETAIL, WHOLESALE STORES AND BAKERIES

Commercial inspection is the verification of legal compliance of fortified foods sold in retail supermarkets, markets, grocery stores, and wholesale stores. It also includes inspection at bakeries as a convenient sampling site for fortified foods namely salt, sugar, flour and oil. This monitoring allows for the detection in the market of brands that are not approved by the Ministry of Health or do not comply with local fortification regulations. It also helps to confirm whether brands that have previously been inspected in factories and importation sites are indeed fulfilling the requirements as claimed by inspectors during the external monitoring process. When non-compliance is observed in certain brands, this type of monitoring provides a warning signal to indicate that the quality control and quality assurance procedures are not adequate in the factories, and that actions must be taken by the Ministry of Health in



order to ensure compliance by the food manufacturers, packagers and importers. In such a situation there is need for improvement of the enforcement system. Furthermore, commercial monitoring serves as an education tool since food inspectors are able to inform the retailers about the existence of the fortification program, the benefits of fortification, their role as retailers and their rights as consumers.

This manual describes the procedures for carrying out the inspection visits at any retail store selling fortified foods. It also describes those responsible for each stage.

Results of commercial monitoring activities should be consolidated in reports to be issued quarterly. The reports assist defining the degree of success in fulfilling the fortification goals and spells out obstacles that need to be overcome and actions to be taken. It is further recommended that an annual report be prepared and published where data is presented graphically to describe the status of the fortification program, along with information from other general food control or surveillance activities.

I. Objectives and Accountability

The purpose of the inspection visits to retail, wholesale stores and bakeries is to ensure that:

- Fortified foods comply with the requirements established in the national standard for general labeling of prepackaged foods and that they have been approved by the Ministry of Health.
- Fortified food items sold on the market or used in bakeries comply with national criteria for micronutrient fortification. Specifically the fortified food should satisfy the following:

Fortified food	Presence	
	(All single samples tested must show presence of indicator micronutrient)	Levels
Refined Wheat Flour	Vitamin A (Retinol) and Iron	(80% of composite samples of each brand comply with the minimum and maximum levels of micronutrients established in the Standard)
Salt	Iodine	

II. Procedure

1. Visits by Inspectors

- Inspectors take samples once a week or as scheduled.
- When inspectors arrive in the villages, towns or cities, they should visit the most popular grocery stores, markets or supermarkets, bakeries and distribution centers, where people buy their supplies.
- Inspectors enter the store and show their credentials identifying them as inspectors of the Environmental. They follow on with a brief explanation about the purpose of the visit.
- They record the name and address of the store, date of visit, name and address (town, village, district, others), in Table A-1.

The Environmental Health Department Inspectors/Ministry of Health are responsible for checking compliance of packaging and labeling and for taking samples of the foods for analysis. They should report on the results of their visits to their supervisor. The Environmental Health Department/Consumer's Protection Department should prepare consolidated reports monthly to the General Director of Primary Health Care and the corresponding Director in the Consumer's Protection Department respectively.

- Inspectors are able to identify the approved brands sold in the store and using Table A-1 they should record name, responsible of the product, the expiration date and lot number if specified. A column is also included in case the food includes any Health/Nutritional claim, for example: “Fortified with”, “Fortified food”, “Good source of”, and similar.
- Choose a sealed packaged of about 1 kg of two brands of fortified food in the store. Stores may have more than two brands. If this is the case, select only two, and the next time the store is visited, select different brands.
- For bakeries take approximately 0.5 kg flour. For samples from 50 kg bags or from bakeries, package them in polyethylene bags, seal and label them with a permanent marker.
- In the case that the inspector bought the samples, use Table A-2

2. Labeling samples and sending them to the laboratory for analysis

- Write the corresponding code to the sample depending on the place where it is taken as indicated in the following table:

Place	Code
Bethlehem	B
Hebron	H
South Hebron	HS
Jenin	J
Jericho	JR
Jerusalem	JM
Nablus	N
Qalqilya	Q
Ramallah	R
Salfeet	S
Tubas	TU
Turkerm	T



- Label each sample using the coding system for EHD.
- Send samples to the Central Public Health Lab for chemical analysis.
- Environmental Health Department will prepare a quarterly report of the samples taken.

3. Analysis of the samples

- Upon receipt of the samples, the laboratory should first detect the presence of the key micronutrients in all samples using qualitative tests.
- If there are samples that come from the same brand, the laboratory may mix up to 5 single samples from the same composite sample. Quantitative determinations are then carried out for key micronutrients.
- The laboratory prepares reports that include the total number of single samples per brand, the number and percent of positive single samples per each micronutrient tested qualitatively, and the individual results of the quantitative tests of each micronutrient analyzed in the composite samples per brand. Results could be categorized in the following micronutrient levels: below the legal minimum, within the legal range, above the upper tolerable level (see Table A-3 for an example).
- Copies of Laboratory reports are sent to the Environmental Health Department who in return sends a copy to the head of division at district level.



III. Records and reporting

Quarterly, Environmental Health Department should prepare a consolidated report from the commercial monitoring, broken down by brand, presenting the percentage of samples showing the presence of the nutrient, below the legal minimum, within the legal range, and above the upper tolerable level. These reports should also be forwarded to the Primary Health Care Director.

COMMERCIAL MONITORING-TABLE A-2

Collection of paid sample

Serial No.:

District:	Place (village/town/neighborhood/city):	Date:
Sample Type:	Production date	Expiration date
Brand Name:	Manufacturing company	Country of origin
Source:	Type of Packaging:	Weight/ Size:
Condition of sample	Temperature	Time of collection

Test Name	Reason for test	Cost
	Total	

Inspector Name: Signature:

Representative of the factory:..... Signature:

Witness:..... Signature:

CPHL USE		
Name of recipient	Date of receiving sample	Sample No.
Examiner Name:	Specific classification	General classification

COMMERCIAL MONITORING-TABLE A-3
LABORATORY REPORT FOR MICRONUTRIENT ANALYSIS OF
RETAIL STORE SAMPLES²
(ONE REPORT PER COMPOSITE SAMPLE)

Date:	Region:	District:
Inspector Name:	Type of Food:	

Brand	Nutrient Tested	# of Samples Tested	Single Positive Samples		Composite Sample (mg/kg)			
			#	%	#	< min	Min- T.Max.	> Tol. Max.

Date

Name:

² This form is to be filled out by the Central Public Health Laboratory, which is in charge of preparing composite samples.



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