



**Part 2:**

**GENERAL SAMPLE TAKING PROCEDURE AT POINT OF PRODUCTION**

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**Frequency of Inspections**

All producers in the country must be inspected at least three times per year by MoCI Standards inspectors. For new facilities that become established, testing should be done once a month for the first three or four months.

Inspections following the initial inspection cycle may be limited to industries and importers that have a history of non-compliance. However, all industries must be inspected once a year regardless of compliance.

All inspections must be unannounced.

**Scope of Inspections**

- General QA practices and record keeping including sample collection, production procedures, and equipment maintenance. This includes ensuring appropriate hygiene levels.



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- Appropriate product packaging to ensure that the fortificants levels claimed are in accordance with the standard levels. In the same manner, the storage areas and practices must be inspected.
- Record keeping is essential. An inspection/investigation record form and checklist are available at the NSL for proper reporting and record system.
  - 1) The production facility must do the following and document it accordingly. Samples during production will be done *every shift or every batch* to confirm that fortification is taking place. In continuous processes, a sample is collected every hour or two hours depending on production volumes and tested qualitatively. A composite sample is made for the shift (or day) and tested quantitatively in-house where possible.
  - 2) The industry/importer/distributor will keep adequate records of all inspections taking place internally and externally.
  - 3) The inspectors will give their inspection documents to the NSL of the MOCI. They will be responsible for all inspection records and will pass necessary information on to the Secretariat of the NFA, e.g. in case of continuous non-compliance.
  - 4) The NSL will be responsible for compilation and data entry as it pertains to all fortification sample results into the Fortification Monitoring Tool. Quarterly reports will be shared with the NFA and with the Global Alliance for Improved Nutrition (GAIN) as suppliers of the quantitative iCheck testing method.

### **General Sample Taking Procedure at Point of Production**

The quality assurance system of **manufacturers** of fortified food products carried out by Ministry of Commerce and Industry Standards Inspectors should address the following:

#### **a. Contact with the General Manager or mill representative**

- As soon as the inspector arrives to the mill, the General Manager or mill representative should be contacted to briefly explain the purpose of the visit.

#### **b. Inspection procedure Checklist**

- Begin the technical inspection with the aid of the checklist presented in Form 3 in the annex. As the inspection takes place, record any non-compliance, observation or comment in Form 2. Examining the raw products
- Raw products before fortification (currently including salt, wheat flour, cooking oil, and sugar) to ensure basic hygiene and Good Manufacturing Practice (GMP) parameters and standards are met.
- A brief explanation of the points to be checked is presented below.:



ASPECTS	EXPLANATION
Cleaning and sanitation	
1. Production area	<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 and/or Standards inspectors of the MoCI shall verify the progress since the last visit. For further explanation refer to the <i>Health Standard Conditions for Food Institutions</i>.</p> <p>The mill must comply with the requirements established in the Good Manufacturing Practice guidelines (adopted by MoCI). Refer to this Standard for further reference on food safety.</p>
2. Packaging area	See above
3. Wheat reception and warehouse	See above
4. Staff facilities and toilettes	See above
Personnel	



<p>1. Hygiene practices required for personnel including no jewelry, clean hands, beard and mustache nets.</p>	<p>Personnel must follow hygiene practices such as washing hands, use of jewelry, protective clothing including beard and mustache nets.</p>
<p>2. Wearing protective clothing</p>	<p>Bear and mustache nets, hairnets, gloves, and no street clothing.</p>
<p>3. Trained in the tasks they perform</p>	<p>The personnel has been trained in accordance to their tasks.</p>
<p>Micronutrient premix: Samples of the fortificant premix must be taken during every inspection visit and sent out for testing to the NSL.</p>	
<p>Packaging, Labeling, Shipping</p>	<p>Ensure product is adequately packaged, labeled, stored and shipped.</p> <p>Number of containers received should be recorded along with lot #, expiry date, and name of person receiving the delivery. The inventory for premix should be updated immediately.</p> <p>Producer should have records confirming this.</p>
<p>Premix inventory is up to date and the appropriate formula is used.</p>	<p>The mill shall have premix in enough quantities to fortify the flour production. Premix formula must be compatible with the one approved by the Pharmaceutical Products Monitoring and Registration Department/Ministry of Health.</p>
<p>Certificate of Analysis is received/lot</p>	<p>Ensure Certificate of Analysis exists for every delivery of the fortificant(s).</p>



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<p>Premix Storage</p>	<p>Fortificant(s) properly sealed and stored in a cool, dry place.</p> <p>Containers should be stored in a clean, cool, dry area away from chemicals (ideally in an air conditioned room).</p> <p>Check if the fortificant(s) used is still within the market shelf life.</p> <p>Check that production facilities have stored at least 6 months worth of premix in an appropriate manner.</p>
<p>5. Handling: “First-in, first-out” system</p>	<p>Container source of the fortificant(s) are immediately sealed after use and stored in a cool dry place.</p>
<p>6. Premix is handled and stored appropriately in fortification site</p>	<p>Fortificant(s) are properly weighted, handled and appropriate records maintained. They’re used as soon as possible. and stored in a warehouse separated from chemicals to avoid cross contamination.</p> <p>Ensure fortificant(s) are properly sealed and stored in a cool, dry place.</p> <p>Ensure sensitive fortificant(s) are in a packing size that can be consumed for one batch of product or for one day’s production.</p> <p>Ensure fortificant(s) are properly weighted and appropriate records maintained.</p> <p>Verify weighed fortificant(s) are properly handled and used as soon as possible.</p> <p>Ensure container source of the fortificant(s) are immediately sealed after use and stored in a cool dry place.</p>



7. Premix dilution (if applicable)	<p>Some mills dilute the premix they receive to improve the precision of their feeders. The mill should ensure that the dilution is homogeneous in order to avoid variation that might affect fortification results.</p> <p>The diluted premix should be stored in a tightly closed container that does not affect the stability of micronutrients and prevent moisture.</p>
8. Homogeneity assessed	
9. Records confirming usage and inventory of Premix.	<p>Premix inventory and usage records should be kept including reconciliation of actual usage versus target usage. Measuring premix usage against actual flour produced is another way (although less accurate) of ensuring proper usage.</p>
<b>Fortification Equipment</b>	
1. Devices and Equipment are checked:	<p>Ensure equipment and measuring devices are calibrated as scheduled.</p> <p>Ensure calibration records are maintained.</p>
2. Records of feeder performance are available	<p>Internal reports show that the feeder is properly running</p>
<b>Flour Fortification</b>	



1. Premix level in feeder adequate during visit	Feeder should be checked periodically to ensure that it contains adequate levels of premix
2. Records of flour used up to date produced/premix Every relevant action must be recorded as part of quality assurance program for inspectors reference.	
3. Establishing and identification of quality assurance for the fortification process.	<p>Verify that the correct equipment is used appropriately for the product being fortified.</p> <p>Ensure mixing method as described is an approved production process.</p> <p>Ensure mixing time is observed and recorded.</p>
Finished Product	
1. Routine analysis of the fortification level of the fortified products (indicating frequency).	<p>Ensure in-house analysis of the micronutrient levels/presence in the finished product is conducted on a routine basis.</p> <p>Ensure quantitative analysis is done by external laboratories on a routine basis.</p>
2. Labeling of finished product is correct.	Manufacturers of processed foods or food products shall include on the label a statement of “nutrition facts” indicating the nutrient(s) and the quantities of said nutrients added in the food. Proper packaging for fortified products includes the use of opaque (where possible) and airtight materials to avoid unnecessary nutrient degradation during transport and storage on the market.



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3. ENRICHED logo is being used	Product nutrient labeling with usage of the ENRICHED logo in accordance with the logo guidelines.

### c. Taking samples

- External inspectors to facilities should have a total of **5 flour samples** and **one premix sample** from each visit:
- **Each sample must be taken in duplicate**, sealed with sample collection materials, and marked in accordance with applicable law and with an attached copy of the relevant provisions. The inspectors are to attach the forms provided in this documents annex. At the end of the visit, take five samples for the inspection by corroborating trials (refer to section 7):

#### Fortification Premix Sample

Standards Inspectors are also responsible for premix inspection at the flour mills:

- 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.
- All premix samples should comply with the specifications established for premix.

#### 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. One composite sample from that day’s production: From production, 500g of flour from any bag in the packaging area before it is weighted and sealed should be taken. Every 10 minutes this step must be repeated until 8 samples have been collected. Using a spot-test, the verification of the presence of iron will be assured. The eight 500g samples from the production line will be combined into one composite sample. Samples should be from the current month





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### **Samples from storage warehouse**

- i. Collect 5 single samples from stored flour in the warehouses, from the same brand and the same type of flour, by selecting bags at random.
- ii. Collect 500 g from each bag.
- iii. Combine and mix the 5 samples well to produce a composite sample from storage.

**A random sample of the finished product will be taken from packages** of the product at the production facility. The smallest package shall be collected. If bulk packing is used the following minimum weights shall be collected:

- o 100g for salt;
- o 100g for sugar;
- o 100g for flour

### **d. Homogenization and labeling**

1. Homogenize all 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 inspection
3. Label each sample using a non-erasable marker with the following information:
  - name of the factory
  - date of inspection
  - lot number
  - An assigned code

### **e. Testing with the BASF Kits**

Initial testing of fortified food will be done using rapid testing methods / kits. If the result is negative, the NSL must be contacted immediately for follow-up procedural instructions. If requested by an inspecting agency or business representative, a third sample will be marked, and given to the representative for the company's own tests. Preliminary inspection report

- Plan to dedicate from 15 to 30 minutes to finish the preliminary inspection report on the major findings during the visit. (Use Table 3).
- If there is something wrong, record it in Form 2, attached in the annex. Finish the report and inform the mill the aspects that must be changed to improve and comply with the standards.
- 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. -
- Leave a copy of the report with mill representative.



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#### **g. Samples transport**

- 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.
- 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 National Standards Laboratory.

#### **h. Records and Reporting**

The **Standards Director** from MoCI receives the samples and the reports from the standards officers. **Standards Director** will send the undiluted premix samples to the National Standards Laboratory to determine the type and amount of iron that was used within 24 hours. Sample of fortified wheat flour will be sent to determine the content of iron and vitamin



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**Form 1:**

**Fortified Wheat Flour – Supervision and inspection. Checklist of Technical Supervision and Inspection Visit to Wheat Mills**

Inspector name:		Time:	Date:	
Wheat mill name:				
Address:				
Telephone:		Email address:		
Aspect	Compliance	Partial Compliance	Non Compliance	Comment
Cleaning and sanitation:				
Production area				
Packaging area				
Grain Reception wheat warehouse				
Staff facilities and toilettes				
Personnel:				



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Hygiene as require in regulations				
Wearing Protective clothing				
Training in tasks they perform				
Micronutrient premix:				
Premix inventory is to date				
Certificate of analysis is received/lot				
Premix is stored under adequate conditions				
Handling” first- in first-out system”				
Premix is handle well fortification site				
Wheat flour fortification:				



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Premix dilution (if applicable)				
Records of feeder performance are available				
Premix level in feeder adequate during visit				
Record of flour produced /premix used up to date				
Flour sample taken for analysis in every shift				
Corrective action taken when				
Ratio wheat produced/premix is not right				
Iron content above factory minimum				
Fortified wheat flour				



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Records of flour sample analyzed using spot test for Iron				
Labeling meets specifications				
Fortified wheat flour is stored adequately				
First-in first- out system applied to dispatch				
Type of Iron in premix				
Inspector( Name):	Signature		Date	
Supervisor (Name):	Signature		Date	



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**Form 2: Fortified Wheat Flour: Supervision and Inspection. Technical Supervision and Inspection Preliminary Report**

<b>Inspector Registry:</b>	<b>Date of inspection:</b>
Mill Name:	Mill Representative
Address:	Telephone No.:
<b>Preliminary Report</b>	
Area 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"/> Fortification <input type="checkbox"/> Site <input type="checkbox"/> laboratory	
Wheat warehouse:	Raw Material warehouse                      other (specify):
Main Findings (Write the aspects that need improvement in order to comply with specifications and standards):	
1. .... .....	



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2. ....  
 ....

3. ....  
 ....

4. ....  
 ....

5. ....  
 ....

Inspector 1.....  Inspector2.....	Received by:(Mill Representative):
Signature (1).                      Signature (2).	Signature:





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Date:	Date:
Supervisor (name and signature):	Date:



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**Form 3: Checklist for Production Site Inspections**

<b>Inspector name:</b>			<b>Date / Time:</b>	
Wheat mill name / Production site name:				
Address:				
Email address:			Telephone:	
Area of Evaluation	Check off and specify in case of non-compliance			Comments
	Compliance	Partial Compliance	Non-Compliance	
<b>Cleaning and sanitation</b>				
1. Production area				
2. Packaging area				
3. Wheat reception and warehouse				
4. Staff facilities and toilettes				



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<b>Personnel</b>				
1. Hygiene practices and protective clothing				
2. Trained in the tasks they perform				
<b>Micronutrient premix</b>				
1. Packaging, labeling, shipping (integrity of packaging material, lot #, production and expiry date)				
2. Premix inventory is up to date and the appropriate formula is used.				
3. Certificate of Analysis is received/lot				
4. Premix storage and handling				
5. Handling: "First-in, first-out" system				
6. Premix is weighed appropriately				



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7. Premix dilution (if applicable)				
8. Homogeneity assessed				
9. Records confirming usage and inventory of premix.				
<b>Fortification Equipment</b>				
1. Devices and Equipment are checked; placement is verified				
2. Records of feeder performance are available				
<b>Flour Fortification</b>				
1. Premix level in feeder adequate				
2. Records of flour used to premix used are up to date				
3. Establishment and identification of quality assurance for the fortification process.				
<b>Finished Product</b>				



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1. Routine analysis of the fortification level of the fortified products (indicating frequency).				
2. Spot test documentation meets national standard				
3. Labeling of finished product is correct including micronutrient levels on label				
4. ENRICHED logo is being used properly				
Inspector( Name):	Signature		Date	
Supervisor (Name):	Signature		Date	

**Form 4: Fortified Wheat Flour: Supervision and Inspection. Technical Supervision and Inspection Preliminary Report**

<b>Inspector Registry:</b>	<b>Date of inspection:</b>
Mill Name:	Mill Representative
Address:	Telephone No.:



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### Preliminary Report

Area 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"/> Fortification |
| <input type="checkbox"/> Site       | <input type="checkbox"/> Laboratory |  |

Wheat warehouse:	Raw Material warehouse:	other (specify):
------------------	-------------------------	------------------

Main Findings (Write the aspects that need improvement in order to comply with specifications and standards):

- 6. ....
- 7. ....
- 8. ....
- 9. ....
- 10. ....

Inspector 1 .....

Inspector 2.....

Received by:(Mill Representative):



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Signature 1	Signature 2
Date:	Date:
Supervisor (name and signature):	Date:



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## Definitions

<ul style="list-style-type: none"> <li><b>Cleaning and Sanitation</b></li> </ul>	
1. Production area	<ul style="list-style-type: none"> <li>Cleaning and sanitation practices take place in each area in order to produce a safe product. Environmental Health Inspectors and/or Standards inspectors of the MoCI shall verify the progress since the last visit. For further explanation refer to the <i>Health Standard Conditions for Food Institutions</i>.</li> <li>The mill must comply with the requirements established in the Good Manufacturing Practice guidelines. Refer to this Standard for further reference on food safety.</li> </ul>
2. Packaging area	<ul style="list-style-type: none"> <li>Ensure that the packaging methods are correct: There should be proper documentation about the packaging procedure. Additionally inspectors will look for leakages in packaging, proper sealing, indentation.</li> </ul>
3. Wheat reception and warehouse	<ul style="list-style-type: none"> <li>Ensure that the environmental conditions are adequate. Products should be stored in a darkened, dry, and cool warehouse. The area should be clean without rodents of any kind. Cleaning schedule should exist.</li> </ul>
4. Staff facilities and toilettes	<ul style="list-style-type: none"> <li>Hygiene for the staff is important, therefore staff toilets and other facilities must be kept clean.</li> </ul>
<ul style="list-style-type: none"> <li><b>Personnel</b></li> </ul>	





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<p>1. Hygiene practices and protective clothing required for personnel including no jewelry, clean hands, beard and mustache nets.</p>	<ul style="list-style-type: none"> <li>• Personnel must follow hygiene practices such as washing hands, use of jewelry, protective clothing including beard and mustache nets, hair nets and gloves, and no street clothes.</li> </ul>
<p>2. Trained in the tasks they perform</p>	<ul style="list-style-type: none"> <li>• The personnel have been trained in accordance to their tasks.</li> </ul>
<p><b>Micronutrient Premix</b></p>	
<p>1. Packaging, labeling, shipping</p>	<ul style="list-style-type: none"> <li>• Ensure product is adequately packaged, labeled, stored and shipped.</li> <li>• Number of containers received should be recorded along with lot #, expiry date, and name of person receiving the delivery. The inventory for premix should be updated immediately.</li> <li>• Producer should have records confirming this.</li> </ul>
<p>2. Premix inventory is up to date and the appropriate formula is used.</p>	<ul style="list-style-type: none"> <li>• The mill shall have premix in enough quantities to fortify the flour production for 6 months. Premix formula must be confirmative with the Certificate of Analysis and and the technical Standard Regulations.</li> </ul>
<p>3. Certificate of Analysis is received/lot</p>	<ul style="list-style-type: none"> <li>• Ensure Certificate of Analysis exists for every delivery of the fortificant(s).</li> </ul>
<p>4. Premix storage and handling</p>	<ul style="list-style-type: none"> <li>• Fortificant(s) and containers are properly sealed and stored in a cool, dry place away from chemicals (ideally in an air conditioned room).</li> </ul>



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	<ul style="list-style-type: none"> <li>• Fortificant(s) are used within the market shelf life.</li> <li>• At least 6 months worth of premix is stored in an appropriate manner.</li> <li>• Appropriate premix handling procedures are followed.</li> </ul>
5. Handling: “First-in, first-out” system	<ul style="list-style-type: none"> <li>• Container source of the fortificant(s) are immediately sealed after use and stored in a cool dry place.</li> </ul>
6. Premix is weighed appropriately	<ul style="list-style-type: none"> <li>• Ensure fortificant(s) are properly weighted and appropriate records maintained.</li> <li>• Ensure sensitive fortificant(s) are in a packing size that can be consumed for one batch of product or for one day’s production.</li> </ul>
7. Premix dilution (if applicable)	<ul style="list-style-type: none"> <li>• Some mills dilute the premix they receive to improve the precision of their feeders. The mill should ensure that the dilution is homogeneous in order to avoid variation that might affect fortification results.</li> <li>• The diluted premix should be stored in a tightly closed container that does not affect the stability of micronutrients and prevent moisture.</li> </ul>
8. Homogeneity assessed	<ul style="list-style-type: none"> <li>• Ensure that the premix and fortified food is properly mixed.</li> <li>• Industry’s quality control records must be assessed for this information</li> </ul>
9. Records confirming usage and inventory of premix.	<ul style="list-style-type: none"> <li>• Premix inventory and usage records should be kept including reconciliation of actual usage versus target usage. Measuring premix usage against actual flour produced is another way (although less accurate) of ensuring proper usage.</li> </ul>



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<ul style="list-style-type: none"> <li><b>Fortification Equipment</b></li> </ul>	
1. Devices and Equipment are checked	<ul style="list-style-type: none"> <li>• Ensure equipment and measuring devices are calibrated as scheduled.</li> <li>- Ensure calibration records are maintained.</li> </ul>
2. Records of feeder performance are available	<ul style="list-style-type: none"> <li>• Internal reports show that the feeder is properly running</li> </ul>
<ul style="list-style-type: none"> <li><b>Flour Fortification</b></li> </ul>	
1. Premix level in feeder adequate during visit	<ul style="list-style-type: none"> <li>• Feeder should be checked periodically to ensure that it contains adequate levels of premix</li> </ul>
2. Records of flour used to premix used are up to date	<ul style="list-style-type: none"> <li>•</li> </ul>
3. Establishing and identification of quality assurance for the fortification process.	<ul style="list-style-type: none"> <li>• Verify that the correct equipment is used appropriately for the product being fortified.</li> <li>• Ensure mixing method as described is an approved production process.</li> <li>- Ensure mixing time is observed and recorded.</li> </ul>
<ul style="list-style-type: none"> <li><b>Finished Product</b></li> </ul>	



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<p>1. Routine analysis of the fortification level of the fortified products (indicating frequency).</p>	<ul style="list-style-type: none"> <li>• Ensure in-house analysis of the micronutrient levels/presence in the finished product is conducted on a routine basis.</li> <li>- Ensure quantitative analysis is done by external laboratories on a routine basis.</li> </ul>
<p>2. Spot test documentation meets national standard</p>	<ul style="list-style-type: none"> <li>• Adequate levels of identified micronutrient determined by Spot Checks are found in factory documentation of flour samples</li> </ul>
<p>3. Labeling of finished product is correct.</p>	<ul style="list-style-type: none"> <li>• Manufacturers of processed foods or food products shall include on the label a statement of “nutrition facts” indicating the nutrient(s) and the quantities of said nutrients added in the food. Proper packaging for fortified products includes the use of opaque (where possible) and airtight materials to avoid unnecessary nutrient degradation during transport and storage on the market.</li> </ul>
<p>4. ENRICHED logo is being used</p>	<ul style="list-style-type: none"> <li>- Product nutrient labeling with usage of the ENRICHED logo in accordance with the logo guidelines.</li> </ul>