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TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR CONDUCTING EXTERNAL MONITORING FOOD FORTIFICATION

1st Edition

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Acknowledgement

This is the first edition of the Guidelines for external monitoring of Fortified Food in Tanzania. The Tanzania Food and Drugs Authority is highly indebted to the staff who worked tirelessly to formulate the draft guidelines which form the basis of these Guidelines. The Authority is also thankful to the Word Bank for their financial assistance in development of these guidelines. All other staff and Management team of TFDA who in one way or another contributed to development of this useful document are very much acknowledged. I thank them all.

Mr. Raymond. N. Wigenge

Director of Food Safety

Foreword

The Tanzania Food and Drugs Authority (TFDA) is a regulatory body established under section 4 of the Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003.

One of the functions of TFDA is to regulate matters related to quality and safety of food for the purpose of protecting the public from health hazards associated with the consumption of food.

These guidelines prescribe the procedure to inspectors on how to conduct effective external monitoring of fortified food in manufacturing facilities, selling outlets and port of entries**.**

It is our hope that inspectors will find the document easier to use and be encouraged to conducting external monitoring of fortified food in their areas of jurisdictions in order to ensure safety and quality of fortified foods to the community.

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Hiiti B. Sillo

Acting Director General

Definitions

Authority:	means Tanzania Food and Drugs Authority (TFDA)
Supervisor of inspection activities:	means any person who is responsible for supervising food inspection activities with his/her area of jurisdiction
Corrective actions:	means action to be taken when the results of monitoring indicate a loss of control.
Corrective measures:	means actions or activities that are used to prevent, eliminate, or reduce food safety hazards.
Fortificants:	means a micronutrient or a micronutrient compound for use in fortification of food;
Premix:	means a blend of food fortificants and specific food vehicle for use in fortification of food;

Background

Micronutrient malnutrition is a problem of public health significance in Tanzania affecting a large number of children and women of child bearing age, but it is debilitating for all ages and for the national economy as well. The deficiencies of micronutrients of even small amount can cause learning disabilities, impair work capacity, and bring on illness and death. The control of vitamin and mineral deficiencies is one of the most crucial developments related to scientific advances. One of the interventions to control micronutrient deficiencies addressed in these guidelines is food fortification with essential micronutrients for prevention or correction of nutritional deficiencies disorders and their resultant disabilities among the population.

Food fortification is becoming widespread as means of delivering micronutrients to the population in many countries and is one of the technologies that offer opportunity to improve lives and accelerate development at low cost with high sustainability.

This recent renewed interest in food fortification is largely because fortification is generally recognized as being the most effective and sustainable way to eliminate dietary micronutrient deficiencies, especially where micronutrient multi-mixes (e.g. vitamin A, vitamin B_1, vitamin B_2, vitamin B_6, vitamin B_{12}, niacin, folate, iron and zinc) can be used. In addition, food fortification is socially acceptable, requires no change in food habits, does not change significantly the characteristics of the food, has readily visible benefits, is relatively easy to monitor, and is the cheapest intervention programme for a government with greater sustainability. The Government of the United Republic of Tanzania has established a National Food Fortification Program which aims at initializing fortification of maize flour, whet flour and edible oil produced by large industries. Selection of these food based on pa capita consumption and availability of technology for fortification. Large scale industries are involved because they are most feasible industries due to their small number which can be easily handled. Small and medium food processors will be brought in board later since they contribute significantly in production of these products.

In the National Food Fortification Program, the Tanzania Food and Drugs Authority has a role to regulate fortified food in the market. These Guidelines have been developed in order to enable the inspectors to conduct effective external monitoring of fortified foods.

The guidelines prescribe the steps to be carried out during conducting external monitoring of fortified food so as to protect and promote public health by ensuring the safety and quality of fortified food**.**

The following sections are included in these guidelines:-

i. Planning inspection activities

ii. Technical audit and inspection

iii. Inspection by corroborating trials

iv. Monitoring of fortified food at ports of entries

v. Annexes

Objective

To provide guidelines for conducting external monitoring of food fortification in manufacturing facilities, food outlets and ports of entries.

SECTION 1: PLANNING INSPECTION ACTIVITIES

1.1 Objectives

The purpose of planning inspection activities is to ensure that:

a) Resources for conducting external monitoring of food fortification at food manufacturing facilities , food outlets and ports of entries are allocated at specified time.

b) Inspectors receive appropriate training on how to assess the compliance of fortified foods in the field

1.2 Accountability

The person responsible for planning inspections shall be the supervisor of those inspection activities.

1.3 Plan, budget and schedule

Based on the total number of manufacturing facilities approved to fortify food that should be inspected, plan at least two yearly inspection to manufacturing facilities. Frequency and intensity of sampling of fortified food products from food outlets shall depend on the population density, amount of food sold in the region, and risk factors such as location close to the borders with other countries where the food is not fortified. Fortified food imports at ports of entry shall be inspected on routine basis.

a) Estimate the financial resources that will be needed considering:

   i. Personnel

   ii. Transportation and fuel

   iii. Approximate number of samples to be analyzed and cost

   iv. Other expenses such as approximate number of extra-inspections.

b) Conduct orientation workshop for the inspectors regarding the fortification process in the manufacturing facilities , the Quality Assurance and Control (QA/ QC) performed by the mill, and auditing and sampling activities during the inspection to factories, outlets and ports of entries.

c) Provide a report to the Authority on the plan, schedule and estimated budget to carry out the whole plan.

d) Ensure cooperation and coordination among the governmental parties involved in the enforcement of regulations as this is important in order perform the exercise effectively and make efficient use of resources. It is recommended that local authority food inspectors be included during food fortification monitoring activities in areas under their jurisdiction

e) Prepare inspection tools for the inspectors**.** Materials to be prepared include:

i. Brochures or leaflets with information on the general labeling requirements for food in general (e.g. registration of approved brands, name and address of supplier, expiration date, net weight, and others) as well as specific information on labeling of fortified foods particularly wheat flour, maize flour and edible oil and fats.

ii. List of approved brands per food. This list should be updated every three months or more frequent if needed.

f) Plan annual training workshops for the inspectors on how to conduct monitoring activities.

1.4 Defining actions to be taken

Actions to be taken when non-compliance is found during a inspection shall be clearly defined. These actions might include warnings and legal actions, which should be considered within the legal framework of the Food legislations depending on whether inspection is conducted in manufacturing facilities, or food outlets as indicated here under.

1.3.1 Manufacturing facilities

a) When a minor non-compliance is found, technical advice should be provided to the production manager on areas that need improvement and follow up with more frequent inspections.

b) When a major non-compliance is found during inspection i, a letter should be submit immediately to the factory clearly stating the defects identified, corrective actions and specific time frame.stating needed to correct them.

c) The Authority should then conduct a comprehensive follow-up inspection inspection. , inspectioninspection to assess implementation of corrective actions. The follow up inspectioninspectioninspection, which may take place ahead of schedule if the identified limitations are considered serious, the actions will be taken as follows:

i. If the factory is found to have not taken any action to solve the problem or if there is proof that the noncompliance is intentional, action should be taken against the factory and this could vary from a written warning to legal action such as a fine and other actions as deemed necessary.

ii. If corrective actions are in process of being implemented, or new unrelated findings that require rectification are identified, continue

providing technical support and conduct more frequent follow up inspection.

1.3.2 Food outlets

1.3.2.1 Retailer, wholesaler or bakery:

a) At the retail and wholesale level, when a brand is not on the approved list or registered with the Authority to be marketed in the country, the product shall be seized and investigation started. When it is confirmed that the brand and/or premises are not registered, then the product should be confiscated.

b) In the case of bakeries, they shall prepare bread and other foods derived from wheat flour and oil, using only products that have been approved. If unauthorized product is found in a bakery, the case should be treated as described in (a) above.

c) If a brand is registered for commercialization, but it is expired or shows signs of spoilage or non-hygienic conditions, the case should be handled in accordance with the Tanzania Food and Drugs (Treatment and Disposal of Unfit Food) Regulations, 2006.

d) When a brand does not meet the minimum legal requirements (micronutrient content, labeling and packaging) as depicted in the fortification regulations, a warning letter shall be sent to the factory, packaging plant or importer responsible for the brand. Sampling priority should be given to these brands in future inspections. Extra inspection of the factories might be considered within the external monitoring activities.

e) If the brands belonging to a specific factory consistently fail to comply with the legal requirements, the Authority should consider organizing a comprehensive auditinspection and if there is proof that non-compliance is intentional; they should apply the prescribed legal actions, which may include the final disposal of the brand.

Note

Micronutrient testing is not carried out at this level; the food samples would be taken and sent by the inspectors of the local authority's food inspection to the regulatory authority together with the report forms.

1.5 Records and Reporting

The supervisor of inspection activities should keep records of the plan, schedule and estimated budget. This information has to be reported to the regulatory Authority.

SECTION 2: TECHNICAL AUDIT AND INSPECTION

2.1 Technical audit and Inspection of manufacturing facilities

This part presents steps for carrying out technical auditing and inspection in manufacturing facilities. The regulatory Authority is responsible for carrying out the auditing and inspection activities of manufacturing facilities approved to fortify food in coordination with the local authorities.

Technical auditing and inspection activities are carried out at manufacturing facilities as part of the enforcement activities performed by the regulatory Authority in order to ensure that fortified foods meets the nutrient quality and safety specifications established in regulations. During the technical audits, the performance of quality assurance and quality control activities conducted by the producer is examined. The conformity of the fortified food with technical specifications is determined through sampling and chemical analysis of fortified food samples collected from the factory. Samples of premix/fortification may also be taken to verify the validity of the Certificate of Analysis (COA) provided by the supplier.

Since technical audits and inspections are based on checking the producer's records, the objectives which are measured by indicators and criteria of success are based on similar objectives used for the QA/QC system. The guidelines also describe the people responsible for each stage. As any enforcement procedure carried out by a government body, the warnings and legal actions to be taken when non-compliance occurs should be defined and applied where necessary

2.1.1 Objective

The purpose of the technical audit and inspectioninspectioninspection is to verify that manufacturing premises have implemented and continuously apply a program for the:-

a) Quality assurance of the micronutrients compound receipt, storage and dilution.

b) Quality assurance of the products fortification process.

c) Quality control of fortified product

The Inspector should conduct audit and inspection of the premises and plan to spend an hour or two to make detailed examination of processes and verify documentation. The the audit and inspection should be conducted with the view to assist the factory perform better and the frequency of the inspection 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 inspection should be done on a monthly basis and be scaled down depending on the success of the fortification in the factory.

2.1.2 Accountability

The people directly responsible for achievement of these objectives are the Authority Inspectors, who should pass on the results of the inspection to their supervisor of

inspection activities. The Supervisor is responsible for preparing the reports to the factories and reporting every six months to the Head of the regulatory Authority.

2.1.3 Procedure

During the inspection, inspector(s) shall follow the procedures stipulated here under:-

2.1.3.1 Conducting opening session

a) Inspectors shall conduct opening meeting with the factory management which includes General Manager, Factory or Production Manager, Quality Assurance and Control department manager and Laboratory Manager.

b) During the meeting inspectors shall explain briefly the purpose and approximate duration of the inspection and that this will be carried out through reviewing of written procedures, records, personnel interviews, observation of the fortification process and taking some samples.

c) Inspector shall inquire from factory management if there are problems that are associated with the implementation of food fortification.

d) Inspector shall record name of attendants to the session in a format prescribed in form ***F1/TFDA/DFS/FI&E/GL/001*** of these guidelines

2.1.3.2 Conducting technical audit and inspection

The inspector (s) shall:-

a) Conduct technical audit and inspection with the aid of the checklist prescribed in form ***F2/TFDA/DFS/FI&E/GL/001 or F3/TFDA/DFS/FI&E/GL/001*** of these guidelines. As the audit and inspection takes place, record any non-compliance.

b) Review the non-compliances found during the last inspection (if any) and recommendations made. Assess the corrective actions and record the findings.

2.1.3.2 Sampling

At the end of audit and inspection, inspector shall take samples by using procedures stipulated under section 3 of these guidelines.

2.1.3.3 Preparation of preliminary report

Inspectors shall plan to dedicate adequate time to prepare the preliminary report on the major findings during the audit and inspection inspection. In the report, provide comments regarding the performance of the quality assurance and control procedures, opportunities for improvement and non-compliance if any in a format prescribed in from ***F4/TFDA/DFS/FI&E/GL/001*** of these guidelines.

2.1.3.4 Conducting closing session

At the end of audit and inspection inspection, the inspector shall;

a) Conduct closing session with the factory management by explaining the major findings presented in the preliminary report.

b) If non-compliances are found inform the general management about the actions to be taken.

c) Leave a copy of the preliminary report to the General Manager.

2.1.3.5 Transportation of sample

a) The inspector shall pack the samples in suitable tight containers, and transport them appropriately, protecting from exposure to heat, humidity and direct sun light.

b) Give the sample to the supervisor of inspection, who will in turn send them to the laboratory for analysis.

c) Once the analytical results are received, the supervisor of inspection shall analyze them and send a final report to the Factory Manager with some interpretation of the results and suggestions for corrective action where necessary.

2.1.3.5 Records and reporting

The supervisor of audit and inspection activities shall keep records which include inspection checklist, forms, preliminary & final reports and laboratory results etc. The final report shall be submitted to the regulatory authority on quarterly basis.

2.2 Inspection of food outlets

Inspection of food outlets is conducted in order to verify 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 edible oil and fats, maize flour and wheat flour. This monitoring allows for the detection in the market of brands that are not approved by the Authority 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 the inspection by inspectors for auditing and inspection are failing in enforcement. In such a situation there is a 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.

Inspection of food outlets is the responsibility of the regulatory authority, in cooperation with local authorities. Monitoring at this level should also involve local authority inspectors in carrying out audit and inspection inspection and taking of samples in their respective areas. Authority is responsible for preparing the sampling Plan and providing the technical training to carry out the inspections.

This part of guidelines describes the procedures for carrying out the inspection inspection at any retail store selling fortified foods. It also describes those responsible for each stage. As any enforcement procedure carried out by a governmental body, warning and legal actions should be given when non-compliances are observed.

Results of commercial monitoring activities should be consolidated in reports to be issued on quarterly basis. 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 in the country, along with information from other general food control or surveillance activities.

2.2.1 Objectives

The purpose of the inspection inspection to retail, wholesale stores and bakeries is to ensure that fortified foods circulating in the market comply with the set legal requirements for such products.

2.2.2 Accountability

The person directly responsible for achievement of this objective is the Authority Inspectors, who should pass on the results of the inspection to their supervisor of inspection activities. The Supervisor is responsible for preparing the reports to the respective product manufacturing facility or importer of such fortified food and report every six months to the Head of the regulatory Authority.

2.2.3 Procedure

During the inspection, inspector(s) shall follow the procedures stipulated here under:-

a) When inspectors arrive in the villages, towns or cities, they should inspection the most popular food outlets where people buy their food supplies.

b) Inspectors should enter the store and show their credentials identifying them as inspectors of the Authority. They should follow on with a brief explanation about the purpose of the inspection.

c) Inspectors should be able to identify the approved fortified brands sold in the store by using format prescribed in *form* ***F5/TFDA/DFS/FI&E/GL/001*** of these guidelines.

d) Take samples of approved fortified foods and conduct spot test for iron and where necessary, take samples for quantitative analysis at TFDA head quarters. They should fill in the form ***F5/TFDA/DFS/FI&E/GL/001*** of these guidelines

e) Choose a sealed packaged of about 500gm or 500ml of each brand of each fortified food in the store. If the food is not available in such quantities, take the nearest larger retail-size presentation. If packages are much smaller, collect sufficient packages to make up the specified weight; (e.g. 2 packages of 250 gm).

f) If the food is sold by weight or volume from large sacks or a barrel, take approximately 500gm or 500ml sample from this food product.

g) Ensure that the sack or the barrel is new; otherwise there is no guarantee that the product inside corresponds to the factory name in the container.

h) Mark the samples appropriately, pack in a box and transport them to the local Food Control office, which in turn sends copies of report and the samples to the Authority on quarterly basis.

2.2.4 Analysis of the samples

Samples from the inspection will be analyzed

a) Upon receipt of the samples, the laboratory should first detect the presence of the key micronutrients in all single samples using qualitative tests.

b) Composite samples based in brand are then prepared by mixing equal amounts (approximately 500 g or 100 mL) of the single positive samples. Up to 5 single samples may be mixed in the same composite sample.

c) Quantitative determinations are then carried out for key micronutrients.

d) 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 acceptable level (see ***F6/TFDA/DFS/FI&E/GL/001*** of these guidelines for an example).

e) Laboratory reports are sent to the supervisor of food inspection responsible for the food fortification programs that will send a copy to the supervisor of food control in the corresponding local office.

2.2.5 Records and reporting

The supervisor of inspection activities shall keep records which include forms and spot-test and laboratory analytical results. The supervisor should prepare consolidated reports for inspection carried out in food outlets in a format prescribed in ***F9/TFDA/DFS/FI&E/GL/001*** on quarterly basis and submit the same to the Authority.

Note

Once laboratory results are received, these are compared with the producer's records. Remember that the results from the mill were obtained using a semi-quantitative method, while the National Laboratory uses a quantitative method. Therefore, some variation between the two results is expected

SECTION 3: INSPECTION BY CORROBORATING TRIALS

3.1 Objectives

The purpose of corroborating trials is to ensure that:-

a) All samples indicate the presence of micronutrients indicators based on the qualitative tests.

b) 80 % of samples contain micronutrients with specified regulatory levels as set in the regulations for fortification.

c) The micronutrients compound samples comply with the specification established for it.

3.2 Procedure for sampling at maize and wheat flour manufacturing facilities

3.2.1 Fortificant/ Premix

Take a 50g sample of the fortificant/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 indicated, and date of sample collection.

3.2.2. Daily composite samples

a) Before the inspection inspection ends, go to the laboratory and check that "daily composite samples" for the last 30 working days are appropriately stored.

b) Choose three daily composite samples at random. In form ***F6/TFDA/DFS/FI&E/GL/001*** of these guidelines write down the production date, estimated iron level, and any other information provided on the sample identification.

3.2.3 Samples from production or storage warehouse

Take two more samples per type of flour being produced that day or from the storage warehouse.

3.2.3.1 Samples from production

a) In the packaging area, the inspector should take 500 g of flour from any bag before weighing and sealing.

b) Repeat step (a) every 10 minutes until 8 samples have been collected.

c) Ask personnel of the mill to help for the verification of the presence of iron in each sample, using the spot-test method.

d) Mix equal amounts of each of the 8 samples to produce a composite sample from production.

3.2.3.2 Samples from storage warehouse

a) Collect 8 samples of 500g each from stores warehouse by selecting bags at random.

b) Verify the presence of iron in each sample.

c) Combine and mix well the 8 samples to produce a composite sample from store.

3.2.4 Homogenization and labeling of composite samples

a) Homogenize all five composite samples and divide each one of them into three portions of 500g.

b) Pack the samples in dark containers and close them tightly. The configuration of samples collected during the inspection is as follows

i. 3 samples, in triplicates, from daily samples kept for the month

ii. 1 sample, in triplicate, collected from production of the day

iii. 1 sample, in triplicate, collected from stored flour in warehouse store

iv. 1 sample of the fortificant/premix used on the day of the inspection.

c) Label each sample with the following information:

i. Name of the factory

ii. Date of inspection

iii. Lot/batch number

iv. Sample ID or sample number

d) The three 500g portions prepared in (a) above are divided as follows:

i. One sample kept for reference by the flour mill laboratory

ii. One sample sent to the Authority to be kept for reference

iii. One sample sent to the laboratory for quantitative testing.

e) The inspector shall hand in the auditing/inspection forms and the samples collected to the Supervisor of Food Inspectors.

3.2.5 Records and reporting (Supervisor of inspectors)

a) The supervisor of the Inspectors shall receive the samples and the report from inspectors.

b) The fortificant/premix samples shall be sent to the laboratory to determine the type and level of micronutrient for confirmation.

c) Record the results from the laboratory in the corresponding section in form ***F6/TFDA/DFS/FI&E/GL/001*** of these guidelines.

d) When results are received from the laboratory, compare them with producer's records. Remember that the results from the producer were obtained using semi quantitative methods while the laboratory uses quantitative method. Therefore some variation between the two results is expected. However, if results differ greatly, for example, iron level reported quantitatively was less than the legal minimum and the daily estimated average was greater than 20 mg/kg, the cause of such discrepancy should be investigated.

e) Analyze the results and complete the report. The analytical results for ALL five samples should be randomly distributed within acceptable range, 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 inspection. Prepare letters to advise the inspected factories of the problem.

f) Prepare a consolidated report every three months and submit it to the Director General of the Authority. These reports shall also be forwarded to the National Food Fortification Alliance.

3.3: Procedure for sampling at edible oil and fats factory

3.3.1 Fortificant

a) Take a 30g 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 of sample collection.

b) Before the inspection is finished, go to the laboratory and check that "daily composite samples" for the last 30 working days are adequately stored.

c) Choose three daily composite samples at random. Fill in form ***F6/TFDA/DFS/FI&E/GL/001*** of these guidelines write down the production date, estimated Vitamin A level and any other information labeled on the sample ID.

3.3.2 Samples from production or storage warehouse

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

3.3.2.1 Samples from production

a) In the packaging area, the inspector should collect one bottle of oil from production. Collect one retail-size bottle or at least 0.5l before packaging and sealing.

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

c) Mix equal amounts of oil (200mL or 200g) of each of the 8 samples and mix well to produce a composite sample from production.

3.3.2.2 Samples from storage warehouse

a) Collect 8 samples from stores warehouse by selecting retail size containers at random. Collect at least 200g (or 200mL) from each container and mix well the 8 samples to produce a composite sample from storage warehouse.

b) Try to obtain the samples at random and where retail packs are not available collect 200g from available containers.

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

3.3.3 Homogenization and labeling

a) Divide all composite samples into three portions of 0.5L. Pack the samples in dark containers and close them tightly.

b) Label the triplicates of each sample with the following information:

   i. Name and address of the factory;
   ii. Product brand;
   iii. Date of inspection;
   iv. Lot/batch number; and
   v. Sample ID or number if any.

c) The three portions are divided as follows:

   i. 1 sample kept at the factory for reference
   ii. 1 sample sent to the Authority for reference
   iii. 1sample is sent to the laboratory for quantitative testing.

d) 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 the inspection supervisor.

3.3.4 Records and Reporting

Supervisor of Inspectors shall:-

a) Receive the samples and the report brought by inspectors from the inspection . Send the samples identified with a code number (do not send original information) to a Reference Laboratory.

b) When results from the laboratory are received, record the results from the laboratory in form ***F6/TFDA/DFS/FI&E/GL/001*** of these guidelines**.** 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.

c) Analyze the results and complete the report. The analytical results for ALL five samples should be randomly distributed within acceptable range, 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 . Prepare letters to advise the inspected factories with the problem.

d) Prepare a consolidated report every three months and submit it to the Director General of the Authority. These reports shall also be forwarded to the National Food Fortification Alliance.

SECTION 4: MONITORING OF FORTIFIED FOODS AT THE PORTS OF ENTRY

4.1 Objectives

The purpose of monitoring fortificants and fortified foods prior to authorization for entry is:-

a) To ensure that the imported products are accompanied by adequate documentation to certify that national standards and regulations are being fulfilled.

b) To confirm that the food complies with fortification requirements based on the presence of one or more key micronutrients in the imported fortified food.

4.2 Accountability

Supervisor of food inspection activities at the port of entry should ensure that the following tasks are performed; collection of samples, testing and reviewing documentation before the food can be allowed to enter the country.

4.3 Procedures

4.3.1 Reviewing the Certificate of Conformity or Certificate of Analysis and Labeling

The food inspector shall perform the following duties:-

a) Review the documents that usually certify the safety (and sometimes quality) of the imported product. Examine the Certificate of Conformity or Analysis, issued by a government authority or an officially recognized body from the country of origin, which would declare –supported by laboratory analysis- that the food fulfills the regulations established in the importer country.

b) Examine the packaging and the labeling to make sure that it indicates the brand name, batch number, country of origin and name and address of manufacturer. The food must comply with labeling requirements established in the regulations for fortified foods. Inspectors should also look out for false health claims that may be contrary to set recognized standards. They should record data in form F7 ***/TFDA/DFS/FI&E/GL/001*** of these guidelines.

4.3.2 Confirming the presence of indicator micronutrients

a) From each consignment randomly collect three representative samples of imported fortified food. Divide each sample into three portions (500g or 100ml per sample).

b) Collect samples based on brand names and perform spot test and record results in form ***F8/TFDA/DFS/FI&E/GL/001*** of these guidelines.

4.3.3 Taking decisions to authorize

a) All samples should test positive for the indicator micronutrient.

b) If samples fail the qualitative test or fail to comply in terms of proper documentation and labeling requirements, the affected brand should not be allowed to enter the country.

c) If documentation is correct, and samples show the presence of the key micronutrient, authorize importation.

4.4 Records and Reporting

The inspector at port of entry shall duly complete inspection form in a format prescribed in form ***F7/TFDA/DFS/FI&E/GL/001*** of these guidelines and submit the report to the head of inspection.

BRIEFING SESSIONS ATTANDANCE - DURING TECHNICAL AUDIT AND INSPECTION

Date: _____ **SECTION 5: ANNEXES**

Premises name: _____
Postal address: _____

F1/TFDA/DFS/FI&E/GL/001

Revision # 1

	NAME	POSITION	SIGNATURE

CHECKLIST FOR INSPECTION OF MAIZE/WHEAT FLOUR MANUFACTURING FACILITIES

Inspection registry:
Name of the facility: .....
Postal address
Physical address
Tel. ..... Fax .....

ASPECTS	MARKS		REMARKS
	ALOCATED	SCORED	
1.1 Cleaning and sanitation			
1.1.1 Production area	2		
1.1.2 Packaging area	2		
1.1.3 Warehouse	2		
1.1.4 Staff facilities and toilets	2		
Sub total	**8**		
1.2 Personnel			
1.2.1 Hygiene as required in regulations	2		
1.2.2 Wearing protective clothing	2		
1.2.3 Trained in the task they perform	2		
Sub total	**6**		
1.3 Written procedures or instructions for:-			
1.3.1 Receipt and storage of premix	2		
1.3.2 Premix dilution (if applicable)	2		
1.3.3 Feeder verification	2		
1.3.4 Sampling of flour for QC	2		
1.3.5 Iron spot test for flour	2		
Sub total	**10**		

ASPECTS	MARKS		REMARKS
	ALOCATED	SCORED	
2. Micronutrient premix			
2.1 Premix inventory is up date	2		
2.2 Certificate of Analysis is received per lot	3		
2.3 Premix is stored under adequate conditions	2		
2.4 "First-in-first out" system in place	2		
2.5 Premix is handled well in fortification site	3		
Sub total	**12**		
3. Flour fortification			
3.1 Premix dilution (if applicable)			
3.1.1 Homogeneity assessed	4		
3.1.2 Adequate storage and handling	4		
3.2 Records of feeder performance available	4		
3.3Premix level in feeder adequate during inspectioninspection	4		
3.4 Records of flour produced/premix used up date	3		
3.5 Flour sample taken for analysis in every shift	4		
3.6 Corrective actions taken when:-			
3.6.1 Ratio flour produced/premix not right	4		
3.6.2 Iron content above factory minimum	4		
Sub total	**31**		
4 Fortified flour			
4.1 Records of flour samples analyzed using	4		
4.1.1 Spot test for iron	4		
4.1.2 Qualitative methods Iron (external lab)	4		
4.1.3 Quantitative method Vit. A (external lab)	4		
4.2 Daily composite sample are prepared	4		
4.3 Last 30 samples are stored and available	4		
4.4 Labeling meets specifications	3		
4.5 Fortified flour is store adequately	4		
4.6 “First-in-first out” system applied to dispatch	2		
Sub total	**33**		

ASPECTS	MARKS		REMARKS
	ALOCATED	SCORED	
GRAND TOTAL	**100**		
IMPLEMENTATION			

B. Actions taken from recommendations of last technical audit /inspection inspectioninspection

Recommendations	Corrective actions	Assessment of corrective action		
		(v)	**(x)**	Comments

C: New Observation (s)

Non-compliances:	Actions to be taken

D: list of samples taken for corroborating tests

Composite sample ID	Factory estimation [Iron] (mg/kg)	Lab. Results from inspection[2]				
		[Iron] (mg/kg)	[Vit.A] (mg/kg)	[Vit B_{12}](mg/kg)	[Folate] (mg/kg)	[Zinc] (mg/kg)

Name and Signature **Name and Signature of Owner/Agent**

CHECKLIST FOR INSPECTION OF EDIBLE OIL AND FATS MANUFACTURING FACILITIES

Inspection registry:
Name of the facility: .....
Postal address
Physical address
Tel. ..... Fax .....

ASPECTS	MARKS		REMARKS
	ALOCATED	SCORED	
1.1 Cleaning and sanitation			
1.1.1 Production area	2		
1.1.2 Packaging area	2		
1.1.3 Warehouse	2		
1.1.4 Staff facilities and toilets	2		
Sub total	**8**		
1.2 Personnel			
1.2.1 Hygiene as required in regulations	3		
1.2.2 Wearing protective clothing	2		
1.2.3 Trained in the task they perform	2		
Sub total	**7**		
1.3 Written procedures or instructions for:-			
1.3.1 Receipt and storage of premix/fortificants	2		
1.3.2 Premix dilution (if applicable)	2		
1.3.3 Feeder verification	2		
1.3.4 Sampling of oil for QC	2		
1.3.5 Test for retnol in oil	2		
1.3.6 Sufficient for the following 3 months	2		

ASPECTS	MARKS		REMARKS
	ALOCATED	SCORED	
Sub total	**12**		
2. Micronutrient premix			
2.1 Premix inventory is up date	2		
2.2 Certificate of Analysis is received per lot	3		
2.3 Premix is stored under adequate conditions	2		
2.4 "First-in-first out" system in place	2		
2.5 Premix is handled well in fortification site	3		
Sub total	**12**		
3. Oil fortification process			
3.1 Premix dilution (if applicable)	4		
3.1.1 Homogeneity assessed	4		
3.1.2 Adequate storage and handling	4		
3.2 Equipment is routinely checked	4		
3.3 Records of oil produced/premix used up date	4		
3.4 oil sample taken for analysis in every shift	4		
3.5 Corrective actions taken when:-			
3.5.1 Ratio oil produced/premix not right	4		
3.5.2 Micronutrients level complies with Specifications	4		
Sub total	**28**		
4 Fortified oil			
4.1 Records of oil samples analyzed using	4		
4.1.1 Semi- quantitative test	4		
4.1.2 Qualitative methods Iron (external lab)	4		
4.1.3 Quantitative method Vit. A (external lab)	4		
4.2 Daily composite sample are prepared	4		
4.3 Last 30 samples are stored and available	4		
4.4 Labeling meets specifications	3		
4.5 Fortified oil is store adequately	4		
4.6 "First-in-first out" system applied to dispatch	2		
Sub total	**33**		
GRAND TOTAL	**100**		

B. Actions taken from recommendations of last technical audit /inspection inspectioninspection

Recommendations	Corrective actions	Assessment of corrective action[1]		
		(v)	(x)	Comments

C : NEW OBSERVATION(S)

Non-compliances:	Actions to be taken

D: LIST OF SAMPLES TAKEN FOR CORROBORATING TESTS

Composite sample ID	Factory estimation [Iron] (mg/kg)	Lab. Results from inspection[2]	
		[Vit.A] (mg/kg)	[Vit E](mg/kg)

Name and Signature
……

Name and Signature of Owner/Agent
……

PRERIMINARY REPORT FORM

Inspection No. _____	**Date of Inspection: _____**
Premises name: _____	**Address: _____**

PRELIMINARY REPORT

1. Areas inspectioninspectioned

☐ Production ☐ Packaging ☐ Fortification site ☐ Laboratory

☐ Final product warehouse ☐ Raw material warehouse ☐ Other: _____

2. Non – compliances . (List of non-compliances found)	**3. Ordered corrective actions/Actions taken**
Inspector	**Premises representative**
Name: _____	**Name: _____**
Signature: _____	**Signature: _____**
Date: _____	**Date: _____**

COLLECTION OF SAMPLES IN FOOD OUTLETS

Date: _____ Place: _____, District: _____, Region: _____

Outlet Name: _____ Address: _____

Sample No.	Common Name	Brand	LABELING INFORMATION					OBSERVATIONS
			Forti. Logo	Name and Address of Manufacturer	Lot No.	Exp.date	Health/Nutrition claims	

Name of Inspectors
1.....
2. .....

signature
.....
.....

LABORATORY REPORT OF MICRONUTRIENT ANALYSIS OF FOOD OUTLET SAMPLES

Region _____ **District:** _____

Brand	Common name	No. of samples tested	Single Positive samples		Composite samples (mg/kg)			
			No.	%	No.	< min	Min – T. Max	> Tol. Max

Report date: _____ **Inspectors name:** _____ **Signature:** _____

REPORT OF INSPECTION AT THE PORTS OF ENTRIES

NAME OF POE &ADDRESS .....

.....

TEL ..... FAX .....

Date	**Common Name**	**Brand**	**Country of origin**	**Amount (MT)**	**Tested Micronutrient**		**Qualitative test (+ or -)**	**Action taken**
					Iron	Vit. A		

Name of Inspectors
1.....
2. .....

signature
.....
.....

IMPORT INSPECTION FORM

DATE:_____**STATION:** _____ **DISTRICT:** _____

Inspector Name:		Supplier Address:	Batch No and size (MT):
Product:	Brand:		Variety of food:
Country of Origin:			Certificate of conformity
Shipping Record ID:			
		Importer: Name and Address:	
Product Examination			
	Adequate	**Inadequate**	**Comments**
Brand Name			
Manufacturer			
Nutrients claims			**SPECIFY NUTRIENTS:**
Expiry Date			
Presence of nutrient			Based on qualitative test on three samples per consignment
Action:			**Signature:**

CONSOLIDATED REPORT FOR SAMPLE COLLECTED FROM FOOD OUTLET

COMMON NAME	BRAND NAME	MANUFACTURER	No. of sample teste	Results						Remarks
				Below min requirement		Within requirements		Above max. requirement		
				No.	%	No.	%	No.	%	