



East, Central and Southern Africa Health Community
Fostering Regional Cooperation for Better Health

Guidelines for Internal and External Monitoring of fortified Edible Oil, Salt, Sugar, wheat flour and maize flour

Technical Audit and Inspection

Second Edition 2020

Foreword

ECSA-HC has been working with partners in direct response to resolutions of the Conference of Health Ministers to scale up Food Fortification initiatives as a critical strategy in managing micronutrient malnutrition among populations of the member states.

Part of the outcome of the intensified collaborative initiatives, was the development of ECSA food control manuals to enhance monitoring and inspection of the fortified food vehicles and smooth implementation of the national food fortification programs.

During The Food Fortification workshop held in Arusha-Tanzania in September 2015, three working groups through which the ECSA capacity building initiative co-implemented by ECSA-HC and GAIN and supported by USAID formed:

- i) Production, Food Safety and Quality Assurance/Quality Control;
- ii) Inspection and Enforcement; and
- iii) Consumption Monitoring and Program Impact. The groups were tasked with identifying capacity and resource gaps and propose ways of filling these gaps in each of the technical areas. Subsequently, they identified priority activities, targets, and developed road maps on how the activities would be implemented to achieve the set targets. Target 2 of the Inspection and Enforcement Working Group was to review the Regulatory Monitoring Frameworks used by countries in the Region. To inform this review, a workshop was organized for this group at the Imperial Resort Beach Hotel in Entebbe, Uganda from the 7th to 10th November, 2016. Its aim was to review the existing guidelines (that countries are using) for gaps and weaknesses and use recommendations from this review to develop a harmonized and practical guideline that all countries can adopt and apply in inspection of fortified

foods and specialized nutritional products. A key recommendation of the Entebbe workshop was that the inspection manuals be merged and be developed into two guidelines namely internal and external monitoring of fortified foods and that of commercial and points of entry inspection guidelines.

This guideline on internal and external monitoring of fortified Edible Oil, Salt, Sugar, wheat flour and maize flour is one of guidelines on food fortification monitoring and is meant to directly contribute to the overall effort to strengthen food fortification in the region.

It is our hope that the use of this guideline will help strengthen food control activities in our countries in order to deliver safe and quality fortified foods to the ECSA population.

Director General

East, Central and Southern Africa-Health Community

Acknowledgement

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During the development of these guidelines, consultations with food control departments and National Standards Bodies of the following ECSA countries were made and input incorporated: Burundi, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Rwanda, Swaziland, South Africa, Tanzania, Uganda, Zambia and Zimbabwe

The guidelines were developed by Dormus Food Safety System Consultants

ECSA is deeply thankful to the above consultants for preparing this manual.

Disclaimer

The content of these guidelines can be adapted to suit country specific contexts. In such a case, the content of the resulting document will be the sole responsibility of the organization adapting the guideline and will not represent the views of the consultants and that of the ECSA-HC. The Use of the content of these guidelines should be duly acknowledged.

Table of Content

Foreword.....	ii
Acknowledgement	iv
Acronyms and Abbreviation	viii
Introduction.....	ix
1.0 Scope of the guidelines	1
2.0 Normative references	2
3.0 Terms and Definition	3
4.0 Requirements for monitoring, inspection and audits	5
4.1 General requirements for monitoring, inspection and audits	5
4.1.1 Planning for monitoring, inspection and audit activities	5
4.1.2 Budgeting for monitoring, inspection and audit activities	5
4.1.3 Scheduling of monitoring, inspection and audit activities	6
4.2 Internal Quality Assurance/ Quality Control	6
4.2.1 Objectives of internal quality control	6
4.2.2 Management of Premix or fortification compound quality	7
4.2.3 Quality control during production	8
4.2.3.1 Guideline on salt iodization	8
4.2.3.2 Guideline on Vitamin A fortification in sugar and oil	9
4.2.3.3 Guideline on fortification of maize flour	10
4.2.3.4 Guideline on fortification of wheat flour.....	11

4.3 External Monitoring.....	12
4.3.1 Technical audit	12
4.3.2 Inspection.....	14
4.4 Sampling of products	15
4.4.1 Sampling at production site	15
4.4.2 Sampling at the warehouse	16
5.0 Methods of test.....	18
Annex A1 (Normative): ECSCA-HC fortification level.....	19
Annex A2: (Normative) Test Methods	20
Annex B (informative): Gantt chart for scheduling activities.....	21
Annex C (informative):.....	22
Premix/fortificants inventory log	22
Annex F (informative): Audit Attendance List	25
Annex G (informative): Audit Check List	26
Annex H (informative): Sample Collection form	27
Bibliography	28

Acronyms and Abbreviation

CAR	Corrective Action Report
COA	Certificate of Analysis
ECSA – HC	East, Central and Southern Africa – Health Community
GAIN	Global Alliance for Improved Nutrition
FIFO	First In First Out
HACCP	Hazard Analysis Critical point
ID	Identification Number
ISO	International Organization for Standardization
MT	Metric Ton

Introduction

Internal and external monitoring of fortified food products are critical components in ensuring compliance to set standards and/or regulations. The success of the monitoring activities heavily relies on how the two monitoring complement each other.

The food processing industry play a key role in the food fortification program because they are responsible for making sure that the product contains the micronutrients in the specified amounts and properties. Internal Quality control and assurance activities are thus vital to ensure that the fortified food products meets and maintain the requirements established in regulations and/or standards. Internal Quality assurance and quality control (QA/QC) for fortified foods does not require the implementation of a new program in factories, but only to incorporate into the ongoing QA/QC procedures those aspects that are specific to food fortification.

In a similar way, food control regulators are expected to perform inspection and or audits at the industry as part of enforcement of the regulations and standards so as to assure safety and quality of fortified foods to the standards and /or regulations.

The internal and external monitoring activities should be carried in a similar manner so as to enable both parties appreciate any action taken during the monitoring. These guidelines are therefore developed in to ensure that those responsible for internal and external monitoring perform quality monitoring in a similar manner and that either party is clear on what to expect from each one. The guideline provides a common sampling method for both which may be adapted to meet the specific need of any party. The annexes provided in these guidelines are purely informative. Test methods are not part of these guidelines but available in separate publication of ECSA-HC manuals of laboratory methods for fortified foods which are normatively referenced to these guidelines.

GUIDELINES FOR INTERNAL AND EXTERNAL MONITORING OF FORTIFIED EDIBLE OIL, SALT, SUGAR, WHEAT FLOUR AND MAIZE FLOUR

1.0 Scope of the guidelines

1.1 These ECSA-HC guidelines on internal and external monitoring are intended for use by the food production industry for their internal quality assurance/control as well as by regulators to monitor, inspect and audit fortified edible oils, salt, sugar, wheat flour and maize flour products.

1.2 The guidelines are **not** applicable for commercial monitoring at the points of entry (border points) as well as at market level monitoring

1.3 These guidelines excludes test methods which are provided in separate ECSA manuals on laboratory methods for fortified methods Parts I, II and III.

2.0 Normative references

In application of these guidelines, ECSA-HC 2007 guidelines for fortification level of Edible Oils & Fats, Edible Salt, Sugar, Wheat flour and Maize flour as annexed to these guidelines as **annex A1** and ECSA-HC Manuals of laboratory methods for fortified foods as listed in **annex A2** are indispensable. Where the guidelines have been adopted or adapted by countries, the relevant national standards and/or technical regulations should be used as the normative references.

3.0 Terms and Definition

For the purposes of these guidelines the following terms and definitions shall apply

3.1 Internal monitoring:

Are in-house quality assurance and control processes that are undertaken by the manufacturing firm so as to ensure compliance of their products to the required fortification levels.

3.2 External Monitoring

Are inspections or audits activities undertaken by relevant government regulatory authorities with the aim of confirming the compliance of fortified food products to the national standards and/or technical regulations.

3.3 Fortification levels

Are the approved and published micronutrient addition levels for the various food vehicles in a country or as adopted by the industry.

Note: Industry may apply different levels depending on its efficiency but the levels should be within the legal minimum and maximum as published by the government. In absence of published levels at country level, industry should use the ECSA guidelines as legal minimum and maximum.

3.4 Inspectors

Are government officials mandated by law to perform external monitoring.

3.5 Inspection

Is the planned or impromptu visit by inspectors to an industry to check and confirm the compliance of the industry to products, hygiene or relevant applicable standards or regulations.

3.6 Technical Audit

Is a scheduled process of systematic examination of the quality system by an external (third party) auditor so as to assure the system's ability to consistently comply to the national standards and/or regulations.

3.7 Training Need Analysis

Is the process of identifying the skill gap and ensuring the relevant training is planned and undertaken

4.0 Requirements for monitoring, inspection and audits

4.1 General requirements for monitoring, inspection and audits

4.1.1 Planning for monitoring, inspection and audit activities

4.1.1.1 Planning for both internal and external monitoring, audits and inspections ensures that enough resources are allocated to fully implement the monitoring and inspection activities.

4.1.1.2 Planning should identify among other things:

- a) The sector, site or department where the monitoring, inspection and audit activities will be done;
- b) The monitoring, inspection or audit activities to be done;
- c) Period and frequency when the monitoring, inspection or audit activities should be undertaken;
- d) The human and equipment capacities required to undertake the activities e.g. number of personnel, transport costs, analysis to be done;
- e) Training need analysis for personnel expected to undertake the monitoring, inspection or audit activities; and
- f) The reporting format for the monitoring, inspection or audit activities by the personnel.
- g) The above recommendations should be documented as an activity plan.

4.1.2 Budgeting for monitoring, inspection and audit activities

4.1.2.1 Sufficient financial resources should be allocated for the implementation of either internal and external monitoring, inspection or audit activities.

4.1.2.1 The allocation of resources should be based on the activities and requirements identified during the planning phase and frequency of the monitoring, inspection or audit activities as identified in the schedule.

4.1.3 Scheduling of monitoring, inspection and audit activities

4.1.3.1 A schedule indicating the period and the personnel responsible for monitoring, inspection or audit activities should development and documented for either internal and external monitoring, inspection or audit activities.

4.1.3.1 However, in the case of external inspection, the schedule should be flexible enough to allow for impromptu inspections or increasing frequency of inspection in cases where there are high noncompliance or where audit activities indicates risks within the quality system. A Gantt chart as informatively annexed as **annex B** may be used for the scheduling of the monitoring, inspection or audit activities

4.2 Internal Quality Assurance/ Quality Control

4.2.1 Objectives of internal quality control

The objectives of internal quality control are to ensure that:

- a) The factory has enough stock of premix or fortification compound within its premises to assure continuous fortification without being affected by the possibility supply delays. The stock held should be based on company estimates and procurement system;
- b) Premix or fortificant are stored under adequate condition and the old stock is exhausted on priority (FIFO);
- c) The premix or fortification compound is used as recommended e.g. appropriate dosage rate, proper dilution where necessary such as the case of iodine compound;
- d) The equipments used such as dosers, weighing scales are appropriately calibrated to ensure the right amounts of premix or fortification compounds are used;

- e) The premix or fortification compound maintains the required characteristics to facilitate proper fortification e.g. for the case of premix it should be free flowing without lumps or liquid state for Vitamin A in oils;
- f) Proper documents are developed and clear records generated, used to inform quality control and maintained; and
- g) Quality and safe products that are adequately fortified are supplied to consumers.

4.2.2 Management of Premix or fortification compound quality

The internal quality system should ensure that:

- a) Any new premix or fortificant received at the factory is hermetically sealed at the point of receiving. Any unsealed or tampered packages should be rejected;
- b) All premix or fortificant received is accompanied by material safety data sheet and a Certificate of Analysis (COA) indicating the results of micronutrient profile and the shelf life of the premix/fortificants. This record should be maintained for at least to the exhaustion of the premix/fortificants;
- c) The factory on random basis should draw a sample of the premix/ fortificant and perform a quantitative analysis either using an internal or external laboratory to confirm the content of micronutrients in the premix or fortificant. This test can also be done where the factory procured large volumes and have stayed long before being exhausted;
- d) A proper schedule of movement of premix or fortificants to and from store is handled in a 'First In First Out' (FIFO) principle or any other principle that will ensure the premix/fortificants do not keep long in the store;

- e) Records of dispatches to the production, including at least but not limited to the type of fortificants/premix; date of production; shift (time); lot number where applicable and amount issued should be kept as shown in **Annex C**
- f) Premix/fortificants should be stored in clean dry area and away from chemical products or other potential contaminants and in the recommended temperatures. Any opened premix/fortificants containers should be tightly closed to minimize exposure to air and light.

4.2.3 Quality control during production

The internal quality control should ensure that:

- a) The calibration of the equipment is updated accordingly. Records of calibration shall be maintained. A schedule of inspection of the equipment as shown in **Annex D** at least on a weekly basis and record of finding should be kept;
- b) As scheduled during a production shift, for both continuous and batch processing, the dosage should be inspected /verified to ensure that it is correct and records maintained;
- c) A production log should be kept indicating as a minimum the time and date of production, amount of product produced, amount of premix/fortificants used and product/premix ration and the name/officer responsible as shown in **Annex E**.

4.2.3.1 Guideline on salt iodization

Iodine is usually carried in various forms such as potassium iodide and potassium iodate. The iodide form is more soluble than iodate form though its stability is less than that of iodate in a product whose moisture content is above 1 % with iodate remaining stable even at moisture content of up to 5 %. It is based on this stability that potassium iodate is the recommended form for fortifying salt with iodine.

There are two processes used in iodating salt namely

a) Dry mixing/ Batch processes

This is the common method used by small scale salt refineries in which iodization is done in small batches

A premix is prepared for dry mixing by mixing potassium iodate with a filler such as calcium carbonate or salt usually in a ratio of 1:9 (i.e. 1 part of iodate salt with 9 parts of the filler). This premix will result to iodine content of about 60 g/kg. The resultant premix should be clearly labeled before storage with information such as name as iodate premix, declare content of iodine (60 g/kg) and date.

b) Wet mixing/ spray mixing process

This is the common method used in large salt refineries where iodate solution is sprayed on salt either on a conveyor belt or in batches and then thoroughly mixed before packaging.

In determining the flow rate of the premix from the sprayer, the following equation may be used

$$\text{Flow Rate (liter/hr) of premix solution} = \{ \text{Mass of salt to fortify (ton/hr)} \times \text{Fortification level (mg/kg)} \} / \text{Iodine conc. in premix solution (g/L)}$$

4.2.3.2 Guideline on Vitamin A fortification in sugar and oil

In sugar fortification, the ratio of sugar produced (MT) to premix used (kg) should be as close to 2.0 (or 1,000 if ratio is expressed in terms of 50 kg – bags of fortified sugar per 25 kg bags of premix) as possible where the target is 7.5 – 8.0 mg/kg in the final product.

To ensure the feeder is discharging the correct amount, in the beginning of shift, the amount discharged per minute is collected on three different times and weighed. A coefficient of variation of the three portions should not exceed 5 %. This amount is compared to the theoretical expected discharge at g/min. If there is a significant difference, adjustment should be done to the feeder.

In oil fortification, the amount of fortificants to be added should be calculated. The equation below may be used

$$\text{Fortificant (g/MT)} = \left\{ \frac{\text{Average targeted Vit. content in oil (mg/kg)}}{\text{Vit. A content in Fortificant (g/kg)}} \right\} \times 1000$$

Using the fortificant calculated above, make a first dilution by adding it to blending tanks and mix adequately before discharging to the fortification tank. The mixing in premix blending tank is deemed adequate when the difference in test results taken at different times is less than 10 %.

4.2.3.3 Guideline on fortification of maize flour

The small scale millers are usually faced with a challenge of using available premix in the market which is usually in high concentration. The millers should therefore use a diluted premix aiming to achieve a 10g to 30 g pre-blend per kilogram of maize flour. This will result to dilutions of 1:33 to 1:100.

To achieve this dilution, a two steps dilution process should be done where for example in a premix whose addition rate is given as 200 g/MT, a pre-blend should be prepared by adding 1 kg of the premix to 50 kg of flour. This will achieve a dilution of 1:51. Add 2.5 kg of the pre-blend to 250 kg of flour. This will result to a dilution of 1:101 which can now be used in fortifying flour at a rate of 30 g /Kg of flour. If the pre-blend is to

be stored, it should be properly packaged and labeled with at least the name as 'pre-blend', addition rate in g/kg and date of manufacture/expiry.

In large scale milling where pre-blends are used, the amount of premix to be added in g/MT should be calculated by multiplying the amount expressed in the fact sheet from the premix supplier by the dilution factor used for preparing the diluted premix in the mill.

In the start of any shift and at determined interval of the schedule for internal control, the feeder/doser discharge rate should be verified by collecting samples at discharge on three different times and weighed. A coefficient of variation of the three portions should not exceed 5 %. This amount is compared to the theoretical expected discharge at g/min. If there is a significant difference, adjustment should be done to the feeder.

To ensure proper fortification, the internal quality control may perform semi quantitative test on samples collected every hour of production such as iron spot test as described in **annex F**

4.2.3.4 Guideline on fortification of wheat flour

Where pre-blends are used, the amount of premix to be added in g/MT should be calculated by multiplying the amount expressed in the fact sheet from the premix supplier by the dilution factor used for preparing the diluted premix in the mill.

In the start of any shift and at determined interval of the schedule for internal control, the feeder/doser discharge rate should be verified by collecting samples at discharge on three different times and weighed. A coefficient of variation of the three portions should not exceed 5 %. This amount is compared to the theoretical expected discharge at g/min. If there is a significant difference, adjustment should be done to the feeder.

To ensure proper fortification, the internal quality control may perform semi quantitative test on samples collected every hour of production such as iron spot test as described in **annex F**

4.3 External Monitoring

4.3.1 Technical audit

The purpose of technical audit is mainly to confirm that the factory being audited has a working quality system that is able to produce and sustain the quality of the products to be in compliance with the national standards and/or regulations. Technical audits should be performed by qualified personnel .

The primary focus in audits is confirming that the firm is in compliance with relevant legal requirements, has proper documentation and records management and that their procedures/manuals/records will assist the factory to comply.

Several auditing standards option exists such as ISO 22000 on Food safety Management Systems, HACCP (Hazard Analysis Critical control Point), ISO 9001 on Quality Management System.

The audit may be performed in two stages in which in the first stage involves desk audit of the factory's documents by the auditor to confirm their completeness and in the second stage where the auditor visits the factory to confirm compliance.

Technical audits are usually scheduled and the factory is usually notified of the audits ahead of time

The stage 2 audit cycle generally follows the following steps:

a) Opening session

This is usually a meeting between the auditors and the processes owners where the purpose of the audit is explained and the audits schedule agreed between the auditors and the processes owners. An attendance list as shown in **Annex G** should be completed

b) Audit

It is the stage where the auditors inspects the processes and seeks evidence of compliance such as checking on records generated, evidence of how corrective actions are taken against factory procedures. The auditors may raise non-compliance either as major or minor. In the case of major, it indicates that the quality system has collapsed and thus it cannot assure consistency in compliance while in the case of minor it indicates that some corrective actions need to be taken to avoid collapse of the system. An auditor is expected to have a check list to guide them on carrying out a detailed audit. A sample check list is as indicated in **Annex H**.

c) Closing meeting

A closing meeting attended by the auditors and processes owners is held after the audit. The purpose of this meeting is to give preliminary report of findings by the auditors on the level of non-compliance, observations by the auditors and areas of improvement as identified by the auditors. The meeting agrees on the duration the factory should be given to provide corrective actions for any noncompliance that would have been identified. An attendance list similar to the opening meeting should be signed.

d) Technical Audit report

The auditors within an agreed time should provide a detailed audit report indicating and detailing any non-compliance and areas of improvement. Once the factory receives the report, they prepare corrective action report

detailing the root cause of the non-compliance, the correction taken and the corrective action put in place to avoid recurrence and submit it to the auditors.

e) Close out

Upon receipt of the Corrective Action Report (CAR), the auditors will review it to determine whether it will address the issue raised and visit the factory to confirm the action as described have been taken. Once this is confirmed, the auditor closes out the audit.

4.3.2 Inspection

Inspection is carried out by inspectors who carry out either impromptu visits or planned visits.

The main objective of an inspection visit is to confirm that the factory complies with the relevant legal requirements implemented by the inspector's agency. In the case of food inspection inspectors, focus is on both quality and safety aspects with food fortification categorized as a quality element.

An inspector should have a checklist prepared from their regulations/standards/law that should guide them on inspection. A sample checklist is shown in **Annex H**.

The inspector should inspect the production area to confirm whether it complies with good manufacturing practices or the legal requirements of the country as defined either in the parent food law, standards or technical regulations.

The inspectors should also assess the personal hygiene of staff in the production area as well as confirm the status of their food handling health certificates as to whether they are valid or expired

They should also inspect the raw materials in this case the premix to confirm that they are stored in the right conditions, that they are not expired and that the factory has enough stock to assure continued fortification.

The inspectors should perform paper trail test by comparing the production capacity over time and the amount of premix used over the same time from the factory records to determine whether fortification has been done as required by law or as claimed by the factory in the case of voluntary fortification.

The inspectors should draw samples for analysis either from the production site or the ware houses at every inspection visit done to any factory.

4.4 Sampling of products

The objective of sampling either for internal or external monitoring should be to draw a representative sample as much as possible from the products being sampled. Inspectors and quality assurance managers should ensure proper composited samples are used to determine the level of compliance. The sampling described here applies to both internal and external monitoring as appropriate

4.4.1 Sampling at production site

4.4.1.1 An inspector should draw about 4 – 8 samples of between 200g – 500g at interval of 10 – 15 minutes from the production line on any visit.

4.4.1.2 Each sample should be packed in appropriate containers and labeled with at least the following minimum information as appropriate:

- a) Name of the product;
- b) Brand name;

- c) Factory name and physical address;
- d) Amount declared by the factory;
- e) In each of the cluster of samples, a code/ID for identification; and
- f) Date of Inspection & sampling.

4.4.1.3 The sample may delivered individually or composited to the laboratory for analysis. The inspector may request analysis per each sample to determine the variation of fortification and the results of the entire samples composited to determine compliance of the products to the legal requirements.

4.4.1.4 During sampling the samples collected by the Inspector should be split and one of the split samples kept as a reference. The internal quality manager may draw parallel sample for comparison test with those provided by the inspectors.

4.4.1.5 In the case of external monitoring, the inspector shall fill a sample collection form as shown in **Annex H**.

4.4.2 Sampling at the warehouse

4.4.2.1 The inspector should ensure that that the sampling is randomly done

4.4.2.2 The inspector should randomly collect 8 – 10 samples of between 200 g – 500 g from the warehouse.

4.4.2.3 The collected samples are mixed well to produce a composite sample from the warehouse.

4.4.2.4 The composited sample is packed in appropriate containers and labeled with at least the following information:

- a) Name of the product;
- b) Brand name;
- c) Factory name and physical address;
- d) Amount declared by the factory;
- e) In each of the cluster of samples, a code/ID for identification; and
- f) Date of Inspection & sampling.

4.4.2.5 The composite sample should then be delivered to the laboratory for further compositing to improve homogeneity and analysis to determine compliance to the national standards/regulations.

4.4.2.6 In the case of external monitoring, the inspector shall fill a sample collection form as shown in **Annex H**.

5.0 Methods of test

Fortified salt, sugar, edible oils, wheat flour and maize flour should be tested in accordance to the ECSA manuals laboratory manuals for fortified foods as listed in **Annex A2** or any other validated method.

Annex A1 (Normative): ECSCA-HC fortification level

NUTRIE NT	Fortificant compound	Level of Addition	Factory Average (Target Level)	Tolerable analytical range at factories		Tolerable analytical range at retail stores		Claim level at the market
				Minimum	Maximum	Minimum	Maximum	
		(mg/kg)	(mg/kg)	(mg/kg)		(mg/kg)		(mg/kg)
Salt (76 g fortificant per metric ton -1000 kg- of salt)								
Iodine	Potassium Iodate	45	45	33.5	60	30	60	43
OIL (69 g fortificant per metric ton -1000 kg- of oil)								
Vit. A	Vit. A (oily)	35	35	30.5	40	20	40	30
SUGAR (100 g fortificant, diluted to 1000 g premix, per metric ton -1000 kg- of sugar)								
Vit. A	Vit. A (water disp.)	7.5	7.5	4.1	15	2	15	7
WHEAT FLOUR (550 g premix of fortificants per metric ton -1000 kg- of wheat flour)								
Vit. A	Vit. A Palm. SD	1	1	0.6	1.4	0.5	1.4	1
B-	Thiamin Mononitrate	9	9.8	5.4	14.2	4.6	14.2	9
B-	Riboflavin	6	6.6	3.6	9.6	3.3	9.6	6
Niacin	Niacinamide	50	60	33.1	86.9	29.8	86.9	58
B-	Pyrodoxine	0	-	-	-	-	-	-
Folate	Folic acid	2	2.3	1.3	3.3	1.1	3.3	2
B-12	Vitamin B12 0.1% WS	0.020	0.020	0.011	0.029	0.01	0.029	0.020
Iro	NaFeEDTA*	30	30	20	40	20	40	30
	Total Iron	-	39	27	51	27	51	39
Zin	Zinc oxide**	80	88	60	116	60	116	88
MAIZE FLOUR (350 g premix of fortificants per metric ton -1000 kg- of maize flour)								
Vit. A	Vit. A Palm. SD	1	1	0.6	1.4	0.5	1.4	1
B-	Thiamin Mononitrate	4.5	6.5	3.6	9.4	3.0	9.4	6
B-	Riboflavin	3	4	2.2	5.8	2.0	5.8	4
Niacin	Niacinamide	25	30	16.6	43.4	14.9	43.4	29
B-	Pyrodoxine	0	-	-	-	-	-	-
Folate	Folic acid	1	1.2	0.7	1.7	0.6	1.7	1
B-12	Vitamin B12 0.1% WS	0.015	0.015	0.008	0.022	0.007	0.022	0.015
Iro	NaFeEDTA*	20	20	10	30	10	30	20
	Total iron	-	31	21	41	21	41	31
Zin	Zinc oxide**	40	49	33	65	53	65	59
<p>* If these iron levels from NaFeEDTA are technologically incompatible with the wheat or maize flours, try lower levels. If even the iron level at 20 mg/kg were found incompatible with wheat flour of its products, switch to 40 mg/kg Ferrous Fumarate. In the case of maize flour, try lower iron levels until finding the one that is technologically compatible.</p> <p>** If these zinc levels from ZnO are technologically incompatible with the wheat or maize flours, try lower levels until finding the technologically appropriate level for each type of flour and their products.</p>								

Annex A2: (Normative) Test Methods

- Manual for laboratory methods for fortified foods, Part I: Determination of Iodine in Salt
- Manual for laboratory methods for fortified foods, Part II: Determination of Vitamin A in sugar and Oil
- Manual for laboratory methods for fortified foods, Part III: Determination of Iron
- Manual for laboratory methods for fortified foods, Part IV: Determination of Vitamin A and Riboflavin in fortified flours

Annex B (informative): Gantt chart for scheduling activities

ABC Co. Ltd or XYZ department					
Monitoring, inspection and Audits schedule					
Activity:	e.g. Monitoring at production, Inspection schedule, Audit Schedule				
Site (e.g)	Date (either in days, weeks or months depending on whether it internal or external monitoring schedule)				
	1	2	3	4	5
Company X					
Company Y					
Company Z					

Annex C (informative):

Premix/fortificants inventory log

ABC Co. Ltd					
Premix/fortificants bin card					
S.No. 0123456					
Location: Store					
Date	(Time)	Dispatched to the production site			
		Quantity	Lot number	Expiry date	Name/signature of issuing officer

Annex D (informative):

Weekly checkup equipments

ABC Co. Ltd Premix/fortificants bin card S.No. 0123456 Weekly inspection of equipments Location: QC/maintenance		Name of inspector:	
		Signature:	
		Date:	
Equipment	Condition	Observation/recommendations	

Annex E (informative):

Production log

Time and/or date	Product produced		Premix used (kg)	Premix/fortificant to product ratio	Name of supervisor	Comments/observations
	MT (A)	Lot ID				

Annex F (informative): Audit Attendance List

Institution auditing:				
Firm being Audited:				
Scope of audit:				
Date of Audit				
Lead Auditor name:				
Name	Position	Sign	Opening	Closing

Annex G (informative): Audit Check List

Institution auditing:					
Firm being Audited:					
Scope of audit:					
Date of Audit					
Aspect (e.g)	Audited against	Compliance		Major	Not Major
		Yes	No		
Cleaning					
Personnel					
Records					

Annex H (informative): Sample Collection form

Inspecting agency logo:	
Name of inspector:	
Name and address of factory and contact person:	
Product Description:	
Brand Name:	
Date of production:	
Batch/Code number of product:	
Number of samples collected:	
Date Sample collected:	
Level of nutrient declared by the factory:	
I declare that the above information is true as provided	
Signature and date by inspector:	
Signature and date by factory representative:	

Bibliography

- ECSA. (2007). Manual for external monitoring of fortified maize flour, (1st Ed.). Arusha. ECSA.
- ECSA. (2007). *Manual for external monitoring of oil fortified with Vitamin. A*, (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for external monitoring of fortified salt.*(1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for external monitoring of iodized salt in small scale operations*, (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for external monitoring of sugar with vitamin A at fortification sites*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for external monitoring of fortified wheat flour*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of fortified maize flour*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of fortified maize flour in small scale operations*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of oil fortified with vitamin A*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of salt fortified with iodine*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of iodized salt in small scale operations*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of fortified sugar fortified with Vitamin A*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of sugar premix containing vitamin A*. (1st. Ed). Arusha, ECSA.
- ECSA. (2007). *Manual for internal monitoring of fortified wheat flour*. (1st. Ed). Arusha, ECSA.

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