

Monitoring and sampling of fortified foods - guidelines

PUBLIC REVIEW DRAFT

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Monitoring and sampling of fortified foods - guidelines

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Foreword

This Kenya Standard was prepared by the Processed Cereals and Pulses TC under the guidance of the Standards Project Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

These guideline are primarily intended to ensure uniform application of monitoring by both internal and external quality control players in food fortification. The guidelines are expected to produce a homogeneous sample for laboratory testing to reduce the variations in results usually associated with sampling. The guidelines will also assist the industries to establish and maintain a quality infrastructure for fortified food products. They may also be used in other food products whose nutrition quality has been enhanced by addition of vitamins and minerals.

During the preparation of this standard, reference was made to the following documents

Guidelines on food fortification with micronutrients, 2006, WHO/FAO.

CAC/GL 09 – 1987: General principles for the addition of essential nutrients to foods.

ECSA manuals for internal and external monitoring of fortified foods.

KS ISO 22000: 2005 Food Safety Management System.

Vitamin and Mineral requirements in Human Nutrition, WHO/FAO, 2004, 2nd Edition.

Acknowledgement is hereby made for the assistance derived from the above sources.

Monitoring and sampling of fortified foods - guidelines

1 Scope

This Kenya Standard provides the minimum requirements for monitoring, sampling and documentation of nutrient premixes and fortified foods.

2 Applications

These guidelines are primarily applicable to premixes, fortified flours, edible salt, sugar, edible fats and oils. They may also be used for all other fortified food products.

3 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

KS EAS 39, *Code of practice for hygiene in the food and drink manufacturing industry*

4 Definition

For the purposes of this standard, the following definitions shall apply:

4.1

internal quality control

is quality control and assurance practices conducted by producers, importers or packers of fortified foods and premixes

4.2

external quality control

is the inspection and auditing activities carried out at production centers (for factories and packers) and importation custom sites usually by regulatory bodies

4.3

establishment

is a site where food fortification is taking place

4.4

control point

stage in production process where it is important to control the quality parameter of fortified foods

4.5

operational prerequisite program

activity that is important to ensure proper fortification of product and which may not have a critical limit/measure.

4.5

Food safety management system

is an activity where an organization in food chain is supposed to demonstrate its ability to control food safety hazards in order to ensure food is safe at the time of consumption

5 Requirements

5.1 General requirements

5.1.1 The production establishment shall comply with all legal requirements of the relevant Laws of Kenya.

5.1.2 The establishments shall ensure and demonstrate good manufacturing practices (GMPs) are observed where specific requirements are not provided in these guidelines.

5.1.3 The establishments shall document all procedures and maintain all records required by these guidelines.

5.1.4 The establishment shall maintain documented information required for control of documents including but not limited to approval, review & updating as well as retention of information generated for food fortification

5.2 Internal quality control/assurance requirements

5.2.1 Establishments shall develop, document and implement an internal quality system that will ensure the products will comply with the relevant national standards and/or regulation

5.2.2 The establishment shall ensure while handling the premix/fortificants that:

- a) All premix/fortificants received to an establishment shall be accompanied by material safety data sheet and certificate of analysis including micronutrient profile and the shelf life of the premix/fortificants. This record shall be maintained for at least to shelf life of the product or as may be defined in the establishments' documented information.
- b) A proper schedule of movement of premix/fortificants to and from store is handled in a 'First In First Out' (in case of batches with same expiry date) and/or "first expiry first out" principle or any other principle that shall ensure the premix/fortificants do not keep long in the store. Records of these movements shall be maintained.
- c) A record of dispatches made 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. A tabular module representation of this information is informatively annexed as Annex A.
- d) Any opened premix/fortificants containers shall be tightly closed to minimize exposure to air and light.
- e) The establishment shall ensure that expired premix/fortificant are not utilized and if any premix expires in the stores shall be disposed according to relevant regulations and records of its disposal shall be maintained for a period of not less than six (6) months after its disposal.

5.2.3 The establishment shall ensure that in the production site:

- a) The hygiene condition is in compliance with KS EAS 39 and all other relevant laws of Kenya;
- b) The calibration of the equipment used in food fortification such as dosers, weighing scale is updated accordingly. Records of calibration shall be maintained. A schedule of inspection of the equipment at least on a weekly basis and record of finding shall be kept. A tabular module is attached as Annex B;
- c) Periodically in a shift, the dosage shall be inspected /verified to ensure that it is correct and records maintained; this shall apply in batch processing as well.

- d) A production log shall be kept indicating to the minimum time and date of production, amount of product produced, amount of premix used and product/premix ration and the name/officer responsible. A tabular module of this information is annexed as Annex C; and
- e) In the production of fortified foods, there shall be internal mechanism for demonstrating status of fortification in the product. Records shall be maintained.

5.3 Planning and realization of safe products

5.3.1 An establishment shall establish, document and implement a food management system that shall ensure safe and quality production of fortified foods such as HACCP, ISO 22000.

5.3.2 As the minimum the documented procedure shall indicate

a) Flow diagrams, process steps and control measures

Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include the following:

- i) the sequence and interaction of all steps in the operation;
- ii) any outsourced processes and subcontracted work;
- iii) where raw materials, ingredients and intermediate products enter the flow;
- iv) where reworking and recycling take place; and
- v) where end products, intermediate products, by-products and waste are released or removed.

The production/quality control team shall verify the accuracy of the flow diagrams by on-site checking.

Verified flow diagrams shall be maintained as records.

b) Control points

The documented system shall indicate the control points within the production point where control measures will be required to ensure consistency of the fortified products.

c) Monitoring of the control points

The food management system shall identify and document control measures (either operational prerequisite program or a critical limit) for each control point that shall be capable of preventing, eliminating or reducing fluctuation on the dosage levels to acceptable factory range and be within the regulatory limits.

d) Action to be taken when control limit is deviated

Planned corrections and corrective actions to be taken when control limits are deviated shall be specified in the food system plan under implementation. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the control point is (are) brought back under control, and that recurrence is prevented.

Documented procedures shall be established and maintained for the appropriate handling of non compliant products to ensure that they are not released until corrective action is taken.

e) Verification of the food safety management system

Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities. The verification activities shall confirm that the control measures are working and new critical points (if

any) are documented and appropriate control measures applied.

6 External quality control

6.1 General requirements

6.1.1 Establishments producing fortified food products shall be visited for inspection with intent to ensure compliance to regulatory limits as established.

6.1.2 These visits shall be carried out at least twice in a year and more frequent where the laboratory test result(s) consistently fails to comply with the regulatory limits.

6.1.3 These inspection visits may be pre-arranged or impromptu to an establishment.

6.1.4 During the inspection the inspector shall be expected to the minimum confirm that the establishment is implementing the documented food system, confirm that all the records required by this standard are generated and documented according to the establishment's policy. A detailed report of inspection shall be generated and documented in accordance with the institutions procedures.

6.2 Sampling

6.2.1 An inspector on each visit shall sample the fortified food products for purposes on analysis in an external laboratory

6.2.2 The samples shall be collected in amber glass bottles or similar appropriate containers drawn from the production line at intervals not less than 15 minutes from a particular point in the line

6.2.3 The sample size shall be four (4) bottles of 200g each, drawn at intervals described in clause 6.2.2. The samples shall be delivered to the testing laboratory for compositing before analysis. The firm being inspected may draw parallel samples and composite for their own internal analysis.

6.2.4 The inspector may draw more than four samples if he/she deems it necessary.

6.2.5 In the case of imported fortified foods and premixes, sampling shall be done in accordance to ISO 5555

6.3 Analysis

6.3.1 The samples submitted shall be composited and a representative sample drawn from the composite in accordance to the methods of analysis being used.

6.3.2 The sample shall be analyzed by a validated methods

6.3.3 The results of analysis shall be communicated to the inspector in accordance with the procedures of the testing laboratory.

7 Documentation and records

7.1 Establishments shall document and implement procedures related to various functions related to food fortification.

7.2 All records that this standard requires shall be generated and stored in accordance to establishment procedures.

7.3 All calibration evidence/records shall be kept.

7.4 Records shall be maintained to demonstrate compliance with the requirements of this standard

Annex A
(informative)
Inventory

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 B
(informative)
(Weekly inspection)

Weekly check up 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 C
(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				