



DRAFT EAST AFRICAN STANDARD

Monitoring and sampling of premixes and fortified foods — Guidelines

EAST AFRICAN COMMUNITY

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 018, Nutrition and foods for special dietary uses.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC should not be held responsible for identifying any or all such patent rights.

Monitoring and sampling of premixes and fortified foods — Guidelines

1 Scope

This Draft East African Standard provides the guidelines for monitoring, sampling and documentation of nutrient premixes and fortified foods.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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

EAS 900, *Cereals and pulses — Sampling*

ISO 5555, *Animal and vegetable fats and oils — Sampling*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

internal quality control

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

3.2

external quality control

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

3.3

establishment

site where food fortification takes place

3.4

control point

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

3.5

operational prerequisite programme

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

3.6

monitoring

process involving the auditing, quality control, quality assurance and inspection of manufacturing practices that ensure safe and quality production of fortified foods. Monitoring includes internal quality assurance and control measures as well as external monitoring by reregulatory authorities.

3.7

quality assurance

activities that facilitate the production of fortified foods with adequate micronutrient levels, of high quality, and are safe to consume

3.8

inspection

examination, measurement, testing of products to verify conformance to specific requirements

4 Requirements

4.1 General requirements

4.1.1 The production establishment should comply with EAS 39.

4.1.2 The establishments should document all procedures and maintain all records required by these guidelines.

4.1.3 The establishment should maintain documented information required for control of documents including but not limited to approval, review and updating as well as retention of information generated for food fortification.

4.2 Internal quality control and assurance

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

4.2.2 The establishment should ensure while handling the premix/fortificants that:

- a) All premix/fortificants received to an establishment should be accompanied by material safety data sheet and certificate of analysis including micronutrient profile and the shelf life of the premix/fortificants. This record should 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 should ensure the premix/fortificants do not keep long in the store. Records of these movements should 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 should be tightly closed to minimize exposure to air and light.
- e) The establishment should ensure that expired premix/fortificant are not utilized and if any premix expires in the stores should be disposed according to relevant regulations and records of its disposal should be maintained for a period of not less than six (6) months after its disposal.

4.2.3 The establishment should ensure that in the production site:

- a) the hygiene condition is in compliance with EAS 39.

- b) the calibration of the equipment used in food fortification such as dosers, weighing scale is updated accordingly. Records of calibration should be maintained. A schedule of inspection of the equipment at least on a weekly basis and record of finding should be kept. A tabular module is attached as Annex B;
- c) periodically in a shift, the dosage should be inspected /verified to ensure that it is correct and records maintained; this should apply in batch processing as well; and
- d) a production log should 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 as per Annex C.

4.3 Planning and realization of safe products

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

4.3.2 As the minimum the documented procedure should indicate the following:

4.3.2.1 Flow diagrams, process steps and control measures

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

- a) the sequence and interaction of all steps in the operation;
- b) any outsourced processes and subcontracted work;
- c) where raw materials, ingredients and intermediate products enter the flow;
- d) where reworking and recycling take place; and
- e) where end products, intermediate products, by-products and waste are released or removed.

4.3.2.1.2 The production/quality control team should verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams should be maintained as records.

4.3.2.2 Control points

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

4.3.2.3 Monitoring of the control points

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

4.3.2.4 Actions to be taken when critical limits are not met

4.3.2.4.1 Planned corrections and corrective actions to be taken when critical limits are not met should be specified. The actions should 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.

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

4.3.2.5 Verification of the food safety management system

Verification planning should define the purpose, methods, frequencies and responsibilities for the verification activities. The verification activities should confirm that the control measures are working and new critical points (if any) are documented and appropriate control measures applied.

5 External quality control

5.1 General requirements

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

5.1.2 These visits should 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.

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

5.1.4 During the inspection the inspector should 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 should be generated and documented in accordance with the institutions procedures.

5.2 Sampling

5.2.1 An inspector on each visit should sample the fortified food products for purposes on analysis in an external laboratory.

5.2.2 The samples should be collected in amber glass bottles or similar appropriate containers drawn from the production line at intervals not less than 15 min from a particular point in the line.

5.2.3 The sample size should be four (4) bottles of 200 g each, drawn at intervals described in 6.2.2. The samples should 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.

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

5.2.5 In the case of points of entry and at market level, sampling of fortified foods and premixes, should be done in accordance with either ISO 5555, EAS 900 or CAC/GL 50.

5.3 Analysis

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

5.3.2 The sample should be analyzed by validated methods.

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

6 Documentation and records

6.1 Establishments should document and implement procedures related to various functions related to food fortification.

- 6.2** All records that this standard requires should be generated and stored in accordance to establishment procedures.
- 6.3** All calibration evidence/records should be kept.
- 6.4** Records should be maintained to demonstrate compliance with the requirements of this standard.

Annex A
(informative)

Workshop representation

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)

Weekly inspection

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				

Bibliography

- [1] *Guidelines on food fortification with micronutrients, 2006, WHO/FAO*
- [2] *CAC/GL 09 – 1987: General principles for the addition of essential nutrients to foods.*
- [3] *ECSA manuals for internal and external monitoring of fortified foods.*
- [4] *Vitamin and Mineral requirements in Human Nutrition, WHO/FAO, 2004, 2nd Edition.*

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