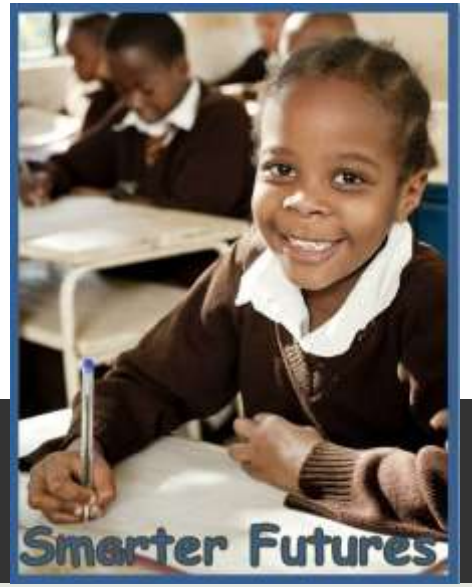
Smarter Futures



National Food Control Systems- Audit

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EVIRAN

- **Implementation of control**
- **Regulatory control of fortified foods focuses on**
  - review of the scope, adequacy and implementation of in-house plan;
  - controls of recipes, labelling and documents;
  - review of practical activities;
  - sampling, if necessary / if non-compliance is suspected

EVIRAN

- **Review of in-house plan and its implementation is designed to verify that**
  - operators manage through their own control of their activities (in-house control) the compliance of the fortification of foods;
  - the quality assurance procedures implemented by the operator, such as
  - instructions and documentation, are adequate.

Paper Trail

- All mills keep records
- Food Laws give mandate to check records

- Develop/adapt/adopt a Code of Practice agreed upon by all stakeholders regarding who does what, where and when

Premix Imports

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Label	Content as authorised and listed	Port of Entry	Every Consignment	Physical Inspection	Port Health	Environmental Health - Harare	Record Check Accept, Hold for detailed inspection – if confirmed - Query with supplier and advise Ministry of Trade
	Best Before Date valid.						
	Sound Packaging						
	Name & Address of Manufacturer, Country of origin Batch Identification		Random sampling for Analysis	Acceptable Sampling Protocol			
Certificate of Analysis (CoA)	Presentation.		Every Consignment	CoA matches Batch Identification and Content authorised			
Conformance to Specification	Content as authorised	Laboratory	Random	Approved Analytical Methods		Regulator and Supplier	
Fit for Purpose	Contents stable			Stability Test (40°C @ 75% RH for 30 days)			

Premix arrival at Production Facility

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Raw Material Inspection	Correct Pre-Mix delivered Quantity as per Order and Bill of Lading Sound Packaging Best Before Date valid CoA matches Batch Identification	Receival Point and/or Stores	Every Consignment	Physical Inspection and Normal Plant Protocols	Store Manager and Quality Assurance (QA) Manager	QA Manager	Record Check Accept or Contact Supplier and/or Transporter
Storage Area	Clean, Tidy, Cool and not in direct sunlight	Store	Weekly	Physical Inspection	Store Manager and (QA) Manager	QA Manager Production Manager	Record Check Rectify
Pre-Mix Storage	FIFO is practiced	Store	Weekly	Identify and Segregate different batches – Identify batch in use	QA Manager	Production Manager Procurement	Record Check Rectify
Finished Product Label	Label as authorised	Receival Point and/or Stores	Every Consignment	Visual and as per Raw Material Inspection	Store Manager and Quality Assurance (QA) Manager	QA Manager	Record Check Accept or Contact Supplier

Process Control

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Feeder	Calibrated	Plant	On Installation and if calibration checks indicate a problem	Record weight dispensed per unit time (see SOP – develop on site)	QC	QA	Record Rectify
Feeder Calibration	Calibrated		Monthly and on Change of Batch and/or supplier				
Feeder	Dosing system on and dosing		Hourly	Visual Check			
Adding	Rapid Test Positive		Minimum 2 hours	Red Spot Test (Iron) and/or BASF Vitamin A Test **RETAIN SAMPLE for Finished Product Inspection**			
Addition Rate	Correct Addition		Minimum once per shift	Check actual pre-mix dispensed matches theoretical (calibration)			
Pre-Mix Usage	Pre-mix used in correct ratio to finished product production		Weekly	Production Records	QA Production Manager	Production Manager	Report

Finished Product Inspection

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Vitamin A Content **IF APPLICABLE**	All samples > XX ppm (legal minimum)	Finished Product Packs.	Minimum 2 hours	BASF Rapid Test	QC	QA Production	Record Rectify
Iron Content	All samples > XX ppm (legal minimum)	Finished Product Packs.	Minimum 2 hours	Akzo Nobel Test for NaFeEDTA			
Label	As authorised.	Finished Product	Hourly	Visual			
Confirmation of Iron Content	All samples exceed minimum	Composite Samples from Process Control	Per Shift, Per Day, Per Week	Quantitative iCheck			
Confirmation of quality by an external lab	All samples complying	External Laboratory.	After every 4 months	Quantitative iCheck/Spec/HPLC	QA	QA Production	Report
Another Marker i.e. Niacin	All samples complying	External Laboratory.	After every 4 months	Quantitative Spec/HPLC	QA	QA Production	Report

Finished Product Inspection – oil/sugar

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Vitamin A Content	All Samples > 15 ppm (legal minimum)	Finished Product Packs.	Minimum 2 hours	BASF Rapid Test	QC	QA Production	Record Rectify
Label	As authorised.	Finished Product	Hourly	Visual			
Confirmation of Vitamin A content	All Samples exceed Minimum	Composite Samples from Process Control	Per Shift, Per Day, Per Week	Quantitative iCheck			
Confirmation of Quality by an External laboratory	All Samples Complying	External Laboratory.	After every 4 months	Quantitative iCheck/Spec /HPLC	QA	QA Production	Report

Inspection and Internal Audit

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Conditions of Storage	Stores in Good Condition FIFO in place and proven	Plant	Quarterly	Audit Check List	Stores QA Production Procurement	Plant Manager Stores QA Production Procurement	Fully Documented Report including non-compliance issues and corrective action taken Must contain confirmation (or reasons why not) previous non-compliance issues have been corrected
GMP and/or HACCP	Being implemented and documented						
Raw Material Inspection and Inventory REPORT	Report available and up to date						
Records of Factory QC	Records Available Corrective Actions Reported						
Pre-Mix Usage	Pre-mix used in correct ratio to finished product production						
Records of QA Activities	Records available						
Record of monthly external testing	Report Results Available						
Fortification Process in Control	Records Available Corrective Actions Reported						

Inspection and External Audit

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Review Internal Audit Reports	Reports Acceptable	Plant	6 Monthly	Review	Environmental Health	Min of Health NFA	Accept or Comment
Repeat Internal Audit Process (above) in presence of QA Manager	Audit Acceptable			Audit			Accept or Issue Corrective Action Letter
Take samples from Composite Laboratory Samples – if deemed necessary from Pack Line and Warehouse	All samples pass Legal Minimum	Plant	Random	Acceptable Sampling Protocol Plant retains 1 of the 3 Composite Samples			Accept or Discuss with Plant Repeat Offenses Revoke License

Imports Inspection

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Certificate of Analysis (CoA)	CoA from acceptable entity and meets authorised requirements	Point of Entry	Every Consignment	Visual	Customs Port Health Environmental Health	Importer	Accept Reject or refer to Government Laboratory
Iron	Fortified		Every Consignment Sample to Protocol	Red Spot Test Ferric or Ferrous		Importer Min Health NFA	Accept or Issue Corrective Action Letter
Micronutrients	Adequately Fortified	Government laboratory	Random	Quantitative	Environmental Health	Importer Min Health NFA	Accept or Issue Corrective Action Letter or Warning Letter
Label	As authorised	Packaging	Every Consignment	Visual	Environmental Health	Importer	Accept or Issue Corrective Action Letter

Imports Inspection – oil/sugar

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Certificate of Analysis (CoA)	CoA from acceptable entity and meets authorised requirements	Point of Entry	Every Consignment	Visual	Customs Port Health Environmental Health	Importer	Accept Reject or refer to Government Laboratory
Vitamin A	Fortified		Every Consignment Sample to Protocol	Qualitative or iCheck		Importer Min Health NFA	Accept or Issue Corrective Action Letter
Vitamin A	Adequately Fortified	Government laboratory	Random	Quantitative iCheck/HPLC/Spec	Environmental Health	Importer Min Health NFA	Accept or Issue Corrective Action Letter or Warning Letter
Label	As authorised	Packaging	Every Consignment	Visual	Environmental Health	Importer	Accept or Issue Corrective Action Letter
Refined	Oil has FFA <XX and/or PV <YY	Government laboratory	Random	Quantitative	Environmental Health	Importer Environmental Health - Harare Treasury	Prosecute Trade Implications
Sugar	?? Sugar <XX	Government laboratory	Random	Quantitative	Environmental Health	Importer Environmental Health- Harare Treasury	ProsecuteTrade Implications

Market Samples

ACTIVITY		HOW			WHO & TO/ BY WHOM		
Indicator	**Criteria of Success**	**Where**	**When (Frequency)**	**Methods**	**Accountability**	**Reported to**	**Actions**
Label	As authorised	District or Provincial Marketplace	Quarterly	Visual	Environmental Health	Environmental Health- Harare THEN TO Min Health, NFA & Industry	Accept or discuss if reason why and/or take corrective action
Fortified	Iron			Random Samples Quantitative			
	If Applicable Vitamin A						
Iron	Above Minimum Level	Government Laboratory		Selection from Random Samples			
Vitamin A							
Another Marker i.e. Niacin							

Methodology

- Register pre-mix suppliers
- Specify the nutrient compounds i.e. Thiamine mononitrate activity minimum 78%
- Specify critical factors in a compound i.e. particle size of $FeSO_4$; free iron in NaFeEDTA
- Pre-mix suppliers provide (at own cost) accredited laboratory data on own pre-mix
- Pre-mix suppliers externally audited (GMP ---- analysis!!!!!) at own cost – yet frequently they have recently been audited i.e. ISO 9000 etc. by highly qualified auditors

Sampling?

Sampling

- Sensitive issue – especially in the area of international trade.
- Cannot treat imports stricter than local production (need to discuss implications with local WTO contact point)
- Fortified flour is heterogenous for micronutrients compared to being homogeneous for moisture

Conformity assessment procedures

- Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.
- *Explanatory note*
  - Conformity assessment procedures include, *inter alia*, **procedures for sampling**, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

Example of Sampling

- Multiple samples taken over an extended period of time i.e. 7 samples of "40g" taken "60 minutes" apart
- Total of 280g is then made into a composite

- Necessity to be practical about sampling
- What is risk to population of non-conformity in fortification?

- Mill producing 10Mt/hour of flour will take 0.09 seconds to produce sample
- Taking a sample over 4 hours against checking the paper work in approximately 15 minutes
- Paper trail does not prevent Regulator from conducting finished product sampling

- Mills, and other food processors, take samples on a very frequent basis to constantly monitor quality and consistency – why not consolidate these samples and use them as being truly representative of actual production?

Instructions on CODEX Sampling Procedures CX/MAS 1 - 1987

- "In particular, the estimate of the value MAY be dependent upon the method of analysis used, but it is ALWAYS dependent on the type of sampling plan and the lot acceptance procedure used"

DISCUSSION

- Food control management should be based on risk analysis and an integrated farm-to table approach.
- These principles highlight the need for a **structured approach for risk analysis** comprised of three separate but closely linked and integral components:
  - i) risk assessment;
  - ii) risk management; and
  - iii) risk communication.

- In particular, risk management provides a process (distinct from risk assessment) for **weighing policy alternatives** in consultation with all the interested parties, considering **risk assessment** and other factors relevant for the **health protection** of consumers and for the promotion of **fair trade** practices, and, if needed, **selecting appropriate prevention and control options**.

- Standard level of fortification and the tolerances that the Canadian Food Inspection agency will apply to determine if fortified flour (national production and imports) is adequately fortified. Tolerances that if the analytical results fall outside they will take regulatory action. This was carried out with the collaboration of the Canadian National Millers Association and based on the mills providing actual analysis results for about 3000 samples!
- http://www.inspection.gc.ca/food/non-federally-registered/product-inspection/flour-samples/eng/1383837268150/1383837269041