



**High Level Strategy &  
Writing Session:  
Developing a Roadmap to  
Manage Aflatoxin Risk in  
Meru County**

University of Nairobi, Chiromo Campus  
Nairobi, Kenya  
January 24-25, 2019

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& Writing Session:  
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January 24-25, 2019

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**Agenda**

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**Official Request by  
Hon. Paul Mworira Bagiine,  
Chairman; Agriculture, Livestock  
and Fisheries Committee, County  
Assembly of Meru**

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**Aflatoxin risk management roles:  
Pillar of aflatoxin co-regulation**

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**Regulatory market mapping  
& matrix**

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**Model Bill**

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**Model Bill Evaluation and  
Gap Analysis**

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**Strategic Plan: Risk Management  
Matrix**

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**Presentations**

# High Level Strategy and Writing Session

## Developing a Roadmap to Manage Aflatoxin Risk in Meru County

University of Nairobi, Chiromo Campus

Nairobi, Kenya

January 24-25, 2019

### Thursday, January 24, 2019

Start Time	Speaker/Activity	Description
8:00 AM		<i>Depart for University of Nairobi, Chiromo Campus</i>
8:30 AM	Dr. Obiero	Welcome
	Everyone	Introduction
<b>9:00</b>	Hon. Paul Mworira Bagiine	Opening remarks & objectives, chairman Agriculture, Livestock and Fisheries committee
9:15 AM	Professor Okoth	Aflatoxin Overview
9:30 AM	Herrman	Aflatoxin incidence in Kenya – 2017 Meru & Surrounding Counties in 2018
10:00		Break
10:30	Group Discussion	Pillars of a Public-Private Partnership; Responsibilities & Benefits
		Government sector: Agriculture
		Government sector: Public Health
	Eliud Mutembi – leader	Industry sector-maize value chain
11:30	Group Exercise	
Noon		Lunch
1:00 PM	Group Exercise	Regulatory Market Mapping – group exercise
1:30 PM	Herrman	Model Bill Introduction
	Group exercise	Model Bill Review – breakout exercise
4:00 PM	Group exercise	Gap Analysis
4:30 PM	Group report back	Summary with recommendations
5:00 PM		Adjourn

### Friday, January 25, 2019

Start Time	Speaker/Activity	Description
8:00 AM	IBIS	<i>Depart IBIS</i>
8:30 AM	Group Discussion	Writing Assignment – Amendments to model bill
9:00 AM	Professor Okoth	Aflatoxin Risk Management
9:15 AM	Sammy Khakata	Aflatoxin analysis in an ISO 17025 accredited lab
9:30 AM	Anne Muiruri	Aflatoxin Proficiency Testing and Control (APTECA)
9:45 AM	Herrman	Strategic Plan – assignment overview
10:00 AM	Group exercise	Vision, mission, goals - breakout
11:30 AM	Group report back	Strategic plan elements
<b>Noon</b>		Lunch
1:00 PM	Group discussion	Final assignments and timeline
1:30 PM	Hon. Paul Mworira Bagiine	Wrap-up – did we meet our objectives?

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**Hon. Paul Mworia Bagiine**

M C A, NTIMA WEST

P.O. Box -3 -60200

Meru

Mobile: +254722590285

**THE COUNTY ASSEMBLY OF  
MERU**



**County Assembly of Meru**

P.O. Box 3 – 60200, Meru

**Landlines:** 064-30040/064-30042

**Email:** [assembly@meru.go.ke](mailto:assembly@meru.go.ke)

**Website:**

[www.assembly.meru.go.ke](http://www.assembly.meru.go.ke)

Our Ref: **MCA/GEN VOL.IV/2.**

Date: **29<sup>th</sup> NOVEMBER, 2018.**

Hon. Paul Mworia Bagiine,  
Chairman; Agriculture, Livestock and  
Fisheries Committee.  
County Assembly of Meru.  
P.O. Box 3, 60200, Meru.

Prof. Tim Herrman,  
Texas A&M Agrilife Research,  
at the university of Nairobi, Chiromo Campus  
Through: Eliud Mutembei,  
Cereal Growers Association.  
Dear Prof. Herrman,

**RE: AFLATOXIN RISK MANAGEMENT IN MERU COUNTY**

It has reached the attention of the Agriculture Committee, Meru County that Texas A&M AgriLife Research (AgriLife) has been conducting field research on the status of aflatoxin in Meru County between 2016 and 2018 through Eliud Mutembei of Cereal Growers Association.

As a committee, we highly appreciate this initiative and would like to engage AgriLife further to assist us understand more on the aflatoxin status in Meru based on your findings and build the capacity of the County assembly members to pass crucial bills on aflatoxin risk management. We therefore request:

1. You share with us the findings of the research that you carried out.
2. You prepare an engagement where Meru County Agriculture committee members will be able to draft bills regarding aflatoxin risk management.

This will be the first County to pass such a bill concerning the Aflatoxin menace resulting in saving the lives of the people of Meru and enhancing food security.

We look forward to hearing from you.

Yours Faithfully,

  
Hon. Paul Mworia Bagiine.

**CHAIRMAN; AGRICULTURE, LIVESTOCK AND FISHERIES COMMITTEE.COUNTY  
ASSEMBLY OF MERU.**

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### Pillars of Aflatoxin Co-Regulation

#### Objective

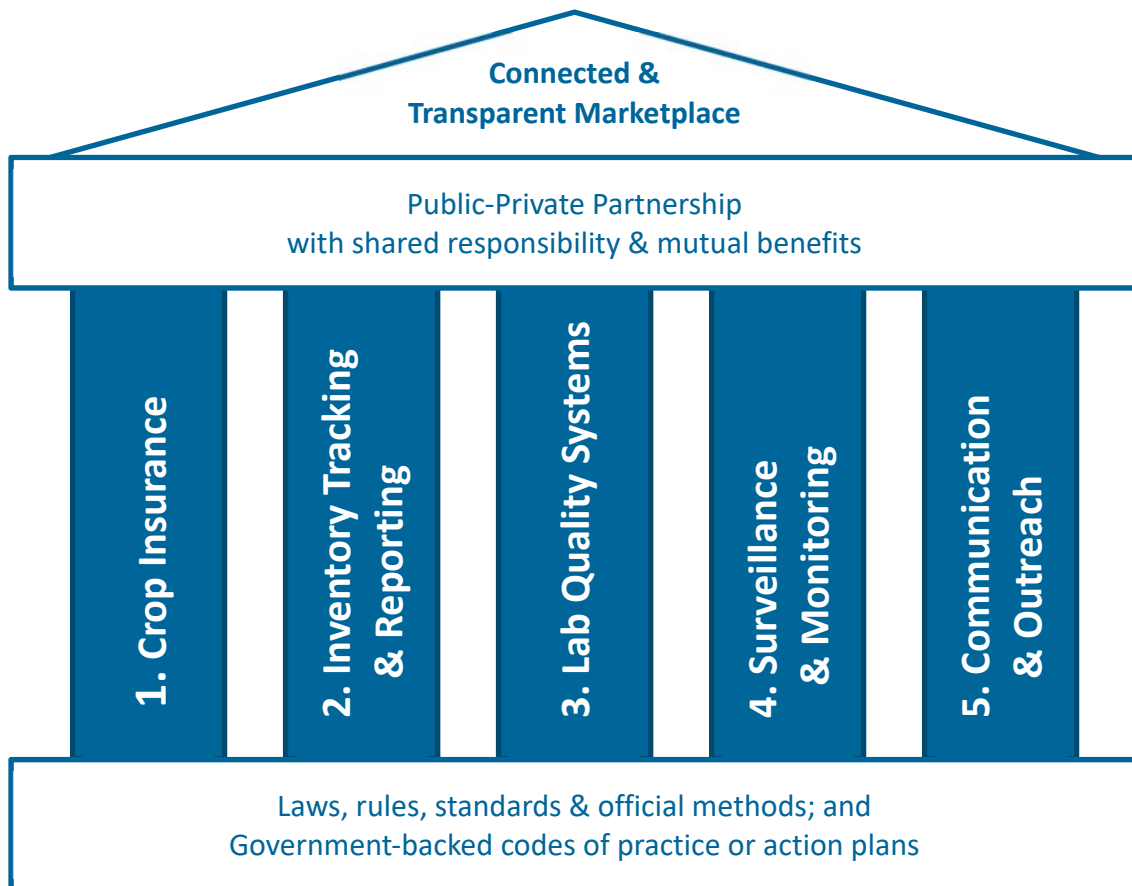
- Conceptualize the essential elements of a successful public-private partnership to manage aflatoxin risk and achieve a connected and transparent marketplace that delivers aflatoxin safe maize, maize products and milk to all of Africa.

#### Resources

- Model Bill

#### Activity

- Take notes on the following page as we review the diagram below and discuss the core responsibilities and mutual benefits for each stakeholder: government, industry and, where appropriate, producers or consumers.



**Responsibilities & Benefits**

**1. Crop Insurance**

*A. Responsibilities:*

Government \_\_\_\_\_

Industry \_\_\_\_\_

Producer/Other \_\_\_\_\_

*B. Benefits:* \_\_\_\_\_

**2. Inventory Tracking & Reporting**

*A. Responsibilities:*

Government \_\_\_\_\_

Industry \_\_\_\_\_

Producer/Other \_\_\_\_\_

*B. Benefits:* \_\_\_\_\_

**3. Lab Quality Systems**

*A. Responsibilities:*

Government \_\_\_\_\_

Industry \_\_\_\_\_

Producer/Other \_\_\_\_\_

*B. Benefits:* \_\_\_\_\_

**4. Surveillance & Monitoring**

*A. Responsibilities:*

Government \_\_\_\_\_

Industry \_\_\_\_\_

Producer/Other \_\_\_\_\_

*B. Benefits:* \_\_\_\_\_

**5. Communication & Outreach**

*A. Responsibilities:*

Government \_\_\_\_\_

Industry \_\_\_\_\_

Producer/Other \_\_\_\_\_

*B. Benefits:* \_\_\_\_\_



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### Regulatory Mapping & Matrix: Maize Value Chain

#### Objectives

- Identify the elements from production to sale and distribution, that must be regulated to manage aflatoxin risk in a maize, maize product and milk value chain

#### Resources

- Kang'ethe, E.K. (2011) Situation Analysis: Improving Food Safety in the Maize Value Chain in Kenya. Roles and mandates of Government Institutions (pgs. 87-89)

#### Activity

1. All participants: For each stage in the simplified maize value chain below, identify the elements that need to be addressed in the law. Please note that some elements will fall under more than one stage. For example, maize may be tested at the production, storage and at the processing stages.

Stage	Elements to be addressed in the law
Production	

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<b>Transport</b>	
<b>Storage</b>	
<b>Processing</b>	
<b>Sale &amp; Distribution</b>	

### **Regulatory Mapping & Matrix: Agency Mandates**

#### **Objectives**

- For each element in the maize value chain, identified in the previous activity, determine and indicate your agency's existing regulatory authority

#### **Resources**

- Kenya Law full text search <http://kenyalaw.org/kl>
- Kang'ethe, E.K. (2011) Situation Analysis: Improving Food Safety in the Maize Value Chain in Kenya. Roles and mandates of Government Institutions (pgs. 87-89)

#### **Activity**

1. Agency Breakout Group: Complete a worksheet for each element in the simplified maize value chain
2. Note your agency's existing authorities and any associated legislation, or mark as 'none' or 'partial'

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**Agency:** \_\_\_\_\_

<b>PRODUCTION</b>					
#	Elements	Mandate	Subsidiary Legislation (Regulation, Rule or Order)	Supporting directives, Guidance Documents & Standards	SOPs, Training Manuals & Records
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

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**Agency:** \_\_\_\_\_

<b>TRANSPORT</b>					
#	Elements	Mandate	Subsidiary Legislation (Regulation, Rule or Order)	Supporting directives, Guidance Documents & Standards	SOPs, Training Manuals & Records
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					



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**Agency:** \_\_\_\_\_

<b>STORAGE</b>					
#	Elements	Mandate	Subsidiary Legislation (Regulation, Rule or Order)	Supporting directives, Guidance Documents & Standards	SOPs, Training Manuals & Records
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

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**Agency:** \_\_\_\_\_

<b>PROCESSING</b>					
#	Elements	Mandate	Subsidiary Legislation (Regulation, Rule or Order)	Supporting directives, Guidance Documents & Standards	SOPs, Training Manuals & Records
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

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**Agency:** \_\_\_\_\_

<b>SALE &amp; DISTRIBUTION</b>					
#	Elements	Mandate	Subsidiary Legislation (Regulation, Rule or Order)	Supporting directives, Guidance Documents & Standards	SOPs, Training Manuals & Records
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

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## **AFLATOXIN RISK MANAGEMENT BILL, 2019**

**A Bill to control the risk of aflatoxin contamination in food and feed in Meru County Kenya; to ensure that food is safe for consumption by all inhabitants**

### **PART I- PRELIMINARY**

#### **1. Short title**

This Bill may be cited as the Aflatoxin Risk Management Bill, 2019

#### **2. Interpretation**

**In this Bill, unless the context otherwise requires:-**

“**Aflatoxin**” means a group of highly poisonous and carcinogenic compounds produced by the strains of the fungi mainly *Aspergillus flavus* and *Aspergillus parasiticus* and related species on a suitable substrate

“**Aflatoxin tested**” means a term in a product label indicating conformance to the Act with regard to product safety

“**Aflatoxin contaminated**” shall refer to crop found to contain detectable levels of aflatoxin exceeding the regulatory levels.

“**Bill**” means the Aflatoxin Risk Management Bill, 2017

“**Cabinet Secretary**” means the Cabinet Secretary for the time being responsible for Agriculture or Cabinet Secretary for the time being responsible for Health

“**committee**” means the National Aflatoxin Prevention and Control Committee

“**Co-regulation**” means a governance option involving public-private partnership in regulation using statutory or government item backed codes of practice or action plans

“**crop**” means all crops specified in the First schedule of this Bill;

“**dealer**” means any person, company or a firm engaged in collecting, aggregating, transporting, storing, selling or processing any crop;

“**grower**” means any person who cultivates and harvests any crop specified in First schedule

**“licensee”** means a person licensed by a licensing authority under this Bill;

**“Mycotoxin”** means secondary metabolites of fungus that produce toxic results in another organism

**“Official sample”** means a sample collected, tested and reported according to this act

**“Test kits”** means affordable test kits that provide quick and accurate aflatoxin level determinations in the field or in the laboratory.

**“Validation”** means obtaining scientific evidence that confirms that a procedure or practice is fit for purpose

**“warehouse”** means a storage facility for the storage of crops specified in schedule 1.

### **3. Objects and purposes of the Bill**

The objective of this bill is to promote food and feed safety in Kenya and in particular to;

- i) Increase awareness on risks associated with aflatoxin
- ii) Reduce the level of aflatoxin contamination in food and feed
- iii) Support research and technology development options for prevention and control of aflatoxin
- iv) maintain aflatoxin safe produce and products all through the value chain at permissible levels

### **4. Application**

This Bill shall apply to all crops specified in the First schedule of this Bill.

## **PART II- ESTABLISHMENT AND FUNCTIONS OF THE NATIONAL AFLATOXIN [MYCOTOXIN] PREVENTION AND CONTROL COMMITTEE**

1. Establishment of the National Aflatoxin Prevention and Control Committee, hereafter referred to as the Committee.

- 1.1 The Cabinet Secretary shall establish a National Aflatoxin Prevention and Control Committee for the purpose of providing coordination in risk assessment, management and communication on aflatoxin contamination in crops in the First schedule.



2. Members of the National Aflatoxin Prevention and Control Committee

3. The National Aflatoxin Prevention and Control Committee shall comprise the following members

3.1 the chair who shall be the Agriculture Secretary and the department responsible for public health shall provide secretariat services

- (i). Agriculture and Food Authority (AFA);
- (ii). Kenya Agricultural & Livestock Research Organization (KALRO);
- (iii). Kenya Bureau of Standards (KEBS);
- (iv). Kenya Plant Health Inspectorate Service (KEPHIS);
- (v). National Cereals and Produce Board (NCPB);
- (vi). Pest Control Products Board (PCPB);
- (vii). Director Veterinary Services (DVS)
- (viii). National Public Health Laboratory (NPHL)
- (ix). A representative from the Council of Governors
- (x). three members each representing academia, private sector and consumers organization
- (xi). An ex-officio expert co-opted by the committee

4. Functions of the Committee

4.1 The Committee shall be responsible for:

- a) providing coordination of measures on prevention and control of aflatoxin, and shall have the possibility, where necessary, of organizing public hearings.
- b) The Committee shall be responsible for the general coordination necessary to ensure seamless implementation of prevention and control measures, and in particular with regard to the adoption of aflatoxin sampling and testing procedures and harmonization of test methods.
- c) The Committee shall promulgate rules to establish Technical Taskforce and timelines Working Groups or specialized sub-committees for the purpose of implementing its mandate.

- d) Develop and publish an annual report of the committee and submitted to the parliament.
- e) The Committee shall meet at least twice annually.

5. Development of aflatoxin prevention and control plan

5.1 The Committee shall develop and publish a three year aflatoxin prevention and control plan.

### **Part III - PILLARS OF CO-REGULATION**

1. For the purposes of this Bill, the Stakeholders/PPs listed in sub-section(i), but not limited to those listed therein, shall be involved in co-regulation

i) Public Stakeholders

Agriculture and Food Authority (AFA); Kenya Agricultural & Livestock Research Organization (KALRO); Kenya Bureau of Standards (KEBS); Kenya Plant Health Inspectorate Service (KEPHIS); Ministry of Agriculture (MOA); Ministry of Health (MOH); National Cereals and Produce Board (NCPB); Pest Control Products Board (PCPB); National Biosafety Authority (NBA); National Irrigation Board (NIB) and the Council of Governors (COG)

ii) Private Stakeholders

Association of Kenya Feed Manufacturers (AKEFEMA); Cereal Growers Association (CGA); Cereal Millers Association (CMA).

2. The PPs described in Section 5 above shall be supported by pillars including but not limited to; crop insurance, inventory tracking and reporting, laboratory quality systems, surveillance and monitoring, communication and outreach which shall be based on laws, rules, standards & official methods, government backed codes of practice and action plans as defined by the Committee. These pillars will enable a public-private-partnership

with shared responsibility and mutual benefits leading to a connected and transparent marketplace through co-regulation.

#### **PART IV - ROLE OF COUNTY GOVERNMENTS**

1. Each county government shall within its area of jurisdiction be responsible for aflatoxin risk management and communication in accordance with Part 2 of the Fourth schedule to the Constitution.
2. Each County Government shall through its legislation and administrative action implement and act in accordance with this Bill and in accordance with the national policy guidelines issued by the Cabinet Secretary on the advice of the Committee under this Bill.
3. Any action done by the County Government under this Bill shall be deemed to be done if done by an authorized representative of that County Government.
4. [Each County Government shall keep a register containing the names and addresses of all growers and dealers of crops falling under the First Schedule of this Bill].
5. The register described in Section 11 above shall at all reasonable times be open to inspection by any co-regulator described in Section 5 above and may make copies of any entry therein in the administration of this Bill.
6. Every county government shall deposit an updated register with the Committee annually and the committee shall keep an inventory.

#### **PART V - Crop VALUE CHAIN AND CO-REGULATION PREVENTIVE CONTROLS**

1. Inspection
  - 1.1 Production

- a) The county or national authority is entitled to enter during regular business hours to inspect seed, fertilizer and pest control products and records
- b) The relevant county authority shall ensure Land Zoning Policies are present and applicable to agricultural land.
- c) All growers shall observe Good Agricultural Practices (GAP) during all farming operations published by KALRO in consultation with the committee.
- d) The Committee shall develop guidelines on use of plant protection products and crop insurance

#### 1.2 Storage

The authorized representative shall inspect;

- a) The moisture content and aflatoxin contamination records during the whole period of storage following a prescribe the monitoring schedule,
- b) Records on the validity of the performance of equipment used to measure and monitor moisture content and aflatoxin contamination,
- c) That the pest control products (pesticides and all others) are used in conformance with the label and registered with PCPB,
- d) Whether the warehouses, silos and any other storage facilities are constructed in a manner to meet sanitary standards with respect to aeration, temperature, sanitation amongst others.

#### 1.3 Transport

The authorized representative shall inspect;

- a) Whether a dealer holds a valid certificate of analysis,
- b) The transportation of crops shall be done in a sanitary manner including measures to maintain quality and safety.

#### 1.4 Processing

The authorized representative shall inspect;

- a) Records on moisture content levels of all raw materials intake at the processing facilities,
- b) Plants and premises for suitable design, layout and construction to facilitate easy maintenance and sanitary production of food,

- c) That all operations in the receiving, inspecting, handling, segregating, preparing, processing, packaging and storing of food are conducted in a hygienic manner and documentation are available to the official control,
- d) Records on establishment, implementation and maintenance of Good Manufacturing Practices (GMP) and HACCP,
- e) Records to ensure that all raw material and finished products are traceable.

### 1.5 Sale and Distribution

The Committee shall prescribe the criteria for labeling and handling of aflatoxin contaminated products and alternative use of such products.

The authorized representative shall inspect:

- (a) Records documenting aflatoxin test results of every batch of a product,
- (b) Product to ensure that it bears the label “aflatoxin tested”,
- (c) Packaging material is fit for purpose,
- (d) That distribution of products is done in a sanitary manner.

## 2 Registration

### 2.1 Registration of growers and dealers

- a) All growers and dealers shall apply for registration with the relevant agency/county government in the format prescribed by this Bill.
- b) The Committee shall provide registration mechanism and keep an inventory of the updated registers.

## 3 Licensing

### 3.1 Licensing of dealers

- a) All dealers must be holders of a valid license.
- b) No person shall under this Bill operate without a valid license.
- c) A person shall not import or export any products without a license/permit.
- d) The Committee shall develop mechanism on how to collect information of licenses issued and keep an inventory thereof.

## **PART VI - TESTING FOR AFLATOXIN CONTAMINATION**

1. All crops listed in the First schedule shall be subjected to testing as provided for in this part.
  - 1.1 The testing referred to in section 1 shall be done by samplers, analysts and laboratories whose qualifications shall be prescribed by the Committee.
  - 1.2 Samples collected, tested and their results reported and interpreted by this law, shall be deemed to be official samples and results.
  - 1.3 In the event of dispute of the results in section 3, the sampling and testing shall be referred to the National reference Lab.
2. This act lays down the sampling methods, methods of analysis and criteria for evaluation of rapid kits for the official control of the levels of aflatoxin in scheduled crops.
3. Analytical results shall be reported and interpreted in a uniform way in order to ensure a harmonized enforcement approach across the country.
4. The Committee shall develop reporting and interpretation for official samples.

### **Sampling**

1. Samples intended for official checking of the levels of aflatoxin content in foodstuffs shall be taken according to the methods described in the Second schedule of this bill.
2. For the purposes of this Bill, aggregate samples thus obtained shall be considered as representative of the lots.
3. All official samplers falling under the prescribed criteria by the Committee under this Bill shall be deemed to be competent.
4. Sampling shall be conducted as provide in the Second Schedule of this Act.
5. Any deviation from the sampling procedure shall be documented.



6. Samples taken by any authorized representative under this Bill shall be in duplicate.

#### Testing.

1. The Committee shall establish criteria for testing samples for Aflatoxin in the scheduled crops. Elements in the criteria shall include; sample grinding, mixing, homogenizing , replication , workers safety, analytical methods validation, testkit approval and disposal of contaminated samples.
2. Sample preparation shall be conducted as provided in the Third Schedule of this Act.
3. Analytical methods validation
  - 3.1 Analytical methods including rapid test kits shall be used for both qualitative or quantitative analysis.
  - 3.2 The Committee shall prescribe procedures for validation, evaluation and approval of rapid test kits used in the country for qualitative and quantitative analysis and designate an agency for validation of the kits.
  - 3.3 In execution of Section 3.2, the Committee shall consider parameters including: accuracy, linearity, precision, method detection limit, cross reactivity of cross-reactive mycotoxin or degradation products, matrix interference effects, and occurrence of false positive and false negative results.
  - 3.4 Other analytical methods shall be validated in accordance to international standards and demonstrate conformance to such standards.
4. The Committee shall prescribe criteria for qualification, verification and authorization of analysts and samplers involved in sampling and analysis of official samples.
5. The Committee shall keep inventory of analysts and samplers.
6. Laboratory certification

- 6.1 The Committee shall develop a mechanism for qualification, selecting and approval of national, county and national reference laboratories for testing official samples on aflatoxin contamination.
- 6.2 The Committee shall establish the functions of the county, national and national reference laboratories.
- 6.3 The laboratory shall have a documented quality management system that complies with an international standard and will demonstrate its conformance with the standard.

## **PART VII- MISCELLENOUS PROVISIONS**

7. Contaminated products
- (i). A crop shall be deemed contaminated if the Aflatoxin contamination level exceeds the regulatory limit.
  - (ii). The Committee shall re-evaluate the regulatory limits upon new risk assessment data.
8. The Cabinet Secretary through the Committee may by regulations make further provisions for prevention and control of aflatoxin contamination
9. General prohibitions and offence penalties
- a) A person shall not;-
    - i. breach or fail to comply with the provisions of this bill;
    - ii. sell contaminated product for use other than that which is prescribed by the committee;
    - iii. operate without a valid license certificate;
    - iv. fail to comply with a lawful requirement or demand made or given by an inspector or analyst or any of the regulators;
    - v. obstruct a person in execution of the powers/duties under this Bill;
    - vi. knowingly make a false statement /misrepresentation with regards to any procedure or requirement under this Bill;
    - vii. Knowingly produce a document or data required under this Bill which is forged.

- b) Any person who contravenes any of the provisions in sub-section (a) above commits an offence and shall be liable, on conviction to a fine not exceeding one million shillings or to imprisonment for a period not exceeding one year, or to both.

10. Subject to this Bill, all the private and public sector regulators described in Section 5 of this Bill shall in consultation formulate and implement administrative measures to ensure smooth and orderly transition to the regime established by this Bill.

## First Schedule: crops and mycotoxin

1. Maize
2. Sorghum
3. Millet
4. Beans
5. etc

## Second schedule

### Sampling

1. sampling for aflatoxin testing shall be performed by certified government officers or private accordance with the procedure laid down below.
2. Each lot or consignment which is to be evaluated must be sampled separately. Large lots or consignment should be subdivided into sub lots to be sampled separately.
3. In the course of sampling and preparation of the laboratory samples precautions must be taken to avoid any changes which would affect the aflatoxin content, adversely affect the analytical determination or make the aggregate samples unrepresentative.
4. Cereals and cereal products may be traded in bulk, containers, or individual packing (sacks, bags, retail packing, etc.). The sampling procedure can be applied to all the different forms in which the cereals are put on the market.
5. As far as possible incremental samples should be taken at various places distributed throughout the lot or sub lot.
6. The following formula will be used as a guide for the sampling of lots traded in individual packings (sacks, bags, retail packings, etc.):

Sampling frequency (SF)=  $\frac{\text{Weight of the lot} \times \text{weight of the incremental sample}}{\text{Weight of the aggregate sample} \times \text{weight of individual packing}}$

Weight of the aggregate sample x weight of individual packing

Weight: in kg

Sampling frequency (SF): every nth sack or bag from which an incremental sample must be taken (decimal figures should be rounded to the nearest whole number)

7. The weight of the incremental sample should be 100 to 300 grams. In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.
8. The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100. Refer to annex to determine the number of incremental samples to be taken.

9. The aggregate sample is made up by uniting and sufficiently mixing the incremental samples. After mixing, the aggregate sample must be divided into equal subsamples. A single subsample constitutes laboratory sample. The mixing is necessary to ensure that each subsample contains portions of the whole lot or sub lot.
10. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample which might arise during transportation or storage.
11. Each sample taken for official use shall be sealed at the place of sampling and uniquely identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

### **Third Schedule:**

#### Sample preparation

1. Finely grind and mix thoroughly each laboratory sample using a process that has been demonstrated to achieve complete homogenization.
2. The replicate samples for analysis and retain purposes shall be taken from the homogenized material.
3. Precaution:
  - Daylight should be excluded as much as possible during the sample processing, preparation and instrument analysis, since aflatoxin gradually breaks down under the influence of ultra-violet light.
  - As the distribution of aflatoxin is extremely non-homogeneous, samples should be prepared and homogenized with extreme care.
  - All the material received by the laboratory should be used for the preparation of test material.
  - **Lot** - an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
  - **Sublot** - designated part of a larger lot in order to apply the sampling method on that designated part. Each subplot must be physically separate and identifiable.
  - **Sampling plan** - is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum level.
  - **Incremental sample** – the quantity of material taken from a single random place in the lot or sub lot.

- **Aggregate sample** - the combined total of all the incremental samples that is taken from the lot or sub lot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
- **Laboratory sample** – the smallest quantity of sample comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.
- **Test portion** – a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the aflatoxin for chemical analysis.

#### **Fourth Schedule**

##### **Analysis**

- 3.5 owner or consignee are responsible for ensuring that the products they trade with comply with all provisions of this Act.
- 3.6 For the sake of efficiency and historical perspective, the owner or consignee dealing with laboratories should retain databases or files on each one from which it receives analytical service.
- 3.7 Having a documented system results in all staff operating to a common standard and provides assurance to customers of test reliability and consistency of service.
- 3.8 all new staff should be issued with a copy of this manual.
- 3.9 Maintain a training file to demonstrate experience and competency to perform the job the individual holds.
- 3.10 Different methods are used for qualitative and quantities testing-HPLC, LCMSMS, test kits and ELASA. The applicant requesting should specify whether they desire qualitative or quantitative testing.

##### Analytical method performance

- 1. The technical sub-committee shall establish a set of performance criteria is established with which the analytical method used should comply.

The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation, reproducibility coefficient of variation, and the percent recovery necessary for various statutory limits. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities, provided the selected method meets the following criteria **referred to in the schedule.....**

##### Test kits performance **(part of the schedules)**

1. A committee to develop the requirements applicable in evaluating performance of the test kits and review of data for the approval of kits shall be established, with KEBs as the Secretariat. The committee shall recommend kits complying with the requirements for certification and authorization for commercialization in the country. The committee shall from time to time review the requirement and the performance of the kits in the market to ensure protection of the consumers.
2. The performance of each test kit shall be evaluated quantitatively by comparing the test kit and reference method results. Each test kit also shall be qualitatively evaluated for ease of use, cost, and sample throughput.
3. Qualitative technologies should not be evaluated for linearity or method detection limit because they only provide a positive or negative result relative to a specified concentration level.

**High Level Strategy  
& Writing Session:  
Developing a Roadmap  
to Manage Aflatoxin Risk  
In Meru County**

University of Nairobi, Chiromo Campus  
Nairobi, Kenya  
January 24-25, 2019

**Agenda**

**Official Request by  
Hon. Paul Mworira Bagiine,  
Chairman; Agriculture, Livestock  
and Fisheries Committee, County  
Assembly of Meru**

**Aflatoxin risk management roles:  
Pillar of aflatoxin co-regulation**

**Regulatory market mapping  
& matrix**

**Model Bill**

**Model Bill Evaluation and  
Gap Analysis**

**Strategic Plan: Risk Management  
Matrix**

**Presentations**





High Level Strategy and Writing Session  
 Developing a Roadmap to Manage Aflatoxin Risk in Meru County

TRANSPORT								
#	Elements	County	AFA	KALRO	KEBS	KEPHIS	MOA	MPHS

STORAGE								
#	Elements	County	AFA	KALRO	KEBS	KEPHIS	MOA	MPHS

High Level Strategy and Writing Session  
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PROCESSING								
#	Elements	County	AFA	KALRO	KEBS	KEPHIS	MOA	MPHS

SALE & DISTRIBUTION								
#	Elements	County	AFA	KALRO	KEBS	KEPHIS	MOA	MPHS

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### Writing Assignment A: The Act

#### Objectives

- For each element identified in the Gap Analysis, identify the relevant Act and write draft language to address the gap

#### Resources

- Kenya Law full text search <http://kenyalaw.org/kl>

#### Activity

1. Agency breakout group: Use the amendment/revision worksheet to document amendments or additions to the Act

High Level Strategy and Writing Session  
Developing a Roadmap to Manage Aflatoxin Risk in Meru County

**Element/Topic(s):** \_\_\_\_\_

**Agency:** \_\_\_\_\_

**Act Title:** \_\_\_\_\_

**Section(s) to be amended or added:**

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**Describe the changes:**

Add a new section. Section to be added after: \_\_\_\_\_

Repeal and Replace a section. Section to be repealed:

\_\_\_\_\_

Delete and substitute a sub-section or paragraph. Subsection/Subsection and paragraph to be deleted:

\_\_\_\_\_

**New draft language:**

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High Level Strategy and Writing Session  
Developing a Roadmap to Manage Aflatoxin Risk in Meru County

List any relevant any related Subsidiary Legislation (Regulations, Rules or Orders) needed to implement the suggested revision.

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**Presentations**

## Analyst Training & Qualification

### Objectives

- Identify training elements
- Assign qualification performance standards
- Determine writing session assignments

### Resources

- KEBS-KALRO Grain Grading Training
- One-Sample-Strategy Handbook
- APTECA Manual
- SOP for Sampling and Testing
- Republic of Kenya Sampling Form
- Analyst Qualification
- Other SOPs

### Activity

1. List training elements:
  - Use of reference material - traceability
  - Preparation of reference material and sample
  - Preparation of Standard Solutions
  - SOPs
  - Uncertainty
  - Proficiency
  - Test performance
  - Results analysis
  - Analyst authorization
  
2. Performance Criteria:
  - Test analysis
  - Required analysis range
  - Number of sample
  - Dixon outlier test

High Level Strategy and Writing Session  
Developing a Roadmap to Manage Aflatoxin Risk in Meru County

**Analyst Training and Qualification**

<i>Training elements</i>	<i>OBJECTIVE</i>	<i>Performance Standards</i>	<i>REFERENCES</i>

\* Denotes control point with recordkeeping requirements

Describe the required records:

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## Preventive Controls

### Objectives

- Identify preventive controls for the prevention and reduction of mycotoxin contamination in maize
- Determine writing session assignments

### Resources

- CODEX ALIMENTARIUS CX/CF 14/8/9
- USDA Mycotoxin Handbook
- USDA Grain Inspection Handbook: Sampling
- USDA Equipment Handbook
- USDA Loss Adjustment Manual Standards Handbook
- APTECA Handbook
- One Sample Strategy Handbook

### Activity

3. From the point of incoming maize at the first point of commerce to outbound raw or processed product, determine relevant sampling and analysis control points. For example:
  - Sampling and testing food safety plan
  - Sampling
  - Grinding/particle size
  - Official sample analysis
  - Control sample analysis
  - Lab scale calibration
  - Retained file samples
  - Corrective actions
  - Recordkeeping & reporting
4. Identify points specific to each sector:
  - Formal (F)
  - SME/Posho (S)
5. Determine writing session assignments

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<i>F</i>	<i>SP</i>	<i>POINT</i>	<i>OBJECTIVE</i>	<i>CONTROL PARAMETER</i>	<i>REFERENCES</i>
X		<b>Sampling frequency</b>	Ensure that representative portions of all maize entering the facility is tested		CODEX (CX/CH 14/8/9)
X		<b>Sampling pattern &amp; sample size</b>	Ensure that the sample represents the entire truckload of maize		CODEX (CX/CH 14/8/9); GIPSA Grain Sampling Handbook (pg 2-12); LAM (pg 260)
X		<b>*Maize Sample Identification</b>	Ensure traceability to sample date, truck ID (if appropriate), and aflatoxin level		GIPSA Grain Sampling Handbook, Chapter 1 (pg 1-8)
X		<b>Subsampling</b>	Ensure that the test portion represents the entire truckload of maize		GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-4)
X		<b>*Maize Retained File Samples</b>	Retain a representative file sample for each composite sample tested; send sample to for verification analysis		GIPSA Mycotoxin Handbook (pg 4-5)
X		<b>*Finished Product Stream</b>	Ensure quality of finished product		APTEC Handbook
X		<b>*Finished Product Retained File Samples</b>	Ensure quality of finished product		APTEC Handbook
X		<b>*Finished Product Identification</b>	Ensure traceability to product run, production date, lot, and aflatoxin level		APTEC Handbook
X		<b>*Particle Size/ Grinder check</b>	Ensure that the sample is finely ground and homogeneous		GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-9)

High Level Strategy and Writing Session  
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X		<b>Grinder cleaning</b>	Ensure that the grinder is cleaned after each official sample		GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-8)
X		<b>Moisture (Grinding)</b>	Ensure that the sample can be properly prepared for testing		GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-6)
X		<b>Segregation/Storage</b>	Ensure that maize is segregated and stored to prevent adulteration		GIPSA Mycotoxin Reference (pg 21)
X		<b>*Lab scale calibration</b>	Ensure that the scale is calibrated		GIPSA Equipment Handbook, Chapter 2 (pg 2-8)
X		<b>*Control sample analysis</b>	Maintain analytical performance to accurately measure aflatoxin concentrations		APTECA & One Sample Strategy Handbooks

\* Denotes control point with recordkeeping requirements

Describe the required records:

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### Writing Assignment B: Subsidiary Legislation

#### Objectives

- For each element identified in the Gap Analysis, write draft subsidiary legislation to address the gap

#### Resources

- Kenya Law full text search <http://kenyalaw.org/kl>

#### Activity

1. Agency breakout group: Use the amendment/revision worksheet to document amendments or additions to the Subsidiary Legislation



High Level Strategy and Writing Session  
Developing a Roadmap to Manage Aflatoxin Risk in Meru County

**Element/Topic(s):** \_\_\_\_\_

**Agency:** \_\_\_\_\_

**Act Title:** \_\_\_\_\_

**Type of Subsidiary Legislation:** \_\_\_\_\_

**Section(s) to be amended or added:**

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**Describe the changes:**

Add a new section. Section to be added after: \_\_\_\_\_

Repeal and Replace a section. Section to be repealed:

\_\_\_\_\_

Delete and substitute a sub-section or paragraph. Subsection/Subsection and paragraph to be deleted:

\_\_\_\_\_

**New draft language:**

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High Level Strategy and Writing Session  
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List any relevant any related supporting directives, guidance documents or standards

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**Writing Assignment C: Directives, Guidance Documents & Standards**

**Objectives**

- For each element identified in the Gap Analysis, write supplemental documents such as Directives, Guidance Documents and Standards to address the gap

**Resources**

- Kenya Law full text search <http://kenyalaw.org/kl>

**Activity**

2. Agency breakout group: Use the amendment/revision worksheet to delineate supplemental documents

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**Element/Topic(s):** \_\_\_\_\_

**Agency:** \_\_\_\_\_

**Document Title:** \_\_\_\_\_

**Select Type of document:**

- Supporting Directive
- Guidance Document
- Standard
- Other: \_\_\_\_\_

**New draft language:**

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List any relevant SOPs, Training Manuals & other records

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**Writing Assignment D: SOPs, Training Manuals, Certification & Records**

**Objectives**

- For each element identified in the Gap Analysis, list and describe/write documents such as: SOPs, training manuals, certification requirements and records

**Resources**

- Kenya Law full text search <http://kenyalaw.org/kl>

**Activity**

- Agency breakout group: Use the amendment/revision worksheet to outline documents that support the implementation of the regulation of aflatoxin risk in maize-value chain

High Level Strategy and Writing Session  
Developing a Roadmap to Manage Aflatoxin Risk in Meru County

**Element/Topic(s):** \_\_\_\_\_

**Agency:** \_\_\_\_\_

**Document Title:** \_\_\_\_\_

**Select Type of document:**

- SOPs
- Training Records
- Work Products
- Other: \_\_\_\_\_

**New draft language/Document description:**

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List any other relevant items

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### Writing Assignment E: Remaining Gaps

#### Objectives

- For each remaining gap, describe how this gap will be addressed within the maize value chain

#### Resources

- Kenya Law full text search <http://kenyalaw.org/kl>

#### Activity

- Agency breakout group: For each remaining gap, identify and/or describe the following:
  - Pillar of co-regulation
  - Stakeholders involved
  - How the gap will be addressed
  - Resources needed
  - Additional documents to be developed



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Developing a Roadmap to Manage Aflatoxin Risk in Meru County

**Gap:** \_\_\_\_\_

\_\_\_\_\_

**Industry Association/Agency/Stakeholder Group:**

\_\_\_\_\_

**How will the gap be addressed (Briefly describe):**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Resources needed to address gap**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**List any acts or subsidiary legislation that will need to be amended**

\_\_\_\_\_

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High Level Strategy and Writing Session  
Developing a Roadmap to Manage Aflatoxin Risk in Meru County

**List other documentation to be developed**

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**APTECA**

***Aflatoxin Proficiency Testing and Control in Africa***



Handbook

January 2019

Version 6.1

**Texas A&M AgriLife Research**

**College Station, TX**

**University of Nairobi Chiromo Campus**

**Nairobi, Kenya**

**BACKGROUND**

To manage the economic and food safety risk of aflatoxin contamination, individuals need real-time information about the level of aflatoxin in cereals, oilseeds and their products. That’s why the APTECA program implements a process approach to measure and manage aflatoxin risk. Accurate measurement of aflatoxin is complicated by the nature of the toxin and the challenges associated with sampling and testing maize. To standardize these processes and reduce the variability of aflatoxin test results, APTECA promotes the use of uniform sampling, testing equipment and methods; proficiency testing; use of laboratory control samples; and third party verification.

**ELIGIBILITY & PARTICIPATION:**

Since 2014, the Aflatoxin Proficiency Testing and Control in Africa, Asia, Americas and Europe (APTECA) program focuses on process verification and aflatoxin risk management. Firms agree to:

- Develop a written APTECA Food Safety plan (Appendix A);
- Collect representative samples of incoming maize and finished product (i.e., maize flour or meal) using the methodology described in the APTECA Food Safety plan and handbook;
- Prepare samples using methodology that retains the representative property of the sample;
- Test ground maize and finished product using field validated testing methods;
- Maintain records that enable third party audit and verification;
- Perform the above activities with trained personnel; and
- Analyze proficiency samples twice a year and submit results to APTECA.

Firms, government agencies, and researchers in Africa that want to participate in the APTECA proficiency testing program can enroll free of charge in 2017 at <http://apteca.tamu.edu>.

**EMPLOYEE PROFICIENCY**

APTECA participants must have a minimum of two employees capable to perform aflatoxin sample analysis. The employee(s):

- Must review the APTECA handbook and submit an approved written APTECA Food Safety Plan;
- Must be trained prior to performing the APTECA procedures described in the handbook and plan; and
- Must successfully complete aflatoxin proficiency testing administered by APTECA.

**PREVENTIVE CONTROLS**

APTECA participants monitor preventative controls and take corrective actions to maintain equipment and analytical performance at six points within the risk management process (Table 1).

**Table 1.** Preventative control points, objectives, and parameters.

<b>POINT</b>	<b>OBJECTIVE</b>	<b>CONTROL PARAMETER</b>
<b>Test kit selection</b> Table 2	Ensure results are accurate within test kit specified range	Field validation by Texas A&M ISO accredited lab
<b>Sample collection</b> Figure 1, Table 3	Ensure that the sample represents the entire truckload of maize	Grind a 2 kg composite sample from individual truckloads.
<b>Grinder check</b>	Ensure that the sample is finely ground and homogeneous	≥60% ±10% of the ground particles (% fines) pass through a 20 mesh sieve
<b>Lab scale calibration</b>	Ensure that the scale is calibrated	50 gram calibration weight measures between 49.8 - 50.2 grams
<b>Control sample analysis</b>	Maintain analytical performance to accurately measure aflatoxin concentrations	Control sample test results duplicate within acceptable range (Table 2)
<b>Retained File Samples:</b>	Retain a representative file sample for verification analysis by AgriLife Research	Verification results duplicate within an acceptable range
<b>Corrective Action</b>	Document changes when a deviation occurs	A deviation is a failure to meet a control parameter

**TEST KIT SELECTION**

In order to address the continual introduction of new aflatoxin rapid test kits on the market and expand the scope of the APTECA program, a field validation process for field-based test kits has been adopted as described below.

Process for Field Validation

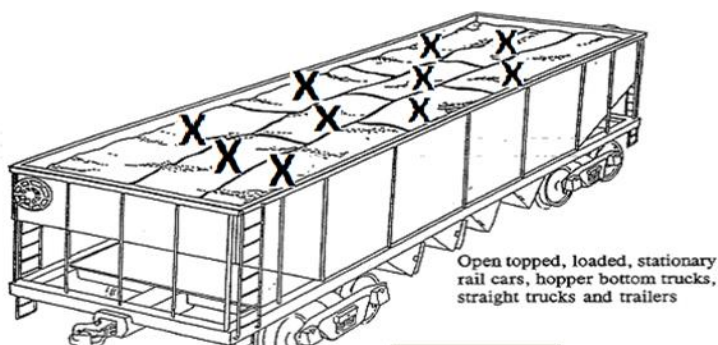
- i. Mill or grain storage operator selects a Performance Verified Test Kit by a competent authority (e.g. Institute for Reference Materials and Measurements EU-RL, USDA Grain Inspection Packers Stockyard Administration)
- ii. Mill or grain storage operator submits APTECA Sampling & Testing Plan;
- iii. Mill or grain storage operator analyst passes qualification exercise using selected test kit;
- iv. Grain storage operator analyst runs two OTSC control samples (low and high concentrations) once a week and submit results to Texas A&M AgriLife at the University of Nairobi;
- v. Grain or grain storage operator analyst retains a file sample for each sample analyzed and submits to AgriLife at the University of Nairobi;
- vi. AgriLife completes statistical data analysis using performance criteria in Table 2.
- vii. Aflatoxin test kits that fail to meet performance criteria within the specified testing test range (Table 2) will no longer be used by APTECA program participants.

**Table 2.** Aflatoxin duplication limits.

<b>If the Aflatoxin control is:</b>	≤ 25 ppb	> 25 to ≤ 50 ppb	> 50 to ≤ 100 ppb	> 100 ppb
<b>Acceptable Duplication limit is:</b>	± 40 %	± 34 %	± 25 %	± 20 %

**SAMPLING & TESTING**

Uniform sampling and testing procedures reduce the variability of test results. APTECA procedures are based on the Codex Standard (CX/CF 14/8/9) or other Code by competent regulatory authority. Each participating location submits a customized APTECA Food Safety Plan to describe how standard operating procedures will be implemented.



**Figure 1.** For bulk loads of grain in railcars or trucks, use a 10-probe pattern and collect 2 kg of maize .

**Table 3.** Number or incremental samples to be taken depending on the weight of the lot.

Lot weight (ton)	Number of incremental sample
≥ 0.05	3
> 0.05 - ≤ 0.5	5
> 0.5 - ≤ 1	10
> 1 - ≤ 3	20
> 3 - ≤ 10	40
> 10 - ≤ 20	60
> 20 - ≤ 50	100

Source: Codex Alimentarius. CX/CF 14/8/9. 2014. Sampling plan design considerations.

### RECORDKEEPING & REPORTING

All participating locations agree to keep records for a period of one year and make records available for review by APTECA program representatives. Records include: particle size log; lab scale log; laboratory reference material log; aflatoxin test results log for incoming maize and finished maize products; corrective action record.

### MONITORING & CORRECTIVE ACTIONS

APTECA monitors personnel, equipment, and performance records to ensure compliance with the program standards.

- Observe sampling procedures;
- Review records; and
- Recommend corrective actions.

Retained file samples sent by the participating mill are analyzed for aflatoxin (without further grinding) by Texas A&M AgriLife Research personnel at the University of Nairobi using Romer FluoroQuant® Afla. APTECA compares the firm's aflatoxin result with the Texas A&M AgriLife Research laboratory result and reports the level of aflatoxin to the company's management. When aflatoxin verification results do not agree, mill operators will perform a review to find the cause of the deviation, and initiate and document corrective actions. Corrective actions may include:

- Adjustment or repair of equipment;
- Retraining of personnel;
- Correction of records;
- Assistance from the firm's management; and/or
- Suspension or removal of an employee or firm from the program.

### CONTACT US

Anne Muiruri  
Analytical Chemist, Program Coordinator  
Texas A&M AgriLife Research, University of Nairobi  
(+254)072379961  
[mawmuiruri@gmail.com](mailto:mawmuiruri@gmail.com)

Tim Herrman  
Professor, State Chemist and Director  
Office of the Texas State Chemist  
001 + 979 - 845- 1121  
[tjh@otsc.tamu.edu](mailto:tjh@otsc.tamu.edu)

Contacts for Aflatoxin Test Kits and price lists (Table 4) are presented below:

Charm – Meikel Brewster, 781-640-2489 US, email [meikelb@charm.com](mailto:meikelb@charm.com)

Neogen – F&S Scientific, Rachel Lilies [Rachel.wangui@fnscientific.com](mailto:Rachel.wangui@fnscientific.com) tel +254 727 800 800

or Jitesh Shah [jitesh.shah@fnscientific.com](mailto:jitesh.shah@fnscientific.com) tel: 00254 20 3594777

Vicam – Willen Joubert +27(11)553-2300 [willem.joubert@microsep.co.za](mailto:willem.joubert@microsep.co.za) Microsep



Table 4: Price list for companies that have offered discounts to APTECA participants that are GIPSA validated and approved.

	<b><u>ROSA FAST (Charm Sciences)</u></b>	<b><u>Veratox (Neogen)</u></b>	<b><u>Reveal Q+ (Neogen)</u></b>	<b><u>AflaTest (Vicam)</u></b>
<b>Range</b> (GIPSA guideline)	5 – 150 ppb	5 – 100 ppb	5-100 ppb	5 – 1000 ppb
<b>Mechanism</b>	Antigen/Antibody color reading of strip	Antigen/Antibody color reading of solution	Lateral flow	Fluorescence of analyte eluted through a column
<b>Extraction Solvent</b>	100 ml 70/30 Methanol/Water	250 ml 70/30 Methanol/Water	125 ml 65/35 Ethanol/Water	100 ml 80/20 Methanol/Water
<b># of samples/run</b>	Up to 4	Up to ~ 40	1	1
<b>Est. time/kit</b>	3 min.	15 min.	12 min	7 min.
<b>Comments</b>	Keep cold & bring to room temp. for testing	Keep cold & bring to room temp. for testing	Refrigeration not required; Test kit dev. & extractor react quickly	Refrigeration not required; Test kit dev. & extractor react quickly
<b>Reader Cost</b>	2000 samples per year for free reader	No cost if purchasing 20 kits	No cost if purchasing 20 kits	On loan, \$1000 order limit for free shipping of kits
<b>Accessory Part # Est. Cost</b>	Incubator No cost if purchasing 2000 tests	No cost if purchasing 20 kits	Each kit comes complete with all test & accessory materials	12 position pump stand w/ 6 pumps  \$1062
<b>Calibration Set Part # &amp; Est. Cost</b>	Included w/ kit	Included w/ kit	Included w/ kit	33020 \$31
<b>Kit Part # Est. Cost # Analyses/Kit</b>	LF-AFQ-FAST-100K \$400 + VAT (100 analyses /kit)	8030 \$180 + VAT (40 analyses/kit)	8085 \$140 + VAT (25 analysis/kit)	AflaTest Columns 12022 \$378 (50 pack) VAT included

## APPENDIX A [COMPANY NAME] APTECA Food Safety Plan

### Company Information

Primary Contact:

Address:

Phone Number:

Fax Number:

Email:

### Scope / Field of Application

This APTECA Food Safety Plan applies to the following products:

### Equipment

Aflatoxin Test Kit and Reader:

### Responsibilities

Quality Assurance manager:

General Manager:

Laboratory manager:

Production manager:

Analyst:

### Definitions

<b>Aflatoxin:</b>	A toxic fungal metabolite that is a group 1 carcinogen
<b>Composite Sample:</b>	A sample formed by compositing or accumulating and combining a number of discrete samples; useful in determining the average composition of a large amount, such as a shipload, carload, or truckload.
<b>Control Sample:</b>	A sample that is carefully subdivided with portions sent to a number of laboratories for analysis and used as a check on laboratory assay procedures.
<b>Control Sample Log:</b>	A mandatory record of control samples performed weekly
<b>Corrective Action Record:</b>	A mandatory record of corrective actions
<b>Flour Aflatoxin Log:</b>	A mandatory record of finished product (i.e., maize flour or meal) aflatoxin analysis
<b>Lab Scale Log:</b>	A mandatory record of scale calibration performed daily
<b>Maize Aflatoxin Log:</b>	A mandatory record for every load of maize received
<b>Particle Size:</b>	Measured as percent passing through a US 20 mesh sieve (841 microns openings)
<b>Particle size Log:</b>	A mandatory record of particle size analysis performed weekly
<b>Retained File Sample:</b>	A duplicate portion of a lot retained in case an analysis is needed following use or distribution of the lot.

**Procedure****1. The [COMPANY NAME] APTECA Food Safety Plan**

- A. This plan includes methodology for sample collection of incoming maize and finished product, sample grinding, sample preparation and aflatoxin testing of maize and flour, recordkeeping, analyst training and qualification, participation in proficiency testing, lab scale calibration, use of control samples, and sample retention for third party verification.
- B. This plan includes monitoring frequency, critical limits, corrective action, testing verification procedures and record keeping.
- C. The APTECA Food Safety Plan supports, but does not eliminate or preempt, the [COMPANY NAME] HACCP plan.

**2. Employee Training and Qualification**

- A. Analyst reads the test kit instructions;
- B. Analyst observes the experienced analyst perform test;
- C. Analyst runs 6 samples tested by the previous analyst and compares results using the Dixon outlier test (<http://www.apteca.tamu.edu>)
- D. Analyst runs three sets of control samples and plots results on the control chart; and
- E. Analyst runs quarterly APTECA proficiency analyses.

**3. Preventive Controls: Incoming Truckloads of Maize**

- A. Maize Sample Collection and Subsampling: All incoming loads of maize will be representative and follow a prescribed pattern and frequency as follows:
  1. Sample Collection:
    - i. Bulk Loads: A \_\_\_-probe sampling pattern performed with a slotted spiral grain probe is used to collect a minimum of \_\_\_ kg.
    - ii. Bags: A bag probe is used to collect a minimum of \_\_\_ kg.
  2. Subsampling:
    - i. The entire \_\_\_kg maize sample is ground;
    - ii. A representative 500 g subsample is obtained using a quartering or riffing technique;
    - iii. 50 g are analyzed for aflatoxin and the remaining 450 g are retained as a file sample.
- B. Maize Particle Size: Particle size of ground maize will be analyzed once per week or when the analyst suspects there is a need to adjust the grinder as follows:
  1. A 50 g representative subsample is weighed and placed on a 20 mesh sieve then covered by pan and lid;
  2. The 50 g sample is shaken for 60 seconds;
  3. The material passing through the 20 mesh sieve is weighed;
  4. The percentage of material passing through the 20 mesh sieve is expressed as a percentage (target particle size  $\geq 70\% \pm 10\%$  passing through a 20 mesh sieve);
  5. Adjust the grinder if less than 60% ground maize passed through the 20 mesh sieve; and
  6. Record results in the Particle Size Log.
- C. Lab Scale Calibration: The laboratory scale will be calibrated daily before use and after electrical outage.
  1. Calibrate the scale daily before use with a 50 g calibration weight (target calibration 49.8- 50.2 grams ( $\pm 0.2$  g));
  2. Record results on the Lab Scale Log; and
  3. Adjust scale if the weight deviates by more than 0.2 g.
- D. Control Sample Analysis: Control samples provided by Texas A&M AgriLife Research will be run at the beginning of the week and when new lots of test kits and reagents are used.
  1. Results of the control sample will be plotted on the control chart.
  2. If the laboratory results are outside the aflatoxin control sample limits, corrective action by the laboratory will be implemented to determine the cause of the deviation (inaccurate measurement).

E. Retained Maize File Samples: Twice a month, \_\_\_\_\_ (Name and Title) will send \_\_\_\_, 450 g retained maize samples to the Texas A&M AgriLife Research laboratory at the University of Nairobi for verification.

#### 4. Finished Product (i.e., maize flour or meal) Preventative Controls

A. Flour Sample Collection: Each hour, a 200 g sample will be collected from the finished product stream. The point of collection will be at the \_\_\_\_\_ line spout on the \_\_\_\_ floor. Samples will be collected \_\_\_\_ (e.g. hourly) and composited every \_ hours (total \_ kg of flour) and tested for aflatoxin following test kit directions.

B. Retained Flour Samples: Every two weeks, \_\_\_\_\_ (Name and Title) will send \_\_\_\_, 500g retained flour samples to the Texas A&M AgriLife Research laboratory at the University of Nairobi for verification.

#### 5. Maize and Finished Product Sample Identification

A. Samples submitted to the Texas A&M AgriLife Research laboratory at the University of Nairobi will have a unique identification number that will provide traceability to the truck or flour production shift and lot as follows:

1. Maize: All retained maize file samples will be traceable to the time, date, truck ID (if appropriate), and aflatoxin level.
2. Finished Product: All retained flour or meal samples will be traceable to the product run, date, lot, and aflatoxin level.

#### 6. Third Party Verification Labeling

A. A logo prescribed by the verification provider will be used for only those products contained in this plan and conforming to the [COMPANY NAME] APTECA Food Safety Plan that contain  $\leq 10$  ppb in the finished product.

#### 7. Records and Reporting Responsibilities

- A. The following records will be retained for a period of one year: particle size log, lab scale log, control sample log, control chart, maize aflatoxin log, flour aflatoxin log, corrective actions record.
- B. Records will document any deviations and corrective actions.
- C. Retained maize file samples are kept for \_\_ days
- D. Retained finished product file samples are kept for \_\_ days.

#### 8. Corrective Actions

- A. [COMPANY NAME] will reject incoming truckloads of maize that exceed 10 ppb.
- B. [COMPANY NAME] will not distribute finished product that contains greater than 10 ppb aflatoxin with the APTECA seal.
- C. Inability to replicate control sample results within the acceptable range will result in a root cause analysis to investigate reagents, kits, reader, scale, and analyst. Once the process is corrected and corrective actions have been documented on the Corrective Action Record, the firm may proceed to analyze samples.
- D. If a sample of finished product is found to contain >10 ppb aflatoxin by Texas A&M AgriLife Research at the University of Nairobi, [COMPANY NAME] will perform a root cause analysis and document corrective actions on the Corrective Action Report.
- E. An investigation will be taken if [COMPANY NAME] quarterly proficiency results have a Z-value score >2 and a corrective action if the Z-value score is >3.

#### Revision History