

2017 Co-Regulation Implementation Plan: Aflatoxin Risk Management in Kenya

DRAFT

Version 1

June 23, 2017 1:00 PM REVISIONS

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**2017 Co-Regulation Implementation Plan:
Aflatoxin Risk Management in Kenya**

Prepared by:

TBD

With input from:

TBD

For further information please contact:

TBD

Executive Summary

TBD

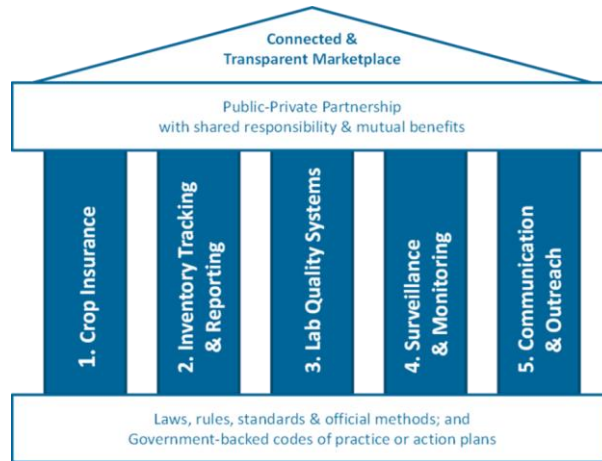


Figure 1. Pillars of Aflatoxin Co-Regulation

Background

TBD

Context

TBD

Stakeholders

Public	Private	Development Partners
Agriculture and Food Authority (AFA)	Association of Kenya Feed Manufacturers (AKEFEMA)	Food & Agriculture Organization (FAO)
Kenya Agricultural & Livestock Research Organization (KALRO)	Cereal Growers Association (CGA)	World Food Programme (WFP)
Kenya Bureau of Standards (KEBS)	Cereal Millers Association (CMA)	
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)

Gap Analysis	
<i>Strengths</i>	<i>Challenges</i>
TBD	TBD
TBD	TBD

Gap Analysis	
<i>Priority Areas for Improvement</i>	
Legal	
<ul style="list-style-type: none"> TBD 	
General	
<ul style="list-style-type: none"> TBD 	
Production (Whole Maize)	
<ul style="list-style-type: none"> Availability of aflatoxin resistant hybrid seeds; Access to quality certified seed; Crop stress; Limited knowledge and information on aflatoxin; and Traceability. 	
Storage & Transport (Whole Maize)	
<ul style="list-style-type: none"> Favorable conditions for the growth of Aflatoxin/poor technologies in preventing and controlling the growth of Aflatoxin; Poor post-harvest handling and storage practices/poor Infrastructure; Low awareness by all actors along the value chain/ Poor extension services performance; and Weak systems for aflatoxin monitoring 	
Processing, Sales & Distribution (Processed Maize)	
<ul style="list-style-type: none"> Design, layout and construction of processing facilities; Unknown levels of aflatoxin contamination in raw material and processed maize products; No government defined criteria for co-regulation; Lack of validated of moisture meter and aflatoxin rapid test kit technologies; and Acceptance of private sector labeling of "aflatoxin tested" product as a product of co-regulated material. 	

An implementation plan addressing the areas listed above can be found on pages X-X.

Implementation Plan

LEGAL						
Objective: To enact appropriate legislation for the control and prevention of aflatoxins.						
Category	Challenge	Strategy	Activities	Responsibilities	Timeline	Resources
	<u>Need legislation across authorities to manage aflatoxin risk</u>	<u>Legislation</u>	<u>High level and stakeholder meetings</u>	<u>MOA (stakeholder meeting)</u>	<u>Start by December 2017</u>	

GENERAL						
Objective: To increase awareness on risks associated with aflatoxin to health, agriculture and trade, and about the technologies and approaches available to prevent and mitigate contamination. To support Research and technology development options for the control and prevention of aflatoxin and other mycotoxins in Kenya.						
Category	Challenge	Strategy	Activities	Responsibilities	Timeline	Resources
	<u>Need to collaborate with CG and City Council to adopt co-regulation</u>	<u>Stakeholder meetings</u>	<u>Labeling 'aflatoxin tested'</u>			
	<u>Need for validated moisture meters and aflatoxin rapid test kits</u>	<u>develop validation protocol & reference material for moisture meters and aflatoxin rapid test kits</u>	<u>private and public sector</u>			

<p>Extension of authority to qualified private analysts</p>	<p>Need options for maize containing >10 ppb aflatoxin (e.g., expanded limits for animal feed; aflatoxin binders; blending action plans)</p>	<p>Need research/risk assessments to evaluate options for expanded limits for animal feed, aflatoxin binders & blending action plans)</p>	<p>EAC alternate uses policy notice; FDA CPG Sec. 683.100. Action Levels for Aflatoxin in Animal Feeds</p>
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<p>PRODUCTION (WHOLE MAIZE)</p>						
<p>Objective: Produce and maintain aflatoxin safe produce and products along the food and feed value chains at permissible levels.</p>						
<p>Category</p>	<p>Challenge</p>	<p>Strategy</p>	<p>Activities</p>	<p>Responsibilities</p>	<p>Timeline</p>	<p>Resources</p>
<p>Production input</p>	<p>Availability of aflatoxin resistant hybrid seeds</p>	<p>Development of aflatoxin resistant hybrid seeds</p>	<p>Commercialization of already developed aflatoxin resistant hybrid seeds</p>	<p>Private sector seed actors</p>	<p>MoA to provide</p>	<p>MoA to provide</p>

			Research on new aflatoxin resistance hybrid seeds	KALRO	MoA to provide	MoA to provide
	Access to quality certified seed.	Government provides incentives to encourage availability of aflatoxin resistant seed	Commercialization of already developed aflatoxin resistant hybrid seeds	MoA KEPHIS	MoA to provide	MoA to provide
Crop yield	Crop stress	GAP	Training GAP	MoA	MoA to provide	MoA to provide
		Climate change mitigation	Promote climate smart agriculture	MoA	MoA to provide	MoA to provide
Knowledge and Information	Limited knowledge and information on aflatoxin	Enhance knowledge and awareness	Intensive extension service	MoA	MoA to provide	MoA to provide
			Provision of training materials in local dialect.	MoA	MoA to provide	MoA to provide
			Sensitization and awareness campaign	MoA	MoA to provide	MoA to provide
			Disseminate information on aflatoxin resistant varieties	MoA	MoA to provide	MoA to provide
Registration	Traceability	Registration of growers	Develop registration mechanism	MoA AFA & CG	MoA to provide	MoA to provide

STORAGE & TRANSPORT (WHOLE MAIZE)						
Objective: Preserve the integrity...						
Category	Challenge	Strategy	Activities	Responsibilities	Timeline	Resources
	<u>lack validation of moisture meter and aflatoxin rapid test kit</u>	<u>identify an approach to perform validation of moisture meters and rapid test kits</u>	<u>MOA will hold a stakeholder (grain millers, labs, traders & others to be determined) forum prior to determining baseline for validation criteria</u>	<u>public & private sectors</u>	<u>start by December 2017</u>	<u>to be determined</u>
	Favorable conditions for the growth of Aflatoxin / Poor technologies in preventing and controlling the growth of Aflatoxin	Develop technologies for aflatoxin prevention and control for transport & storage	Support and expand the use and adoption of proven storage technologies in preventing and controlling aflatoxin	KALRO/AFA/ MoA/KEPHIS/ Private Sector/ MoH		
	Poor post-harvest handling and storage practices/ Poor Infrastructure	Incorporate Aflatoxin control initiatives and best transport and storage practices	Adopt appropriate post-harvest handling practices	NCPB/MoA/AF A/KALRO/Private Sector/ MoH		
	Low awareness by	Develop efficient extension services	Develop and disseminate information and	NCPB/MoA/AF A/KALRO/		

all actors along the value chain/ Poor extension services performance	and information sharing systems for prevention and control of Aflatoxin	awareness on the cause and mitigation of Aflatoxin in transport and storage	MoH/ Private Sector
Weak systems for aflatoxin monitoring	Strengthen/develop robust monitoring systems	Implement robust aflatoxin monitoring systems	NCPB/MoA/AF A/KALRO/ MoH/ Private Sector

PROCESSING, SALES & DISTRIBUTION (PROCESSED MAIZE)						
Objective:						
Category	Challenge	Strategy	Activities	Responsibilities	Timeline	Resources
Preventive Controls in Processing, sale and distribution	Design, layout and construction of processing facilities	education/awareness	develop awareness material with model designs	public sector		
	unknown levels of aflatoxin contamination in raw material and processed maize products	implementation of GMP measures <u>and co-regulation preventive controls</u>	engagement and capacity building of staff and analysts;	private sector	start by December 2017	to be determined
Testing			testing raw material and products;	private and public sector	start by December 2017	to be determined

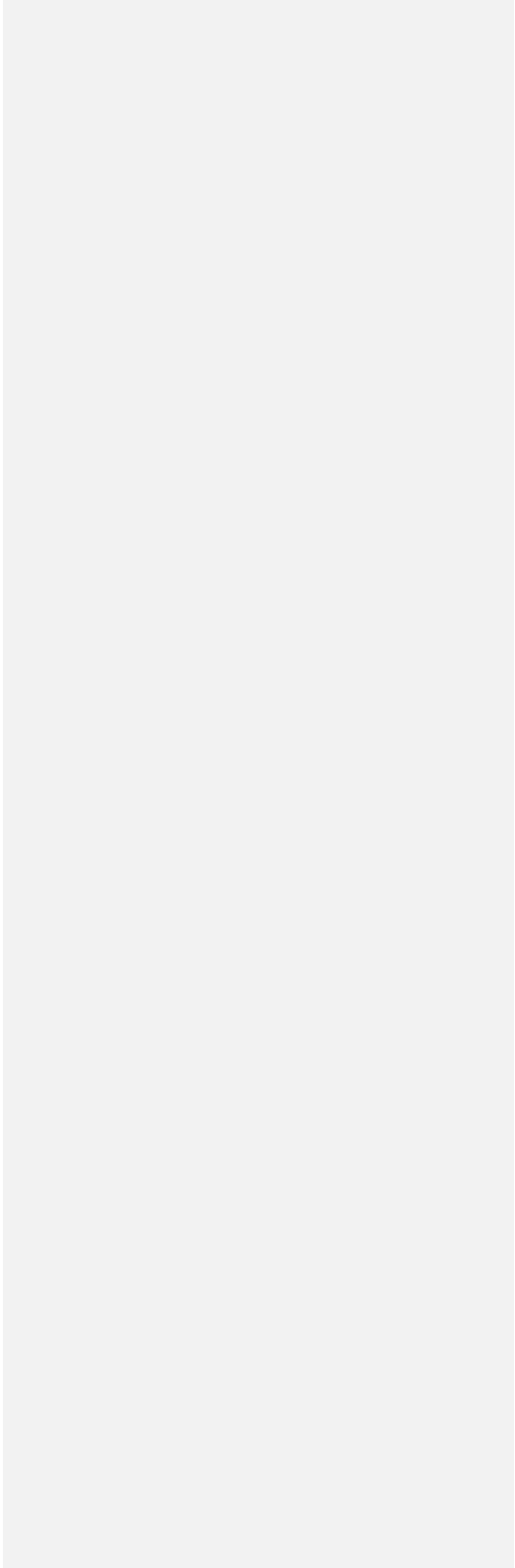
	No government defined criteria for co-regulation	Develop code of regulation for co-regulation <u>preventive controls and action plans</u>	Food safety plan which include quality system	private and public sector	start by December 2017	to be determined
			qualification of analysts	public sector	start by December 2017	to be determined
			gazetment of analysts	public sector	start by December 2017	to be determined
			develop validation protocol & reference material for moisture meters and aflatoxin rapid test kits	private and public sector	start by December 2017	to be determined
	lack validation of moisture meter and aflatoxin rapid test kit	identify an approach to perform validation of moisture meters and rapid test kits	MOA will hold a stakeholder (grain millers, labs, traders & others to be determined) forum prior to determining baseline for validation criteria	public & private sectors	start by December 2017	to be determined
finished product	acceptance of private sector labelling of "aflatoxin tested" product as a	develop code of regulation for co-regulation that defines labelling of	enforcement	private and public sector	start by December 2017	to be determined

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product of co-regulated material	"aflatoxin tested" product
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Concluding Remarks

The _____ looks forward to working throughout the coming years with public stakeholders in all relevant ministries and county government, as well as and private stakeholders across the maize value chain to manage aflatoxin risk through a co-regulation.



APPENDIX TBD. Definitions

APTECA
GAFTA
GIPSA
HPLC

APPENDIX TBD. Legislative Matrix by Maize Value Chain Stage

PRODUCTION (WHOLE MAIZE)		
<i>Element</i>	<i>Legislation</i>	<i>Notes</i>
Land preparation	Crop ACT No. 16 of 2013; Part II section 12(2c)	All aspects of production in this section. Can enable legislation of the right laws and guidelines.
Land preparation	Crops ACT No. 16 of 2013; section 4 (b)	Cross contamination (pollination)
Land preparation	Plant protection ACT 342 section 4 (1), 3(g)	Occupation of land and reduction & prevention of spread of pest and diseases
Land preparation	Agriculture and Food Authority ACT No. 13 of 2013 23 (a) and (e)	Restriction of land use for agriculture production.
Seed	Crops ACT No. 16 of 2013; section 12(2c), 8 (i), 31(1c), 40 (2c),(2f),	(c) affordable farm-inputs including quality seeds, planting materials and market linkage; Have provision on aflatoxin resistant cereal seed varieties
Seed	Seeds and variety ACT CAP 326 section 1 (e), 3B (2C), 3C (1C)	(Coregulation of seeds) Agency has the capacity to certify seed quality; propose to have aflatoxin included as one of the parameters; The use of uncertified seeds.
Time and method of harvesting	Plant protection ACT 342 section, 3 (e), (g)	Prohibition on cultivation and harvesting to control spread of pest and diseases.
Planting	Plant protection ACT 342 section 3 (g)	
Plant protection product	PCPB ACT 346 No. 6 of 2009 6(b) and 15(b)	6(b)to consider applications for registration of pest control products and to make recommendations thereon to the Minister; 15 (b) prescribing the form in which applications for registration shall be made and the information to be furnished therewith
Irrigation	CAP 372 No. 8 of 2002	(a) to develop principles, guidelines and procedures for the allocation of water resources;
Crop Insurance		

STORAGE (WHOLE MAIZE)		
Element	Legislation	Notes
Farm/Local collection point:	Crops Act No.16 of 2013(section 12 (2)h)	The Authority may, in accordance with rules and regulations made under this Act and subject to any other law, put in place programmes for ensuring the provision of the following incentives and facilities to growers and dealers of scheduled crops— Post-harvest facilities and technologies including storage, processing, distribution and transport facilities;
Storage structure/type	CAP 338 (Section 4:1(a))	The functions of the Board shall be to regulate or to control the collection, movement, storage, sale, purchase, transportation, marketing, processing, distribution, importation, exportation, disposal and supply of maize, wheat and scheduled agricultural produce;
	CAP 254 Section 7	Preparation of food under insanitary conditions; Any person who sells, prepares, packages, conveys, stores or displays for sale any food under insanitary conditions shall be guilty of an offence.
Storage container	CAP 254 Section 7	Preparation of food under insanitary conditions Any person who sells, prepares, packages, conveys, stores or displays for sale any food under insanitary conditions shall be guilty of an offence.
Drying/moisture monitoring	None?	
Warehouse inspection/receipt	None?	
Pest Control practices & products	CAP 346 Section 15 (g)	Regulations : respecting the manufacture, storage, distribution, display and use of any pest control product
	CAP 324 Section 8(2d)	Direct or authorize the disinfection or fumigation of any vehicle, vessel or aircraft suspected of harbouring any pest or article likely to infect any plant with disease;
Sampling	AFA Act No. 13 of 2013	The Authority shall, in consultation with the county governments, promote best practices in, and regulate, the production, processing, marketing, grading, storage, collection, transportation and warehousing of agricultural products excluding livestock livestock products as may be provided for under the Crops Act;
Cleaning and sorting	None?	
Grading	AFA Act No. 13 of 2013	The Authority shall, in consultation with the county governments, promote best practices in, and regulate, the production,

		processing, marketing, grading, storage, collection, transportation and warehousing of agricultural products excluding livestock livestock products as may be provided for under the Crops Act;
	CAP 338 Section 30(1d)	Regulations: provide for the standards to which maize, wheat or scheduled agricultural produce acceptable for delivery to the Board shall conform and the grading and classification of maize, wheat or scheduled agricultural produce;
	Crops Act No.16 of 2013 (sections 8k)	Establish and enforce standards in grading, sampling and inspection, tests and analysis, specifications, units of measurement, code of practice and packaging, preservation, conservation and transportation of crops to ensure health and proper trading;
Sampling	Crops Act No.16 of 2013 (sections 8k)	Establish and enforce standards in grading, sampling and inspection, tests and analysis, specifications, units of measurement, code of practice and packaging, preservation, conservation and transportation of crops to ensure health and proper trading;
Testing	Crops Act No.16 of 2013 (sections 8k)	Establish and enforce standards in grading, sampling and inspection, tests and analysis, specifications, units of measurement, code of practice and packaging, preservation, conservation and transportation of crops to ensure health and proper trading;
Segregation	CAP 254 (37d)	Any substance commonly used for human consumption which is found on premises used for the preparation, storage, or sale of that substance and any substance commonly used in the manufacture of products for human consumption which is found on premises used for the preparation, storage or sale of those products, shall be presumed, until the contrary is proved, to be intended for sale, or for manufacturing products for sale, for human consumption;
Bulking/Aggregation	None?	
Disposition	None?	
Blending/Mixing	None?	

TRANSPORT (WHOLE MAIZE)		
Element	Legislation	Notes
Type of transport (open, closed)	CAP 338 (Section 4:1(a)	The functions of the Board shall be to regulate or to control the collection,

		movement, storage, sale, purchase, transportation, marketing, processing, distribution, importation, exportation, disposal and supply of maize, wheat and scheduled agricultural produce;
	Crops Act No.16 of 2013 (sections 8-c&k)	Section 8 (c)AFA enjoin the Ministry responsible for transportation and communications to effect an efficient, regular and economical means of transporting scheduled crops, for purposes of reducing marketing costs and ensuring stable consumer supply;
		Section 8 (k)establish and enforce standards in grading, sampling and inspection, tests and analysis, specifications, units of measurement, code of practice and packaging, preservation, conservation and transportation of crops to ensure health and proper trading;
	Crops Act No.16 of 2013(section 12 (2)h)	The Authority may, in accordance with rules and regulations made under this Act and subject to any other law, put in place programmes for ensuring the provision of the following incentives and facilities to growers and dealers of scheduled crops— Post-harvest facilities and technologies including storage, processing, distribution and transport facilities;
	Crops Act No.16 of 2013(section 40 (2)k)	Regulations: rules for ensuring food safety including handling, transportation, processing and market standards of food crops and crop products;
	AFA Act No. 13 of 2013	The Authority shall, in consultation with the county governments, promote best practices in, and regulate, the production, processing, marketing, grading, storage, collection, transportation and warehousing of agricultural products excluding livestock livestock products as may be provided for under the Crops Act;
Cross-contamination (trucks, bags, etc.)	CAP 338 (Section 4:1(a))	The functions of the Board shall be to regulate or to control the collection, movement, storage, sale, purchase, transportation, marketing, processing, distribution, importation, exportation, disposal and supply of maize, wheat and scheduled agricultural produce
	Crops Act No.16 of 2013(section 40 (2)k)	Regulations: rules for ensuring food safety including handling, transportation, processing and market standards of food crops and crop products

	Crops Act No.16 of 2013 (sections 8-k)	Section 8 (k) establish and enforce standards in grading, sampling and inspection, tests and analysis, specifications, units of measurement, code of practice and packaging, preservation, conservation and transportation of crops to ensure health and proper trading;
Bulk	CAP 338 (Section 4:1(a))	The functions of the Board shall be to regulate or to control the collection, movement, storage, sale, purchase, transportation, marketing, processing, distribution, importation, exportation, disposal and supply of maize, wheat and scheduled agricultural produce;
Import/export	CAP 338 (Section 4:1(a))	The functions of the Board shall be to regulate or to control the collection, movement, storage, sale, purchase, transportation, marketing, processing, distribution, importation, exportation, disposal and supply of maize, wheat and scheduled agricultural produce;
	CAP 254 Section 28 (1d)	Regulations: respecting the importation or exportation of food, drugs, chemical substances, cosmetics and devices in order to ensure compliance with this Act and any regulations made thereunder;
Trading	CAP 338 (Section 4:1(a))	The functions of the Board shall be to regulate or to control the collection, movement, storage, sale, purchase, transportation, marketing, processing, distribution, importation, exportation, disposal and supply of maize, wheat and scheduled agricultural produce;

PROCESSING, SALES & DISTRIBUTION (PROCESSED MAIZE)		
Element	Legislation	Notes
Sampling	CAP 496 KEBS (Standards) Part 1 (2)	CAP 496 Standards: The word is mentioned under definitions but needs to be further expressed
	CAP 242 Public Health Part 11, Sect. 134 e	CAP 242 Public Health part 11,sect.134e – needs to include sampling of animal products for aflatoxin
	Crops Act No. 16 of 2013 Part2 para.8k	
	CAP 254(Food Drugs, and chemical substances Act sect.2, sect.28(j), 30(1)(a,b,)),11,31,32(1), 35	CAP 254 Food Drugs, and chemical substances Act sect. 30(1)(a,b,)- authorizing officers to sample (anything that can be used to prepare, preserve, store, pack or convey food) from any premise

Visual examination/sorting/grading	CAP338: NCPB Part5 sect.24 (1)(2), Part8 sect.30(1,d) Crops Act 16 of 2013 part 2(8k) Act No. 54 of 2012: KEPHIS Part 5(h)	Crops Act 16 of 2013 – grading laws Sorting does not appear in the Acts related to food CAP338: NCPB Part5 sect.24 (1)(2), Part8 sect.30(1,d) – refers to maize from NCPB to millers Act # 54: KEPHIS – grading of plant produce
Packaging & Packaging materials	Packaging: Crops Act no.16 of 2013 sect.40(2h), Packaging materials : CAP 254 : sect 30 (1a), (12)	Act no. 16 of 2013: sect.40(2h)– packaging of crops
Labelling	CAP 254: Food, Drugs and Chemicals Act part 3 sect28(1b,i), part 1 (2a) CAP 242 sect 134 (L) - Act no. 326: Seeds and Plant varieties (KEPHIS) sect.4b, sect 4e - Act no. 345: Fertilizer and animal food substances sect 19(e) – Cabinet makes rules for packing, branding, sealing, etc.	<i>Article</i> definition according to Cap 254 is any food and any labelling or advert material on the food CAP 242 sect 134 (L) – need for law when there is mislabeling (misbranding, mis-description) CAP 254 sect 28 – minister makes regulations on labelling ,
Testing	CAP 496 : KEBS sect 4(1)(c) – KEBS is mandated to test commodities, (h)(i), Sect. 14 (1)(g) – seize and detain for testing, sect 14a(1a), sect 14b(1)(2) – testing for compliance Dairy Industry CAP 336: sect.19(r) CAP 254: Food, Drugs and Chemicals – sect 28(1)(e), sect 30(11) CAP 242: Public Health 134(b), (g),sect 132	CAP 336: sect.19(r) – testing any article connected to dairy produce also in examination, inspection and analysis KEBS Sect.2 – defined under codes of practice in CAP 496 CAP 254 : sect 30 (11) – sample to be taken for testing to public analyst
Adulteration	CAP 242 sect 134 (L) – there is need for a standard to prohibit adulteration	Needs more wording
Licensing	Crops Act no. 16 of 2013-Sect 6 part 1 (1a) CAP 338 NCPB- Part 5 sect.24	
Removal/Recall/seizure	CAP 242 : Public Health sect 134 (b) (i), sect 132, sect 133, 134,131 – seizure of unwholesome food CAP 254: sect 30(7) CAP 496 sect 14A, (1g) – KEBS	CAP 496 sect 14A, 1(g) – KEBS seizes and detain for testing
Exports	NCPB Act no.338 Part 4 sect 4(1a) CAP 254 regulation 9 (2)(3) regulation 10 (1)(2)(3)	

	CAP 242 sect.134 (g) – inspection of manufacture	
Traceability	Crops Act no. 16 of 2013 sect 40 (2h)	Regulations for traceability purposes are given
Inspection	CAP 336: sect.19(r) – also in examination/testing, inspection and analysis CAP 505: sect 21 (1c) – powers to inspectors CAP 242 sect.132 (g) – inspection of manufacture CAP 242 sect.9(6) – duties of inspectors	
Imports	CAP 338 NCPB: Part 4 sect 4 (1a) CAP 254 : reg 8 (1)(2) reg 9 , CAP 242: Public Health sect.63(1)(c) CAP 242 sect 134(l) – prohibits import of contaminated food	

APPENDIX **TBD**. Test Kit Validation Protocol

Design & Performance	Objective	Performance Standard	Reference
Fit for purpose		≤ 2.0 ppb minimum level of detection	
Accuracy		<u>To be determined</u>	
Reproducibility		<u>To be determined</u>	
Validation Validated against official method (HPLC)*		<u>Validated against official method (HPLC) ¹</u>	
Rapid <u>afatoxin test</u> results		<u>To be determined</u>	
Quantitative results		<u>Must produce Quantitative results</u>	

¹ Denotes item with recordkeeping requirements

APPENDIX **TBD**. Analyst Qualification

Training Element	Objective	Performance Standard	Reference
Education & training ¹		Must hold a Bachelor’s degree	
Criminal history ¹		Must hold a Certificate of Good Conduct	
Competence		Training procedure & criteria for qualification <u>TBD</u>	
<u>Level of approval</u>			
Training ¹		Must complete hands-on training	
Legal status ¹		Must be a legal entity	
Affiliation ¹		Must be affiliated with a physical, registered establishment	

Laboratory status ¹	Must provide a verifiable quality management system
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¹ Denotes item with recordkeeping requirements

APPENDIX **TBD**. Preventive Controls for Co-Regulation

Control Point	Objective	Performance Standard	Reference
Sampling frequency	Ensure that maize is tested before entering the facility	Defined in food safety plan & based on risk	CODEX (CX/CH 14/8/9)
Sampling pattern & sample size	Ensure that the sample represents the entire lot of maize	Sampling pattern: dependent upon the size of the lot <i>(research patterns for bulk & bag)</i> Minimum sample size: ≥ 1 kg for bags & ≥ 10 kg for bulk	ISO 24333; GAFTA 124; MOH sampling & testing of aflatoxin SOP; CODEX (CX/CH 14/8/9); GIPSA Grain Sampling Handbook (pg 2-12); LAM (pg 260)
Maize Sample Identification ¹	Ensure traceability to sample date, truck ID (if appropriate), and aflatoxin level	Chain of custody defined in the food safety plan	GIPSA Grain Sampling Handbook, Chapter 1 (pg 1-8)
Subsampling <u>after grinding</u>	Ensure that the test portion represents the entire lot of maize	Grind the entire sample	GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-4)
<u>Ground</u> Maize Retained File ¹	Retain a representative file sample for each lot tested; send sample to for verification analysis	≥ 0.5 kg minimum Retain for: <u>time to be determined</u> Store to: protect sample integrity	GIPSA Mycotoxin Handbook (pg 4-5) <i>Note: May conflict with MOH SOP</i>
Finished Product Stream ¹	Ensure quality of finished product and ensure that at least 1 kg is retained as evidence	<u>How to collect incremental samples: TBD</u> ≥ 1 kg minimum Retain for: <u>time to be determined</u> Store to: protect sample integrity	APTEC Handbook
Finished Product Retained File Samples ¹	Ensure quality of finished product	≥ 1 kg minimum Retain for: <u>time to be determined</u> Store to: protect sample integrity	APTEC Handbook
Finished Product Identification ¹	Ensure traceability to product run, production	Chain of custody defined in the food safety plan	APTEC Handbook

	date, lot, and aflatoxin level		
Particle Size/ Grinder check ¹	Ensure that the sample is finely ground and homogeneous	≥ 60% (with a 10 % variance) passes through a 20 mesh sieve	GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-9)
Grinder cleaning ²	Ensure that the grinder is cleaned after each official sample	Grinder is purged by discarding a small portion of the first 10-15 g of the sample to be tested	GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-8)
Moisture (Grinding)	Ensure that the sample can be properly prepared for testing	≤ 13.5% moisture prior to grinding	GIPSA Mycotoxin Handbook, Chapter 4 (pg 4-6)
Segregation/ Storage	Ensure that maize is segregated and stored to prevent adulteration and preserve integrity	Defined in the food safety plan; maize must be stored to preserve integrity	GIPSA Mycotoxin Reference (pg 21)
Balance calibration ¹	Ensure that the balance is verified within working range before use	Utilize a standard weight to verify within working range of the balance	GIPSA Equipment Handbook, Chapter 2 (pg 2-8)
Control Reference material sample analysis ¹	Maintain analytical performance to accurately measure aflatoxin concentrations	Duplication: TBD Frequency: TBD Corrective actions: TBD	APTECA & One Sample Strategy Handbooks
Proficiency testing program		Z score > ± 2: acceptable Z score 2-3: investigation Z score > ± 3: corrective action	
Test Portion Size		≥ 25 g	ISO 160560
Interlab comparison of official sample verification results		TBD Lab must be ISO accredited is desired, verifiable lab quality management system is mandatory	

¹ Denotes item with recordkeeping requirements

² Denotes item that may be applicable to SME/Posho millers

APPENDIX **TBD**. Regulatory Authority Matrices by Maize Value Chain Stages

PRODUCTION (WHOLE MAIZE)											
Element	AFA	KALRO	KEBS	KEPHIS	MOA	MOH	NCPB	PCPB	NIB	No. 16 of 13 Part VI. 34e	NBA
Land preparation	X	X		X	X						
Seed	X	X		X	X			X			
Time and method of harvesting	X	X		X	X	X					
Planting	X	X		X	X	X					
Plant protection product	X	X		X	X			X			
Irrigation				X	X				X		
Crop Insurance					X					X	

STORAGE (WHOLE MAIZE)											
Element	AFA	KALRO	KEBS	KEPHIS	MOA	MOH	NCPB	PCPB	NIB	No. 16 of 13 Part VI. 34e	NBA
Farm/Local collection point	X				X						
Storage structure/type	X				X	X					
Storage container	X		X	X	X	X					
Drying/moisture monitoring	X		X		X	X					
Warehouse inspection/receipt	X				X	X					
Pest Control practices & products	X		X	X	X	X		X			
Sampling	X		X		X	X					
Cleaning and sorting	X	X	X		X	X					

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Grading	X	X	X	X	X
Testing	X	X	X	X	X
Segregation	X	X		X	X
Bulking/Aggregation	X		X	X	
Disposition					
Blending					

TRANSPORT (WHOLE MAIZE)											
Element	AFA	KALRO	KEBS	KEPHIS	MOA	MOH	NCPB	PCPB	NIB	No. 16 of 13 Part VI. 34e	NBA
Method of transport (vessel)	X		X		X	X					
Cross-contamination (trucks, bags, etc.)	X		X		X	X					
Bulking/Aggregation	X			X	X						
Import/export	X		X	X	X	X	X				
Trading	X		X		X	X					

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PROCESSING, SALES & DISTRIBUTION (FINISHED PRODUCT)											
<i>Element</i>	<i>AFA</i>	<i>KALRO</i>	<i>KEBS</i>	<i>KEPHIS</i>	<i>MOA</i>	<i>MOH</i>	<i>NCPB</i>	<i>PCPB</i>	<i>NIB</i>	<i>No. 16 of 13 Part VI. 34e</i>	<i>NBA</i>
Sampling	X				X	X					
Inspection						X					
Packaging	X					X					
Visual examination/ sorting/grading				X		X	X				
Testing			X		X	X					
Seizure						X					
Licensing	X										
Imports						X	X				
Labelling					X	X	X				
Exports						X	X				
Traceability	X										
Adulteration						X					

APPENDIX TBD: Draft language for proposed bill

Title: Aflatoxin

Scope: Maize (whole and processed)

Definitions

- A. Aflatoxin
- B. Aggregate sample
- C. Analyst
- D. Authority
- E. Inspector
- F. Laboratory
- G. Lab sample
- H. Lot
- I. Plantation grower
- J. Processers
- K. Retain sample
- L. Sampler
- M. Small hold growers
- N. Sub-lot
- O. Test sample
- P. Traders (Wholesalers, retailers and handlers)
- Q. Transporter
- R. Warehouse

Purpose

- A. Contribute to Food Security and Safety in Kenya through Abatement of Aflatoxin Contamination.

Objectives

- A. To produce and maintain aflatoxin safe produce and products along the food and feed value chains at permissible levels
- B. To increase trade of Aflatoxin safe food and feed in Kenya;
- C. To increase awareness on risks associated with aflatoxin to health, agriculture and trade, and about the technologies and approaches available to prevent and mitigate contamination;
- D. To reduce the level of aflatoxin contamination in foods and feed; and
- E. To support Research and technology development options for the control and prevention of aflatoxin and other mycotoxins in Kenya.
- F. To propose appropriate legislation for the control and prevention of aflatoxins

Inspection

A. Production

1. The seed and fertilizer shall be inspected and certified by the relevant authority
2. Pest Control products (herbicides, insecticides, other, etc.)
3. Land Zoning (Agro-ecological zones) – Agricultural land etc. – Policies are present

B. Storage

1. Moisture Content and Aflatoxin contamination in Maize shall be monitored.
2. Equipment to measure and monitor moisture content and Aflatoxin contamination in maize shall be validated by the relevant agency authorized by the Cabinet Secretary
3. Pest control products (pesticides and all others) to be used to control storage pests shall be regulated by PCPB
4. Storage facilities shall be monitored to conform to construction and sanitary standards (referenced in an AFA policy) (factors include aeration, temperature, sanitation etc.)
5. Commercial Maize Aggregators having warehouses, silos any other storage facility shall be **licensed** subject to such lawful conditions as maybe determined by the relevant regulating agency authorized by the Cabinet Secretary

C. Transport

1. Certificate of analysis shall accompany any produce being transported from point of origin. The certificate shall be provided by relevant regulatory agency and shall include information regarding final destination of maize
2. A person shall not transport without a valid certificate of analysis.
3. The transportation of cereals shall be done in a sanitary manner including measures to maintain quality and safety

D. Processing

1. Plants and premises shall be of suitable design, layout and construction to facilitate easy maintenance and sanitary production of food
2. Processing plants and premises shall not be used unless licensed by the competent authority
3. All suppliers of raw material must possess a certificate of analysis from a competent authority
4. Every dealer who owns, operates or is in charge of a processing plant or premises shall ensure 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.

E. Sale and Distribution

5. Every batch of a maize product meant for human consumption must have been tested for aflatoxin contamination and labelled “aflatoxin tested”.

Testing results shall be availed to the official control upon request during inspection.

6. Distribution of maize products shall be done in a sanitary manner.
7. A person shall not import or export any maize products without a license/permit from the relevant regulatory agency.

Registration

A. Registration of actors in the cereals values chain.

1. Growers
 - 1.1 The authority shall maintain updated register:
 - 1.2 The registration shall be renewed by the authority annually.
 - 1.3 The grower shall have the freedom to register with an association or cooperative
 - 1.4 The grower shall apply GAP.
2. Traders
 - 2.1 The authority shall provide registration mechanism for cereal traders.
 - 2.2 All traders shall apply for registration with the relevant authority.
 - 2.3 The authority shall maintain updated register of all traders.
 - 2.4 The traders shall apply for renewal of the registration annually.
 - 2.5 The traders shall comply with all food safety regulation in this section
(list all regulations and authorities).
3. Transporter
 - 3.1 The authority shall provide registration mechanism for ~~cereal-maize and maize products~~ transporters.
 - 3.2 All transporters shall apply for registration with the relevant authority.
 - 3.3 The authority shall maintain updated register of all transporters.
 - 3.4 The transporter shall apply for renewal of the registration annually.
 - 3.5 The transporters shall comply with all food safety regulation.
4. Processors
 - 4.1 The authority shall provide registration mechanism for cereal processors.
 - 4.2 The authority shall maintain updated register of all processors.
 - 4.3 All processor shall apply for registration with the relevant authority.
 - 4.4 The processors shall apply for renewal of the registration annually.
 - 4.5 The processors shall comply with all food safety regulation.
5. Warehouses
 - 5.1 Warehouse will register with the authority.
 - 5.2 The authority shall provide registration mechanism for cereal warehouse.
 - 5.3 All warehouses shall apply for registration with the relevant authority.
 - 5.4 The authority shall maintain updated register of all warehouses.
 - 5.5 The warehouse shall apply for renewal of the registration annually.
 - 5.6 The authority shall conduct inspection of the premise and issue a complier certificate

Commented [I1]: Avoid duplicate licensing of millers

- 5.7 The warehouses used to hold cereals shall comply with all food safety regulation.
- 6. The designated authority shall provide a registration mechanism.
 - 6.1 Application form and Registration fee
 - 6.2 Time
 - 6.3 Registration record
 - 6.4 Registration certification

Licensing

- A. Licensing of :
 - 1. Aggregators
 - 2. Marketing Agents/ Brokers
 - 3. Transporters
 - 4. Store / warehouse operators
 - 5. Processor
 - 6. Distributors, Wholesalers/ Retailers
- B. Licensing components:
 - 1. Personnel/Analysts / Handlers
 - 2. Testing facilities
 - 3. Storage facilities
 - 4. Processing Facilities & Equipment
 - 5. Blending food and feed
 - 6. Packing materials
 - 7. Labeling

Commented [I2]: Avoid duplication with registration section

Commented [I3]: Intention was proof of authorization or certification

Enforcement

- A. Revocation, suspension of license
- B. The licensing Authority will have powers to issue or deny issuance of license to an applicant subject to such lawful conditions as the Authority may determine..
- C. A licensing authority may alter, suspend or revoke the license of a license holder who in its opinion has contravened any part of this law.
- D. A person described in section 2 above shall surrender their license upon revocation.
- E. A person aggrieved of the decision of the Licensing Authority may petition the High Court for reverse orders

Commented [I4]: Need to review and define terms

Penalties (group requests to add under enforcement)

- A. Breach of the ACT
 - 1. Obstruct a person in the execution of the duties assigned by the ACT
 - 2. Use of invalid/fake/Forged documents
 - 3. Practicing without a license

Commented [I5]: May include civil penalties; reference Fair Administrative Hearing Act

Schedules/Forms

- A. Specific commodity and product standards/maximum limits for aflatoxin levels;
- B. Labelling information and instructions;

- C. Conditions for transporting produce/food/ feed;
- D. Conditions for produce/food/ feed storage;
- E. Code of practice-cereals and others;
- F. Description of food packaging materials;
- G. Guidelines on the appropriate storage and transport facilities;
- H. Aflatoxin Test Methods-Method Performance Criteria.

Co-regulation Preventive Controls

- A. The Cabinet Secretary shall prescribe preventive measures towards Aflatoxin prevention and control.
- B. All maize growers shall observe Good Agricultural Practices (GAP) during all farming operations.
- C. All maize Processors shall observe Good Manufacturing Processes (GMP) at all stages of manufacture.
- D. Any person who transports maize or maize products, or owns, operates or is in charge of a processing plant or premises shall ensure implementation of Hazard Analysis Critical Control Points (HACCP) principles
- E. Production
 - 1. Land preparation:
 - 1.1 Site selection
 - 1.2 Seed (planting material)
 - 1.3 Crop insurance
 - 1.4 Plant protection product (e.g., biocontrol; AlfaSafe™)
 - 1.5 Time to harvest
 - 1.6 Method of harvest
 - 1.7 Planting Time
 - 1.8 Irrigation
 - 2. Storage
 - 2.1 Farm/Local collection point:
 - 2.1.1 Type of storage
 - 2.1.2 Storage container
 - 2.1.3 Moisture monitoring
 - 2.1.4 Drying
 - 2.1.5 Pest Control practices & products
 - 2.1.6 Sampling
 - 2.1.7 Sorting
 - 2.2 National Cereals and Produce Board of Kenya (NCPB) and commercial:
 - 2.2.1 Moisture monitoring
 - 2.2.2 Drying
 - 2.2.3 Aeration
 - 2.2.4 Cleaning
 - 2.2.5 Grading
 - 2.2.6 Sorting
 - 2.2.7 Pest Control practices & products

Commented [I6]: May drop co-regulation term

- 2.2.8 Sampling
- 2.2.9 Testing
- 2.2.10 Segregation
- 2.2.11 Temperature monitoring
- 2.2.12 Warehouse inspection
- 2.2.13 Warehouse receipt
- 2.2.14 Labeling (bill of lading)

F. Transport

1. TBD

- 1.1 Type of equipment (open, closed)
- 1.2 Cross-contamination (trucks, bags, etc.)
- 1.3 Bulk
- 1.4 Import/export
- 1.5 Trading

G. Processing

1. TBD

- 1.1 Visual examination/sorting/grading
- 1.2 Sampling
- 1.3 Testing – of whole maize at entry and processed flour
- 1.4 Segregate
- 1.5 Labeling
- 1.6 Processes that decrease aflatoxin levels (gravity separation/sifting/bran/germ/other by-products)
- 1.7 Processes that increase aflatoxin levels (tempering)
- 1.8 Pelleting
- 1.9 Storage items from above (same as National Cereals and Produce Board of Kenya (NCPB) and commercial)
- 1.10 Type and condition of packaging material
- 1.11 Traceability
- 1.12 Adulteration
- 1.13 Inspection – of premise and documentation
- 1.14 Licenses (SME/POSHO/MILLERS)

H. Sales and Distribution

1. TBD

- 1.1 Labeling
- 1.2 Type and condition of packaging material
- 1.3 Traceability
- 1.4 Retail/wholesale conditions – Inspection
- 1.5 Recalling (Removing/ Seizure)
- 1.6 Exports
- 1.7 Licenses (SME/POSHO/MILLERS)

Policy

- A. The National Food Safety Policy 2013

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- B. Draft EAC Aflatoxin Prevention And Control Strategy And Action Plan 2016 (Developed by Kenya, Uganda, Tanzania, Rwanda and Burundi) with the following key strategies:
 - 1. Agriculture (Biocontrol and Post-Harvest Handling)
 - 2. Impact of Aflatoxin on Human Health
 - 3. Impacts on Animal Health
 - 4. Impacts on Trade
 - 5. Impacts on the Environment (Alternative Uses and Disposal Systems)
 - 6. Research and Technology in Advancement of Aflatoxin Control
 - 7. EAC Communication Strategy on Aflatoxin Prevention and Control
- C. Food Security and Nutrition Policy 2011

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References

Legal Notice 1911 8th August 2014

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