

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)= Weight of the lot x weight of the incremental sample

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 requirements 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.