

Building an Aflatoxin Safe East African Community

Technical Policy Paper 8



Aflatoxin Standards for Food

Knowledge Platform 2015
Situational Analysis East Africa Region



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On the cover: A researcher at the International Livestock Research Institute, Busia, Kenya.
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Foreword

Ensuring the safety of the food supply is a responsibility shared by the public and private sectors. This includes international regulatory agencies and national governments, as well as food producers, processors, and traders. Most often evaluating food safety is based on established and mutually recognized standards. Harmonized standards are necessary to facilitate the efficient flow of goods in domestic, regional and international markets, and to ensure that products are safe and of good quality. Standards are needed to encourage entrepreneurship so that businesses know that they can access new markets by meeting standards. Consumer confidence depends on these same standards, assuring the efficacy and safety of natural and processed foods.

Established standards can also create conditions conducive to free and fair global trade; in the absence of standards for foods, nontariff barriers to trade may be unfairly imposed. The development of standards for tolerable limits of aflatoxin in foods for the East Africa region began in 1990. More recently, harmonized standards for several grains and pulses were adopted by the East Africa Community (EAC). Some countries within the EAC have additional standards for tubers and dairy products. It is speculated that both the EAC regionally harmonized and national standards have been extrapolated from the international standards setting body, the Codex Alimentarius Commission (Codex), or adopted from other countries outside of the region, rather than methodically developed based on rigorous risk assessment and analysis of actual consumption levels of aflatoxin prone foods by the EAC population. The region is also plagued by a weak regulatory environment, a vast informal trade network, and high levels of on-farm consumption of aflatoxin prone foods that combine to make the enforcement of standards a significant challenge. Additionally, there are no special standards for aflatoxin prone foods that are commonly consumed by infants and young children. As aflatoxin depresses the immune system, the development of this same type of special standards for people living with AIDS (PLWAs) would also be a best practice for the region.

We are hopeful that this paper will lay the groundwork for more rigorous adherence to standards among agricultural producers, traders, food processors, and the retail sector. It is also a call to action to address the urgent need to review existing standards, and adopt new standards as appropriate for the region, based on dietary trends among vulnerable groups, as well as consumption levels of aflatoxin prone foods among the general population.

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Executive Summary

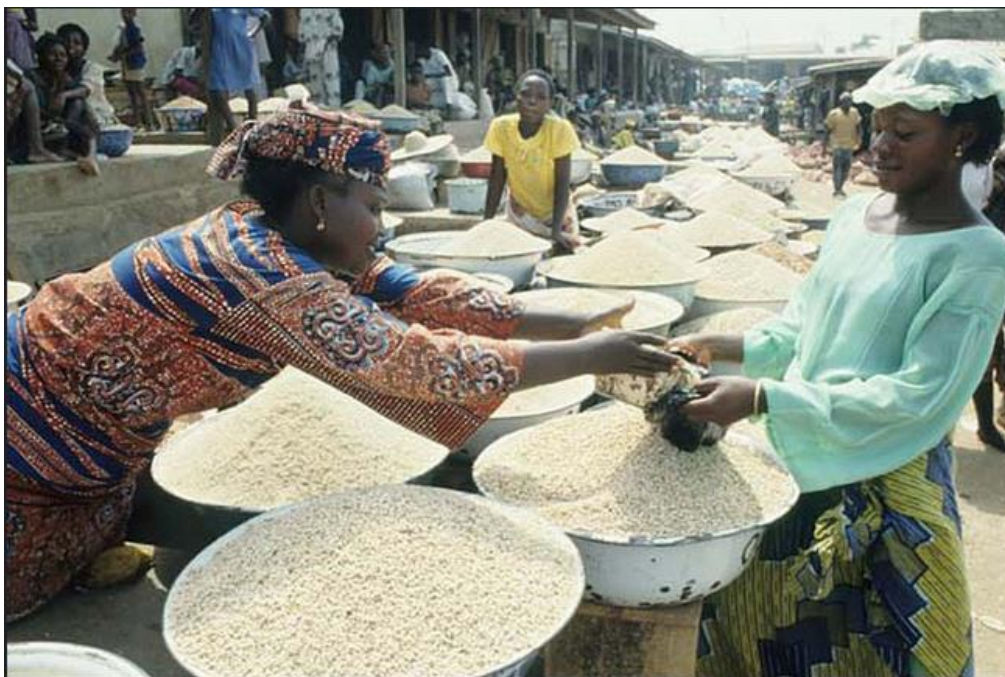
Aflatoxins are a group of naturally occurring toxic secondary metabolites produced, primarily, by two species of the ubiquitous fungus *Aspergillus* (*A. flavus* and *A. parasiticus*) when they grow under favorable conditions for toxin formation. Among the naturally occurring forms of aflatoxins are aflatoxin B₁ (AFB₁), B₂ (AFB₂), G₁ (AFG₁) and G₂ (AFG₂). Governments regulate food contamination by aflatoxins to protect and promote public health, and at the same time promote fair trade. Regulation of aflatoxin contamination in food involves formulation and enforcement of maximum limits (MLs) tolerated in the food. Although most countries formulate their own MLs for aflatoxins in food, many of them rely on limits formulated by regional or international bodies.

At the international level, the Codex Alimentarius Commission (Codex) is the body responsible for formulating MLs for contaminants such as aflatoxins in foods. Codex prescribes an ML of 15 µg/kg for total aflatoxins (sum of AFB₁, AFB₂, AFG₁, and AFG₂) in peanuts, Brazil nuts, hazelnuts, pistachios, and almonds for further processing; it also prescribes an ML of 10 µg/kg for processed Brazil nuts, dried figs, hazelnuts, pistachios, and almonds. It sets a level of 0.5 µg/kg for aflatoxin M₁ in milk. In general, Food and Agriculture Organization (FAO)/World Health Organization (WHO) member states adopt and enforce MLs as set by the Codex. Nonetheless, countries that consider Codex MLs inadequate for protection of their consumers may formulate their own MLs, provided such limits are science-based. However, for aflatoxins in main staples such as maize and rice, Codex has not been able to formulate an internationally acceptable ML. The failure to set an international ML is attributable to the huge differences in perceived risks, food consumption patterns, and in the levels of aflatoxin contamination in food produced from different agro-ecological regions around the globe.

Due to the absence of consensus on aflatoxin MLs at Codex for these foods, countries and regions have formulated national or regional MLs. The United States has a guideline level of 20 µg/kg and the European Community (EU), a more stringent ML of 4 µg/kg for total aflatoxins in food. In developing countries, MLs for total aflatoxins range from 10 to 20 µg/kg, with 10 µg/kg being the most frequently set level. Lower MLs, such as 4 µg/kg for total aflatoxins set in the EU, can serve as a barrier to trade and incur additional costs for producers, processors, and traders.

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The setting of MLs for aflatoxins in food standards in countries of the EAC began in the 1990s, when most of these countries started setting standards for specific foods. To date, the EAC partner states use an ML of 5 µg/kg for aflatoxin B₁ and 10 µg/kg for total aflatoxins in selected foods, cereals, and pulses. An ML standard of 0.05 µg/kg is set for aflatoxin M1 in milk. The EAC recently adopted these limits as harmonized MLs for the region. The development of common standards in the EAC stems from the Standardization, Quality Assurance, Metrology, and Testing Act (SQMT) Act of 2006.



Buying maize in a Kenyan marketplace. IITA

As in other developing countries, in the EAC countries there are many challenges to the food control systems and hence enforcement mechanisms for the MLs. These include the presence of multiple and uncoordinated agencies, weak inspection capacities, and lack of clarity on roles and responsibilities of food regulatory bodies. Another big challenge is regulation of safety for foods consumed by people in the rural areas who are subsistence farmers. In subsistence communities, which comprise more than 70 percent of the population, rates of on-farm consumption for the household vary from 60 to 90 percent across the region, meaning that most aflatoxin-prone staple foods are consumed without any quality control. Both informal and formal markets remain largely unregulated, as does the food processing industry. Aflatoxin testing services are centralized in cities, and they are expensive and unreliable.

Analysis of the MLs in the EAC region shows that they are directly adopted from Codex or other countries without consideration of the unique factors of the region, most particularly high consumption of aflatoxin-susceptible staple foods such as maize and groundnuts. None of

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the EAC partner states has established a risk assessment system to weigh the various factors that play an important role in establishment of MLs for aflatoxins in food. This shortcoming is compounded by lack of a centralized information management system that is capable of disseminating timely information to key stakeholders to enable timely decisions and appropriate interventions. To improve regulation of aflatoxins in the EAC region, standards that are based on dietary consumption patterns of the population are needed as a first step. This should be followed by improved communication and coordination among existing regulatory bodies, raising awareness among policy makers, farmers, traders, food processors, and consumers, and inclusion of appropriate technologies for aflatoxin abatement along the value chain. This will encourage and enhance investment in aflatoxin mitigation measures, thus enabling the strengthening of food safety risk assessment, coordination, and inspection and analysis systems.

Introduction: About Standards

What is a Standard?

A standard is a document that provides requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose. A standard is a recommendation, voluntary, available to the public, developed through a consensus of all parties, and based on sound science, experience, and technology. In contrast, a regulation is legislation, available to the public, developed by an authority under public scrutiny and mandatory. In order for the standard to move to the status of legal authority through legislation, it is first published or gazetted by the government. One of the roles of governments is to develop standards to ensure products safety. To this end, governments have formed “bureaus of standards” with this responsibility. The national standards bodies are affiliated with the International Organization for Standardization (ISO), which develops international standards.

The Standards Development Process

Standards are developed by standards bodies through multi-stakeholder participation, beginning with technical committees (TCs). TCs are made up of consumer organizations, members of academia, and relevant industry and government representatives. TCs represent the interest of the public in the development process. Because their members are experts in the sector they represent, they shape future policies for the sector by contributing their expertise. Standards bodies make decisions during the development process by consensus, as members are allowed to vote at different stages of the process. The development process has six stages: proposal, preparatory, committee, enquiry, approval, and publication.

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Proposal Stage

The proposal stage begins when the need for a standard is recognized and registered with the standards body. The need may be recognized from industry, a consumer organization, or by the standards body itself. The proposal is sent to the relevant committee or its secretariat.

Preparatory Stage

In the preparatory stage, the TC forms a subcommittee, referred to as the working group (WG). The task of the WG is to prepare a working draft (WD) of the standard. The WG may source the standard from the ISO if any of its members has an appropriate standard for the WG to adapt and adopt. This process is called domestication of the standard. Once a draft has been agreed upon by consensus by the WG, the draft is circulated to the entire TC.

Committee Stage

At the committee stage, the draft is shared and members of the TC make their comments on the draft. The committee comments are received and incorporated, and the second draft is sent back to the TC for comments. Next, comes a vote to push the draft to the next stage. Once approved by consensus by the TC, the draft moves to the enquiry stage.

Enquiry Stage

At the enquiry stage, the draft is circulated to stakeholder members of industry, academia, consumer organizations, and non-government organizations (NGOs) to solicit comments. A specific period for this public scrutiny is set by the TC. The comments are received by the TC, which incorporates them, and forwards the final draft to the entire membership of the TC for a vote which moves the draft to the approval stage.

Approval Stage

During the approval stage, the final draft standard is sent to the approval board of the standard authority. Board members make comments and vote on whether the standard is to be approved. Once approved, the standard can be implemented as a voluntary document. For the standard to have obligatory compliance, it moves to the publication or gazettelement, which leads to action by the government.

Publication

At the publication stage, the WG forwards the standard to the responsible government ministry, or appropriate regional organization. The standard is then published in the relevant

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national or regional organizational format to give it the *locus standi* to make it industry compliance with the standard obligatory.

Benefits of Standards

Standards ensure:

- That products and services are safe, reliable, and of good quality
- That when a business applies the standards it can access new markets because the consumers have confidence in its products
- That the playing field for businesses is leveled, because all are required to comply
- The best conditions for free and fair global trade.

Audit and Certification

An audit is an inspection done to ensure that the product is being produced according to the standard. Once the audit body is satisfied the standard is met, it makes a recommendation to the appropriate committee that the product can be certified. To be certified, the product must consistently meet the standard. This allows the business to use the quality mark (Q mark) of the certifying body on its product. Certification is voluntary, but, because of market demands, certifications are often perceived as mandatory.



Aflatoxin infected maize. IITA

Constraints in Standards Setting

Since standards are evidence-based, lack of scientific evidence (data) may delay standards development. The WG in the preparatory stage requires the information to make a committee draft. It is the responsibility of industry and academia to provide the data to be used to allow standard drafting. However, a company may not be willing to provide its data, if it perceives that disclosure may infringe on its product rights and company secrets. In the event that data does not exist in the country, reference is made to the CAC. In a particular case, adapting and adoption of standards set in different countries may not serve another country's best interests, because the realities on which the foreign standards have been set are different. This is especially true for aflatoxin standards for feed within the East Africa region. The formation of the TCs can delay the drafting of standards, because these committees operate on voluntarily basis. In some of the EAC partner states, there are often not enough experts qualified to serve, especially from the private sector.

Finally, the funding of the standards development process in some of the states is donor sourced. Inability to secure the funds may hamper the process.

Compliance

Compliance is conforming to the standard. It is the duty of the industry to comply. Effective assurance of compliance is constrained by the following factors:

- Some industries use the Q mark when products they manufacture meet the required standards.
- There may be inadequate personnel to enforce the standards.
- Monitoring and surveillance of compliance by the industry is very expensive. Products need to be sampled regularly, and analyzed to determine whether they meet the standard for the industry to continue to use the Q mark. This surveillance can be done at the market or at the industry level.
- Some of the partner states, for example Zanzibar and Rwanda, have standards bodies that were set up only in the last decade. They have no history of use of standards and this constrains compliance.
- Lack of a culture that demands industry adheres to standards affects compliance. In many instances, industry takes shortcuts when compliance is deemed to be costly and would affect the company's bottom line.
- Industry is sometimes unaware of the benefits of complying with the standards.
- Customers are unaware of product differentiation based on quality, specifically the importance and significance of the Q mark. In many cases, because of poverty, substandard products lacking the Q mark are cheaper. Many consumers would purchase these rather than the certified and more expensive ones.

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- Well-equipped laboratories with competent personnel are needed to monitor and carry out surveillance on compliance. A shortage of these facilities has created a bottleneck. Results take too long to be released to the industry to adjust production to meet quality standards.
- An overall compliance strategy is lacking. Such a strategy is necessary to meet the needs of small microenterprises (SMEs) which at start-up may have difficulties meeting the standards. The While the objective is not to have two tiers of standards, an overall strategy that enables the SMEs to meet the standards requirements is needed.
- Some importers and exporters of the products are not aware of the standards requirements and do not demand quality from the products they import or export.
- The national bureaus of standards are not the competent authorities to oversee compliance. This function should be vested in a food safety authority. Some of EAC's partner states, including Uganda, Tanzania, and Zanzibar, have established food and drug safety authorities, which are better situated to deal with monitoring and standards compliance by the industry. This leaves the standard bureau as a standards-setting body only.
- Duplicative mandates of government agencies may create confusion in the industry and interfere with standards compliance. These roles and responsibilities should be clearly delineated and coordinated.

Standards Setting in Developed Countries

Standards have costs as well as benefits. In the USA, it was estimated that the annual cost of regulatory enforcement, testing, and other quality control measures was USD\$466 million annually (CAST 2003). The European Union has undertaken measures to reduce regulatory burdens with the following initiatives:

- Codification (omnibus bills): all amendments made to one piece of legislation over the years are incorporated into a single new act, reducing volume and complexity
- Recasting: similar to codification, but the legislation is amended at the same time as previous amendments are incorporated to form one consolidated text
- Repeal: unnecessary and irrelevant laws are removed
- Review/sunset clauses: laws are reviewed or automatically removed after a given period
- Revision: laws are modified to keep them up to date.

Other options include:

- Self-regulation: voluntary agreements or codes of conduct among private bodies

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- Co-regulation: the desired outcome is set down in law but the decision on how to achieve it is left to the parties involved.



Grain milling in Uganda. Bakhresa Group

Global Standards Setting

Consumers worldwide are concerned about food safety. Codex Alimentarius Commission (Codex) is an international body formed jointly by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations and charged with the responsibility of formulating food safety standards, including MLs for contaminants such as aflatoxins. In food contaminants standards setting work, Codex bases its decisions on scientific advice/evaluations from another UN body, the Joint FAO/WHO Committee on Food Additives (JECFA). According to the Codex Procedure Manual (2013), the JECFA deploys experts to the field to conduct risk assessment and recommend the maximum tolerable intake, such as provisional maximum tolerable daily intake (PMTDI) as a health safety guideline. Based on the risk assessment and intake level recommendation, a contaminant ML is to be set by the Codex, with consideration of appropriate sampling plans and analytical capacities for the contaminant. The Codex would consider setting an ML for a food if its contribution to exposure meets one of the following three conditions (FAO 2013):

- 1) Contributes 10 percent or more of an endpoint (daily or weekly tolerable intake) such as PMTDI, in at least one of the WHO Global Environment Monitoring Systems(GEMS)/Food Consumption Cluster Diets, or
- 2) Contributes 5 percent or more of a daily or weekly tolerable intake in two or more of the GEMS cluster diets, or
- 3) Leads to a significant impact on total exposure for specific groups of consumers, although it does not contribute 5 percent or more of the daily or monthly tolerable intake, in any of the GEMS cluster diets.

It is important to note here that endpoints such as PMTDI are not applicable to aflatoxins, as these toxins are both genotoxic and carcinogenic. According to WHO (2005), risk assessment for compounds that are both genotoxic and carcinogenic should be based on Margins of

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Exposure (MOE) and a value below 10,000 is considered to be a health concern. The MOE is the ratio between a toxicological threshold (such as benchmark dose lower limit [BMDL]) and exposure in an individual. A BMDL of 170ng/kg bw/day was calculated for aflatoxins and represents the lower limit of the benchmark dose (BMD) at 95 percent confidence estimated as the dose required to produce a small response (10 percent extra cancer risk) above the control for rodents (EFSA 2007).

Aflatoxin exposure can be estimated by multiplying consumption data of a certain food item and the occurrence of aflatoxin in this food item (AFB1 alone or total of aflatoxin); and then summing up the results from each food item consumed. A probable daily intake (PDI) in µg/kg bw/day) is thus obtained. This PDI can be compared against relevant recommendations and guidelines in order to assess the severity of exposure in a given population (Shephard 2008).

Food consumption data can be obtained either from national or regional food databases, or from purposely designed diet surveys in a population of interest.

Aflatoxin contamination is extremely heterogeneous, particularly in large-sized food commodities such as groundnuts, whereby only a few moldy nuts in a store or bag may increase aflatoxin levels significantly. Thus good sampling practice is critical. Analytical methods typically employ either high throughput rapid ELISA or equivalent techniques if a suitable antibody is available, or liquid chromatography (in an advanced level, coupled with mass spectrometry), which is advantageous for high sensitivity and specificity, with the ability to measure multiple chemicals simultaneously (Shephard et al. 2013). The choice of method depends on both the requirement of the country and the availability of equipment and skills. In general, FAO/WHO member states adopt and enforce MLs as set by the Codex. Nonetheless, countries that consider Codex MLs inadequate for protection of their people are allowed by the WTO to formulate their own, provided such limits are science based. Some regional bodies, including the European Food Safety Authority (EFSA), conduct their own risk assessments to advise the European Union on making decisions on MLs for aflatoxins for food to be consumed in the region.

Setting MLs for Aflatoxin in Foods

Aflatoxins are a group of naturally occurring toxic secondary metabolites produced primarily by two species of the ubiquitous fungus *Aspergillus*: *A. parasiticus* and *A. flavus*. *A. parasiticus* resides in a soil environment, whereas *A. flavus* is more adapted to the aerial parts of plants (leaves, flowers). Aflatoxins are a by-product of the *Aspergillus* fungus, and thrive in high temperatures in humid environments. Plants that have been damaged by insects or poor nutrition are more prone to aflatoxin contamination. Aflatoxins are commonly found in groundnuts, maize, rice, dried cassava, cotton products, chili peppers, dried fish, milk and other dairy products and beans. Contamination occurs both before and after harvest.

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Food gets contaminated with aflatoxin at various levels in the food chain when fungi infest the food and produce the byproduct, aflatoxin. Contamination of crops by *A. flavus* and *A. parasiticus* occurs at temperatures between 24°C and 35°C with 7-10 percent relative humidity (Williams et al. 2004). This means that contamination mainly affects the area between 40° north and 40° south of the equator, and thus is more common in developing countries within the tropical region (Cardwell and Cotty 2002). Fungal contamination and toxin production can occur before harvest and continue to increase postharvest under hot and humid conditions. Contamination in the field often happens as a result of insect damage and drought stress (Hell et al. 2000). Storage practices, which vary largely by the agro-ecological zone, can affect fungal growth and aflatoxin production in grains. Other techniques--including proper drying of grains, improved ventilation at storage, hand-sorting moldy grains, and pesticide use--proved to be effective in aflatoxin reduction at the postharvest stage (Hell et al. 2000). Studies have indicated that food processing may reduce aflatoxin contamination. Dry and wet milling segregates fractions of the commodity and hence reduces aflatoxin levels in the consumed fraction. Chemical processing such as ammoniation may also greatly reduce aflatoxin levels (Park 2002).

Aflatoxins are the most potent of mycotoxins and regarded as genotoxic and a Class I carcinogen. Among the naturally occurring aflatoxins, aflatoxin B₁ is the most important compound with respect to both prevalence and toxicity for animals. In view of the health effects of aflatoxins, human exposure through food should be kept as low as possible. The use of biomarkers, such as aflatoxin DNA adducts and AF-alb adducts, has provided evidence for the exposure of human populations in various geographic locations and has been particularly helpful for investigating the health effects associated with this exposure, as discussed below.

Global comparative exposure data has shown that in The Gambia and Benin, over 90 percent of young children had detectable levels of AF-alb adducts and the exposure was high in all age groups, in strong contrast to the less than 1 percent detectable rate in the developed world (Gong et al. 2008). This exposure pattern clearly demonstrated a huge public health burden in sub-Saharan Africa with the magnitude of exposure varying from 3 to >1000 pg AF-alb adducts per mg albumin in children (Gong et al. 2003; Gong et al. 2004). Exposures vary largely among different agro-ecological zones. Climate conditions, storage practice, and food type all account for the variability (Hell et al. 2000). Strong seasonal influence on exposure has been demonstrated in various countries. In The Gambia, research has repeatedly shown higher exposure in the dry season than the wet season. This is possibly because the dry season is shortly after the groundnut harvest; high consumption of groundnuts may have contributed to high aflatoxin exposure in this period (Wild et al. 2000; Castelino et al. 2014).

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To minimize aflatoxin exposure, food standards should consist of legally mandatory specifications of maximum limits of the toxins. A food standard is a document consisting of detailed technical specifications for a product, providing guidance to industry and regulators. According to the Codex, the ML for a contaminant in food is the maximum concentration of that substance legally permitted in that commodity. Products exceeding the maximum levels should not be placed on the market or consumed by humans or animals.

MLs for contaminants such as aflatoxins in food standards are formulated and enforced to protect the public health. Apart from ensuring food safety, application of MLs in food regulations promotes fair practices in food trade which in turn may prevent trade barriers and disputes. However, vulnerable populations, such as infants and young children, or people living with AIDS (PLWA) require more stringent standards due to the immunosuppressive nature of aflatoxin in the body.

Normally, MLs are established only for food in which the contaminant may be found in amounts that could place consumers at risk. The ML setting process is normally preceded by a risk assessment step. The risk assessment involves evaluation of the toxicological information, including identified toxic substance(s); metabolism by humans and animals, as appropriate; toxicokinetics and toxic dynamics in foods; information on acute and long term toxicity; and integrated toxicological expert advice regarding the safety of intake levels of contaminants, including information on any population groups which are especially vulnerable. Availability of validated qualitative and quantitative data from representative samples, and appropriate sampling protocols, as well as dietary consumption patterns for humans and animals, are important requirements for the risk assessment. Other important aspects to address in development of maximum limits for contaminants in foods are the postharvest contamination processes, production and manufacturing practices, and economic aspects related to contaminant level management and control for the food.

Codex MLs for Aflatoxins

The Codex specifies a maximum limit of 15 micrograms per kilogram, which is 15 parts per billion ($15 \mu\text{g}/\text{kg} = 15 \text{ ppb}$) for total aflatoxins (sum of AFB1, AFB2, AFG1, and AFG2) in peanuts, Brazil nuts, hazelnuts, pistachios, and almonds for further processing. A maximum limit of $10 \mu\text{g}/\text{kg}$ is also set for ready-to-eat Brazil nuts, dried figs, hazelnuts, pistachios, and almonds. A level of $0.5 \mu\text{g}/\text{kg}$ is set for AFM1 in milk, signifying the importance of protecting children from aflatoxin exposure. However, for aflatoxins in staple foods, such as maize and rice, the Codex has not been able to formulate an internationally acceptable ML.

There are three principal reasons for the failure to set an international maximum limit:

1. Differences in national food consumption patterns. For example, maize flour consumption in Africa can be higher than $400 \text{ g}/\text{person}/\text{day}$, in contrast to an average maize flour

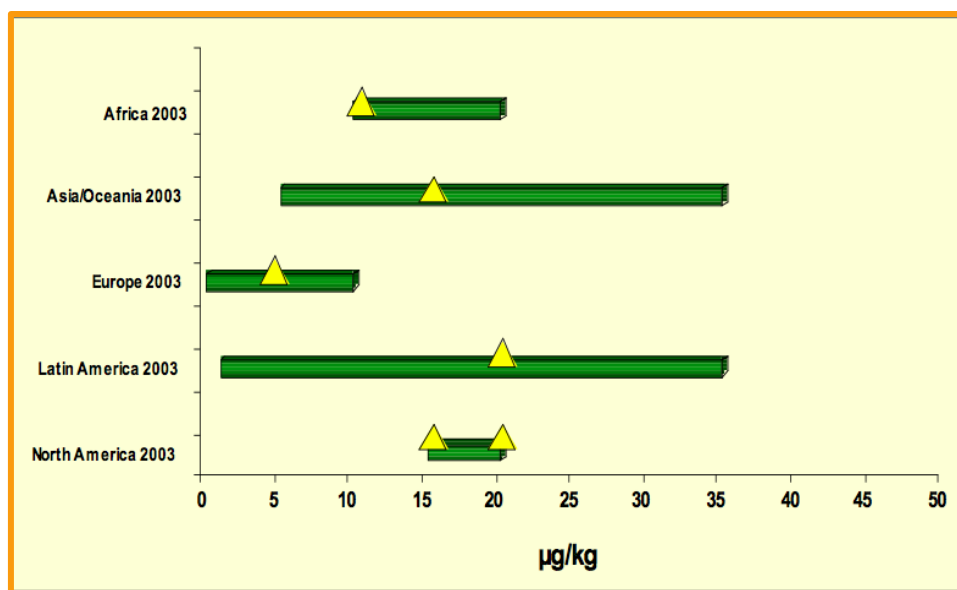
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consumption of 8.8 g/person/day for Europeans, 31.2 g/person/day in the Far East, 31.8 g in the Middle East, and 40 g in Latin America (WHO 2003).

2. Lack of sufficient contamination data for staple foods within the developing world. In response to a recent call for data by JECFA, only one African country submitted data for aflatoxin contamination in rice. Data were received for only 81 samples of sorghum and none of them were from Africa.

3. The difference in aflatoxin contamination in food produced from different agro-ecological regions of the world. In the data collected by JECFA in 2013, there was a very large discrepancy in contamination whereby the average level in rice from Asia was 0.3 $\mu\text{g}/\text{kg}$, as compared to an average of 35.2 $\mu\text{g}/\text{kg}$ from Africa.

The United States has a guideline level of 20 $\mu\text{g}/\text{kg}$ for total aflatoxins (sum of AFB₁, AFB₂, AFG₁, and AFG₂) for food. The European Community enforces a more stringent ML of 4 $\mu\text{g}/\text{kg}$ for total aflatoxins in food. Europe also implements an aflatoxin-free requirement for foods for infants and an ML of 0.1 $\mu\text{g}/\text{kg}$ for processed, cereal-based foods and baby foods for infants and young children (EU2006). The comparative data of total aflatoxin limits in food among different regions worldwide (as of 2003) is shown in Figure 1 (Van Egmond et al. 2007).



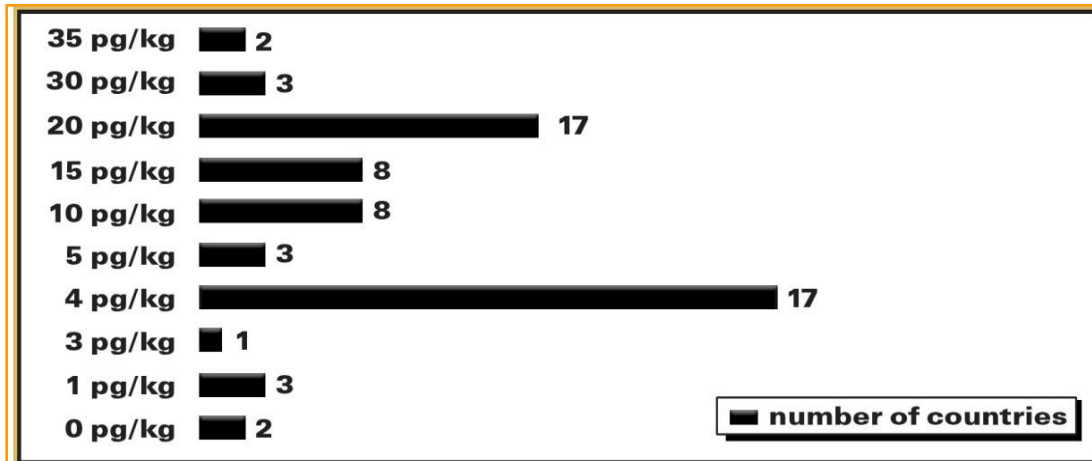
Source: van Egmond et al. 2007

Figure 1: Ranges (bars) and typical MLs (Δ) for total aflatoxins in food

According to FAO (2004), in 2003 only 60 countries had MLs for AFB₁ or total aflatoxins, or for AFM₁; 15 of these countries are in Africa. The number of countries with MLs on total aflatoxins is shown in Figure 2 (FAO 2004). MLs for AFB₁ range from 1 to 20 $\mu\text{g}/\text{kg}$, with 2 $\mu\text{g}/\text{kg}$ and 5 $\mu\text{g}/\text{kg}$ being the most frequently regulated levels. With regard to AFM₁, of the 60 countries, 22 had a limit of 0.5 $\mu\text{g}/\text{kg}$ and 34 a limit of 0.05 $\mu\text{g}/\text{kg}$. The discrepancy in MLs set by different national and regional food safety regulatory bodies exerts

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considerable impact on trade. Stringent limits such as 2 µg/kg (for AFB1) and 4 µg/kg (for total aflatoxins) set in the EU force producers, traders, and processors in other countries to incur more operating costs as they strive to meet them. If they do not comply with the limits, they may incur additional costs from rejection of shipments.



Source: FAO 2004

Figure 2: Worldwide limit for total aflatoxins as of 2003

Enforcement of Regulations

The existence of MLs for aflatoxins in foods cannot be effective in the absence of effective and efficient compliance by the private sector, coupled with enforcement by governments. Developed countries have very effective food control systems, such as the U.S. Food and Drug Administration—which regulates across both the public and private sectors; but developing countries have very weak enforcement by regulatory agencies and largely uncontrolled food marketing and processing systems. This situation is exacerbated by high on-farm household consumption of food products, informal trading systems, and the threat of significant economic losses throughout the value chain which could result from enforcement of standards. In the rare cases in which potentially contaminated commodities are scrutinized, the lack of quality-control, standardized testing protocols and sparse availability of laboratory facilities is a further hindrance. When contaminated commodities are rejected they are often reintroduced into the marketplace for low-income consumers. Currently, the onus falls mainly on large-scale commercial exporters for global markets to ensure compliance with the importing countries' requirements or risk significant financial losses.

Waliyar et al. (2008) described in detail some of the problems encountered in the establishment of mycotoxin testing laboratories in developing countries. These include difficulties in obtaining sufficient political commitment for funding and lack of adequate infrastructure, such as the reliable electrical supply, instrumentation, computerization and commercialization that modern laboratories require. Their report

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shows further that, even once laboratories are established, other problems arise, including finding qualified local analytical and technical staff and the challenge of relying on imported operational supplies and instrument parts, in most cases, through expensive local agents. Hence, existing laboratories are concentrated in areas that have these utilities and are not accessible to food market routine testing, yet this is where most contamination takes place. Lastly, donors rarely consider the recurrent cost of their projects, after the initial funding period has subsided, and governments may not have the political will or monetary resources to sustain laboratory facilities.

The Situational Analysis

In the EAC region, maize, milk, and groundnuts are the main sources of aflatoxin exposure. All of these are commonly used as complementary foods, creating a high risk for infants and young children. Only a few studies of the extent of aflatoxin contamination in food and population exposure to contaminated food have been carried out in East Africa. Results from surveys carried out in Uganda (1966-2005) have consistently shown aflatoxin levels in foods above the recommended ML of 10 ppb maximum. The most susceptible foods in Uganda were groundnuts and their products. Locally processed food products, including baby foods, were found to have contamination of up to 20 ppb (ML is 5ppb for baby foods). Studies show varying levels of contamination, by crop, region, and season. Per capita consumption ranges from 150-500g /person/day (Kimanya et al. 2008). Other studies conducted in Kenya (Azziz-Baumgartner 2005; Gong et al. 2012; Yard et al. 2013; Castelino et al. 2014a), Tanzania (Shirima et al. 2013) and Uganda (Asiki et al. 2014). show consistently high aflatoxin exposures.

Consumption Patterns for Susceptible Foods

The majority of EAC inhabitants consume cereals as staple foods. Other commonly consumed foods include cassava, dried fish, locally processed cereal-based complementary foods, cured fish, cassava, and groundnuts. Unfortunately, these foods are highly vulnerable to fungal infection, including mycotoxin-producing fungi, and hence aflatoxin contamination. Uganda, Rwanda, and Burundi have more diverse dietary consumption patterns, with roots, tubers, and plantain contributing the highest proportion of energy intake. Relatively high amounts of groundnuts are consumed in Uganda, where they are the third most commonly consumed food. On-farm consumption comprises between 60-90 percent of the household food basket across the East Africa region. This situation presents significant challenges to the successful implementation of dietary-based aflatoxin control. Table 1 shows the per capita consumption and aflatoxin contamination patterns in countries of the EAC as reported by the EAC's aflatoxin working group in April 2013 (Dar es Salaam, Tanzania [EAC/TF/405/2013]).

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Table 1: Per capita food/aflatoxin consumption in East Africa region.

Foodstuff/country	Per capita food consumption (g/person/day)	Average contamination (ng/g)
Maize		
Kenya	400	131.7
Uganda	69	9.7
Tanzania	405	49.7
Groundnuts		
Burundi		12.5
Uganda	65	15.0
Tanzania		25.1
Cassava chips		
Uganda		0.5
Tanzania	214***	0.9
Sorghum		
Tanzania	40	3.0
Milk		
Kenya	750ml	0.8
Tanzania	750ml	0.9

Source: EAC report (EAC/TF/405/2013), 2013

Aflatoxin MLs in the EAC

Setting of maximum limits for aflatoxins in food for human consumption in countries of the EAC region began in the 1990s (Mugula and Lyimo 1992). The MLs recently adopted are 0.05 µg/kg for aflatoxin M₁ in milk, and 5 µg/kg for aflatoxin B₁ and 10 µg/kg for total aflatoxins in other foods. Regionally harmonized EAC standards are necessary to ensure equal protection of the public and facilitate regional and international trade. Before the advent of harmonized standards, MLs differed among countries. Table 2 lists MLs recently adopted by the EAC.

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*Table 2: Recently adopted EAC MLs.**

EAC Number	Food stuff	Total aflatoxins (µg/kg)	Aflatoxin B ₁ (µg/kg)
EAS 2:2012	Maize grain	10	5
EAS 46:2012	Dry beans	10	5
EAS 51:2012	Wheat	10	5
EAS 128:2012	Milled rice	10	5
EAS 284:2012	Pearl millet**	10	
EAS 331:2012	Green gram	10	5
EAS 754:2012	Chickpeas	10	5
EAS 755:2012	Cow peas	10	5
EAS 756:2012	Dry pigeon peas	10	5
EAS 757: 2012	Sorghum grains	10	5
EAS 758:2012	Finger millet (<i>Eleusine coracana</i>)	10	5
EAS 759:2012	Dry whole peas (<i>Pisum Sativum/arvense</i>)	10	5
EAS 760	Lentils	10	5
EAS 761:2012	Dry split peas	10	5
EAS 762:2012	Dry soy beans	10	5
EAS 763: 2012	Dry fava beans	10	5
EAS 764:2012	Rough (paddy) rice	10	5
EAS 764:2012	Brown rice	10	5

*EAC Secretariat Standards Office

** Whole and decorticated Senegalese varieties of *Pennisetum*

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Table 3 illustrates the range of MLs for food commodities that were in force in Tanzania before 2012.

Table 3: MLs for aflatoxins in Tanzanian foods standards.

Standard	Food Product	Aflatoxin limits (µg/kg)
TZS 328	Maize flour	5 for B ₁ and 10 for total aflatoxins
TZS 438	Maize grain	5 for B ₁ and 10 for total aflatoxins
TZS437	Wheat grains	5 for B ₁ and 10 for total aflatoxins
TZS 439	Wheat flour	5 for B ₁ and 10 for total aflatoxins
TZS765	Sorghum flour	5 for B ₁ and 10 for total aflatoxins
TZS1083	Soya beans	5 for B ₁ and 10 for total aflatoxins
TZS874	Pearl millet/ bulrush flour	5 for B ₁ and 10 for total aflatoxins

Source: TBS Standards Catalogue 2014

Regulatory Infrastructure

Assurance of food safety in a country requires a fully functional and modernized food safety regulatory system supported by appropriate legislation. According to the FAO (2008), an effective and efficient food regulatory system is comprised of four main components: a food control administration, inspection services, laboratory services, and information, education, communication and training.

Three options of organizational arrangements are recommended by the FAO for management of food-safety regulation in a country. These are a single agency system, an integrated system, or a multiple agency system. All countries within the East Africa region operate a food-safety regulatory system based on the multiple-agencies model. Under the multiple-agencies system, food safety regulatory responsibilities are shared among government ministries including as health, trade and industry, tourism, livestock, and agriculture. Unfortunately, this structure has resulted in overlapping mandates, and has often produced conflicts among these agencies. This diffusion of food-safety responsibilities greatly hampers food safety at every level of the value chain. In all the EAC partner countries, the establishment of food standards is vested with the Bureau of Standards. Overlap and conflicts are most often encountered in areas of enforcement. This is because, although enforcement of food standards is mandated to bodies under ministries, such as those responsible for health, agriculture and livestock issues, it is also either mandated or delegated to the bureaus.

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Selling maize at the market. IITA

In Tanzania, the overlap in function is evident between the Tanzania Bureau of Standards and the Tanzania Food and Drugs Authority, which is under the Ministry of Health and Social Welfare.

In the rest of the EAC partner countries, overlap and conflicts in enforcement may involve more than two agencies. For instance, in Uganda the Ministry of Health has a Food Desk in the National Drug Authority, and there are several departments charged with environmental sanitation, food safety, and public health (FAO 2012). All these entities are responsible for food-standards enforcement. Additionally, under the Uganda Ministry of Agriculture, Animal Industry and Fisheries there are other bodies, namely the Dairy Development Authority (DDA) and the Uganda Coffee Development Authority (UCDA), which are, respectively, responsible for inspection of the dairy products and regulation of coffee. The situation of food regulation in Kenya is similar to that in Uganda. The Kenya Bureau of Standards (KEBS) is the major standards setting and enforcing agency, although other agencies under the Ministry of Public Health and the Ministry of Agriculture are also empowered to enforce the same standards. There is much less information on standards enforcement in Burundi and Rwanda, as these countries are in the first stages of establishing food safety systems. It is expected that, to a great extent, the systems in those two countries will be formulated in accordance with those in the other partner states.

For political and historical reasons, the EAC partner states do not have a single unified system or an integrated system. To remedy this situation, it would be helpful to clearly identify and define, or redefine the role of each agency to avoid duplication and overlap of functions. The Tanzania Food, Drugs and Cosmetics Act (2003), was enacted in this spirit to establish TFDA as the sole agency responsible for food safety enforcement in Tanzania. TFDA is slowly taking on its role and it is hoped that the coordination system will improve.

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In Uganda, a Food Safety Bill, intended to replace the Food and Drugs Act and based on the FAO Model Food Law, awaits approval by the Parliament. However, even if this legislation is approved, it may not be able to fully solve the coordination challenge in Uganda as other agencies with overlapping mandates still exist.

Generally, in East Africa, the enforcement of aflatoxin regulations is hampered by a long list of issues not different from those in other developing countries. These include, but are not limited to, inadequate public knowledge, inadequate capacity within responsible institutions, inadequate legislation, political interference, a weak inspectorate, inadequate laboratory capacity, inadequate human resources capacity, low levels of awareness among stakeholders, and lack of adequate epidemiological evidence to support government food safety mandates.

Policy Recommendations

Given the public health, economic, trade, and food security impacts of aflatoxin contamination of food, there is need to address the areas that have been identified through interventions that reach across all stakeholders. We list here policy recommendations for standards for food, which, if adopted by the EAC and partner states, will greatly enhance regional and national efforts to minimize the negative impact of aflatoxins on human health and the economy.

1. The EAC should continue the policy of standardization of MLs for aflatoxin-prone foods produced, imported and consumed in the region.
2. The EAC should play a leadership role in standardization of methods to measure aflatoxin contamination across the tripartite and North African trade zones represented by COMESA, the Economic Community Of West African States (ECOWAS), the Southern African Development Community (SADC), and Middle East and North Africa (MENA) region on the continent, and seek to influence decisions, legislation, and the regulatory environment at those levels.
3. Adequate funding should be allocated to appropriate regional and national research institutions to assemble and analyze East African-specific data for the setting of aflatoxin limits for foods.
4. Partner states and the EAC should support and participate in international standards-setting bodies to ensure that the unique conditions of aflatoxin contamination and abatement in the EAC are transparently taken into consideration and addressed.
5. Existing national and regionally harmonized standards should be newly reviewed for the based on current assessments that accurately reflect risks now known regarding the East Africa regional food supply contamination levels, dietary consumption patterns, health status, special considerations for vulnerable groups, and demographics.

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6. These updated standards should include a subset for vulnerable populations who are more adversely impacted by aflatoxins such as such as infants and young children, particularly the 1,000 Days population, and persons suffering from suppressed immune systems or co-infections from HIV/AIDS.
7. Affordable and appropriate technologies and testing protocols for monitoring and compliance systems to track aflatoxin in the food chain, from “field to fork,” need to be readily available and economically accessible to all stakeholders at the community, county, national and regional levels.
8. A policy regime that places the burden of proof for compliance on private sector traders, processors, producers, wholesaler, and retailers, with partner state government agencies serving in a regulatory and oversight role, should be adopted at national and regional levels.
9. Centers of Excellence for aflatoxin testing in humans and in foods should be identified or established in the East Africa region to ensure that adequate evidence and information for risk assessment and decision making is available, accurate, and timely.
10. The EAC and COMESA, working with the private sector, and ministries of health, trade and agriculture, and bureaus of standards across the region, should harmonize procedures for enforcing maximum levels, sampling and testing protocols, and institute a uniform surveillance system.
11. The EAC should identify, establish, and implement comprehensive policy and program mechanisms to prevent, minimize, and reduce aflatoxin contamination of foods consumed across the region.
12. The EAC’s five-year communications strategy should provide consumers with the information they need to ensure the food products they consume are safe.
13. The use of logos to identify aflatoxin safe foods for the general public, and also during the 1,000 Days should be explored.

List of Abbreviations and Definitions

Term	Definition
ALARA	As low as reasonably achievable
ALARP	As low as reasonably practicable
ARSO	African Regional Organization for Standardization
BBN	Bureau Burundais de Normalisation et Contrôle de la Qualité
BMD	Benchmark dose
BMDL	Benchmark dose lower limit
BW	Body weight
CAC	Codex Alimentarius Commission (standards referred to as the Codex)
CBA	cost benefit analysis
COMESA	Common Market for Eastern and Southern Africa
EAC	East African Community
EFSA	European Food Safety Authority
FAO	United Nations Food and Agriculture Organization
GAP	Good Agricultural Practice
GATT	General Agreement on Tariffs and Trade
GEMS	Global Environment Monitoring Systems
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
KEBS	Kenya Bureau of Standards
MAAIF	Ministry of Agriculture, Animal Industry, and Fisheries
ML	Maximum permitted limit
MOE	Margins of Exposure
MRA	Mutual Recognition Agreement
MRL	Maximum Residue Level

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Term	Definition
MTTI	Ministry of Tourism, Trade, and Industry
PMTDI	Provisional Maximum Tolerable Daily Intake
PDI	Probable Daily Intake
PLWA	People living with AIDS
Ppm	Parts per million
Q mark	Quality mark
RBS	Rwanda Bureau of Standards
RIA	Regulatory Impact Analysis
SPS	Sanitary and Phytosanitary Measures
SQMT	Standardization, Quality Assurance, Metrology, and Testing
TBS	Tanzania Bureau of Standards
TC	Technical committee
UNBS	Uganda National Bureau of Standards
UNDP	United Nations Development Program
WG	Working group
WHO	World Health Organization
WTO	World Trade Organization

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