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***East Africa Community Secretariat***

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Aflatoxin Standards for Food

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Acronyms

AFB1 Aflatoxin B1

AFB2 Aflatoxin B2

AFG1 Aflatoxin G1

AFG2 Aflatoxin G2

AFM1 Aflatoxin M1

ARSO African Regional Organization for Standardization

BBN Burundi Bureau de Nomalisation

CAC Codex Alimentarius Commission

COMESA Common Market for Eastern and Southern Africa

EAC East African Community

EFSA European Food Safety Agency

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 of Critical Control Point

ISO International Organisation for Standardisation

# JECFA Joint FAO/WHO Expert Committee on Food Additives

KEBS Kenya Bureau of Standards

MAAIF Ministry of Agriculture, Animal Industry and Fisheries

ML Maximum limit

MOE Margins of Exposure

MOH Ministry of Health

MRA Mutual Recognition Agreement

MRL Maximum Residue Level

MTTI Ministry of Tourism, Trade and Industry

PMTDI Provisional Maximum Tolerable Daily Intake

RBS Rwanda Bureau of Standards

RDA Recommended Dietary Allowance

SPS Sanitary and Phytosanitary Measures

SQMT Standardization, Quality Assurance, Metrology and Testing

TBS Tanzania Bureau of Standards

TBT Technical Barriers to Trade

UNBS Uganda National Bureau of Standards

UNDP United Nations Development Programme

UNIDO United Nations Industrial Development Organization

WHO World Health Organisation

WTO World Trade Organisation

WTO/SPS World Trade Organisation, Sanitary and Phytosanitary Agreement

WTO/TBT World Trade Organisation, Technical Barriers to Trade Agreement

**Executive Summary**

Contamination of aflatoxins in foods is regulated to promote public health, and at the same time promote fair trade. Aflatoxins are a group of naturally occurring toxic secondary metabolites produced, primarily, by two species of the ubiquitous fungus Aspergillus when they grow under favourable conditions for toxins formation. Among the naturally occurring forms of aflatoxins are aflatoxin B1 (AFB1), B2 (AFB2), G1 (AFG1) and G2 (AFG2).

Regulation of aflatoxins 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. At Codex level, an ML of 15 µg/kg is set for total aflatoxins (sum of AFB1, AFB2, AFG1 and AFG2) in peanuts, Brazil nuts, hazelnuts, pistachios and almonds for further processing; an ML of 10 µg/kg is also set for processed Brazil nuts, dried figs, hazelnuts, pistachios and almonds. Similarly, a level of 0.5 µg/kg is set for Aflatoxin M1 in milk.

In general, FAO/WHO member states adopt and enforce MLs as set by 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 of the world. Due to the absence of consensus on aflatoxin MLs at Codex for these foods, countries and regions have formulated national or regional MLs. The USA 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 regulated 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, processers and traders.

The setting of MLs for aflatoxins in food standards in countries of the EAC region began in the 1990s when most of these countries started setting standards for specific foods. To date, the Partner states use a ML of 5 µg/kg for aflatoxin B1 and 10 µg/kg for total aflatoxins in selected foods, cereals and pulses in particular while 0.05 µg/kg is set for aflatoxin M1 in milk.. These limits were recently adopted by the EAC as harmonised MLs for the region .The development of standards in the East Africa Region (EAC) stems from The Standardization, Quality Assurance, Metrology and Testing Act (SQMT) Act, 2006.

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, who comprise more than 70% of the population, rates of consumption of home grown food vary from sixty to ninety percent across the region, with the majority of staples aflatoxin prone foods consumed without any quality control. Both informal and formal markets remain largely unregulated, as is the food processing industry. Aflatoxin testing services are centralised in cities, 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 the EAC member 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 is compounded by lack of a centralised 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, as a first step, standards that are based on dietary consumption patterns of the population are needed. This should be followed by improved communication and coordination among existing regulatory bodies, awareness raising 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

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 under high temperatures, and 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, chilli peppers, dried fish, milk and other dairy products and beans, Contamination occurs both before and after harvest. Food gets contaminated with aflatoxin at various level in the food chain when fungi infest the food and produce the by product, aflatoxins. Contamination of crops by A. *flavus* and A.*parasiticus* occurs at temperatures between 24˚C and 35˚C with 7-10% relative humidity (Williams et al, 2004). This means that contamination mainly affects the area between 40˚N and 40˚S of the equator, and this 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 post-harvest under hot and humid conditions. Contamination in the field often happens as a result of insect damage and lack of irrigation (Hell et al, 2000). Storage practices, which vary largely by the agroecological 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 usage proved to be effective in aflatoxin reduction at post-harvest stage (Hell et al 2000). Studies have indicated that food processing may reduce aflatoxin contamination. Dry and wet milling segregated fractions of the commodity and hence reduced 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 are 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, their exposure through food should be kept as low as possible. The use of biomarkers such as aflatoxin DNA adducts and AF-alb 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.

The global comparative exposure data has shown that in the Gambia and Benin, over 90% of young children had detectable levels of AF-alb and the exposure was high in all age groups, in strong contrast to the less than 1% 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 etal, 2003, Gong et al, 2004).

The exposure vary largely between 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 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).

To minimize aflatoxins 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 Alimentarius Commission, maximum limit (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

# Principles and practices in formulation of maximum limits for aflatoxin in foods

MLs for contaminants such as aflatoxins in food standards are formulated and enforced to preserve the public health. Apart from esnuring food safety, application of MLs in food regulations promote 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, is an important requirement for the risk assessment. Other important aspects to address in development of MLs for contaminants in foods are the post-harvest contamination processes, production and manufacturing practices and economic aspects related to contaminant level management and control for the food.

## The Global Context

Consumers worldwide are concerned about food safety. Codex Alimentarius Commission (Codex) is an international body formed jointly by the World Health Organisation (WHO) and the Food and Agriculture Organisation (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), JECFA convey 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. Codex would consider setting an ML for a food if its contribution to exposure meets one of the three conditions stated below (FAO, 2013);

(1)     Contributes 10% or more of an endpoint (daily or weekly tolerable intake) such as PMTDI, in at least one of the WHO GEMS/Food Consumption Cluster Diets, or

(2)     Contributes 5% 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% 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 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 bench mark dose (BMD) at 95% confidence estimated as the dose required to produce a small response (10% 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, 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 groundnut, 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 throughputnrapid 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 Codex. Nonetheless, countries that consider Codex MLs inadequate for protection of their people are allowed by WTO to formulate their own MLs, provided such limits are science based. It is in that context regional bodies such as the European Food Safety Agency (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.

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### CODEX MLs for Aflatoxins

# At Codex level , an ML of 15 µg/kg (15 ppb) is set for total aflatoxins (sum of AFB1, AFB2, AFG1 and AFG2) in peanuts, Brazil nuts, hazelnuts, pistachios and almonds for further processing; an ML of 10 µg/kg is also set for ready-to-eat Brazil nuts, dried figs, hazelnuts, pistachios and almonds. Similarly, a level of 0.5 µg/kg is set for AFM1 in milk, signifying the importance of protecting children from aflatoxin exposure.

# 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 three reasons:

1) Differences in national food consumption patterns. For example, maize flour consumption in Africa can be higher than 400 g/person/day, in contrast to an average maize flour consumptions (move to reference format WHO (2003)) of 8.8 g/person/day for Europeans, 31.2 g/person day in the for Far East, 31.8 g/day for Middle Easterners, and 40 g/person/day in Latin America.

2) Lack of sufficient contamination data for staple foods within the developing world. CAC-write out if first time in text (2004) shows that in a recent call for data by JECFA ditto here, only one African country submitted data for aflatoxin contamination in rice. Data were also 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 µg/kg with an average of 35.2 µg/kg from Africa.

# The USA has a guideline level of 20 µg/kg for total aflatoxins (sum of AFB1, AFB2, AFG1 and AFG2) for food.

# The European Community enforces a more stringent ML of 4 µg/kg for total aflatoxins in food. Europe also implements an aflatoxin free requirement for foods for infants and an ML of 0.1 µg/ kg for processed cereal-based foods and baby foods for infants and young children (EU, 2006).  The comparative data of total aflatoxins limits in food between different regions worldwide (as of 2003) is shown in Figure 1 (Van Egmond et al, 2007).

# According to FAO (2004), only 60 (15 in Africa) countries had MLs for AFB1 or total aflatoxins, or for AFM1 in 2003. The number of countries with MLs on aflatoxin B1 and total aflatoxins is shown in Figures 2 and 3, respectively (FAO, 2004). MLs for AFB1 range from 1 to 20 µg/kg, with 2 µg/kg and 5 µg/kg being the most frequently regulated levels. With regard to AFM1, of the 60 countries, 22 had a limit of 0.5 µg/kg and thirty-four a limit of 0.05 µg/kg. The discrepancy in MLs set by different national and regional food safety regulatory bodies exerts considerable impact on trade. Stringent MLs such as 2 µg/kg (for AFB1) (I think this is only for milk....please check the facts and clarify)and 4 µg/kg (for total aflatoxins) set in the EU forces 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.

According to CAC (2014), at Codex level, an ML of 15 µg/kg (15 ppm) is set for total aflatoxins (sum of AFB1, AFB2, AFG1 and AFG2) in peanuts, Brazil nuts, hazelnuts, pistachios and almonds for further processing; an ML of 10 µg/kg is also set for processed Brazil nuts, dried figs, hazelnuts, pistachios and almonds. Similarly, a level of 0.5 µg/kg is set for AFM1 in milk, signifying the importance of protecting children from aflatoxin exposure. A comparison of total aflatoxins MLs globally (as of 2003) is shown in Figure 1.



Figure 1. Ranges (bars) and typical MLs (∆) for total aflatoxins in food (van Egmond et al, 2007)



Figure 2. Worldwide limit for aflatoxin B1as of 2003 (FAO, 2004)





 Figure 3. Worldwide limit for total aflatoxins as of 2003, Source : (FAO, 2004

## 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. Whereas developed countries have very effective food control systems , such as the US Food and Drug Administration which regulates across both the public and private sectors, developing countries have very weak enforcement by regulatory agencies combined with largely uncontrolled food marketing and processing systems. This situation is exacerbated by high consumption of home grown food, informal trading systems and the threat of significant economic losses throughout the value chain which could result from enforcement of standards. In rare cases when potentially contaminated commodities are scrutinized, the lack of quality control standardized testing protocol and sparse availability of laboratory facilities is a further hindrance. 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 a reliable electrical supply, instrumentation, computerization and commercialization that modern laboratories require. The report shows, further, that once laboratories are established other problems arise, which include developing local capacity with respect to qualified analytical and technical staff and reliance 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, and governments may not have the political will or monetary resources to sustain laboratory facilities.

# The Situational Analysis

In the EAC region the aflatoxin susceptible foods of maize and groundnuts are the main sources of aflatoxin exposure, however high levels of milk consumption in some regions also create a significant risk, especially for infants and young children.

Only a few studies have been carried out in East Africa, to understand the extent of aflatoxins contamination in food and their exposure. Results from surveys carried out in Uganda (1966 – 2005) have consistently shown high 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 as compared to 5ppb for baby foods. Studies that have been conducted show varying levels of contamination, by crop, region, and season just as per capital consumption which 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 high exposures of aflatoxins in the populations.

## Consumption Patterns for Susceptible Foods

# Majority of EAC inhabitants consume cereals as staple foods. Other foods consumed include cassava, dried fish, locally processed cereal-based complementary foods, cured fish, groundnuts, Unfortunately these foods are more vulnerable to fungal infestation, mycotoxins and hence aflatoxin contamination. Uganda, Rwanda & 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 Ugandan, ranking as third most commonly consumed food. In general, 30 – 50% of the food consumed by EAC is own produced, raising a challenge for market based aflatoxin interventions e.g. regulations. The per capita consumption patterns and aflatoxin contamination patterns in countries of the EAC, generated by an EAC aflatoxin working group in April, 2013, Dar es Salaam, Tanzania (EAC/TF/405/2013) are shown in Table 1.

# \*Table 1:  Food consumption and total aflatoxins contamination levels for maize grain, groundnuts, cassava chips, and sorghum grains cow’s milk in the EAC countries

|  |  |  |  |
| --- | --- | --- | --- |
| **Food stuff/Country** | **Per capita food consumption (g/person/day)** | **Average Aflatoxins contamination (ng/g)** | Reference |
| **Maize grain** |  |
| Kenya | 400 | 131.7 |  |
| Uganda | 69 | 9.7 |  |
| Tanzania | 405 | 49.7 |  |
| **Groundnuts (peanuts)** |  |
| Burundi |  65\*\* | 12.5 |  |
| Uganda | 15.0 |  |
| Tanzania | 25.1 |  |
| **Cassava chips** |  |
| Uganda |  214\*\*\* | 0.5 |  |
| Tanzania | 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 MLs for aflatoxins in food for human consumption in countries of the EAC region began in the 1990s (Mugula and Lyimo, 1992; Muriuki and Siboe, 1995). As shown in Table 3, 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  (Willy Musinguzi, Personal communication).  Harmonized standards in the EAC are necessary to ensure equal protection of the public and facilitate trade in the region and internationally. Before harmonization, the same limits were enforced in Tanzania, Kenya and Uganda for cereal and cereal products. Table 4 shows, as an example, the range of food commodities and MLs that were in force in Tanzania.

# Table 3: Food commodities for which harmonised aflatoxin maximum limits were recently adopted in the EAC region\*

|  |  |  |  |
| --- | --- | --- | --- |
| EAC Number | FOOD | Total Aflatoxins (µg/kg) | Aflatoxin B1(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( whole and decorticated) of Senegalese varieties Pennisetum Glaucum | 10 | 5 |
| 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(Eleusine Coracana) | 10 | 5 |
| EAS 759:2012 | Dry Whole Peas( Pisum Sativum /arvense | 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 Faba Beans | 10 | 5 |
| EAS 764:2012 | Rough(paddy) rice | 10 | 5 |
| EAS 764:2012 | Brown Rice | 10 | 5 |

# \*EAC Secretariat Standards Office,

**Table 4. Maximum limits for Aflatoxins as set in given foods standards in Tanzania**

|  |  |  |
| --- | --- | --- |
| **Standard**  | **Food Product**  | **Aflatoxin limits (µg/kg)**  |
| **TZS 328:** **TZS 438:**  | **Maize Flour** **Maize Grain**  | **5 for B1 and 10 for total aflatoxins.** **5 for B1 and 10 for total aflatoxins.**  |
| **TZS 437:**  |  **Wheat Grains**  | **5 for B1 and 10 for total aflatoxins**  |
| **TZS 439:**   | **Wheat flour**  | **5 for B1 and 10 for total aflatoxins**  |
| **TZS 765:**  | **Sorghum Flour**  | **5 for B1 and 10 for total aflatoxins**  |
|  **TZS 1083**  | **Soya Beans**  | **5 for B1 and 10 for total aflatoxins**  |
| **TZS 874**  | **Pearl millet/ bulbrush flour-**  | **5 for B1 and 10 for total aflatoxins**  |

Source: TBS Standards Catalogue 2014

## Regulatory infrastructure

Assurance of food safety in a country requires an efficient and effective 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, inspectorate services, laboratory services and information, education, communication & 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 that is based on the multiple agencies model. Under the multiple agencies system, the food safety regulatory responsibilities are shared between government Ministries such as Health, Trade and Industry, Tourism, Livestock and Agriculture. Unfortunately, this structure has resulted in overlapping mandates, and often conflicts among these agencies.  This diffusion of food safety responsibilities greatly hampers the food safety at every level of the value chain. In all the EAC countries, food standards setting responsibility is mandated to Bureau of Standards, but the overlap and conflicts are most often encountered in 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 also either mandated or delegated to the bureaus.

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 member countries the 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 very similar to that in Uganda. The Kenya Bureau of Standards (KEBS) is the major standards setting and enforcing agency, although other agencies under Ministries of Public Health and Agriculture are also empowered to enforce the same standards.

There is much less information on standards enforcement in Burundi and Rwanda compared to the other EAC countries as these countries are in their infancy 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 member states.

For political and historical reasons, the EAC member states do not have a single unified system or an integrated system. To remedy this situation, it would be helpful to clearly identify define, or redefine the role of each agency to avoid duplication and overlap of functions. It is in that spirit, the Tanzania Food, Drugs and Cosmetics Act (2003), was enacted 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. 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 of Uganda. However even if approved, the law may not be able to fully solve the coordination challenge in Uganda as the other agencies with overlapping mandates still exist.

Generally, in East Africa the enforcement of aflatoxin regulations is hampered by a catalogue 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, weak inspectorate, inadequate laboratories capacity, inadequate human resources capacity , low levels of awareness among stakeholders and lack of adequate epidemiogical evidence to support.

**Recommendations**

Given the public health, economic, trade and food security impacts of aflatoxins, there is need to address the areas that have been identified through interventions that cut across all stakeholders. Below are Policy recommendations for Standards for Food, which if adopted by the EAC the impact of aflatoxins on human health and economy can be minimized:

1. There is need for East African Community (EAC) to continue the policy of harmonization of maximum levels (MLs) of aflatoxin in foods and animal feeds within the region.
2. There is need for EAC to play a leadership role in harmonization of standards across the tripartite and North African trade zones represented by COMESA, ECOWAS, SADEC and MENA on the Continent in order to influence decisions at those levels.
3. There is need for EAC to involve research institutions in the region in generation of appropriate data for the setting of MLs at regional and international levels.
4. The EAC will participate in, and support the participation of Partner States with international standards setting bodies to ensure that the unique conditions of aflatoxin contamination and abatement are best considered and addressed.
5. MLs for aflatoxin in foods in the East Africa Region should be newly reviewed based on risk assessment to appropriately reflect risks on aggregate food supply contamination levels, dietary consumption patterns, health status and demographics.
6. MLs should take into consideration vulnerable groups such as infants, 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”, should be made available and economically accessible to all stakeholders.
8. The burden of proof of compliance should rest with the private sector traders, processors, producers, wholesalers and retailers, with Partner State government agencies should serve in a regulatory and oversight role.
9. Centers of excellence for aflatoxin testing in humans and in foods should be identified or established in the EAC region to ensure that adequate and accurate evidence and information for risk assessment and decision making is available and timely.
10. The EAC should harmonize standards for enforcing MLs levels, sampling and testing protocols and institute a uniform surveillance including early warning and alert system and monitoring and evaluation (M&E) across the region
11. Establish and implement mechanisms to prevent, minimize or reduce aflatoxin contamination of foods.
12. Establish infrastructure to enhance food safety and ensure that increased food production is protected from aflatoxin contamination e.g. by ensuring appropriate drying and storage facilities

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