Building an Aflatoxin Safe East African Community

Technical Policy Paper 6

Biocontrol for Aflatoxin

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Situational Analysis East Africa Region

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Authors:

Kitty Cardwell, National Institute of Food and Agriculture (NIFA), United States Department of Agriculture, Washington DC

Peter Cotty, Agricultural Research Service (ARS) United States Department of Agriculture, University of Arizona, Tucson, Arizona

Ranajit Bandyopadhyay, International Institute of Tropical Agriculture, Ibadan, Nigeria

Charity Mutegi, International Institute of Tropical Agriculture, Nairobi, Kenya

Francesca Nelson, International Institute of Tropical Agriculture, Dar es Salaam, Tanzania

Moses Marwa, East African Community, Arusha, Tanzania

Victor Manyong, International Institute of Tropical Agriculture, Dar es Salaam, Tanzania

Contact IITA:

f.nelson@cgiar.org or c.njuguna@cgiar.org

IITA Tanzania East Africa Region Hub
Plot No. 25, Mikocheni Light Industrial Area
Mwenge, Coca Cola Road, Mikocheni B
PO Box 54441, Dar es Salaam, Tanzania

Cover: A farmer broadcasts Aflasafe in a maize field in Kenya. *Photo: IITA*

Foreword

Scientists have long been aware of high levels of aflatoxin contamination in the African food supply, and have known for over two decades the detrimental effects of aflatoxin ingestion on human and animal health. However, ameliorating these risks has proven to be a complex undertaking. In contrast, throughout the developed world, aflatoxin rarely enters the value chain at unsafe levels. This can be attributed to cooperation and rigorous enforcement of standards shared between government and the private sector, in combination with application of modern technologies to minimize contamination at the point of production. Within the agriculture sector, the most effective aflatoxin control measure to date has been through biological control, a process whereby the toxic species of *Aspergillus flavus*, the fungus producing aflatoxin, is crowded out of the fields by atoxigenic species. The species of the fungus are specific to their geographical location, requiring the development of regional products of what is now known as “Aflasafe™.” Aflasafe™ is applied by the farmer directly onto the field, reducing the prevalence of aflatoxin in crops up to 90 percent. While there will always be “aflatoxin hotspots," where soil levels are so high that even a 90 percent reduction will not make crops grown there safe, the use of Aflasafe has the potential to shift the bulk of the staple crops of the East Africa region into compliance with maximum tolerance levels for both human food and animal feed. Biocontrol products are commercially manufactured in the United States and Europe, and have played a significant role in preserving markets for maize, cotton, and a variety of nuts. Currently, Aflasafe products for the East Africa region are in varying stages of development.

Once a crop has become contaminated with aflatoxin it becomes costly and difficult to remove it from the value chain. This is especially true for the countries of East Africa—Burundi, Kenya, Rwanda, Tanzania, and Uganda—where over half of aflatoxin prone staple foods are either consumed on-farm or traded informally. The first line of defense is therefore to prevent contamination at the farm level. Aflasafe is an environmentally sound and highly effective technology for prevention. This paper is intended to establish the scientific knowledge platform to inform policy makers, donors, program designers, and other stakeholders about key aspects of the biological control of aflatoxin, including hurdles that would need to be overcome and the outline of a business model that would make this product available and affordable to all farmers. It proposes a policy regime under which Aflasafe can be manufactured, traded, and utilized in the most efficient and cost effective manner throughout the region. In combination with other good agricultural practices (GAP), such as improved plant varieties and appropriate postharvest handling practices, Aflasafe promises to become the cornerstone of an aflatoxin-safe food and feed supply strategy in the near future.

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Executive Summary

Crop infection by fungi *Aspergillus flavi* frequently results in aflatoxin contamination, a problem that starts in farmers' fields and has consequences that extend to the health of the people and commerce of affected regions, including East Africa. Aflatoxin contamination in staple foods, such as maize and groundnuts, and high-value specialty crops, such as nuts and spices, significantly disrupts trade. However, even more important than trade for East Africa, are the impacts of aflatoxins on the resident consumer. Consumers in East Africa are highly exposed to these potent toxins in staples such as maize, groundnuts, and tubers. Chronic exposure to aflatoxins results in immune suppression, stunting, low birth weights, and liver cancer. Acute exposure, in the parts per million (ppm) range, may result in acute symptoms such as liver failure and subsequent death. Aflatoxin contamination of feed results in increased mortality of livestock and reduced feed conversion. Furthermore, exposure of domestic animals can result in transfer of aflatoxins to humans through milk and other animal products. The significant trade and public health burdens of aflatoxins clearly dictate a need for mitigation along the value chain.

Entry of aflatoxins into the value chain is best addressed at the point of initial production during crop development in farmers' fields. One of the most promising and cost-effective solutions is through the introduction of atoxigenic (i.e., cannot produce aflatoxin) genetic groups of the fungus that frequently causes aflatoxin contamination. The atoxigenics displace the aflatoxin producers from fungal communities. This type of biological control has been shown to successfully reduce the total aflatoxin contamination of a treated crop by at least 75 percent—and often more. Reductions achieved by biocontrol are effectively maintained throughout the value chain from harvest to consumption because the beneficial fungi remain with the crop throughout transport, storage, and processing.

Biocontrol with atoxigenic *A. flavus* has long-term and area-wide benefits. Although only a single application is made each season, the atoxigenics persist in treated fields between seasons. Thus, when the atoxigenic is applied the second season, there is already a reduced potential for contamination from the first year's treatments and this results in additive reductions in contamination. Aflatoxins continue to reduce over time when atoxigenics are applied each season, resulting in very low aflatoxin levels. Furthermore, the atoxigenics disperse beyond field boundaries, influencing the fungal communities surrounding treatment areas. This results in area-wide reductions to the aflatoxin-producing potential of fungal communities and benefits to both targeted and associated crops. Biocontrol with atoxigenic *A. flavus* is a well-developed technology that has been intensively used in the United States for over two decades.

Only atoxigenic *A. flavus* that is endemic in and highly adapted to the area targeted for aflatoxin management are used. There is variability among atoxigenics in the area to which they are best adapted. The generic name given to atoxigenic-based biocontrol technology in Africa is Aflasafe. Researchers now think that two or three Aflasafe products, each containing four atoxigenic genetic groups of *A. flavus*, will be sufficient to provide aflatoxin management across the East Africa. One product, Aflasafe KE01™, has already been successful at reducing aflatoxin contamination in farmer field trials in Kenya and transitioned to a Government of Kenya (GOK) -led scale-up phase during 2015.

Several considerations must be addressed for biological control to be sustainable in the East Africa region. The science requires highly specialized and ongoing technical capacity to identify the best atoxigenic strains for the region, thereby ensuring optimal results from biocontrol programs. There are legal and regulatory considerations to frame and agree upon, and the framework adopted should be compatible with the larger mandate for regionally harmonized EAC polices legislation and regulations.

Scale-up of the technology to farmers across the region requires oversight and a strong extension and training program with specific and ongoing technical transfer of knowledge and practical technique. Adoption of Aflasafe™ by small farmers, who comprise a majority of the producers across the region, will require an appropriate business model. Issues related to differentiated quality and prices for aflatoxin safe foods and feed need to be thoughtfully considered and resolved as new demand for these superior products could easily outstrip the supply. Models of a comprehensive biocontrol implementation initiative should blend and balance governmental action, the leadership of continent-wide institutions such as Partnership for Aflatoxin Control in Africa (PACA) based at the African Union Commission, regional economic organizations such as the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA), private sector participation, and strong public-private partnerships. A communications strategy reaching all stakeholders along the value chain is also an essential element for biocontrol activities in the region. As a first step, we move forward to share the science and sociology of biological control to enable policy makers to make informed decisions on how best to manage and maximize the benefits of this technology for reduction of aflatoxin contamination in their countries.

Introduction

Today, 47 percent of the population of sub-Saharan Africa lives below the poverty line, surviving on less than $1.25 per day (World Bank 2013). Within the East Africa region, this includes a majority of those who work in agriculture, many of whom are women. For the extremely poor—including urban dwellers and landless and subsistence farmers alike—income growth has remained flat, at approximately half of the $1.25 line over the past decade. The levels of extreme poverty are further reflected by the persistence of inordinately high rates of childhood stunting over the past two decades, an indicator of chronic under-nutrition (UNICEF 2004).

Agriculture throughout the East Africa region has not reached its potential for small- to medium-scale producers. Staple crop production is almost exclusively rain fed, and can be further characterized by low productivity on marginal lands, suboptimal crop quality, lack of access to modern inputs, and constraints imposed by lack of access to formal markets. Both public and private sector extension services are weak. Seasonal household food insecurity is the norm for many small farmers, and persistent food insecurity is seen at the subsistence farming level. Dietary preferences are deeply embedded in the culture and significant shifts in consumption patterns would require intensive and costly nutrition education and behavior-change interventions.

National food security requires three elements: a robust and productive agriculture sector, the ability of households to obtain safe, nutritious food, and a level of health among the population that ensures adequate utilization of nutrients from the diet (Frison et al. 2006). Dietary consumption patterns and cultural practices also have a significant influence on food security and nutrition at the household and community level. Throughout sub-Saharan Africa, where a most workers are employed in the agriculture sector and agribusiness comprises a significant proportion of the gross domestic product, agricultural is also a key driver of economic growth and sustainable development.

An important element of food security is that food is safe and nutritious. The International Institute of Tropical Agriculture (IITA), the EAC, and the United States Agency for International Development (USAID) have formed a partnership to tackle one of the most urgent food safety issues currently affecting Africa. This is the threat of aflatoxin, a naturally occurring, soil-borne fungus that contaminates many of the staple foods and feeds consumed each day by humans and the animals that provide food for humans. Aflatoxin contamination of foodstuffs impacts hundreds of millions of men, women, and children across the region, regardless of socioeconomic status, occupation, age, or gender. Aflatoxin renders food unsafe to eat and anti-nutritional; therefore it has the potential to seriously affect food security (Shephard 2005).

The control of aflatoxin is a complex undertaking, requiring the participation of the health, agriculture, and agribusiness sectors and the commitment of government at every level. The sharing of information, the advent and application of new technologies and best practices, appropriate communications, and relationship-building throughout the multi-sectoral network are all critical to the success of this undertaking. To realize an aflatoxin safe community, region, and continent, we seek to establish a science-based understanding of the dimensions of aflatoxin issues within the East Africa region and to develop a strategic policy framework from which a cascade of responsive programs and activities will unfold.

Problem Statement

As processing technologies advance and the demand for food rises, food safety at all levels of the agricultural value chain continues to gain visibility as a priority for consumers, producers, processors, traders, regulatory bodies, and policy makers. Many food safety issues can be easily and affordably addressed through behavior change, technological innovation, and application of best practices. However, those that are intrinsic to the plant and animal lifecycles pose a unique and significant challenge. Among these is aflatoxin, a toxin produced by the fungus *Aspergillus flavus*, which occurs naturally in the soils of all tropical regions. The fungus is non-systemic and causes contamination by migrating from the soil onto the plant host, through either air-borne spores or direct contact of the vulnerable part of the plant with the soil. *A. flavus* infection leads to aflatoxin contamination in susceptible commodities such as maize, milk, groundnuts, tree nuts, cassava, yams, cotton, spices, rice, dried fish, fruits, beans, and other legumes. Many of these are consumed as dietary staples across Africa, resulting in high levels of human exposure (Shephard 2005).

Crops grown in the tropics are regularly exposed to the fungus and to the stressors that can result in vulnerability to aflatoxin prior to harvest. Contributing factors include susceptible varieties, high heat, too much or too little rain, poor soil fertility, insect damage to crops, and poor harvest practices. Contaminated commodities continue to accumulate aflatoxin after harvesting given inadequate drying or ongoing insect or moisture damage in storage and during transit to market (Waliyar et al. 2015). Thus, once the crop has become contaminated with the fungus in the field, the potential for aflatoxin production extends throughout the value chain to the point of consumption. The outcome of this cycle of contamination results in the production, marketing, and consumption of both human food and animal feed that often exceeds both national and internationally established tolerances for safe levels of aflatoxin.

Aflatoxin is classified as a Class I carcinogen by the World Health Organization (WHO) for both humans and animals. Consumed in high doses, it can lead to death by acute aflatoxicosis, which presents as sudden liver failure.

Prolonged and chronic consumption of lower, non-lethal doses of aflatoxin have been shown to cause immunosuppression, stunting among infants and young children, and liver cancer in both humans and animals. Aflatoxin may interact negatively and synergistically in People Living with AIDS (PLWA) and those afflicted by the hepatitis B virus (HBV), accelerating the negative outcomes of these conditions, as in coinfection with tuberculosis in PLWA. Aflatoxin is believed to exacerbate environmental enteropathy, further inhibiting the absorption of essential nutrients from the intestinal tract. The transition from breastfeeding to complementary foods and the family pot is a particularly high-risk period for infants and young children, as levels of aflatoxin in the diet spike over a relatively short period of time.

Recently published studies from Uganda and Kenya have challenged the previous conventional wisdom that small farmers face the greatest risk from aflatoxin-contaminated foods due to high levels of on-farm consumption and a diet of unregulated, aflatoxin-prone staple foods. These newer studies found high elevated serum aflatoxin levels throughout the general population of both of these countries regardless of geographical location, socioeconomic status, level of education, occupation, or gender. These findings exemplify the urgency of a concerted effort to address the threat of aflatoxin as a public health issue.

According to the United Nations Food and Agriculture Organization (FAO), approximately 25 percent of the world's food crops are affected, with countries between the 40º parallels north and south of the equator most at risk. This includes all countries within the East Africa region. Aflatoxin contamination is not adequately controlled or regulated within the indigenous food supply of these countries due to a weak regulatory environment, shortages of trained personnel for testing, inadequate laboratory facilities to monitor food and feed products, and reluctance on the part of the private sector to incur the additional costs of testing in the absence of price differentiation for aflatoxin safe food and feed. As a result, hundreds of millions of people in the region consume high, unsafe levels of aflatoxin through their daily diets. With aflatoxin-prone staple foods such as maize and groundnut comprising significant proportions of food and feed, humans and livestock across the East Africa region are continually at significant risk of adverse health effects from aflatoxin.

Exceptions to this trend are products destined for export to countries with strict enforcement of aflatoxin standards. However, over the past decade, the region has lost most of its shares in the global marketplace for aflatoxin-prone foods, being unable to conform with the more rigorous standards of Europe and North America, for example. This is especially true for groundnut, cotton, and maize products.

Dogs, pigs, calves, and poultry are extremely sensitive to aflatoxin contaminated feeds. Aflatoxin is secreted in the milk of both humans and animals. Aflatoxin safe, certified dogfood is available in the EAC, but similarly certified infant cereal is not.

This serves as a stark reminder of the need to empower consumers to increase demand for safer food and thus motivate farmers and traders to respond accordingly. Aflatoxin in feed also lowers the production of otherwise healthy livestock, decreasing milk and egg yields, and resulting in toxic residues in dairy, meat, and poultry products. Throughout East Africa, damaged and moldy grains that contain high levels of aflatoxin are fed to animals and used for home-brewed alcohol.

Studies in both the large, formal and smaller-scale, urban dairy sector have revealed high levels of contamination in fresh cow milk entering the food chain; there is no available data on home brewed beers and spirits. Clay binders are currently used in the commercial dairy industry across the region; however these binders are not approved for use as mycotoxin binders by any regulatory entity or food and feed safety authority, either nationally, or within the EAC and COMESA regulations.

Standards for maximum tolerance levels of aflatoxin in food and feed commodities, as well as for some processed foods, do exist across the East Africa region, and include a number of EAC and COMESA regionally harmonized standards for many of the aflatoxin-prone commodities. However, in the general absence of enforcement of these standards, quantification of the impacts of aflatoxin contamination in the agriculture sector nationally, regionally, or among the continent-wide trade zones of the Middle East and North Africa (MENA), COMESA, the Economic Community of West African States (ECOWAS) and the Southern Africa Development Community (SADAC) can only be hypothetically expressed. This uncertainty is perpetuated by the lack of adequate training and testing equipment for border and customs officials, coupled with the absence of market differentiation between safe and Aflatoxin contaminated goods. Similarly, as goods are rarely declared contaminated, the lack of disposal systems and officially sanctioned alternative uses for Aflatoxin contaminated commodities is presently a moot point. While international trade losses attributable to Aflatoxin contamination have not been recently estimated, it is probable that they total hundreds of millions of dollars each year for the region. For many products that are realizing new export market potential, such as farmed fish, groundnuts, and macadamia nuts, adequate and modernized Aflatoxin control measures are an absolute precondition to the sustainable growth of the industry.

The most effective and efficient way of reducing Aflatoxin in both feed and food is to control, prevent, or minimize contamination through “good agricultural practices” (GAPs). GAPs begin at the point of production and include sound postharvest handling and storage practices. The development of an East Africa regional GAP model for Aflatoxin control is a priority and should include, in addition to the aforementioned elements, response mechanisms for global climate change (GCC) adaptations.

While GCC is highly localized, variable, and still largely unknown, anticipated changes in humidity, rainfall, and temperature patterns within the EAC partner states all hold potential for increasing Aflatoxin contamination throughout the region.

GAPs include the use of drought- and insect-resistant varieties, the application of inputs to ensure plant health, timely harvesting of crops, appropriate drying methods to discourage the growth of fungi and bacteria, storage conditions to preserve quality and integrity, and the use of innovative technologies such as biological control. Biological control prevents Aflatoxin from entering the food supply in the first place, thereby reducing the need for complex and intensive monitoring, testing, enforcement and disposal systems for contaminated food and feeds at multiple points along the value chains (Cotty et al. 1996; Cotty 2006).

Biological control of Aflatoxin in the field works by encouraging the growth of similar but atoxigenic strains of *Aspergillus flavus*, which crowd out the toxin-producing strains. Biocontrol products approved by the U.S. Environmental Protection Agency (EPA) have been manufactured and used in the United States for over two decades; they control aflatoxin in maize, groundnuts, pistachios, and cotton. More recently, African regulators have allowed the experimental use of locally developed Aflasafe products on maize and groundnut in large areas in Burkina Faso, Kenya, Nigeria, Senegal, and Zambia. In Nigeria, Aflasafe™ is approved for commercial use as well. This paper describes the routes by which commodities become infected throughout the value chain, illustrates the scientific principles of how biological control of *A. flavus* works in crops in the field, and discusses social and regulatory implications. The development of Aflasafe products for Burundi, Tanzania, Rwanda and Uganda is currently underway in tandem with a scale-up in Kenya.

History

The U.S. Experience: Three Decades of R&D

In the United States, crops in several parts of the country have chronic problems with aflatoxin: cotton in Arizona and Texas, maize (corn) in Texas, peanuts in Georgia, and pistachios in California. While there are sporadic occurrences of aflatoxin in other places, often due to extreme changes in weather patterns, these geographical areas have consistent concerns. In 1990, the U.S. Department of Agriculture's Agricultural Research Service (USDA-ARS) began researching biological control of *A. flavus* on cotton in Arizona. Cotton is a cash crop grown in the hot, dry zones of Arizona. Farmers realize their maximum profits by selling the cotton seed for oil and feed. The high oil content cotton seed is a favorite feed additive for dairy farmers throughout the United States. However, aflatoxin is carried from the feed, through the dairy cow, into milk.

Standards for aflatoxin in the United States are based on a number of factors, including the characteristics of consumption. Because milk is a mainstay in the diets of infants and young children, there is a very strict regulatory limitation on aflatoxin in milk--five parts per billion (0.5 ppb). Due to the hot, dry climate of Arizona and consistently high prevalence of particularly toxic strains of *A. flavus*, there was a strong commercial incentive for cotton producers to find a way to control the aflatoxin.

Early research indicated that aflatoxin was not required by the fungus to infect plants (Cotty 1989) and that toxic and non-toxic strains of *A. flavus* co-existed in the soil (Cotty 1997). The overall toxin-producing potential of the *A. flavus* population in soil determined the extent of aflatoxin concentration in crops (Cotty et al. 1994). The populations of *A. flavus* in the soils consisted of many strains of the fungus that survive and perennate in clonal lineages. Studies showed that up to 30 percent of a soil population might be atoxigenic. The research question was whether that population distribution could be manipulated to favor the atoxigenic strains. In theory, seeding fields with atoxigenic strains before the increase of the resident *Aspergillus* population would provide a founder population of introduced atoxigenic strains that would preferentially occupy the food sources first, thereby out-competing other resident strains, including the toxic strains, resulting in products with reduced or no aflatoxin. The choice presented was not whether or not there would be fungi in the commodity, but rather whether it could be determined, through deliberate selection, which strains make up the populations in the field (Cotty et al. 1994).

Scientists at the Agricultural Research Service of USDA were the first to show that people can successfully manipulate soil communities of *Aspergillus flavus*--increasing the proportion of the population that is atoxigenic and making sure that the atoxigenic strains are available to inhabit plants before the toxic strains do (Cotty and Bayman 1993). The first commercially available products, AF36 and Afla-guard, proved so successful in demonstration field trials that all Arizona cotton farmers wanted to treat their land with AF36 (Cotty 1997; Cotty and Antilla 2003). Afla-guard was also tested and proven effective in groundnuts (Dorner and Lamb 2006) and maize (Dorner et al. 1999), as was AF36 in maize (Brown et al. 1998) and pistachios (Doster et al. 2004, 2014).

In 1998, the Arizona state cotton growers' organization, the Arizona Cotton Research and Protection Council, raised resources to build a factory to manufacture enough AF36 to meet farmers' needs statewide. By 2005, the technology had spread to other crops, and most of the maize farmers of south Texas, who were also plagued by serious aflatoxin problems, began to purchase these biological control products from the Arizona factory. Demand now far outstrips supply, due to increased demand for maize and pistachios.

The Benin Meeting: Inroads to Africa

In 1995, IITA research teams in Nigeria and Benin were finding high levels of *Aspergillus flavus* and aflatoxin in maize in West and Central Africa (Cardwell 2001). Concerned about the implications of such high levels of toxin in a staple food, and considering the role of maize as a primary complementary food for infants, IITA assembled a meeting of international experts to determine the best course of action (Cardwell and Miller 1996). The meeting resulted in several important outcomes:

1. A child health study was funded to evaluate the impact of aflatoxin on very young children in Benin and Togo.

2. International researchers began thinking about the best control interventions in agriculture that could be implemented for Africa.

3. Further research was conducted to demonstrate the significant anti-nutritional factors that aflatoxin poses for weaning infants (Gong et al. 2002, 2004).

4. The urgent need to address high aflatoxin levels of staple foods in West Africa, especially those frequently consumed by infants and young children, indicated that biological control might be the best way forward for aflatoxin control in Africa (Cardwell and Cotty 2002).

The African Process and Results

IITA started biocontrol research in Africa in the Republic of Benin in the late 1990s with funding from the German government. In 2003, the biocontrol effort moved to Nigeria with continued funding from the German government and in collaboration with USDA-ARS and the University of Ibadan. Initially, more than 4,200 *Aspergillus* strains collected from maize and soil samples in Nigeria were tested for aflatoxin-producing capacity, and several atoxigenic strains were identified (Atehnkeng et al. 2008a; Donner et al. 2009). Using vegetative compatibility testing, more than 20 atoxigenic vegetative compatibility groups (VCGs) were selected which have no aflatoxin producers within the entire VCG, thus ensuring maintenance of atoxigenicity due to lack of genetic exchange with aflatoxin producers. After sequencing the aflatoxin biosynthesis gene cluster, it was found that these naturally occurring atoxigenic VCGs cannot produce aflatoxins, since their aflatoxin-producing genetic apparatus is defective (Donner et al. 2010). The atoxigenic VCGs were evaluated for growth rate, sporulation, and competitiveness in vitro (Atehnkeng et al. 2008b) and in vivo (Atehnkeng et al. 2014). Information generated from strain characterization work led to the identification of several candidate atoxigenic strains for field evaluation.

Field efficacy of an experimental formulation consisting of four native atoxigenic strains was evaluated on maize in 2007 and 2008 in four agro-ecological zones in Nigeria. The four strains (La3303, La3304, La3279, and Ka16127) were individually formulated on sterile sorghum grain and subsequently mixed in equal proportions. The blended product was applied on soil (40 kg/ha), two to three weeks before flowering. Grains from treated and untreated fields were analyzed for aflatoxins at harvest and after storage. Proportions of the *A. flavus* population in each of the four applied strains in soil before treatment and in harvested grains were determined using vegetative compatibility analyses. Application of the strain mixture resulted in reduced aflatoxin content and significantly ($P < 0.05$) increased the combined frequencies of the VCGs of the applied strains recovered from the soil and grain (Atehnkeng et al. 2014). Aflatoxin reductions of 67–95 percent were associated with a 74–80 percent combined incidence of the VCGs of the four atoxigenic strains on the treated crops. (The incidence of La3303 was less, suggesting that it was not well adapted in the region and is unsuitable as a biocontrol strain.) The applied atoxigenic strains remained with the crop into storage and reduced postharvest increases in contamination. The results suggest that the evaluated multi-strain product has potential to contribute to reduced aflatoxin contamination in Nigeria. This is the first report of a field evaluation of an endemic strain mixture effective at reducing aflatoxin contamination during crop development (Atehnkeng et al. 2014).

The product has been trademarked with the name Aflasafe™, and is currently registered with Nigeria's National Food and Drug Administration and Control (NAFDAC). The four strains of Aflasafe™ are La3279, La3304, Ka16127, and Og0222. Further research demonstrated that the optimum rate of application of the product is 10 kg/ha applied two to three weeks before plant flowering. Aflasafe™ works equally well in maize and groundnut crops. Field testing of Aflasafe™ in Nigeria by about 2,000 farmers between 2009 and 2013 consistently showed a decrease in contamination in maize and groundnuts by 80–90 percent or more. Due to increased demand for Aflasafe™, a demonstration-scale manufacturing plant with a capacity to produce five tons of Aflasafe™ per hour has been constructed on the IITA campus in Ibadan for producing the product for use in different countries (Bandyopadhyay and Cotty 2013).

The success of the project in Nigeria has led to the expansion of biocontrol research in Burkina Faso, Burundi, Ghana, Kenya, Malawi, Mozambique, Rwanda, Senegal, Tanzania, The Gambia, Uganda, and Zambia. IITA has identified separate sets of four competitive atoxigenic strains isolated from locally grown maize to constitute a biocontrol product called Aflasafe KE01™ in Kenya and Aflasafe BF01 in Burkina Faso, Aflasafe SN01 in Senegal, and Aflasafe ZM01 and Aflasafe ZM02 in Zambia. In 2014, testing of the Senegalese product Aflasafe SN01 was extended to The Gambia.

In 2012, G20 leaders launched a new initiative—AgResults—which included Aflasafe in Nigeria as one of the first three pilot projects to encourage the adoption of agricultural technologies by smallholder farmers. IITA's experience in Nigeria has shown that the cost of biocontrol (about $1.8/kg with a recommended use of 10 kg/ha) is affordable for most farmers in the country. The biocontrol product Aflasafe SN01 can potentially reinstate groundnut exports to the European Union lost by Senegal and The Gambia due to aflatoxin contamination.

Maize cobs with Aspergillus growth. J. Atenhkeng, IITA

Principles of Application: When & How

The formulated product is designed for small-scale growers. Farmers will need annual training and technical assistance with ongoing extension services to understand:

- The basics of aflatoxin management
- When the risks for contamination are highest
- Good agricultural practices (GAP) to control aflatoxin and increase yields
- How to use biological control applications with fertilizers and pest control
- Optimum harvest time
- Optimum postharvest management
- Entrepreneurship 101: how to seek the best markets for aflatoxin-free products.

Scaling up Biocontrol Technology

The economic dimensions of scaling up biocontrol will remain a challenge for the short to medium term in the East Africa region. Challenges revolve around the ability of small-scale farmers, who comprise the majority of producers, to afford biocontrol products, to gain access to adequate testing equipment or services, and to receive the necessary extension services to appropriately use the product. A second challenge will be whether the science and technology infrastructure exists in each country to properly manage the selection of atoxigenic strains and the subsequent manufacture and distribution of Aflasafe. There are concerns about finding a non-food carrier for the biocontrol strain, which is currently distributed on killed sorghum grains. Finally there is a question about the logistics of growing and distributing sufficient quantities of the inoculum for the annual requirements of each country to keep pace with demand and planting seasons. A sustainable business model of biocontrol-agent production, and purchase and use by small scale farmers has yet to be fully designed and piloted.

However, with public support and private sector participation, these issues can be successfully addressed.

The Science and Technology of Biological Control

Natural populations of *A. flavus* consist of toxigenic strains that produce variable amounts of aflatoxin and atoxigenic strains that lack the capability to produce aflatoxin (Cotty and Bayman 1993; Dorner 2006; Dorner and Lamb 2006; Atehnkeng et al.2008a 2014). Carefully selected and widely distributed atoxigenic strains are applied on soil during crop flowering to out-compete and exclude toxic strains from colonizing the crop. In Africa, Aflasafe was first developed by IITA in partnership with the U.S. Department of Agriculture's Agricultural Research Service, the African Agriculture Technology Foundation (AATF), and several national institutions. It is currently in different stages of development, adoption, and commercialization in at least a dozen African countries, each country with strains that are native to that country.

Maize (left) and groundnut (right) colonized with strains of A. flavus *during competition experiment. IITA*

The most prevalent of the atoxigenic strains found in local soils are the strains that are most likely to be fit and adapted to the local conditions. Therefore, for each country or agro-ecological zone, specific strains are selected to be best adapted to the indigenous conditions. Usually, four native atoxigenic strains from various parts of the country are combined to produce a multi-strain formulation for each country.

Biocontrol Strain Selection and Product Development

To be selected, candidate atoxigenic strains must be:

- Adapted to the agroecology
- Highly competitive with toxic strains

- Clonal in nature with a stable atoxigenic genotype
- Shown by molecular analysis to lack the genes needed to produce aflatoxin, and
- Low in production or non-producers of cyclopiazonic acid (Abbas et al. 2011).

In each country, product development begins with collection of samples of field soils and crops at harvest and in farmers' stores across various agroecological zones. The samples are collected in partnership with national institutions. Samples are analyzed for aflatoxin to obtain baseline information on the relative toxigenicity of the population. Aflatoxin is extracted from the grain or soil samples using standard laboratory protocols (Cotty1989). Prevalent non-toxic strains are selected for further evaluation. Examples of the most toxic strains are set aside for in vitro competition analyses, with the assumption that the non-toxic strain will need to out-compete the most toxic of the local strains as evaluated in vitro. The competition test is conducted in the laboratory by combining the candidate atoxigenic strains and the toxigenic strains on the same substrate. Grains and kernels inoculated with the toxigenic strain alone serve as a control for the toxin reduction. After incubation and aflatoxin analysis, atoxigenic isolates that reduce aflatoxin by more than 90 percent in the co-inoculated treatments are selected for further genetic evaluation (Probst and Cotty 2012).

Identification of VCGs is a technique to determine whether the highly competitive atoxigenic isolates are genetically related to each other. In nature, *A. flavus* species that are genetically related belong to the same VCG or family. Those that do not exchange genetic material under conducive conditions belong to different VCGs and are not going to cross-breed with aflatoxin producing strains. Ultimately, the VCG family groups identified in an area can be found in the local environment for many years to come, although the proportions in the community may vary from year to year (Grubisha and Cotty 2010). A VCG that is widely distributed is likely to be a good biocontrol agent because it has the innate ability to survive over years and across different agro-ecologies. Researchers reject toxigenic VCGs that have aflatoxin-producing members within the VCG, and VCGs that are restricted to only a few locations.

Strains are catalogued in a library of approximately 5,000 isolates and then annotated with information about origin, strain type, toxigenicity, and other important characteristics. Strain storage techniques are described based on the criteria of the Handbook of Plant Pathology, CMI. The rigorous process of biological control strain selection results from many cycles of testing, strictly selecting only those strains that:

- Do not produce aflatoxin
- Are in VCG groups with wide geographic distribution
- Have no toxigenic member
- Have deletion mutations in aflatoxin biosynthesis genes, and
- Vigorously outcompete toxic strains.

It is ideal to have 8-12 native strains selected as initial candidates for field testing.

Field testing of the 8-12 candidate strains is carried out in two or three mixed formulations of three to four strains each. The mixtures are applied in farmers' fields in collaboration with national partners, primarily the extension and research departments of the ministries responsible for agriculture. Evidence of field trial efficacy is measured in reduced aflatoxin and abundant recovery of the candidate strain VCG from the crop produce (Atehnkeng et al. 2014). Four strains with the most abundant recovery in grains at harvest and soil three months after crop harvest are chosen for formulating the final biocontrol product.

Scientific Criteria for Technology Adoption

There are four criteria that must to be developed to lay the groundwork for successful biocontrol programs.

1. Biosecurity issues must be considered in the laboratory facilities, where class II biosecurity hoods are needed for handling *Aspergillus flavus* samples, and fume hoods and appropriate protective gear are needed for aflatoxin extraction. Technical training (and annual retraining) of laboratory staff on safety procedures is required. A physically secure facility with access limited to authorized personnel is mandatory, as is the strict inventory and control of live biological materials.
2. Technical transfer and applicator training is critical for the success and safety of biocontrol agents. Farmers must know how to secure, handle, and store supplies, when and how to apply to their fields, and how to monitor product performance.
3. Import and export permits are required if soil, crop, and biological samples are shipped to laboratories outside a country.
4. Manufacturing facilities to scale up production of inoculum require highly skilled oversight and technical expertise. Most countries will purchase their biocontrol formulation from inoculum production plants from outside the country, so appropriate shipping and receiving conditions must be assured.

Legal and Regulatory Considerations

Biocontrol products generally fall under a pesticide registration process with components that assess human health considerations, environmental impacts, and efficacy. Registration can be done at the country level, or registration requirements can be formulated for regional standardization.

Intellectual Property Issues

The atoxigenic isolates used as active ingredients in the biopesticide Aflasafe are part of the natural biodiversity of the EAC nations. Therefore these isolates are owned by the nations where they are obtained and should be used for the maximum benefit of the population. The techniques and expertise for producing the biopesticide Aflasafe (which includes the atoxigenic isolates of *A. flavus* as active ingredients) have been developed through a partnership between IITA, USDA-ARS, and national institutions. The technology will be provided with training and assistance, as funding permits, to parties within nations or across the region. Selection of both public and private partners for deployment activities will be upon consultation with stakeholders, donors, regional economic communities, and components of national governments involved with health, agriculture, and/or environmental protection. Technologies building on the Aflasafe core technology will be required to be distributed to farmers at cost or a sliding scale to ensure economic accessibility. Manufacturing utilizes several "off the shelf" technologies, including grain cleaners, roasters, conveyors, storage structures, seed coaters, and packaging equipment. Privately held patents may apply to manufacturing equipment. However, in each case, other pieces of equipment can be substituted to achieve the same goal with varying degrees of cost and efficiency. Thus, control over these equipment patents should not restrict the scale-up of the technology.

Oversight of Internal Markets

Worldwide regulatory standards for maximum limits of mycotoxins in foods vary (Egmond and Jonker 2005). Tolerances set by countries for internal regulation may range from 0 to 30 ppb for foods destined for human consumption. It is clear that where food security could be affected, regulatory enforcement of toxin limits should be carefully thought through. However, management practices to reduce aflatoxin also tend to increase yields, leading to food security improvements over time through both higher incomes for farmers and improved food quality and utilization.

The EAC currently has a number of harmonized standards for aflatoxin in foods. Continuing with the expansion of the harmonized regulatory standards regimen within the partner states in the trade and production spheres, and agreement on monitoring protocols, would be laudable. Early protocols for internal monitoring could be designed to reliably assess public health exposure risks and the efficacy of aflatoxin control programs. Ultimately, the most sustainable goal is to develop scientifically sound and neutral regulatory oversight to foster responsiveness in both formal and informal markets to meet legal requirements and compliance.

This level of regulatory oversight has the potential to become a strong motivator for farmers to use GAPs, for traders to seek low toxin commodities from good farmers, and food and feed producers to deliver a higher quality, safe product.

Maize at the market. R. Bandyopadhyay, IITA

Demand for Biocontrol

The average small-scale farm in the EAC region has little or no purchasing power to acquire new equipment or other production inputs. This poses a practical challenge to the implementation of aflatoxin control initiatives in the agriculture sector, and specifically for the design of a reality-grounded business model for biocontrol scale-up ventures. The challenge is augmented by limited leverage to accelerate demand among consumers in the marketplace. Even with the advent of superior aflatoxin safe products, the public has little or no awareness of the value of clean products, and there is a small or non-existent price differential for aflatoxin-free products in the local market system. Therefore, it is necessary to formulate policies that will drive demand for Aflasafe products into common usage. There are several models for regional or national implementation of effective biocontrol systems, ranging from a completely private-sector-driven approach to full-scale governmental intervention, or a blend of public-private partnerships. Regardless of which model of intervention is chosen, regional governments must commit resources and energy for the long run to bring the aflatoxin problem under control.

Creating Demand for Aflatoxin Control Technology

Government enforcement and regulatory oversight of aflatoxin standards in food and feed are challenges throughout the EAC. This is attributed in part to the perception of a high cost of surveillance, the questionable reliability of sampling and analysis, and inadequate laboratory capacity for aflatoxin analysis. Other challenges include limited availability of aflatoxin experts in government institutions; high cost of aflatoxin analysis and subsequent commodity rejection for the private sector; potential for use of counterfeit quality stickers on products; lack of a model to enforce standard regulations in informal markets and cottage industries; and lack of market differentiation between safe and contaminated products to motivate stakeholders to adhere to standards.

Nevertheless, these perceived constraints are surmountable, and the establishment of models for government oversight of local food safety is obligatory if there is to be sustainable management of aflatoxin for the long term. Regulatory oversight is a key driver and will ultimately determine the extent of adoption of aflatoxin control technologies, including biocontrol, by the farm sector. It is important to understand that regulatory oversight does not require 100-percent monitoring. Periodic checks and the consequence of penalty or reward for the regulated community will do the trick. Public awareness alone, however, has never been shown to be a sustainable driver of market behavior. Checks and balances will be needed.

Other governmental roles in implementation of aflatoxin control through the use of biological control:

- Health sector training recommendations
- Area-wide management program as a public health good
- Provision of incentives to growers with support from government departments, such as ministries of agriculture and trade
- Area-wide programs to promote investment in programs
- Extension to ensure incorporation into best management practices
- Special programs to assist subsistence and smallholders.

Development of Farm Sector Demand

The majority of crop and livestock production systems in the EAC are small or subsistence farms, characterized by cultivation of low value crops and animals, low and inconsistent use of inputs, a propensity to sell best quality produce and reserve low quality residuals for household consumption, and a practice of feeding contaminated grains and legumes unfit for human consumption to livestock. Farmers produce on small, rain-fed plots with limited extension services to advise them on modernized cultivation. Access to improved varieties and other superior planting materials is limited. These characteristics highlight the challenges that need to be overcome in promoting uptake of innovative products and technologies by the agriculture sector. It will be important to develop industry- and consumer-based demand to jump-start the use of biocontrol technologies.

The Feed Industry

Animal production industries can favor use of Aflasafe-treated grains based on animal performance. In West Africa this has been the case for the poultry industry where use of Aflasafe-treated maize for feed resulted in demonstrably lower mortality and faster weight gain. Other industries such as fish producers would also see financial gains from using grains treated with the atoxigenic biocontrols. In the case of aquaculture, the use of safe feeds could be instrumental to the expansion of exports into the global marketplace. Other industries, such as dairy, would gain by avoiding aflatoxins in milk and potential losses due to fines, loss of markets, or dumping under a more stringent regulatory regime. Dairy industries are relatively easier to regulate for aflatoxins because milk, as a liquid, is easily sampled, and there exist only a small number of large producers for formal markets.

Food Processors

Processors of maize and cassava flour, milk products, and groundnut-based products, which already operate under strict food safety standards, are seeking aflatoxin-free products. Aflasafe-treated grain would provide an immediate market for locally purchased commodities.

Premium Products

Higher-income consumers could, in the short term, create new market demand for aflatoxin safe foods. This is likely to occur spontaneously with sensitization about the detrimental health impacts of eating unregulated and untreated produce. Once a premium market exists, farmers will have financial motivation to produce Aflasafe treated maize, groundnuts, and other aflatoxin-prone commodities that could potentially result in lateral transfer of the health benefit effects via on-farm consumption into rural households.

The disadvantage of this approach is that it will create a two-tier user base, leaving mostly the urban poor still chronically exposed to aflatoxin. The advantage, however, is that the more Aflasafe is used in the production systems, the lower the toxin levels will be in general, lifting quality across the sector.

Cultural Perceptions

There is need to sensitize the public, traders, food processors, policy makers, and consumers on the dangers of aflatoxin contamination and the benefit of biocontrol technology. Awareness raising, to ensure positive market reaction to products that meet appropriate aflatoxin standards, must be done by advertising and communications professionals and those with specialized social marketing experience. Social marketers understand how to shape attitudes to change market-player behavior. Grain traders want to buy their products cheaply and sell for a profit, but they also care about the health and wellbeing of their families. Consumers want to buy food cheaply, but they also care about the health of their children. It will be important to understand how much such sensitization will contribute to consumer willingness to pay higher prices for safer products. Ability of consumers to pay a premium price and demand aflatoxin safe labeled products could be motivation for farmers to treat crops in the field. Information is also needed to reach traders, processors, and consumers to assure them that the treatment of food crops with Aflasafe will not harm them.

Awareness raising would also help dispel existing misconceptions such as:

- Aflatoxin contamination only occurs in certain geographic areas;
- There is no health risk in feeding moldy grains to livestock;
- Only grains that are visibly contaminated with mold contain aflatoxin;
- Visual inspection of grains and legumes is sufficient to test for the presence of aflatoxin;
- Blending or mixing freshly harvested grains with moldy ones helps clean the aflatoxin contaminated grains;
- Biocontrol is a form of genetic modification and therefore may be dangerous.

Bags of Aflasafe KE01™ packed into 30-kg bales, ready for shipment from the Aflasafe factory at IITA-Ibadan to Kenya for distribution to farmers by the National Irrigation Board.
R. Bandyopadhyay, IITA

Development of Health-Based Demand

The population of the EAC should know that aflatoxin-free foods will result in reduced stunting, healthier children, and lower cancer rates among adults. Building such awareness is expected to create a desire for safe foods.

Smallholder producers, like other members of society, have many different constraints and concerns. Like all consumers, they are driven by the hopes and desires for health and wellbeing of their own families. Reducing aflatoxins can be achieved through proper use of Aflasafe, and motivation of growers to create wholesome food for themselves and for the market can drive the adoption of Aflasafe.

Potential Private Sector Roles

It is important to remember that smallholder growers who expect to market part of their harvest are private-sector actors who will make decisions based on market demand. One of the constraints to adoption of biological control products such as Aflasafe is that smallholder farmers are often too poor to reliably implement good farming practices. Due to limitations of economies of scale, their ability to acquire farm inputs and knowledge products is limited. Franchise models exist, in which capitalized entrepreneurs aggregate small-scale farmers under their corporate umbrella. The franchise owners purchase and provide inputs with the aim of increasing production, and make sure that aflatoxin biocontrol is practiced. They provide the technical knowledge packages and develop accountability among franchised growers. At the end of the season, the franchiser may provide market services and connect with a premium market. Franchisers work on a margin of all transactions so they have a vested interest in the success of their growers.

Farm-to-market aggregation services with Aflasafe promotion is another model whereby the commodity supply-chain actors could be engaged and actively seek Aflasafe-treated maize to enhance sales to industry and other premium markets. Growers who know that there is market demand for their Aflasafe-treated produce are likely to continue to use the product each growing season.

Finally, the manufacture and distribution of biological control products such as Aflasafe will ultimately be most successful as a private-sector, for profit, operation. It is likely to require public-sector resources to create the physical and human-resource infrastructure and demand, but ultimately the making and distribution of Aflasafe can be operated on a business model. The collateral private-sector development is likely to be within dealerships and distribution. Aflasafe can become another farm product—like fertilizer—that farmers purchase from sales agents.

While we cannot predict all the potential commercial spin-offs and benefits of incorporating aflatoxin controls into mainstream market practices, there is little doubt that there are significant benefits to be achieved throughout society from making the initial investments.

Situational Analysis

Background

Food consumers in the EAC continue to be chronically exposed to aflatoxin due to the high contamination levels in susceptible staple foods, especially maize, milk, and groundnuts. Byproducts from both maize and groundnuts are commonly used as animal feeds, exposing livestock to aflatoxin and resulting in aflatoxin-contaminated milk. There are no known fungicides with high efficacy in managing aflatoxin-producing molds and the aflatoxin contamination they produce. Biological control, in conjunction with other GAPs, has the potential to dramatically reduce aflatoxin contamination across the region. High efficacy has been reported in field trials using Aflasafe on maize in Kenya, with reductions recorded as high as 98 percent.

The vast potential for biocontrol of aflatoxin in East Africa stems from both wide and long-term benefits of applications. Atoxigenic *A. flavus* are already known in several East African nations (Probst et al. 2011). As the fungal populations change in treated fields so that aflatoxin producing fungi are less common and crop contamination is dramatically reduced, these changes move into nearby fields and even throughout the area, reducing contamination on a regional basis. In addition, the beneficial changes caused by applications are partially carried over to subsequent seasons. This means additive benefits occur and fields treated in the second planting season build upon positive changes carried over from applications made to fields in the previous planting season. These effects provide opportunities for programs directed at area-wide management of aflatoxins where contamination throughout target regions will be reduced throughout the life of the program.

Key areas in the EAC where such area-wide programs will be most important are places with perennial and widespread incidence of aflatoxins such as those observed in the Kitui, Machakos, Makueni, and Tana River counties in Kenya. In addition to reductions in contamination across a target area, area-wide programs have the potential to reduce the quantity of biocontrol product required each year and in so doing, the perennial cost of contamination.

Product Development

The full profile and distribution of the atoxigenic species of *A. flavus* across the East Africa region are currently unknown; however it is hypothesized that four to five individualized Aflasafe products will need to be developed to provide full coverage across the region. Efforts are underway by IITA and partner national research institutions to identify atoxigenic genetic groups that are widely distributed in all countries in the region, including EAC partner states. Such widely distributed strains have the potential to be effective in reducing aflatoxins where such strains are native. Use of effective regional strains will lead to development of regional products that can be used in multiple countries. This will result in increased efficacy of the products as well as cost efficiencies.

Unique Challenges

Although in general biological control has the same requirements wherever it is used, each region requires characterization of its resident fungi. Some atoxigenic VCGs of *A. flavus* have already been identified in parts of the EAC, for example, Kenya (Probst et al. 2011). However, the relative adaptation of these to the diverse agro-ecosystems across the EAC is currently unknown and it is hypothesized that four to five individualized Aflasafe products will need to be developed to provide full coverage across the East Africa region. Similarly, awareness among various stakeholders--farmers, government officials, consumers, and industries that utilize crops susceptible to contamination--is required.

Awareness of both the health effects of aflatoxins and of potential interventions such as biological control is highly variable across regions. Neither the economic costs nor the losses to human and animal productivity due to aflatoxin contamination have been adequately quantified for East Africa.

Registration of Aflasafe

It is clear that registration of the native beneficial fungi as a biological control product will depend on the statutory process of the regulatory framework in each country. Before registration of the product, a technical dossier must be assembled and delivered to the registration authority. Typically this dossier should include information on: the product, the formulation process, the ecotoxicological and biosafety parameters, and quality assessment criteria. Harmonization of registration procedures across the EAC partner states and beyond (e.g. COMESA) would benefit manufacture, distribution, and marketing of regional Aflasafe products currently under development.

Manufacturing and Distribution of Aflasafe

Large-scale manufacturing and commercialization of biocontrol products are a prerequisite to large-scale adoption of the technology. Aflasafe, used in ongoing efficacy trials in the region, is currently manufactured at an IITA plant in Nigeria, although strains native to the target country for application are used. In the medium to long term, it is important to set up manufacturing plants of appropriate scale to supply East Africa. However, setting up and operating these facilities requires investment and a skilled workforce. Additionally, to ensure cost effectiveness of the product for farmers, public institutions in the region should initially take a significant role in the registration and manufacturing of the product until such time as market forces allow Aflasafe to evolve into a profitable enterprise. This will require both financial and technical support at the initial stages to set up and operate a manufacturing facility. The potential production capacity should be sufficient to meet anticipated demand for the product throughout all aflatoxin-prone areas in the region. In manufacturing and scale-up of Aflasafe, mechanisms for quality control and biosecurity should be put in place at every stage.

Manufacturing facilities can be designed and implemented to fit a wide range of demand. Currently, modular facilities are being designed in which one module could produce enough Aflasafe to cover up to 200,000 hectares a year. Such facilities could provide product for the initial stages of deployment and be expanded by addition of modules as needed. All manufacturing requires modern laboratory space for production of fungal material and quality control, ability to acquire and clean sorghum grain, roasters to sterilize the sorghum grain, seed treaters to coat the roasted sorghum fungus, and a line to package and ship the end product.

Initial distribution will vary across the region by country. It is anticipated that government agencies are likely candidates to launch initial distribution, such as the Ministry of Agriculture, Kenyan Agricultural and Livestock Research Organization (KALRO). Public-private partnerships also have a pivotal role in the commercialization and scale up of Aflasafe in the East Africa region. Whereas public institutions in the region can undertake manufacturing of Aflasafe, they lack efficient channels to distribute the product to the farmers nationally. There is need therefore for the public institutions to partner with the private sector stakeholders which already have established distribution channels and networks, or are willing to invest in such networks, to deliver the product to farmers. The public-private partnerships may also involve donor agencies to ensure the availability of financial and technical resources throughout the production and supply chain. Players in the private sector which could be involved in such partnerships include: agro-chemical companies, private food producers engaging in contract farming, farmer associations, and food aid distributors such as the World Food Program and USAID Food for Peace (FFP). The partnerships would, however, be faced with the challenge of regulating the mark-up by private companies, to ensure that they profit without significantly increasing farmer costs. Ultimately, it is in the interest of the pubic to ensure cost-effective production of maize and groundnuts with low levels of aflatoxin.

Sustainability

One of the challenges related to sustainability of the proposed intervention is the adoption rate of the technology by farmers. Although aflatoxicosis outbreaks have been common in the region, and maize and groundnuts are staples important to food security, they remain low-value crops whose production is characterized by low use of inputs. It is therefore important to conduct socio-economic studies to determine farmers' willingness and capability to adopt the technology and how much they would be willing to pay for it. Experiences in Nigeria, where Aflasafe has been adopted as a farm input, show that farmers have obtained up to 510 percent return on investment (Grace et al. in press). Studies conducted in Kenya by the International Food Policy Research Institute (IFPRI) demonstrated that farmers are willing to pay 60 percent more than the estimated market price for biocontrol if the product is made available, but more studies are required to understand the willingness to pay in Kenya and other EAC partner states.

It is also necessary to raise awareness among stakeholders on the health implications of aflatoxin to ensure that consumers appreciate the need for managing contamination.

Currently, there is limited technical expertise in the region on the development, manufacturing, and quality control aspects which need to be strengthened to outlast the lifespan of the Aflatoxin Policy and Programs for the East Africa Region (APPEAR) effort now underway with assistance from USAID/East Africa, scheduled to end in 2016. Although it is desirable to have donor support and public institutions taking the lead in the initial production of Aflasafe, the manufacturing plant(s) should be semi-autonomous to ensure efficient operation and limit bureaucracy. Sorghum, whose grains are used as carrier material for Aflasafe, is widely cultivated in the drier areas in the region. This ensures a constant supply of sorghum grains for manufacture of Aflasafe, besides being a source of income for the farmers in the region contracted to supply raw material to the Aflasafe manufacturing plants. However, using sorghum grains as a carrier material is likely to raise concerns on whether priority use of the crop is as a staple food or a commercial product. There is a need to conduct research to find alternate non-food carriers.

Centers of Excellence Concept

In an effort to promote and mainstream biocontrol technology to manage aflatoxin contamination of food and feed, there is a need to develop human capacity and establish physical infrastructure within the EAC. Creating Centers of Excellence is an effective way to move forward. For instance, Centers for Excellence would:

Research—Establish baseline status of aflatoxin contamination of food and feed in the EAC; monitor contamination levels; continuously identify more efficacious atoxigenic strains of *A. flavus* in the region; and improve the efficacy of biocontrol product(s).

Support—Raise the commitment of stakeholders to the development of biocontrol for aflatoxin, and help establish the logistics of the transfer of biocontrol products to end-users. The cost of Aflasafe produced within the EAC is likely to be less than a product manufactured elsewhere.

Quality control—Ensure that the Aflasafe manufacturing process guarantees quality and cost-effectiveness.

The proposed Centers of Excellence will also benefit from international expertise from partner institutions which have participated in the development and deployment of biocontrol technology in other countries and regions.

Laboratory workers sorting isolates into Aspergillus species. R. Bandyopadhyay,IITA

Biocontrol Activities in the EAC Partner States

Biocontrol activities are at different stages of development, from planning to advanced operational phases, in all partner states of EAC. Although many nations have recognized the need for the development of biocontrol technologies, the creation of programs has depended on special funding. The major donors for biocontrol activities by country are:

- ***Kenya***— USDA-Foreign Agricultural Service (FAS); USAID, the Bill & Melinda Gates Foundation (BMGF), and the World Bank; 2010-2016
- ***Tanzania***—BMGF, USDA-FAS in partnership with USAID East Africa, Africa RISING (USAID); 2012
- ***Rwanda***— USAID-Rwanda, USDA-FAS in partnership with USAID; APPEAR; 2012-16
- ***Burundi***— APPEAR (USAID); 2013-16
- ***Uganda***— APPEAR (USAID); 2013-16.

USAID has undertaken a comprehensive review of key aspects of the potential for biocontrol to address aflatoxin issues across the region. The "Programmatic Environmental Assessment," February 2015, has been completed and is valid for 1 year. Analysis of an Aflasafe funding proposal is underway, and approval of Aflasafe use under USAID programs is pending the approval of the Environmental Mitigation and Monitoring Plan (EMMP).

At the inception of country activities, the national agriculture system and other stakeholders (including donors, NGOs, health sector) in each country were educated about biocontrol. In all the countries, the biocontrol researchers met with the officials in the ministry of agriculture and the national agriculture research systems (at the ministry and university levels) and discussed the research and application aspects of biocontrol. In all cases, the member states welcomed the biocontrol initiative. The leadership was requested to nominate an institution and an individual to be the primary contact point for biocontrol research and development (R&D). The nominated primary contact institutions were the Kenyan Agricultural and Livestock Research Organization (KALRO), the National Mycotoxin Task Force for Tanzania (a technical committee of the Tanzania Food and Drugs Authority), the Rwanda Agricultural Board (RAB), the Institut des Sciences Agronomiques du Burundi, and Uganda's National Agricultural Research Organization. In addition, biopesticides registration authorities and other regulators such as quarantine departments dealing with import and export of agriculture consignments were contacted and informed of the proposed projects.

Presently, biocontrol actions are most advanced in Kenya followed by, in order, Tanzania, Rwanda, Burundi, and Uganda. Below is a summary of the progress of biocontrol in EAC partner states.

Kenya. The foundation for biocontrol in Kenya was laid when the *Aspergillus* strain composition was examined in Kenyan maize following an aflatoxicosis outbreak in 2004. Highly toxic S-strains of *A. flavus* were found with extremely high frequency in the grain samples from Eastern province (Probst et al. 2007). After receiving more maize samples from the 2005 and 2006 growing seasons in Kenya, the USDA-ARS group determined the population structure of *A. flavus* in different districts, plus the frequency of S-strains, and mapped the distribution of *Aspergillus* strains in Kenya (Probst et al. 2010).

While studying the population biology and *Aspergillus* community structure in Kenya, researchers identified nearly 100 L-strain isolates of *A. flavus* from grain samples from four Kenyan provinces (Probst et al. 2011). These isolates belonged to 53 VCGs, of which 11 are widely distributed in Kenya. Twenty-three isolates belonging to 19 VCGs were subsequently evaluated for their potential to reduce aflatoxin concentrations in viable maize kernels co-inoculated with highly toxigenic S-strains in multiple tests (Probst et al. 2011). Following further evaluations in the laboratory, 13 atoxigenic isolates belonging to 12 VCGs were finally selected for their potential value in biological control within highly toxic *Aspergillus* communities.

With approval from the Kenya Standing Technical Committee on Imports and Exports (KSTCIE), the 13 atoxigenic isolates were field-tested and evaluated at KALRO research stations in Kiboko and Katumani and by the National Irrigation Board in Bura. From these evaluations, the four most effective atoxigenic isolates were identified to constitute the Kenya-specific biocontrol product Aflasafe KE01. Factors considered in identifying the best four strains included: wide occurrence in nature in Kenya; ability to colonize multiple substrates; ability to be recovered naturally across years; ability to move from the soil and colonize grain (strain recovery); efficacy in displacing toxigenic fungi and thereby reducing levels of aflatoxin; significant reduction in aflatoxin concentration in maize in treated plots; diversity as determined by molecular assays; and inability to produce aflatoxin due to inherent defects in aflatoxin biosynthesis pathway genes.

A trademark—Aflasafe KE01™—was obtained for Kenya through the Agricultural Technology Foundation (AATF). With permission from Kenya's Pest Control Products Board (PCPB), Aflasafe KE01 was evaluated for efficacy in more than 500 farmers' fields for two seasons in 2012-13.

The results showed that Aflasafe KE01 is highly effective at preventing aflatoxin contamination of maize in the counties that have for decades been most effected by aflatoxins—Machakos, Makueni, Kitui, and Tana River. Aflatoxin reduction in these four areas ranged from 93 to 98 percent. Second, there is an ongoing health emergency across the country: Kenyan families are frequently exposed to maize with aflatoxin concentrations more than 50 times that allowed in pet food. In one test area, 40 percent of control farms produced maize with aflatoxin content exceeding 1,000 ppb. Aflasafe KE01 is the only technology known to prevent aflatoxin formation during crop development through consumption. This is especially relevant given the high levels of on-farm consumption in Kenya.

Based on registration dossiers containing efficacy data and toxicology/eco-toxicology information, the PCPB accorded provisional registration to Aflasafe KE01 in 2014 for conducting large-scale treatment and further data generation. The registrant of the product is KALRO. IITA and USDA-ARS will continue to technically back-stop KALRO for further development and commercialization of the product. There are efforts to continuously generate efficacy data over the years.

The USDA-FAS, the APPEAR project of USAID East Africa Regional mission, and PACA (with funds from the United Kingdom Department for International Development (DFID) through Meridian Institute) have also committed support for building an Aflasafe modular manufacturing facility at KALRO Katumani. The plant is under construction and scheduled to begin operations this year. The partnership among IITA, KALRO, and USDA-ARS is building this manufacturing facility that will be handed over to KALRO to operate with technical support from IITA and USDA-ARS.

To alleviate exposure of poor families in Kenya to the dangerous aflatoxin concentrations commonly found in some areas, biocontrol must be made readily available across the region and procedures for utilizing this biocontrol in an area-wide manner must be developed and deployed. Policy makers at the national level understand the importance of this effort. Kenya's State Department of Agriculture and two county agriculture ministers have expressed the desire for large-scale deployment of Aflasafe KE01.

The essential requirements for large-scale deployment are:

- Availability of a manufacturing facility for the production of Aflasafe KE01

- Development of a marketing and distribution plan for the product
- Further demonstration of product value in food and feed sectors
- Transfer of manufacturing, marketing, and distribution responsibilities to the private sector, and
- Full registration of the product by PCPB.

In response to a serious outbreak of aflatoxin contaminated maize in March 2015 across the Tana region, the Kenyan National Irrigation Board (NIB) purchased of 8.1 tons of Aflasafe KE01 from the IITA manufacturing plant in Nigeria. The Ministry of Agriculture, Livestock and Fisheries Development (MLFD) also procured 220 tons of aflasafe to treat maize fields in 11 other priority counties. Working in cooperation with the MLFD extension service, farmers have treated 865 acres of maize fields in the Bura, Hola and Galana-Kulalu irrigation schemes. From these areas, 193 soil and maize samples have been collected and are being analyzed at the KALRO Regional Mycotoxin Research lab in Kenya, and at the USDA-ARS lab in Arizona. During this initial phase of aflasafe treatment, the maize will be marketed through the Kenyan National Cereals and Produce Board.

Tanzania. In collaboration with Tanzania Food and Drugs Authority, Sokoine University of Agriculture, ARI-Naliendele, and the Nelson Mandela African Institution of Science and Technology, 510 maize and groundnut samples were collected from all major regions in 2012. From these samples, 5,017 *Aspergillus* isolates were obtained; 818 were identified as atoxigenic based on grain colonization tests. A staff member from ARI-Naliendele received training and performed the initial microbiological analysis at an IITA lab in Ibadan. All the atoxigenic isolates were purified. Following testing of the purified isolates via simple sequence repeat (SSR) genetic marker analysis, 20 atoxigenic isolates belonging to 18 widely distributed SSR groups were selected for further evaluation.

These isolates had defects in one or more genes for aflatoxins and cyclopiazonic acid--and could reduce aflatoxin by more than 95 percent in laboratory trials. During 2014, selection of the 10-12 isolates was completed. These are being used for initial field trials during the 2015 cropping season to compare their efficiency at displacing toxigenic strains. From the trials, four isolates will be selected to constitute a biocontrol product to be evaluated in the field for two seasons beginning 2015-16. Field tests are underway to determine the efficacy of potential Aflasafe products. This validation exercise will continue through 2016, with national scale-up anticipated in 2017.

The isolate collection in Tanzania is a good representation of Tanzanian isolates required for identifying regional strains for East Africa. The Tanzanian strains are being further characterized and compared with strains from other East and Southern African countries. This comparison will receive a fillip when more collections are generated from Rwanda, Burundi, and Uganda with funding from USAID-Rwanda, APPEAR, USAID-Tanzania, Africa RISING and USDA-FAS.

Rwanda: Leaders of the Rwanda Agriculture Board (RAB), the Rwanda Bureau of Standards, and other organizations in the Ministries of Agriculture, Health, and Trade took up the question of aflatoxin and the potential of biocontrol for aflatoxin mitigationin 2013. RAB was identified as the lead partner for biocontrol development. In collaboration with RAB, 210 samples (175 maize and 35 groundnuts) were collected from the field at harvest for identifying biocontrol strains. A staff member from RAB came with the samples to IITA-Ibadan to receive training on aflatoxin and biocontrol research methodologies. Following training, he obtained 1036 *Aspergillus* isolates from the grains and began to characterize the isolates at IITA-Ibadan using microbiological and chemical methods. Atoxigenic strains from Rwanda have now been by USDA-ARS for further development of Aflasafe products for field tests in the near future. Also, using the Delphi survey methodology, a cost-benefit analysis of various aflatoxin mitigation technologies was carried out. The Delphi data is currently being analysed.

Burundi. Scientists from the Institut des Sciences Agronomiques du Burundi (ISABU) collected 500 samples (390 maize and 120 groundnuts) from across the country in 2014. After getting export permits from Plant Protection Organization of Burundi, the samples were shipped to KALRO Katumani for further drying and grinding, then to IITA for microbial and mycotoxin analysis, with permission from the Kenya Plant Health Inspectorate Services (KEPHIS). However, a portion of the samples was retained in KARI/IITA Mycotoxin Research & Training Laboratory in Katumani for microbiological analysis.

Uganda. A Memorandum of Understanding (MOU) was signed between the Ugandan Ministry of Agriculture and IITA, enabling Uganda's National Agriculture Research Organization (NARO) to begin collecting samples during the last quarter of 2014. Further work on strain identification and product development began in 2015.

Regional Efforts

Scientists with responsibilities for plant health and food safety throughout the East Africa region have received training on microbiological and chemical aspects of biocontrol at IITA Ibadan and at the USDA-ARS laboratory in Arizona. IITA is supporting four Master of Science students at local universities, who are undertaking studies on different aspects of Aflasafe and the biological control of aflatoxin. A visiting scientist from the University of Nairobi is attached to the program. In addition, IITA and the USDA-ARS have supported KALRO in establishing a regional Mycotoxin Research Facility in the Katumani Center. This facility is expected to serve key aspects of the East Africa regional aflatoxin management and control capacity. In Burundi, an MOU was signed with ISABU to undertake training for staff involved in the project. In Uganda, there are commitments through an MOU with NARO to develop capacity of the National Crops Resources Research Institute (NACCRI) and NARO staff involved with the project. In Tanzania, Ministry of Agriculture staff members have been trained on microbiological techniques to perform biocontrol and aflatoxin analysis.

Moving forward, donors will need to consider the best approach to continue to build the local capacity within the EAC partner states.

Most countries have regulations and procedures governing biopesticide registration although registration guidelines remain limited, except in Kenya. Two biopesticide registration training workshops have been held in the last five years, and further efforts have been made to harmonize registration protocols in the EAC partner states and COMESA.

To avoid the complexities of registering country-specific products in each country, a major regional focus is to identify regional atoxigenic strains found in multiple countries in the region. *Aspergillus* isolates collected from the EAC partner states are a huge resource toward identification of regional strains. Atoxigenic strains from these countries are compared using SSR markers to identify genetic groups of atoxigenic *Aspergillus* that are widely distributed in all the countries in a region. Already genetic groups have been identified that co-occur in more than two countries, and members of these genetic groups can be further evaluated for field efficacy to identify the most adapted and effective biocontrol strains.

Future Challenges

Effective models for the success and sustainability of biocontrol technologies will initially face a number of challenges. These include the following:

- Biocontrol agents are not currently registered as biopesticides in any of the EAC partner states, and there is no regionally harmonized legislation or regulation in place to facilitate either the manufacturing or trade of Aflasafe products.
- Under a fully privatized and traditional business model, cost constraints are likely to present barriers to entry for the majority of farmers in the East Africa region.
- Biocontrol is most effective when delivered in combination with a package of other GAPs rather than as a "stand alone" vertical program. Support for extension services is needed. Government extension services will require enhanced capacity for biocontrol programs. Until this happens, the initial management and fiscal burden will have to be placed on NGOs and other donor organizations.
- Management of market dynamics needs to be carefully considered. As the general public becomes more educated about the threats of aflatoxin, the demand for affordable, aflatoxin safe foods could rapidly exceed the supply. Inequities between higher and lower income consumers could evolve, with more expensive aflatoxin safe foods becoming unaffordable for the poorer consumers.

- Preferential and uneven application of biocontrol technologies, driven by donor priorities and limited government funding, could create “winners and losers” between different crops and individual countries.
- Without communications programs to disseminate factual information at all levels of stakeholders, perceptions regarding the introduction of a live biological agent into the food chain could create public backlash.
- Limited supplies of aflatoxin safe feeds could quickly become captured by the commercial livestock industry catering to high-income consumers and exporters.

The Legal and Regulatory Framework

Presently there are no regionally harmonized or national standards for the registration, production, trade, or commercialization of biocontrol products in the East Africa region. The products currently under development specifically for the region must be registered as biopesticides with the relevant regulatory agencies prior to scale-up from the pilot field-testing stage. Registration is likely to be a time consuming, complex, and expensive undertaking, and efforts should be made to move forward as expeditiously and efficiently as possible. This process may also be supported by legislative actions within the EAC which can subsequently be gazetted to partner states to streamline approvals.

Intellectual Property Rights

We propose that the intellectual property rights for each of the regionally specific East Africa Aflasafe products continue to be held in trust by IITA on behalf of the nations from where the biocontrol strains are collected. IITA is the parent research and development institution. IITA’s existing gene bank currently holds plant material (germplasm) of all major food crops of Africa. This germplasm is held in trust on behalf of humanity under the auspices of the United Nations. It is distributed without restriction for use in research for food and agriculture. Relinquishing the patents for regional Aflasafe products to “for profit” private sector agribusiness entities could significantly restrict its economic accessibility for producers as well as constrain quality control and quality assurance of the product.

Manufacturing and Quality Control

Biocontrol products now being utilized for pilot tests across the region have been manufactured in Nigeria. The expansion of biocontrol programs in the region will require a regional manufacturing capability. The first plant to manufacture Aflasafe is scheduled to open in Kenya in 2015 as a partnership among IITA, USDA-ARS, and the GOK. Similar manufacturing operations should be strategically placed across the East Africa region.

While governments, NGOs, or donors may choose to directly support and manage initial manufacturing operations, this model could be diversified to divest a portion of manufacturing and distribution to the private sector over time. It is likely that this type of dualistic public-private model structure will be best suited for biocontrol efforts in East Africa for the short to medium term.

Marketing and Distribution

The logistics of distribution and the economics of marketing systems pose one of the major challenges to the scaling up and sustainability of biocontrol programs. This is largely driven by the wide variation in farmers' ability to pay. Given the well documented and widespread negative health outcomes due to the consumption of aflatoxin-contaminated food, especially during the first 1,000 days of life and for the substantial population of PLWA in the East Africa region, we propose that Aflasafe follow a parallel model to that which the international community and the EAC have embraced for childhood immunizations. Under this model, those who can afford to pay receive their polio vaccine from their private sector health care provider, while those who cannot pay, receive their vaccine from a subsidized immunization program.

The benefits of the eradication of the polio virus far exceed the cost of providing vaccination services for a nominal fee at public health clinics. Similarly, the best biocontrol model includes a marketing strategy to reach all relevant farmers, regardless of their ability to pay. The benefits of the elimination of aflatoxin-contaminated commodities from the food and feed supply ultimately far exceeds the cost of biocontrol. A number of similar distribution models have been shown to be effective. In the United States, for example, the Arizona Cotton Research and Protection Council, supported by a nominal crop tax, provides the aflatoxin biocontrol product AF36 to cotton farmers at cost (Bandyopadhyay and Cotty 2013). In Nigeria, a private-sector firm, Doreo Partners, has partnered with IITA and USDA-ARS on a commercialized model whereby farmers receive a premium price for aflatoxin safe corn. The success of this model hinges on aggregation levels through small farmer cooperatives that are sufficient to provide a reliable supply to Nigeria's larger poultry producers and premium food processors (Masha et al. 2013).

East Africa has abundant opportunities for creative marketing and distribution models. NGO-supported agricultural-input distribution programs could include biocontrol products, as could emergency relief packages, which often distribute seeds and tools. Aflasafe can be provided to PLWA engaged in agricultural production through the PEPFAR-supported Nutrition Assessment, Counseling, and Support (NACS) food-distribution program. Famine Early Warning Systems (FEWS) that predict drought and insect infestations, which cause aflatoxin levels to spike, can alert governments of the need for special distribution programs in certain geographical areas.

Aflasafe could also be distributed along with other agricultural inputs supplied by WFP emergency relief and Purchase for Progress contract-farming operations. Private-sector organizations such as the East Africa Grain Council have expressed interest in promoting the use of Aflasafe among constituent members. There is no “one size fits all” for the marketing and distribution of biocontrol products, and each program will need to be designed and implemented in the context of multiple local conditions.

Training and Extension Services

Training is required at every level of any model that is adopted, and programs will need to be tailored accordingly. For example, technical assistance and training can be provided to articulate regulations and legislation, develop regionally harmonized aflatoxin testing protocols, develop laboratory facilities, and to train trainers for a multi-sectoral communications program. As the larger program for the scaling up of biocontrol is designed, each of the six key elements should have a detailed training component. At the same time, extension agents must be trained in the science, economics, and management of biocontrol. Initially this can be done by NGOs and donor supported programs with the goal of institutionalizing a curriculum within the Ministry of Agriculture, for secondary and vocational agricultural schools, and at universities.

Standardized Testing Protocols

Throughout the EAC, many regulatory bodies and their affiliated laboratories are collaborating with international experts to standardize and upgrade the quality of their testing protocols for aflatoxin in agricultural commodities, feed, and food products. This is an important undertaking, and it should continue to receive attention and financial support from the donor community. At the producer level, there is also a need to identify and distribute standardized and affordable test kits. Transporting commodities from remote agricultural areas to central laboratory facilities for testing can be done with ease during the pilot stage, but this is not a sustainable model that can be duplicated under the scale-up of biocontrol. The array of test kits should be evaluated for cost, reliability, and durability for use by small farmers, extension agents, and traders, and the distribution and training for the use of these kits should occur in tandem with scale-up programs. With increased and widespread use of Aflasafe for multiple years in area-wide application programs, the general level of atoxigenic strains will increase to a level that the entire crop in the area will be aflatoxin safe. This in turn will increase confidence about the safety of crops in treated areas--leading to less intensive sampling and testing. Such a situation has begun to take place in parts of southeastern United States where aflatoxin biocontrol products have been used widely for the last 15 years.

Stakeholder Communications

Some key points about safety:

- Biocontrol technology is natural and environmentally safe. It uses principles that occur in nature. Science augments nature to increase the safety of food crops.
- Biocontrol technology uses native strains, and people are already exposed to them. Therefore, there are no added risks.
- Native, atoxigenic strains replace toxin-producing strains, making the entire environment safer. *Aspergillus* spores contain tens of thousands ppb of aflatoxin through which people are exposed to the toxin. In treated areas, the air will become safer to breathe due to a reduced concentration of toxin-producing spores.
- Aflatoxin is a known occupational safety hazard in jobs such as crop harvesting, threshing, storage, and further processing. Treated crops will reduce the occupational hazards. Women will enjoy the primary benefits, as they perform harvesting, threshing and processing activities. In Nigeria and the United States, biocontrol has been registered by the regulatory authorities as positive for public health.
- The total amount of *Aspergillus* fungus on the crop remains the same whether treated or not. But the proportion of safe strains increases on the treated crop. Since the total amount of fungus does not change, there are no increased risks for *Aspergillus*-linked allergies due to application of biocontrol.
- Biocontrol strains are selected with utmost care. The strains used for making Aflasafe belong to genetic groups all of whose members are non-toxin producers. Therefore, chances of recombination are extremely minimal if not non-existent.
- The strains used for making Aflasafe have naturally occurring genetic defects that do not allow the strains to produce aflatoxins.

The stakeholder community for biocontrol program communications is vast and a thorough communications program is vital to the acceptance and scale-up of this technology. While there is the danger of creating pluralistic markets where high-end consumers dominate the purchase of limited aflatoxin safe foods, conversely there is a potential consequence of consumers rejecting foods that have been treated with the atoxigenic species if they are not adequately educated on its safety. This extends to policy makers, regulators, traders, and processors. Most important, farmers need awareness-raising, motivational messages, and practical instruction on handling, application, and monitoring of Aflasafe. Communicating the importance of reduced aflatoxin consumption is especially critical in communities with the highest levels of on-farm consumption, as these farmers would otherwise be less motivated than commercial producers to invest in this technology. As with other communications and information-sharing endeavors, cellular technologies could play a useful role.

Monitoring and Evaluation (M&E)

As a first step in the monitoring and evaluation process, it would be helpful to build an inventory of models for biocontrol programs that currently exist in both developed and developing countries, reflect upon the strengths and weaknesses of each approach, and determine which are the best fit for the East Africa region. The second step is to develop short-, medium-, and long-term indicators of success across the health, agriculture, and trade sectors to describe the impact of biocontrol. Examples of these would include seasonal assessments of treated fields, testing of commodities at the farm gate, assessing serum aflatoxin levels of consumers who have transitioned to aflatoxin safe diets, and cost-benefit analyses and timelines to determine how to transition traders, and food, feed and livestock producers to aflatoxin safe commodities.

Policy Recommendations

Based on the data presented in this paper, we make the following recommendations.

1. The development of an East Africa regional GAP model for aflatoxin control is a priority and should include biocontrol, insect and drought resistant species, optimal cultivation and harvesting practices, appropriate postharvest handling and storage, response mechanisms for GCC, and an aflatoxin early warning system.

2. Working together, the EAC, COMESA, and the PACA should develop the regional model needed to facilitate the biocontrol element of this GAP model. Such a model is multifaceted and should encompass eight key elements:

   - The legal and regulatory framework
   - Intellectual property rights
   - Manufacturing and quality control
   - Marketing and distribution systems
   - Training and extension services
   - Standardized commodity testing protocols
   - Stakeholder communications
   - Sustainability considerations, and
   - Monitoring and evaluation.

3. Business models for the manufacture, distribution, and application of biocontrol products to benefit of farmers at all income levels, and especially those living below the poverty line, should be designed, piloted, and evaluated within each of the EAC partner

states. The models should be country specific and include a scale-up strategy maximizing the role of the private sector.

4. For the short to medium term, public-private partnerships should be explored for the manufacturing and distribution of Aflasafe.

5. For high impact results, and to protect the public health, maize and groundnut should be considered as the priority crops for application of biocontrol products.

6. Mechanisms to deliver biocontrol technologies to address on-farm consumption and reach small-scale producers should also be given high priority.

7. Mechanisms to promote an equitable system for the distribution of aflatoxin safe foods in the marketplace should be developed to buffer the impacts of high end consumers and livestock producers dominating the aflatoxin safe food and feed supplies that biocontrol will yield.

8. As a necessary element of a comprehensive aflatoxin control initiative, and especially for successful biocontrol programs, an inventory and analysis of test kits should be conducted. Kits identified as being most affordable and reliable should be made readily available to farmers and other stakeholders along the value chain.

9. The EAC Five-Year Communications Strategy should include a comprehensive biocontrol component that will reach all producers of aflatoxin-prone crops and other stakeholders involved in the biocontrol package.

10. The EAC, COMESA, and partner state ministries of agriculture, trade and industry, environment, and other relevant regulatory agencies, should work together to fast-track regional harmonization of key aspects of the biocontrol protocol for East Africa to ensure the efficient flow of Aflasafe products across the region.

11. International donor agencies, such as the World Food Program, USAID Food for Peace (FFP), USDA, and other nongovernmental organizations (NGOs) working in agriculture-linked emergency relief and development, school feeding, contract farming and/or local commodity purchases, should be encouraged to include biocontrol products and extension support services in their programs.

12. Simultaneously with an expanded supply of aflatoxin safe food and feed in the marketplace, food and feed safety regulatory authorities should begin to more stringently enforce standards to accelerate demand.

13. The FEWSNET and FAO Famine Early Warning Systems should be expanded to include variables signaling impending "aflatoxin hotspots" for biocontrol in response to drought, insect infestation, severe weather conditions and GCC.

14. An analysis should be conducted to determine the most cost-effective and efficient manufacturing and distribution system for Aflasafe to supply the EAC over the long term.

15. While the longer term goal is to create sufficient demand for Aflasafe products to establish a sustainable business model, for the short to medium term, public institutions and donors should provide financial and technical support at the initial stages of manufacturing and demand creation.

16. Centers of Excellence should be established throughout the East Africa region to ensure the highest quality of research, development, product assurance, scale up, and sustainability for biocontrol initiatives.

List of Abbreviations and Definitions

Term	Definition
AF-alb	Aflatoxin albumin adducts
AFB1	Aflatoxin B_1
APPEAR	Aflatoxin Policy and Programs for the East Africa Region
ARS	Agricultural Research Service of the U.S Department of Agriculture
COMESA	Common Market for Eastern and Southern Africa
EAC	East African Community
FAO	United Nations Food and Agriculture Organization
FAS	U.S. Department of Agriculture Foreign Agriculture Service
FEWS	Famine Early Warning Systems
FFP	USAID Food for Peace
GAP	Good Agricultural practice
GCC	Global climate change
ISABU	Institut des Sciences Agronomiques du Burundi
KALRO	Kenyan Agricultural and Livestock Research Organization
KARA	Kenya Agriculture Research Institute
KSCIE	Kenya Standing Committee on Import and Export
ECOWAS	Economic Community of West African States
MENA	Middle East and North Africa
NARO	National Agriculture Research Organization (Uganda)
NACS	Nutrition and Care & Support
M&E	Monitoring and evaluation
NACS	Nutrition and Care & Support
NARO	National Agriculture Research Organization (Uganda)
NGO	Nongovernmental organization
PACA	Partnership for Aflatoxin Control in Africa
PCPB	Pest Control Products Board (Kenya)

Term	Definition
PLWA	People living with AIDS
PPM	Parts per million
PPB	Parts per billion
SADC	Southern Africa Development Community
SSR	Simple sequence repeat
IITA	International Institute of Tropical Agriculture
USDA-ARS	United States Department of Agriculture-Agricultural Research Service
USDA-FAS	United States Department of Agriculture- Foreign Agricultural Service
UNICEF	United Nations Children's Fund
VCGs	Vegetative compatibility groups
WFP	World Food Program
WHO	World Health Organization
USAID	United States Agency for International Development

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