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Comparative Analysis of the National Biosafety Regulatory Systems In East Africa

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ABSTRACT

This paper analyzes the current and proposed biosafety systems in Kenya, Tanzania, and Uganda using a set of components and characteristics common to functional and protective biosafety regulatory systems. It also assesses how those systems take into account the major international legal obligations that relate to biosafety, such the Cartagena Biosafety Protocol. The paper identifies certain areas in each country's biosafety regulatory systems where further development and clarification would improve the biosafety system, making it more functional and protective. Those areas include: (1) the addition of procedures to ensure the food safety of genetically engineered organisms; (2) the inclusion of the standard and criteria for making an approval decision; (3) the differentiation of regulatory procedures based on the relative risk of the organism; and (4) an explanation of how socio-economic considerations will be defined and assessed. Finally, the paper discusses possible ways the three countries can coordinate and harmonize their national biosafety regulatory systems so they are efficient, effective and make the best use of limited scientific and legal capacity.

Keywords: Biosafety, East Africa, Cartagena Protocol, genetic engineering, regulation, biotechnology

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1. INTRODUCTION

Genetically engineered (GE) plants and animals have the potential to benefit both developed and developing countries. To reap the benefits from those organisms, they must be safe to humans and the environment. To ensure those organisms are safe, it is essential to establish a biosafety regulatory system[2] that independently reviews and approves each product for safety before it is released into the environment or ingested by humans.

Over the past several years, three countries in East Africa – Kenya, Tanzania, and Uganda -- have made it a priority to establish a working biosafety regulatory regime for GE organisms. Those governments established committees responsible for drafting the laws, regulations, guidelines, and other documents that establish the biosafety regulatory system and authorized government agencies to implement the biosafety regime. To develop and implement a biosafety regulatory system, those committees and government agencies have, among other things, (1) analyzed their current laws and regulations applicable to agricultural products and food and their obligations under international conventions and treaties; (2) conducted meetings to hear from interested stakeholders and the public; and (3) reviewed biosafety systems already in place in other countries (such as the United States and the European Union) as well as model

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[2] For the purposes of this paper, the term "biosafety regulatory system" means a regulatory regime responsible for assessing and managing the potential risks that could be posed from GE organisms. A biosafety regulatory system addresses potential risks to the environment and biological diversity as well as any food/feed risks from eating GE organisms or food made from GE organisms.

laws developed by the Organization of African Unity (the "African Model Law") and other experts.

This paper analyzes the current and proposed biosafety regulatory systems in Kenya, Tanzania, and Uganda. To analyze those systems, Section 2 sets forth a number of the essential components needed for a protective and functional regulatory system. Section 3 explores the major international obligations that need to be taken into account when establishing a biosafety regulatory system. Then, Section 4 briefly sets forth the current status of biosafety regulation in each country. Section 5 discusses some issues that arise when the biosafety regulatory systems in the three study countries and the African Model Law are analyzed using the components from Section 2 and the international obligations set forth in Section 3. Finally, Section 6 discusses possible ways forward for East African countries to efficiently and effectively put in place coordinated biosafety regulatory systems that protect the environment and human health while complying with international obligations.

2. COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

A protective biosafety regulatory system ensures that genetically engineered organisms present no significant risks to human health or the environment. Such a system, however, must also be functional, which means that it should be understandable, workable, equitable, fair, adaptive, and enforceable. (UNEP-GEF Biosafety Unit 2004).

Existing biosafety regulatory systems from around the world reflect, among other things, the type of government in the country, the politics of the country, the country's view on the relative safety of GE organisms, and the country's regulation of food, agriculture, and environmental issues. Establishing those systems required balancing numerous goals and trading

off different interests. Through an analysis and comparison of different existing biosafety regulatory systems, however, one can identify key characteristics and components that are generally important to a functional and protective biosafety regulatory system (Jaffe 2004). Incorporating each of those characteristics and components in a functional and protective biosafety regulatory system involves problem solving because there can be tensions between the different characteristics. Those key characteristics and components are set forth below:

COMPREHENSIVE

A biosafety regulatory system should be comprehensive (Jaffe 2004). First, it needs to cover the different stages of development for a GE organism (UNEP-GEF Biosafety Unit 2004), such as releases into the environment as confined and unconfined field trials, releases of commercial products, and consumption of GE organisms by humans and/or animals. Second, a comprehensive regulatory system analyzes the range of potential safety issues associated with GE organisms. It not only addresses the environmental and biodiversity issues highlighted in the Biosafety Protocol, but also food safety issues and any other potential safety questions (such as worker safety). (von Grebmer 2005). Finally, the regulatory system's scope includes all plants and animals that could be engineered and the different products that they might produce. Comprehensive regulatory systems cover not just engineered plants used for food or feed but plants engineered to produce non-food substances, non-food crops such as trees, and engineered animals.

ADEQUATE LEGAL AUTHORITY

The biosafety regulatory system needs sufficient legal authority to subject each GE organism to a food-safety and environmental risk assessment and approval process before any unconfined release into the environment or any GE organism is placed into commerce (Jaffe 2004; Cohen et al. 2005). Such mandatory authority over GE organisms helps ensure protection of the environment or human health. "Clear responsibility and legal authority is important not only for ensuring the protection of health and the environment, but also for providing the public and technology developers with a clear understanding of the regulatory pathway to market." (Pew Initiative 2004).

To ensure adequate legal authority for a biosafety regulatory system, countries need to decide whether they can establish a system using existing laws or whether they need to pass new biosafety-specific legislation. An example of a country that used existing laws for its biosafety regulations is the US, which regulates GE organisms using a coordinated framework involving numerous laws and several agencies. (OSTP 1986; Jaffe 2004). Countries such as the European Union, South Africa and New Zealand have established new laws to specifically address GE organisms (Jaffe 2004). Whether a country passes a new law or uses existing laws, the legal authority for the biosafety regulatory system still needs to be exercised within that country's broader legal system, including its constitution, its judicial system, and its other laws and regulations.

A CLEAR SAFETY STANDARD

Biosafety regulatory systems usually establish safety standards for their approval processes. (Jaffe 2004). The safety standard sets forth what level of protection must be satisfied

to approve an application and what factors the government will consider before making an approval decision, including the baseline for any risk analysis. (UNEP-GEF Biosafety Unit 2004; Jaffe 2004; Jaffe 2005). The safety standard guides the government on how to use its legal authority to regulate genetically engineered organisms. The standard also identifies whether the benefits from the GE organism or the opportunity costs of not introducing the organism will be considered. (Delmer 2005). In a functional and protective system, all interested parties know and understand the safety standard beforehand and government decisions apply that standard in a uniform and fair manner.

PROPORTIONATE RISK-BASED REVIEWS

Biosafety regulatory systems look at each application individually and assess any potential risks to human health and the environment through a scientific risk-based analysis. The system usually has the flexibility to treat products differently depending on the potential risks and concerns raised. (Delmer 2005). It prioritizes applications it reviews based on the potential risk and give the most scrutiny to products with the most relative risk while allocating less resources and time to products that raise less concern (Jaffe 2005). Irrespective of the review procedure, all GE organisms must still meet the applicable safety standards. The procedures and the data needed to meet that standard, however, should vary depending on the nature of the product and its potential risks, so that the potential risks match the regulatory procedure.

The key to establishing a proportionate risk-based review process is providing the biosafety regulatory system with the flexibility to address particular products differently depending on the nature of the product (the organism and the added gene), and the use of the product (a confined laboratory experiment, a field trial or a commercial release) (Kinderlerer 2002). For example, a confined field trial does not require the same detailed risk assessment and

governmental review as a commercial release of that same product; the confined trial is released under specific conditions, limited in duration, and designed to have minimal impact on the environment while the commercial release may not be controlled and will remain in the environment. Thus, if a biosafety regulatory system allows for proportionate risk-based reviews, it seeks to minimize the regulatory costs for products with minimal risks.

TRANSPARENT AND UNDERSTANDABLE

A common component of many biosafety regulatory systems is transparency (UNEP-GEF Biosafety Unit 2004; UNEP-GEF Biosafety Unit 2003; Pew Initiative 2004). Public access to information about the regulatory system and the organisms that go through it can lead to greater public confidence in regulatory decisions. (Pew Initiative 2004).

Biosafety regulatory systems that are transparent and understandable usually provide to the public information about:

- the regulatory process, including the steps, data requirements, and time lines for the applicant (a roadmap of the process and what is expected of the applicant);
- how the agency will conduct its review, what criteria and standards it will use, and who will be the accountable public officials;
- where, when and how the public can be involved in the regulatory process;
- particular applications that seek approval from the government (the application without the confidential business information); and
- the agency decision on a particular application, including the analysis of a particular application and the reasoning behind its decision (McLean, et al. 2002).

With that information, interested persons can understand how the regulatory system will process applications, what information the public will have access to, what opportunities for public participation exist in the process, and what is the basis for any decisions.

While making information available to the public, however, the regulatory system must balance the competing interests of the applicant, who may want to keep some information confidential for business purposes. A regulatory system with no protection for trade secrets and proprietary information might not receive any applications because private enterprises would not be able to successfully market a product if certain information is not kept confidential. Thus, a good regulatory system must also protect from disclosure confidential business information of applicants.

PARTICIPATORY

Public participation is found to be a component in biosafety regulatory systems in democratic societies. (UNEP-GEF Biosafety Unit 2004; Mclean, et al. 2002). Public participation can include the opportunity to provide information and comments to regulators on regulations, guidance documents, and specific applications before a regulatory decision has been made. (Pew Initiative 2004). Also, it may include the opportunity to provide oral and/or written testimony at public hearings. In most instances, the regulatory system responds to relevant comments in its decision-making documents to improve its overall decision and assure the public that any relevant concerns were seriously considered. Thus, while public participation helps to inform the decision-making process, the ultimate decisions remain with the regulatory agencies and the designated leaders.

POST APPROVAL OVERSIGHT

A biosafety regulatory system does not stop its oversight once a GE organism has been approved for a confined field trial or for a commercial release. The system continues to ensure adequate protection of humans and the environment after the product is released into the environment or enters the marketplace. Post approval activities can include monitoring for adverse environmental or health effects and monitoring for compliance with any risk management conditions imposed on the GE organism (Cohen et al. 2005).

FLEXIBLE AND ADAPTABLE

Biotechnology is a rapidly changing discipline and it is impossible to fully anticipate the range of future applications. Thus, if a country is setting up a biosafety regulatory system to address currently unknown applications of genetic engineering, flexibility to adapt to new evidence on risks and benefits, and new types of products can be important. (von Grebmer 2005; UNEP-GEF Biosafety Unit 2003).

There are several ways to build flexibility and adaptability into a biosafety regulatory system. First, laws, regulations, and guidance can be written broadly to accommodate not just the products being proposed today but products that might be developed ten or twenty years from now. Non-flexible systems either do not have the authority to regulate new products or put in place moratoriums while they put new laws, regulations, and procedures in place to address them. Second, the regulatory system should learn from its experiences regulating products and adapt accordingly. (Falck Zepeda and Cohen 2005). As the system regulates more products, it should become familiar with the benefits and risks of particular applications, allowing some

applications with low risk to get a streamlined review process while increasing regulatory scrutiny for products that are similar to previous high-risk applications.

EFFICIENT, WORKABLE AND FAIR

While the primary responsibility of a biosafety regulatory system is to ensure that GE organisms are safe for humans and the environment, it is also important that the system is efficient, workable and fair. Efficient regulatory systems minimize costs to applicants and the government agencies that implement it. Functional systems make decisions promptly in a reasonable amount of time, understanding that if its decision-making process takes too long or never is completed, the non-decision is in effect a rejection. Finally, fair systems treat similar products in a similar manner and decisions on those similar products are consistent with one another. (Jaffe 2004). The system should be fair and equitable to developers, researchers, and their products.

3. INTERNATIONAL OBLIGATIONS RELEVANT TO BIOSAFETY

Countries do not have complete discretion when deciding how to set up their biosafety regulatory system. There are several international treaties and agreements that relate to biosafety. If a country is bound by those international agreements, then the biosafety regulatory system must be compliant with those obligations. The international obligations that most directly affect biosafety are discussed below.

CARTAGENA BIOSAFETY PROTOCOL

The Cartagena Biosafety Protocol ("Protocol"), which became effective on September 11 2003, is a binding international agreement related to its parent treaty, the Convention on Biological Diversity (Secretariat of the Convention on Biological Diversity 2000). The Protocol currently is a primary driving force behind the establishment of national biosafety regulatory systems in countries that have ratified, or acceded to the Protocol. The Protocol empowers countries to establish biosafety procedures and provides the scientific and legal boundaries under which such systems should operate. It has the potential to effectuate a common set of processes and procedures for biosafety that will safeguard the environment and the public while allowing for international commerce and product innovation. (Secretariat of the Convention on Biological Diversity 2000; Jaffe 2005).

The Protocol's scope is the "transboundary movement, transit, handling, and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4)." Under the Protocol, living modified organisms (LMOs) are organisms (such as seeds, trees or fish) that contain novel genetic material introduced through *in vitro* techniques (e.g. recombinant DNA) or cell fusion (Article 3). Although the Protocol covers all LMOs, it primarily addresses two particular uses of LMOs: (1) those that will be intentionally introduced into the environment; and (2) those directly used for food, feed, or processing ("FFP"). For LMOs used for other purposes, such as LMOs used in the laboratory, the Protocol leaves any regulation to the discretion of the individual country. The Protocol also does not cover products derived from LMOs, such as processed foods that have ingredients that came from LMOs.

To ensure the safe transfer, handling, and use of LMOs, the Protocol sets up two separate procedures. For the first time that LMOs will be intentionally introduced into the environment, the Protocol sets up an "Advance Informed Agreement ("AIA")" procedure (Article 7). That procedure requires that an exporter of an LMO provide a notice with detailed information about the LMO to the importing country (Article 8). The importing country then reviews the information, conducts a risk assessment, and decides, based on the risk assessment results, whether to approve or reject the LMO (Articles 10 and 15). In deciding whether to accept the LMO, the importing country can invoke risk management measures to address issues that arise from the risk assessment (Article 16). The importing country also can err on the side of precaution and not approve an LMO if there is insufficient information to adequately assess its particular potential risks (Article 10(6)).

The second procedure set up by the Protocol is for LMOs for FFP (such as corn, soybeans, wheat, or other grains that directly will be fed to humans or animals or used for processing). For those LMOs, the AIA procedure is not required (Article 11). Instead, the Protocol establishes a simpler system that reflects the decreased likelihood that those LMOs will affect the exporting country's biodiversity. Before the LMO can be exported to another country, the only requirement is that the safety decision in the exporting country is communicated to other countries through the Biosafety Clearinghouse. A country may require the exporter to seek its prior consent, however, under its domestic regulatory framework, as long as that requirement has been posted on the Biosafety Clearinghouse (Article 11).

The Protocol also contains numerous other provisions that complement the review procedures for LMOs discussed above and address issues important to a uniform and comprehensive biosafety regulatory process. For example, there are provisions on simplified

procedures for certain LMOs that do not present risks (Article 13), on public awareness and participation (Article 23), and on confidential information (Article 21). Thus, the Protocol establishes procedures and legal obligations to assess and manage the potential risks of LMOs on biological diversity, taking also into account risks to human health.

If countries look to the Protocol for guidance when establishing their own domestic regulatory systems, there a number of areas where the Protocol maybe helpful. First, the Protocol establishes a system which gives proportionate treatment to an LMO based on its proposed use. For LMOs intentionally released into the environment - an activity that poses, on a relative scale, greater potential risk to biodiversity - the Protocol establishes an informed consent process requiring a detailed risk assessment, risk management, and consent by the importing country. For an LMO used for FFP - an activity where the risk of harm to biodiversity is significantly less - the Protocol does not require advanced informed consent but allows parties to make decisions based on the safety decision from the exporting country or to conduct their own risk assessment. For the contained use of an LMO in a laboratory or greenhouse - an activity with less potential risk than a deliberate release - the Protocol has no required procedures. Thus, depending on the LMOs use, the Protocol establishes different procedures that correspond to the relative risk of that activity. Second, the Protocol provides for differential treatment of LMOs based on particular risk characteristics. Article 13 sets up a "simplified procedure" that allows certain LMOs that would normally qualify for the AIA procedures to have a streamlined process or complete exemption from AIA if that LMO can be released safely. Also, Article 7 allows the Parties to collectively exempt certain LMOs from the AIA procedures if those LMOs are not likely to have adverse effects. Finally, the Protocol provides useful details about the information

needed for a risk assessment (Annex II) and an explanation of what a scientific risk assessment of an LMO should entail (Annex III).

Although the Protocol comprehensively covers many issues, it leaves unresolved issues that each country must address when establishing their biosafety regulatory regime. First, the Protocol has no discussion about what level of protection is adequate before an LMO is approved or how much potential risk must be identified to justify withholding consent. The Protocol is silent on what happens after a risk assessment is conducted and some potential risks are identified (as will invariably happen since most activity has some potential risk). Instead, each individual country decides what safety standard that it believes must be satisfied before consenting to an LMO. Second, although Article 26 of the Protocol allows parties to take into account, consistent with other international obligations, socio-economic considerations that arise from LMOs, the Protocol only vaguely defines socio-economic considerations and does not explain how they might be factored into the procedures set forth in the Protocol (Jaffe 2005). Individual countries have to decide what socio-economic considerations can or should be included in their decision making process and when and how those issues will be analyzed (Fransen 2005). Finally, the Biosafety Protocol does not comprehensively address all the major risk issues associated with GE organisms. While the Protocol provides detailed legal and scientific procedures to ensure that LMOs do not adversely affect biological diversity, it does not substantively address human health or food-safety concerns surrounding LMOs (Kalibwani, et al. 2004). Those concerns actually maybe more important biosafety concerns to the world's population than biodiversity risks. Thus, a biosafety regulatory system only implementing the Protocol may miss relevant food safety issues.

WORLD TRADE ORGANIZATION AGREEMENTS

There are several other international agreements that may directly impact countries establishing national biosafety regulatory systems. First, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) provides countries with the sovereign right to establish appropriate levels of sanitary and phytosanitary protection in international trade, which includes the areas of food and agriculture (The World Trade Organization 1995). Under the SPS Agreement, those protections must do so in a way that minimizes negative trade effects (Article 5.4). The SPS Agreement also requires in Article 5.5 that countries "avoid arbitrary or unjustifiable distinctions in the level of protection they consider to be appropriate for different situations, if such distinctions result in discrimination or disguised restrictions on international trade." (Zarrilli 2005). The SPS Agreement does allow countries to adopt precautionary measures when relevant scientific evidence is insufficient (similar to Protocol) but only allows that decision to remain for a reasonable period of time while additional scientific evidence is actively gathered (The World Trade Organization 1995a; Kinderlerer 2005). Finally, the SPS Agreement also sets forth risk assessment procedures that include the use of both scientific and socio-economic considerations (SPS Agreement) but it provides a fairly narrow definition of which socio-economic considerations can be legitimately used in the decision-making process. Thus, the SPS Agreement may restrict the scope of a biosafety regulatory system.

Two other agreements under the World Trade Organization also could impact biosafety. The General Agreement on Tariffs and Trade ("GATT") could impact national biosafety regulations systems because it requires that "like products" be treated in the same manner, whether produced domestically or imported (The World Trade Organization 1994). Under

GATT, it is unclear whether GE products can legitimately be distinguished solely by their process of production (Zarrilli 2005). In addition, the Technical Barriers to Trade Agreement ("TBT") requires that countries technical regulations may not be more trade-restrictive than necessary to fulfill a legitimate objective (The World Trade Organization 1995b). The TBT maybe relevant to provisions on the labeling and tracing of GE organisms and their products, where various regimes may not meet the "no more trade-restrictive than necessary" requirement.

The SPS and TBT Agreements encourage the use of international scientific standards. The SPS Agreement recognizes the standards developed by three relevant organizations: the FAO/WHO Codex Alimentarius Commission, the Office of International des Epizooties (OIE – the World Organization for Animal Health), and the International Plant Protection Convention (IPPC). Those standard-setting bodies all have their working groups on safety aspects of GMOs and GM foods, and the resulting standards, recommendations, and guidelines may become the basis for WTO members sanitary and phytosanitary measures or technical regulations.

Finally, it is important to note that the relationship between the Biosafety Protocol and the WTO and its agreements currently is unclear. The WTO may or may not find that the Biosafety Protocol's obligations are consistent with WTO obligations and it may not recognize the Protocol in disputes between members, if one member is not a party to the Protocol. Clarification of the relationships between the WTO and the Protocol may come in the near future when the WTO Dispute Settlement Body rules on the case between the United States and the European Union over its GE approval moratorium.

THE CODEX ALIMENTARIUS COMMISSION

Under the auspices of the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO), the Codex Alimentarius Commission was established to

develop internationally acceptable standards for use in the areas of food quality and food safety. The SPS Agreement specifically cites Codex standards, guidelines, and recommendations as the preferred international measure for facilitating international trade in food.

The Codex has been working on food safety issues surrounding GE organisms and their food products for a number of years and has generated consensus documents that discuss how to conduct food safety risk assessments for GE organisms and their food products. Those documents include "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology," and "Guideline for the Conduct of Food Safety Assessment of Food Produced Using Recombinant-DNA Microorganisms." (Codex Alimentarius Commission 2003a; Codex Alimentarius Commission 2003b). Thus, it is important to take those documents into account for biosafety decisions involving food safety issues.

INTERNATIONAL PLANT PROTECTION CONVENTION

The International Plant Protection Convention (IPPC) establishes the sovereign authority to regulate the entry of plants, plant products, and other regulated articles with the use of phytosanitary measures. Those measures, however, must be technically justified, transparent, and not applied in a way that constitutes either a means of arbitrary or unjustified discrimination or a disguised trade barrier. Similar to Codex, the IPPC currently has working groups addressing issues involving GE organisms that fall within the scope of the international agreement.

4. BIOSAFETY REGULATORY SYSTEMS IN KENYA, TANZANIA, AND UGANDA

All three East African countries in this study currently have interim biosafety regulatory systems as well as proposals to make those systems more comprehensive and complete. The following is a summary of the current status of the biosafety regulatory systems in each country.

KENYA

In Kenya, the National Council for Science and Technology (NCST) is the government agency currently responsible for overseeing the implementation of the biosafety regulatory system. That office issued Regulations and Guidelines for Biosafety in Biotechnology in 1998 (Traynor and Macharia 2003; Republic of Kenya 1998). Those regulations were issued under the existing Science and Technology Act of 1980, although that Act has no regulatory authorities and no means to enforce compliance with the regulations (Traynor 2003). The NCST also established the National Biosafety Committee (NBC) to develop the country's biosafety policy and review GMO applications. (Harsh 2005). The membership of the NBC includes representatives from relevant government Ministries as well as representatives from civil society and the national universities (Traynor 2003; Macharia 2005).

Under the interim Kenyan biosafety regulatory system, applications to import or release GMOs (including applications for confined field trials) are submitted to the relevant Institutional Biosafety Committee (IBC) where they are reviewed and assessed for compliance with the guidelines before submission to the NBC (Republic of Kenya 1998). Then, those applications are forwarded to the NBC, where those applications are reviewed by the NBC and/or a technical subcommittee of the NBC. A recommendation is made by the NBC and the NCST Secretary decides whether to approve the application (Traynor 2003). To date, Kenya has approved five confined trials. (Macharia 2005).

In July 2002, Kenya began working on a number of legal documents to turn its interim biosafety regulatory system into a permanent and comprehensive system. Those documents included revised regulations, a biosafety law, and a national Biotechnology and Biosafety Policy. Although those documents have progressed in the last few years, none have been finalized. The most recent version of the biosafety law is the Biosafety Bill of 2005 (Republic of Kenya 2005).

TANZANIA

The structure of Tanzania's biosafety regulatory system is described in its National Biosafety Framework (NBF) issued in March 2005 (United Republic of Tanzania 2005). In that system, the National Biosafety Focal Point (NBFP), who is responsible for review and approving applications and overseeing the implementation of biosafety issues, is the Ministry responsible for environment (United Republic of Tanzania 2005). The NBFP gets advice on technical and policy issues from the National Biosafety Committee, comprised of government and non-governmental organizations, as well as the Competent Authorities, which are other agencies with areas of relevant expertise within the government. The NBF also discusses Institutional Biosafety Committee, who perform biosafety functions within any institution conducting genetic engineering.

Finally, the regulations that will establish Tanzania's biosafety system will be promulgated under authority recently established in the Tanzanian Environmental Management Act of 2004 (EMA), which was signed by the President of the Republic on July 1 2005 (United Republic of Tanzania 2004). That law provides the legal authority for the Ministry of Environment to regulate GE organisms. The NBFP is now working on the regulations to

implement the biosafety provisions of the Act and to establish the procedures identified in the NBF.

Tanzania also has established a specific interim biosafety regulatory process for permitting small-scale confined field trials of plant and plant products. Under the authority of the Plant Protection Act, the Ministry of Agriculture and Food Security promulgated Schedule 18 (United Republic of Tanzania, Schedule 18). That document puts in place a review and approval process for all small-scale confined field trials involving GE plants. It requires the completion of a detailed application which is reviewed by the Agricultural Biosafety Advisory Committee (ABSAC), a technical advisory committee which is a competent Authority of the Ministry of Agriculture and Food security (MAFS). The application is also reviewed by the National Biotechnology Advisory Committee (NBAC), which is a national committee on biotechnology issues based under the Ministry of Science Technology and Higher Education (MSTHE). With the advice of the ABSAC and the NBAC, the Minister then decides whether to allow the field trial and issue a permit (United Republic of Tanzania, Schedule 18). Schedule 18 also gives the Tropical Pesticides Research Institute (TPRI), which is a Plant Biosafety Office consisting of biosafety inspectors, the ability to require risk management measures to ensure that the field trial does not affect the environment or human health.

UGANDA

The interim biosafety regulatory system in Uganda is coordinated by the Uganda National Council for Science and Technology (UNCST). That office established in 1995 the National Biotechnology Committee (NBC) made up of representatives from other government agencies and civil society (Nampala 2005; Wafula 2005). The NBC is the "national administrative arm on matters concerning biosafety." (The Republic of Uganda 2004a). The

main function of the NBC is technical advice on biosafety issues, including the assessment of individual applications for activities with GE organisms. (Republic of Uganda 2004a).

The NBC has been responsible for writing the draft National Biotechnology and Biosafety Policy (Republic of Uganda 2004a), draft National Biosafety Regulations (Republic of Uganda 2004b), Guidelines on Biosafety in Biotechnology for Uganda (Republic of Uganda 2002), and a number of draft manuals addressing specific issues surrounding biosafety regulation, such as confidential business information. Those documents set forth the current and proposed biosafety regulatory framework for Uganda. Under the biosafety system identified in those documents, the UNCST will be the competent authority to carry out biosafety regulation. It will be advised on policy matters by the National Biotechnology Advisory Committee (NBAC), which is an inter-ministerial committee, and the NBC.

5. COMPARATIVE ANALYSIS OF EAST AFRICAN BIOSAFETY REGULATORY SYSTEMS AND THE AFRICAN MODEL LAW

Kenya, Tanzania, and Uganda are each moving forward to establish functional and effective biosafety regulatory systems that allow them to benefit from safe applications of genetic engineering. Their current and/or proposed systems have reached a stage of development where they can be analyzed to determine how well those systems will achieve a functional biosafety system that ensures an adequate level of protection to humans and the environment and how well they incorporate the characteristics and components that were identified in Section 2 of this paper. Some of the major issues that arise from that analysis are set forth below and summarized in Table 1.

Table 1--Comparison of countries and major issues

COUNTRY	Comprehensiveness of biosafety system	Legal Authority	The Safety Standard	Socio-Economic ɔnsiderations	Proportionate Risk Based Reviews
Kenya	Addresses all GE organisms at different stages of development; addresses environmental issues; does not address food safety issues	Will use new legal authority established in biosafety-specific legislation to be passed by Parliament	Not established in biosafety bill or guidelines	To be included in biosafety regulatory process but no details are provided	Kenyan biosafety bill does differentiate procedures based on activity to be conducted with the GE organism
Uganda	Addresses all GE organisms at different stages of development; addresses environmental issues; does not address food safety issues	Using existing Science and Technology Law to promulgate biosafety regulations; however, the law may not authorize the biosafety regulations	Not established in biosafety policy or regulations	To be included in biosafety regulatory process but no details are provided	No distinctions are made based on activities to be conducted
Tanzania	Addresses all GE organisms at different stages of development; addresses environmental issues; does not address food safety issues	Parliament recently passed comprehensive Environmental Management Act which included legal authority to regulate biosafety	Not established in Environmental Management Act but National Biosafety Framework document sets forth some decision criteria	To be included in biosafety regulatory process but no details are provided	The National Biosafety Framework and Environmental Management Act make no distinctions for different activities; Schedule 18, however, is a good example of a proportionate risk-based approach for small-scale confined trials

Table 1--Comparison of countries and major issues (continued)

COUNTRY	Public Participation	Transparency	Inclusion of Products of GMOs	Interim Measures	Institutional Biosafety Committees
Kenya	Good involvement of public in process establishing biosafety system; biosafety bill calls for public participation with individual applications	Biosafety system provides for giving public information about both process and individual applications	Biosafety system does not include such products in approval requirements	Kenyan National Science and Technology Council established NBC and regulations under its operating statute	Established under Kenyan Guidelines to conduct activities such as reviewing risk assessments and monitoring release sites
Uganda	Good involvement of public in process establishing biosafety system; regulations call for public participation for individual applications	Biosafety system provides for giving public information about both process and individual applications	Biosafety system does not include such products in its approval requirements	Uganda Science and Technology Council established NBC and National Biosafety Guidelines under its operating statute	IBCs in Uganda review and clear prospective applications before they go to NBC and conduct training and oversight
Tanzania	Good involvement of public in process establishing biosafety system; National Biosafety Framework and Environment Management Act call for public participation but Schedule 18 does not provide such an opportunity	Biosafety system provides for giving public information about both process and individual applications	The National Biosafety Framework and the Environmental Management Act both include products of GMOs in their review and approval procedures	Established Schedule 18 to address small-scale confined field trials under the authority granted in the Plant Protection Act	IBCs in Tanzania review risk assessments, monitor release sites, and hold discussions on the social and economic impact of alternatives to the proposed GMO.

In addition, the African Model Law is also analyzed as it is one of the documents given consideration throughout Africa when a country begins drafting laws and regulations to address biosafety.

ISSUES SURROUNDING THE BIOSAFETY SYSTEMS OF KENYA, TANZANIA AND UGANDA

While each country has made tremendous progress in establishing a functional and protective biosafety regulatory system, those systems continue to evolve and mature. By comparing those systems with the key characteristics and components found in already existing biosafety regulatory systems, issues are identified regarding those evolving systems that will help them achieve biosafety systems that are functional, comprehensive, transparent, participatory, and efficient. Those issues are discussed below.

Comprehensiveness – The Need to Address Potential Food Safety Risks

One goal of the regulatory systems in all three countries is to comprehensively address all potential risks from any GE organism. For all three countries, the current or proposed regimes have definitions that are broad enough to capture all different GE organisms, whether plants, animals, or microorganisms. In addition, those systems do not distinguish GE organisms based on the products they produce or the intended purpose, so they capture GE organisms that are engineered for food or feed use, engineered for industrial purposes, and engineered to produce a pharmaceutical. Each of the biosafety regulatory systems also captures the range of activities that might occur with a GE organism. The Kenyan Biosafety Bill and the Uganda draft Biosafety regulations covers contained use, introduction into the environment, and the placing of GE organisms on the market (Republic of Kenya 2005; Republic of Uganda 2004b). The Tanzanian Environmental Protection Act addresses research and releases into the environment (no distinction is made between experiments and commercial products) while Schedule 18 and the Plant Protection Act address small-scale confined field trials (United Republic of Tanzania 2004; United Republic of Tanzania, Schedule 18). Therefore, each country's system has the

ability to address the full range of potential environmental issues that might arise from any type of activity involving a GE organism.

Although all three countries' biosafety regulatory systems address environmental issues, they have not yet set forth how they will assess any potential food safety risks that might arise from some GE organisms. Although there is a small likelihood that eating a particular GE organism will have a harmful health effect, biosafety regulatory systems should analyze all potential risks to humans, including food safety issues. By including a food safety regulatory process for GE organisms as a component of the biosafety regulatory system (although not necessarily in the same statute or with the same government agency), GE organisms that are ready to be commercialized can have food safety issues addressed simultaneously with environmental issues. Food safety also is an important issue when GE organisms are imported solely for food and feed purposes, such as grain shipments for food aid (von Grebmer 2005).

All three East African countries state that potential risks to human health are to be addressed through a comprehensive biosafety regulatory system. In Kenya's Biosafety Bill, "biosafety" is defined in part as "the avoidance of risk to human health." (Republic of Kenya 2005). Similarly, in the Uganda draft National Biotechnology and Biosafety Policy, biosafety is defined to include risks posed to human health (Republic of Uganda 2004a). The Tanzanian NBF identifies allergenicity and toxicity as two food safety concerns with GE organisms and EMA defines biosafety to include "risks to human health." (United Republic of Tanzania 2005; United Republic of Tanzania 2004). In none of the legal or policy documents for any of the three countries, however, is there any discussion about which agency will be responsible for ensuring the food safety of GMOs, the procedures they will use to conduct any food safety

assessment, nor the legal authority under which that agency would take action. This is in sharp contrast to the extensive discussion about how each system addresses environmental risks.

One potential reason for the absence of any discussion on how the regulatory system will address food safety may be that biosafety activity in East Africa has been focused on complying with obligations set forth in the Biosafety Protocol. Although the Protocol mentions that it can also apply to "risks to human health," it is primarily an environmental agreement and its provisions do not mention anything about assessing or addressing food safety issues surrounding GE organisms (Jaffe 2005).

To ensure that a biosafety regulatory system is in place that can address the full range of potential risk that arise from a GE organism, the three East African countries need to identify how food safety issues will be addressed. Those countries could identify in their biosafety policy the existing food laws and agencies that would address food safety concerns for GE organisms and summarize the procedures that will be used for any review and approval process. Alternatively, those countries could empower the same agency conducting the environmental risk assessment under their biosafety law to also conduct food safety assessments, providing a one-stop regulatory process that handles all safety issues. It should be noted that whichever path is chosen, food safety assessments need not be conducted for GE organisms at all stages of development. Food safety assessments are usually conducted when a GE organisms is released either in large-scale unconfined field trials or prior to release as a commercial product.

Adequate Legal Authority – Using Existing Laws or Establishing New Laws

The three countries in East Africa are taking different paths to ensuring that their biosafety regulatory systems have adequate legal authority to review and approve GE organisms.

An analysis of those contrasting methods provides insight into the possible options available to legally ground a biosafety system and the advantages and disadvantages of those options.

Until late 2005, Uganda had decided not to develop a specific biosafety law but instead proposed to promulgate biosafety regulations under the legal authority contained in the Uganda National Council for Science and Technology Statute No. 1 of 1990 (Republic of Uganda 1990; Wafula 2005). A review of that statute, however, finds that the UNCST Statute does not contain typical regulatory functions and powers (e.g. the authority to protect the environment, the power to issue permits and conduct inspections, etc...) and therefore does not provide adequate legal authority for the regulatory system was being proposed. While there may be other existing Ugandan statutes that provide authority for the regulations, the proposed regulations are not legally supported by the UNCST Statute.

The UNCST Statute's primary purpose is to establish the UNCST and its functions. Those functions include advising on science and technology issues, assisting in the promotion of indigenous science and technology, assisting in technology transfer, recognizing and honoring scientists, disseminating research, and so on (Republic of Uganda 1990). The statute also establishes the powers of the UNCST, which include sponsoring, promoting and encouraging science and technology activities (Republic of Uganda 1990). The powers the statute provides to the UNCST do not address conducting risk assessments, approving activities, permitting activities, or conducting inspections as those activities are not usually needed for the educational and promotional functions assigned under the UNCST Statute. In addition, nothing in the statute identifies that the UNCST has any role in safeguarding the environment or human health from science and technology activities, including GE organisms. Therefore, while the UNCST is a government office that should be involved in setting Uganda's biosafety policy, the statute

authorizing its creation does not provide legal authority to regulate GE organisms. If regulations are finalized based on that authority, they might not withstand a legal challenge. Thus, to provide adequate legal authority for the biosafety regulatory system, Uganda might consider either using other existing statutes or getting its Parliament to pass biosafety legislation.3

Kenya initially made the same decision as Uganda and drafted Regulations and Guidelines for Biosafety in Biotechnology, which were issued in 1998 under the Science and Technology Act of 1980 (Traynor 2003). The Science and Technology Act, however, does not confer regulatory authority to the NCST. Therefore, it was determined that the regulations carried no legal weight and were not enforceable (Traynor 2003). Thus, the NBC and other government representatives decided that current legal authorities would not legally sustain a biosafety regulatory system and that a specific biosafety law needed passage by Parliament.

The Kenyan Biosafety Bill of 2005 will provide adequate legal authority to regulate the biosafety of GE organisms (Republic of Kenya 2005). The Bill specifically sets up a National Biosafety Authority, identifies the functions of that authority, and sets forth the legal requirement to obtain government approval before conducting activities with GE organisms. It discusses the information required of applicants, the risk assessment process, and the role of different regulatory agencies in ensuring compliance. Finally, the Bill identifies as one of its objective "to ensure an effective level of protection" where GE organisms may have an adverse effect on human health or the environment. Thus, if passed by the Kenyan Parliament, the bill would provide adequate legal authority for the government to assess and address risks posed by GE organisms.

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3 In late 2005, some Ugandans began the process of drafting biosafety-specific legislation to authority their biosafety regulatory system. Those preliminary drafts have not yet been made public nor have they been released as government draft documents. Thus, it is not included in this paper's analysis.

In Tanzania, a review was conducted of existing legislation that might address biosafety and concluded that no single legislative instrument adequately addressed biosafety concerns. (United Republic of Tanzania 2005). In addition, it was determined that while existing legislation might provide for some interim measures for a biosafety regulatory framework, there was a need for new biosafety-specific legislation. (United Republic of Tanzania 2005). In contrast to Kenya, however, Tanzania decided not to draft and enact an independent biosafety bill but to include provisions for regulating GE organisms in the much broader Environmental Management Act of 2004. By taking this path, Tanzania was able to establish the legal authority for their biosafety regulatory system faster than their two neighbors, both of which began addressing biosafety regulatory concerns much earlier than Tanzania.

The Tanzanian Environmental Protection Act (EMA) is a law that addresses numerous environmental issues, one of which is GE organisms (United Republic of Tanzania 2004). As a regulatory statute, EMA provides the government with the authority to obtain information, grant approvals, inspect, and enforce. The provisions that directly address GE organisms also provide legal authority to ensure that those organisms are reviewed and approved before they are released into the environment. Under the general authority to conserve and protect biological diversity, EMA gives the Ministry of the Environment authority to set forth regulations that manage the biosafety risks associated with LMOs, which are defined to include risks to human health and the environment (United Republic of Tanzania 2004). EMA also defines "risk assessment" to include "the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socio-economic conditions and ethical values of the country or its populace which may be posed by the import, contained use, deliberate release or placing of the market of GMOs or its products." (United Republic of Tanzania 2004). Finally,

EMA requires that "major development in biotechnology including the introduction and testing of genetically modified organisms" require the developer to conduct a detailed "environmental impact analysis." (United Republic of Tanzania 2004). Thus, EMA illustrates that only a few statutory provisions in a broader statute may be all that is needed to establish the legal authority for a biosafety regulatory system. With those legal provisions, the details of the system can to be provided in promulgated regulations.

The Standard for Making an Approval Decision – Establishing an Adequate Level of Protection

As stated in Section 2, a key component of a biosafety regulatory system is a clearly articulated safety standard which is used to judge applications for approval by the government. The Kenyan and Ugandan biosafety regulatory systems do not provide such a standard. The Tanzanian system provides some criteria or benchmarks for an approval decision, although those criteria are potentially restrictive and not well-defined.

In Uganda, neither the draft Biosafety Policy nor the draft Regulations set forth a clear safety standard for approving a GE organism. The draft regulations state that an approval is required before any activity involving a GE organism but do not provide the criteria which will be used to determine whether to grant the approval (Republic of Uganda 2004b). Similarly, the Kenyan Biosafety Bill sets forth what the Authority shall take into account in reaching a final decision – the information submitted by the applicant, the risk assessment, the relevant comments from the public, and so forth – but does not provide the legal benchmark or safety standard that must be met for an approval (Republic of Kenya 2005).

The Tanzania NBF does set forth some specific criteria that must be met before an approval is granted. The NBF states that no approval should be given unless the GMO will: "I)

Benefit the country without causing any risk/significant risk to human health and animal health, biological diversity and the environment; ii) contribute to sustainable development; iii) not have adverse socio-economic impacts; iv) accord with the ethical values and concerns of communities and does not undermine community knowledge and technologies." (United Republic of Tanzania 2005). How to apply those criteria or what they mean is not discussed anywhere in the NBF or in any other documents that establish Tanzania's biosafety regulatory system. Thus, without a more thorough explanation, it is hard to know how an application for the release of a GE organism can meet those criteria. For example, "sustainable development" is very vague and needs a definition if different stakeholders are to be able to understand how GE organisms will be judged to fit within sustainable development. Also, depending on how they are interpreted, the criteria described in the NBF are potentially restrictive and could prevent many GMOs that are safe for humans and the environment from being approved either because they do not "benefit the country," they have some socio-economic impacts, or they neither contribute nor hurt sustainable development.

While the Tanzanian NBF includes the statement set forth in the previous paragraph, the confined field trial permitting process established under Schedule 18 and the EMA make no mention of those criteria or that standard. Nowhere in Schedule 18 is there any discussion about any safety standard that needs to be met or any criteria that must be satisfied when the agency is determining whether a request for a permit will be approved or rejected (United Republic of Tanzania, Schedule 18). Similarly, EMA does not discuss the criteria mentioned in the NBF (United Republic of Tanzania 2004) or any decision-making standard for GE organisms. Hopefully, in the biosafety regulations to be issued under EMA, Tanzania will set forth details

about the level of safety that needs to be achieved and the benchmark that will be used to determine approval of a release.

One interesting part of Tanzania's biosafety regulatory system is that they are the only country of the three which affirmatively states that the benefit of a GMO should be considered in the approval process. The NBF states that implementation of the biosafety framework should recognize both the "potential benefits and risks of modern biotechnology." (United Republic of Tanzania 2005). Thus, the NBF suggests that Tanzania will consider not only the potential risks but the potential benefits when approving GE organisms for release into the environment.

Addressing Socio-Economic Considerations in the Decision-Making Process

All three countries state that their biosafety regulatory system need to address socio-economic considerations that might arise from individual GE organisms. The Tanzania NBF states that "the social, economic, and ethical considerations shall be taken into account in Biosafety decisions," (emphasis added) and that it is one of the responsibilities of the NBC to facilitate the undertaking of "socio-economic impact assessment." (United Republic of Tanzania 2005). The Uganda draft Regulations state that no approval shall be given unless the GMO will "not have adverse socio-economic impacts." (Republic of Uganda 2004b). The current version of the Kenya Biosafety Bill states that "in reaching a final decision, the Authority **shall** take into account ... (e) socio-economic consideration arising from the impact of the GMO on the environment." (Emphasis added) (Republic of Kenya 2005).

Other than the references mentioned in the previous paragraph, however, no country elaborates on what socio-economic considerations will be considered, how they will be analyzed, and how they will be factored into the decision-making process. What is the definition of

"socio-economic considerations?" What information will be used to analyze any socio-economic impacts and what will be the baseline for the analysis? Who will perform the analysis and at what stage in the development process? For the biosafety regulatory system to be fair, predictable, and transparent, the details surrounding the inclusion of socio-economic considerations in the decision-making process should be spelled out in more detail than is currently available in the documents from Kenya, Tanzania, and Uganda. Without sufficient details, the system could be perceived as unfair to the applicants and the public who both will not know how specific applications will be judged in this area.

Without more details on the interaction between socio-economic considerations and the decision-making process, it is unclear whether the three biosafety systems might violate the Biosafety Protocol or WTO obligations. Article 26 of the Protocol allows for taking into account socio-economic considerations of LMOs, but places conditions on that analysis. First, it limits the socio-economic considerations to those effects that arise "from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities." (Secretariat of the Convention on Biological Diversity 2000). Thus, the plain language of Article 26 does not allow all socio-economic considerations of LMOs to be considered but only those that directly arise from impacts on biological diversity (Mackenzie et al. 2003). Some stakeholders believe, however, that the socio-economic impacts of LMOs are much broader and could include concerns such as "impacts on farmers' incomes and welfare, cultural practices, community well-being, traditional crops and varieties, domestic science and technology, rural employment, trade and competition, the role of transnational corporations, indigenous peoples, food security, ethics and religion, consumer benefits, and ideas about agriculture, technology, and society (La Vina

2004)." While those broader socio-economic considerations may be valid societal concerns relevant to GE organisms, they may not be properly part of a biosafety regulatory system consistent with the Protocol.

Second, the Protocol states that inclusion of socio-economic considerations must be done in a manner that is consistent with other international obligations (Kalibwani 2004). In general, WTO rules emphasize procedures for decision-making that primarily rely on scientific risk assessments and greatly limit the ability to make decisions based on non-safety concerns. WTO rules sometimes do allow the narrow use of non-safety concerns. For example, the SPS Agreement does set forth a risk assessment procedure that includes both scientific and socio-economic considerations (The World Trade Organization 1995). Some of the relevant economic factors under the SPS Agreement include: "the potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks (The World Trade Organization 1995)." That exception, however, is narrowly defined and primarily allows for cost/benefit analysis to play a role in certain decisions.

Therefore, to try to comply with WTO rules and the plain language of the Article 26, countries that include socio-economic considerations in their domestic regulatory systems might tailor what they will consider to only what is allowed by Article 26 (e.g. socio-economic concerns directly linked to impacts on biodiversity). That may greatly narrow the socio-economic issues that the three countries can address in their biosafety systems. Broader socio-economic considerations, however, might be addressed through other means, such as voluntary

processes implemented by research institutions and companies or other laws and regulations (Fransen et al. 2005).

Any assessment of socio-economic considerations that is to be conducted should occur when a GE organism is ready to be commercially released. When a GE organism is used in a contained laboratory or in a confined field trial, the GE organism is not expected to persist in the environment and there are minimal effects of that organism on the population of the country and no significant socio-economic considerations to analyze. If a country is concerned about conducting GE organism research as a whole, those issues should be addressed in a policy context. If socio-economic considerations are to be analyzed for individual GE applications, the proper time is when that organism is seeking approval for commercial release.

Proportionate Risk-Based Reviews

Proportionate risk-based reviews of GE organisms allow the regulator to streamline the approval of safer applications while spending more time and resources on applications that pose greater relative risk. The current and proposed regulatory systems in the three countries differ tremendously on how extensively they have incorporated that component into their biosafety regulatory systems.

The Kenyan Biosafety Bill clearly differentiates aspects of its review and approval procedures based on the relative risk of either the GE organism or the specific activity to be conducted with the GE organism. The Bill specifically defines "contained use" and sets forth separate procedures for approval of contained use applications. (Republic of Kenya 2005). Those applications only need provide the limited information required by the Third Schedule (paragraph 14) and there is no need for both notice to the public and an opportunity for public

comment (paragraph 21). However, those applications still require approval from the Authority and they do need to conduct a risk assessment (although it is assumed to be a limited one). The Biosafety Bill also distinguishes between applications for introduction into the environment (paragraph 15) and placing of the GMO on the market (paragraph 16).[4] (Republic of Kenya 2005). When one reads those provisions and the schedules they refer to, however, there is no distinction in procedures or information required for those two different situations, although they have different levels of potential risk. Thus, while the Bill establishes different procedures for field trials and commercial releases, the reality is that the procedures are virtually identical. The Biosafety Bill does allow, however, for a risk assessment to be omitted if "sufficient experience or information exists to conclude that the GMO or activities do not pose a significant risk to the environment." (Republic of Kenya 2005).

In the proposed Uganda biosafety regulatory system, there are few elements of proportionality. The draft Biosafety Policy does not mention that different activities with a GE organism have different relative risks or that the Protocol allows for different regulatory treatment of those activities (Republic of Uganda 2004a). Similarly, in the draft Regulations, applications for contained use, confined field trials, and commercial release are treated the same, requiring the same procedures, data and risk assessment. The Regulations do acknowledge, however, that there may be categories of GMOs which can be exempt from the regulations if it has been established that they "are not likely to have adverse effects on human health or the environment." (Republic of Uganda 2004b).

The best example of a proportionate risk-based review process in the region is the Tanzanian approval process for confined field trials under Schedule 18. That document sets

[4] Based on the definitions in the Bill, it is assumed that introductions into the environment are confined and unconfined field trials while "placing on the market" is the commercial sale of a GMO.

forth a procedure to allow for the review and approval of small-scale confined field trials, which due to their size and confined nature, pose relatively little risk (United Republic of Tanzania, Schedule 18). Under that procedure, there is no need for a thorough risk assessment, but the completion of an application with limited information requirements. No food safety assessment is required nor are socio-economic issues considered or analyzed. Thus, the procedures in Schedule 18 do a good job at balancing the regulatory process with the potential risk of the activity.

Although Schedule 18 puts in place a proportionate risk-based review process, the Tanzanian NBF suggests that all GMOs, regardless of their intended use, need to have detailed risk assessments and prior authorizations consistent with the Biosafety Protocol's AIA procedure. The NBF specifically states that imports of GMOs for contained use and for food, feed or processing will require application of the AIA procedure (United Republic of Tanzania 2005). WTO rules require that imports are treated the same as domestic products so if imported GMOs for contained use need a full risk assessment as set forth in the Protocol, then the same would be required for the contained use of a domestically engineered organism. Also, EMA states that its regulations cover "research" and that the "testing of GMOs" require detailed environmental impact assessments (United Republic of Tanzania 2004). Under such an interpretation, EMA is not a proportionate risk-based approach because it covers contained uses in the laboratory or confined field trials in the same manner as commercial releases. Thus, the language in the Tanzanian NBF and EMA may contradict what is trying to be accomplished by Schedule 18 and the regulation of confined field trials under the Plant Protection Act. Hopefully, the regulations that are promulgated to implement the biosafety provisions of EMA will shed light on the inconsistencies within the Tanzania biosafety regulatory system.

Public Participation

As set forth in Section I, public participation in a biosafety regulatory system usually involves two separate components: (1) the opportunity to provide comments and opinions on the laws, regulations, and policies before they are adopted, and (2) the opportunity to provide comments before an application for a GE organism is approved by the regulatory agency. Public participation is different from public awareness, where the government educates and informs the public about biosafety, biotechnology, and the regulatory process.

All three countries in this study have involved the public in the process of drafting their biosafety regulatory system (laws and regulations) and their biosafety policy. Kenya has conducted a number of public stakeholders meetings beginning in 2001 to address the country's biosafety policy and biosafety law (Traynor 2003; Kenya Council for Science and Technology 2003), although some commentators have criticized Kenay for not making their process more inclusive and participatory. (Harsh 2005). Similar workshops and stakeholder meetings have been conducted in Uganda and Tanzania (Consent Stakeholder Consultative and Awareness Initiative 2003; Wafula 2005).

All three countries also provide for some level of public participation in the review and approval process for individual GE organisms. In Tanzania, EMA provides for broad participation in agency decision-making (United Republic of Tanzania 2004). Also, the NBF sets forth a broad and inclusive public participation policy. The NBF states that "public awareness and participation shall apply to all stages of the biosafety decision-making process from the time the application is received." (United Republic of Tanzania 2005). A plain reading of that language and other language throughout the NBF suggests that public participation and the opportunity to comment is to be provided at all stages of development of a GE organism,

including contained use, confined field trials, and commercial releases. If that is a proper reading of Tanzania's policy, however, it is not being implemented in the permitting process for confined field trials under the Plant Protection Act and Schedule 18. Nowhere in Schedule 18 is there any discussion about public participation or the opportunity for the public to comment on an application before the regulatory decision is made (United Republic of Tanzania, Schedule 18).

Kenya and Uganda also provide for public comment on applications. In Uganda, the draft Regulations state that the competent authority is to make the application available to the public and allow the public the opportunity to make comments and be consulted (Republic of Uganda 2004b). In Kenya, the draft Biosafety Bill states that the Authority will provide notice in at least two national newspapers about each application for release into the environment of a GE organism and provide thirty days for the public to respond to the notice (Republic of Kenya 2005). Thus, whereas Uganda and Tanzania provide for public comment for all applications, the Kenyan Biosafety Bill does not provide for public comment for applications for the contained use of a GE organism. That distinction actually may result in a more efficient and workable regulatory system in Kenya since the potential impact of contained use experiments on the public and the environment is minimal.

While all three countries provide the opportunity for the public to comment on applications, the value of that opportunity depends on how those comments are used in the decision-making process. In Kenya, the Biosafety Bill states that the Authority "shall take into account ... (d) any *relevant* comments submitted by the public." (Emphasis added) (Republic of Kenya 2005). The addition of the word "relevant" is important because it rightfully allows the Authority to take into accounts comments that are specific to the issues it is deciding (such as the

scientific risks of a GE organism) and ignore irrelevant comments, such general opinions that GE organisms are bad or harmful. In Uganda, the draft Regulations is written more broadly than in Kenya and states that the competent authority "shall ... take into account the views and concerns expressed by the public" without any qualification (Republic of Uganda 2005b). Thus, the Uganda decision maker may feel compelled to consider comments that the Kenyan decision maker has the legal authority to dismiss.

In Tanzania, the NBF states that "Public opinion as gauged through the procedures for public participation *must be taken* into account in the decision." (Emphasis added) (United Republic of Tanzania 2005). That language suggests that if the public was against a GE organism for a non-scientific reason, that opinion should be factored into the decision. If such public opinion swayed a decision, it is unclear whether the decision would be consistent with international legal obligations that limit decision-making to scientific evidence and the results of risk assessments.

Transparency

Public participation in the biosafety regulatory system cannot occur unless the regulatory system is transparent. The legal documents from all three countries establish provisions that ensure their systems are transparent. All three countries state that they will provide to the public the applications for GE organisms as well as the final decisions concerning all applications (Republic of Kenya 2005; United Republic of Tanzania 2005; Republic of Uganda 2004b). In addition, the Ugandan draft Regulations and the Tanzanian NBF specifically state that they will make available to the public the risk assessment of the GE organism (United Republic of Tanzania 2005; Republic of Uganda 2004b).

All three biosafety regulatory systems also balance the rights of the public to information with the rights of the developer or applicant to protect confidential business information. Each country has detailed provisions in their documents that allow for the protection of confidential business information (Republic of Kenya 2005; Republic of Uganda 2004b; United Republic of Tanzania 2005). The provisions in all three countries protect confidential information but also ensure that the public receives at least a minimal amount of information about the GE organism that cannot be claimed confidential (such as a description of the GE organism and a summary of the risk assessment). Those provisions are consistent with the Biosafety Protocol, which promotes transparency but allows for protection of confidential information in Article 21.

Scope of the Biosafety Regulatory System – Inclusion of Products of GMOs

In most countries that have established biosafety regulatory systems, those systems only require approval for each particular GE organism at each stage of development and do not require premarket safety approval for each individual product derived from those GMOs (the term "product" generally means foods and non-reproducing materials such as edible oils, industrial materials, and pharmaceuticals). Instead, the food safety and environmental risks assessments for the particular GE organism includes an analysis of the different products that might be produced from the GE organisms and whether those products might pose any environmental or food safety risks.

Only the Tanzanian biosafety regulatory system explicitly includes products of GMOs in its regime. The Scope section of their NBF states that the biosafety regulatory systems includes "products of GMOs" and the approval processes it describes require advance informed consent for both a GMO, a product of a GMO, or any material derived by processing a GMO (United

Republic of Tanzania 2005). The definitions in EMA also mention that risk assessments are to be performed on both GMOs and their products. If the Tanzanian biosafety system is supposed to approve each product of a GMO using the same procedures, risk assessments, and information requirements as would be done for a GMO, the system could receive thousands of applications from persons and companies who do not know very much about the GMO. For example, a GE tree could be used to make dozens of different products including paper, wood furniture, and wood picture frames. Similarly, GE maize could be used to make maize oil, maize starch, and maize syrup and could be found in Coke, Fanta, Pepsi, Corn Flakes, Corn meal, and hundreds of other food products. Is it anticipated that under the Tanzanian Biosafety regulatory system, soda or paper would require an approval if they were made from a GMO? The person who makes the paper or soda would know about the wood he used or where he got his corn syrup but those persons would not have information about the genetic construct of the GMO or information about the engineered protein. Therefore, from both a practical and a scientific viewpoint, it may not make sense to approve products that are derived from the GMO.

Interim Regulatory Systems

The long term goal is to have a working biosafety regulatory system that is comprehensive, covering potential risks for potential organisms at different stages of development. For many African countries, including the three in this study, currently there is limited research and product development using genetic engineering (Sithole-Niang, et.al 2004). Thus, there may not be an immediate need for a comprehensive regulatory system at this time. In those situations, interim regulatory systems that address immediate needs – such as confined

field trials for GE plants – can play an important role in allowing biotechnology to advance while more permanent regulatory systems are established.

Kenya, Tanzania and Uganda have each established interim biosafety regulatory processes to address any immediate biosafety needs. Kenya's NCST has issued regulations and guidelines for activities with GE organisms and approved five confined trials (Macharia 2005). It has established the NBC both to review applications for GE organisms and draft the government's biosafety policies (the biosafety policy and draft Biosafety Bill). Similarly, Uganda established its NBC in 1995 along with functional national biosafety guidelines (Nampala 2005). The NBC has reviewed two applications for GE organisms, although neither experiment was ever carried out.

Tanzania's interim biosafety regulatory system includes an approval process for small-scale confined field trials using the legal authority it has under its Plant Protection Act. Those requirements, which are identified in Schedule 18, state that "no person can conduct a confined field trial of any GE plant without authorization from the Minister under this Schedule." (United Republic of Tanzania, Schedule 18).

There are two issues that arise with the interim measures. First, there is a question about whether there is legal authority to support them. For example, while the Kenyan regulations and guidelines have been used to approve 5 trials, there is general consensus that those procedures are not legally supported by the Kenyan Science and Technology Act (Traynor 2003). By contrast, there is probably adequate legal authority in the Tanzanian Plant Protection Act for Schedule 18, since it is limited to small-scale confined field trials for GE plants. The Tanzanian NBF, however, found the Plant Protection Act inadequate to address biosafety, "particularly with regard to risk assessment and management, ... issues of environmental impact assessment, ..."

(United Republic of Tanzania 2005). Thus, that law would probably not support more complete regulation of GE plants as they move toward commercialization.

The second issue that arises with interim measures is what happens to them when new legislation is put in place. For example, Tanzania recently passed EMA, which provides for regulation of the release of GE organisms into the environment. Will that law now regulate small-scale confined field trials instead of Schedule 18? Will there be review and approval under both EMA and the Plant Protection Act? It would also be inefficient if two reviews were required. Similarly, the Kenyan NCST and the NBC have gained experience regulating GE organism experiments under their interim processes. The Kenya Biosafety Bill calls for the National Biosafety Authority managed by a Board from a number of government agencies (Republic of Kenya 2005). Will that authority make use of the existing expertise from the NCST and the NBC? Will the documents that make up the current Kenyan biosafety regulatory system become regulations and guidelines promulgated under the Biosafety Bill after it is passed? While the biosafety regulatory systems in the three countries transition from interim procedures to new legal authorities, it is important that the knowledge, experience, and work already completed is transferred and built upon.

Efficiency – The Value of Institutional Biosafety Committee

Biosafety regulation has the potential to be costly and time consuming, both for the researcher who is trying to produce a useful GE organism and for the government who is trying to ensure adequate protection of humans and the environment. Thus, it may be beneficial if regulatory procedures are as streamlined as possible, while not compromising safety. The biosafety regulatory systems in all three countries have multiple steps with many different people

and committees conducting different parts of the process. One part of the regulatory process in all three countries that should be analyzed more closely for its added value is the Institutional Biosafety Committees (IBC), particularly for private institutions.

All three East African countries require every institution that conducts activities with GE organisms, both public and private, to establish an IBC. An IBC is usually made of scientists and other people from the institution that oversee the biosafety aspects of any genetic engineering that is occurring at the institution. The Kenyan Guidelines for release into the environment state that the "IBC will ensure that experiments relating to GM and releases by the institution conform to the provisions of the Guidelines." (Republic of Kenya 1998). The IBC is also required to undertake a risk assessment, monitor release sites, and provide its findings to the NBC (Republic of Kenya 1998) Similarly, in Uganda, the IBCs' functions include reviewing and clearing prospective applications before they go to the NBC, reporting regularly to the NBC, training, and oversight. Tanzania also establishes IBCs, which conduct many of the activities identified above for Uganda and Kenya but are also required "to hold discussions on the comparative ecological, economic and social impact of alternatives" to the proposed GMO (United Republic of Tanzania 2005).

Based on the functions of the IBCs set forth in the biosafety regulatory systems, those committees perform an initial review step in a multi-step approval process and conduct self-monitoring of the institution's activities. Is this self-regulation valuable? Should it be trusted when it is done by a private corporation? Do the IBC reviews make experiments with GE organisms safer? Are the preliminary reviews conducted by the IBCs valuable to the NBCs when they re-review the applications? Those and other questions should be answered to determine if the IBCs add value to the overall regulatory process and its goal of ensuring safety

to humans and the environment. Based on the functions of the government actors in the existing and proposed biosafety regulatory systems for all three countries, most activities conducted by the IBC are repeated by the NBC and/or the competent authority. When IBCs or other similar institutional committees have been established in developed countries such as the United States, they self-regulate in areas where there is no governmental oversight. For Kenya, Uganda, and Tanzania, however, the IBCs conduct activities that generally are duplicated at the national level.

Finally, even if there is merit to IBCs for public institutions, the same may or may not be true for private institutions. For private companies and businesses, there maybe little public benefit from the company self-policing itself and any initial review they might provide to the NBC might get very little deference. Therefore, it would be valuable to conduct a research study to determine whether IBCs allow the NBC to be more efficient because they defer to the IBC's judgment and oversight or whether IBCs just conduct activities that are then repeated by the NBC or competent authority.

One way to reduce overlap or duplication but keep IBCs would involve making them the primary regulatory body for contained use activities and limiting their role for confined field trials and commercial releases. In such a regulatory system, the IBC might be the only body responsible for ensuring that contained use experiments safely meet the government's protection standards and procedures. No researcher would be able to do a contained experiment without IBC approval. The IBC would submit its approval to the NBC who would have 30 days to object to the approval. If the NBC did not object, then the IBC approval decision would stand and the experiment could legally proceed. For confined field trials which require a review in each country by the NBC, the IBC might play a minor role to ensure that the researcher provides the necessary information to the NBC. It also might work with the researcher to establish plans

and procedures to carry out the terms of the issued permit. Finally, for commercial releases where the NBC has an extensive review of food safety, environmental safety and any other risk issues, the IBC might play no role. Under such a system, duplication would be avoided and the IBC would be given the primary role in activities involving GE organisms where potential risks and public concern are minimal.

ANALYSIS OF THE AFRICAN MODEL LAW

One example of a law that attempts to set forth a comprehensive biosafety regulatory regime is the African Model Law[5]. That document sets forth language that could be adopted by African nations that want to legislate in order to meet their Biosafety Protocol obligations (Organization for African Unity 2002). However, a review of that law finds that while some of the provisions are well drafted, others would not help achieve some of the characteristics and components of a biosafety regulatory system set forth in Section I of this paper.

Some African Model Law provisions worth considering by nations drafting their own biosafety law include Article 5 on Public Participation and Article 10 addressing "Unintentional Release and Emergency Measures." Article 5 is both comprehensive and well written. It provides for notice to the public about upcoming decisions in which they can comment, requires that information relevant to the decision be made available before the public's comments are due, and ensures that the decision-maker looks at the public's comments before making a decision. Article 10 addresses what can be done to prepare for an emergency situation, what needs to be done if an emergency arises, and who has the responsibility to inform others who may be affected by such an incident.

[5] For background on the African Model Law, see Kalibwani, et al., 2004.

Other African Model Law provisions also help ensure the biosafety regulatory system is transparent, fair, equitable, and predictable. The first two parts of Article 12 on Confidential Business Information balance the need to protect commercial information while providing the public with at least some minimum information. Similarly, paragraph 1 of Article 15 on Offences and Penalties set forth in a predictable and transparent fashion what will be considered the major offences under the statute. Finally, the definitions in Article 1 are generally well written and help establish a comprehensive but also flexible regulatory system.

While the African Model Law provisions mentioned above could enhance a biosafety regulatory system, there are other provisions in the African Model Law that do not produce a biosafety regulatory system that is fair, equitable, predictable, and proportionate. Article 2 addressing "Scope" and the definition of "deliberate releases" both include "products of genetically modified organisms." It is unclear why products of genetically modified organisms, such as purified pharmaceuticals or processes foods, would need to go through the notification and consent procedures set forth in the Model Law. The product should go through whatever regulatory systems exist for similar products produced by other means (e.g. from conventional crops or from industrial factories) but there is no significant environmental or biodiversity concerns that require the procedures set forth in the Model Law. Similarly, Article 14 on "Liability and Redress" seems overly broad and may not be necessary in most countries where the application of existing liability law can adequately address any liability issues that may arise.

Also, although Article 6 does set forth one or more safety standards, those standards are restrictive, difficult to understand, and maybe hard to apply in a fair and predictable manner. Paragraph 7 states that there must be "firm and sufficient evidence that the genetically modified organism ... pose no risks/significant risks ...." Paragraph 9 then states that an approval should

not be given unless the product (1) benefits the country without causing risk; (2) contributes to sustainable development; (3) does not have adverse socio-economic impacts; and (4) does not accord with the ethical values and concerns or communities or undermine community knowledge and technologies. It is unclear how those two different standards work together and how they will be applied. What is "full and sufficient evidence?" What would be considered an adverse socio-economic impact? What is meant by "contribute to sustainable development?" Based on what is written in the African Model Law, depending on how those safety standards are interpreted and applied, there might never be a GE organism that could be approved.

Finally, it should be noted that the African Model Law as written, is not a particularly efficient and effective system. The Model Law does not incorporate the principle of proportionality and instead treats all applications and products with the same process and procedures. There is no statement that confined field trials will be treated differently that commercial releases or that there may be different requirements for living modified organisms whose primary purpose is food, feed, or processing.

6. COOPERATION, COORDINATION, AND HARMONIZATION OF BIOSAFETY REGULATORY SYSTEMS IN EAST AFRICA

Currently, all three countries in this study are in the process of establishing national biosafety regulatory systems. Although those systems are at different stages of development and have different histories, none of them has been finalized. Thus, there is an opportunity to improve the individual systems, coordinate their operations, and even harmonize the procedures and policies among the three countries. What follows is a suggested path forward which provides for both further work by individual countries to finalize their national biosafety systems while

simultaneously working in a collaborative and cooperative fashion to coordinate and harmonize those systems so they are efficient, effective, and make the best use of limited scientific and legal capacity.

TIMING OF A REGIONAL EFFORT

Although none of the three countries has a legally established and fully operating biosafety system, now is the time to begin harmonizing those systems to allow them to work together in a coordinated fashion in the future. While some people might argue that each country needs to get its own biosafety regulatory system established and running before it can consider efforts at coordinating with its neighbors, the best time to begin a regional harmonization effort is before the biosafety regulatory systems are fully functioning under an authorized legal mandate. If the biosafety system is to be based on detailed legislation, once that legislation is passed by Parliament, a later regional effort at harmonization might require additional legislative activity in particular countries. In addition, working on regional harmonization efforts at the same time as individual countries are working on their own biosafety system will allow for countries to use their resources in an efficient manner and share their lessons, best practices, and list of things to avoid.

Successful East African Community regional harmonization efforts have occurred before each individual country has established the necessary legal and regulatory systems. For example, environmental assessment guidelines for shared ecosystems in East Africa were successfully developed before all three countries had the legal authority and regulatory procedures in place to conduct the Environmental Impact Assessments (The East African Community, Environmental Assessment Guidelines). Those Guidelines were recently approved by the Sectoral Committee on the Environment and Natural Resources of the EAC and

eventually will be adopted by each country (Wafula 2005). Therefore, there is precedent for addressing regional environmental issues, even before the necessary legal and regulatory systems are in place. Thus, now is an opportune time for the three countries to discuss establishing similar biosafety regulation.

POTENTIAL AREAS FOR COLLABORATION, COOPERATION, COORDINATION, AND HARMONIZATION

The discussion below sets forth several substantive ways in which the three countries in this study could begin a collaborative effort to coordinate and harmonize their biosafety regulatory systems. While implementing all of the suggestions would lead to systems that would be well coordinated and harmonized, efforts in this arena also could occur more gradually by establishing some cooperation and coordination initially while waiting for each country to gain more experience with GE organisms before any extensive harmonization effort.

Adoption of Codex Standards for Assessing the Food Safety of GE Organisms.

Under the Codex Alimentarius Commission, the governments of the world's nations have issued several consensus documents addressing the food safety issues surrounding GE foods. Those documents should form the basis for the food safety risk assessments of GE foods that are conducted in Kenya, Tanzania, and Uganda. Thus, if each country adopted those documents in their biosafety policy and implemented their risk assessment procedures, the region would move toward a harmonized approach for addressing the food safety issues surrounding GE organisms.

Harmonizing Applications, Data Submissions, and Government Documents

For each country's approval process, the developer will need to complete an application form and submit specific data and information about the GE organism. It might be beneficial if each country's application form asked for similar information in a similar manner. That would make it easier to fill out the forms and would standardize the expectations of developers about what is required of them from neighboring countries.

Coordinated biosafety regulatory systems also might accept the same data, when it is relevant to the issue being addressed. For example, when conducting a food safety assessment of a GE organism that will be commercially released, it may not matter where the laboratory tests for toxicity or allergenicity were conducted. Test results from a neighboring country or even a developed country that previously analyzed the food safety of the GE organism may be acceptable. Other types of data that might be portable from one jurisdiction to the other might be molecular data, evidence of gene stability, or harm to non-targets. Even certain environmental data might be used in more than one jurisdiction if the same environmental conditions and issues exist in both places. For data on certain environmental issues and questions, however, it probably will be necessary to submit data from tests conducted solely in the country for which the release is requested.

One way to help ensure that data is portable from one country to another country is for those countries to establish the same field and laboratory standards. Kenya, Tanzania, and Uganda harmonized field and laboratory standards for their regulation of seed, which resulted in greater acceptance of data across countries and increased seed availability (Minde 2004). A similar collaborative effort by the countries to establish standards for the GE organism risk assessment testing that will be needed in an application would allow relevant data generated in

one country to be submitted in the other countries, if it is relevant to potential risk issues in those countries.

Government issued documents related to GE organisms, such as notification, permits, and inspection reports could be standardized. The East African Community recently harmonized its Sanitary and Phytosanitary Standards, Measures, and Procedures and included in that process standard forms to be used in different situations (The East African Community 2004). In fact, one such standardized document already in existence is the permit form for importing LMOs into the country. A similar effort could produce uniform permits and inspection checklists for the different activities involving GE organisms. It could also produce common tags and labels for GE organisms that are being moved among countries for research and field testing.

Establishment of Common Regulatory Pathways for Different Activities Involving GE Organisms

As stated earlier, different activities involving GE organisms have different potential risks. Many biosafety regulatory systems provide each activity with risk-appropriate regulatory procedures so that limited resources are allocated primarily to activities that raise the most potential concern while minimizing the regulatory costs and time involved in the regulatory process for activities with little potential risk (Kinderlerer 2002). It could be beneficial if the three countries implemented similar review and approval procedures for four different activities involving GE organisms: contained use experiments, confined field trials, commercial releases, and GE organisms only used for food, feed or processing. Establishing risk-based procedures for those categories and harmonizing those procedures among the three countries could simplify field trials and commercial releases activities in the individual countries and reduce the regulatory burden for GE products that might be marketable in more than one country.

Contained Use Experiments. Contained use experiments involve working with GE organisms inside a laboratory or greenhouse that is physically separated from the outside environment. Such physical separation, along with institutionalized procedures for containment, eliminates virtually any risks that might be posed by the GE organism to the environment. While the three biosafety regulatory systems in Kenya, Tanzania, and Uganda all require review and approval of such activities, the potential risks posed by such activities support establishing streamlined, regulatory review procedures that result in quick decisions.

One possible regulatory pathway for contained use experiments would make the IBC the primary regulator for such activities. Instead of requiring review and approval by the NBC for each experiment, the regulatory system could establish the IBCs as the decision-maker, requiring the investigator to submit the applications to the IBC for review and approval. If the IBC approved the submission, they would notify the NBC of their approval and allow the NBC a set period of time to object to the approval. If there was no objection, the approval would stand and the experiment would proceed. Thus, the NBC could veto or overrule an IBC decision, but if the NBC did not act, the IBC permit would be the legal permission to proceed.

A second possible regulatory procedure would be to require NBC approval for such applications but provide a legal mechanism to exempt such activities from review and approval once such applications become familiar and routine. The NBC might scrutinize the first few applications but over time, routine experiments that pose no real risk would become exempt from needing a permit. It might stifle agricultural research, waste precious regulatory resources, and provide little added protection to the environment and human health if contained use experiments required extensive risk assessments that tried to assess and address speculative or unlikely environmental and food safety risks.

Confined Field Trials. A confined field trial is a restricted environmental release of a GE organism under conditions that are designed to prevent the spread of the organism from the field trial site or its persistence in the environment. It is usually small-scale in size (less than one hectare) and conducted for research purposes in order to evaluate the performance of the organism or to collect data to analyze the safety of the organism (United Republic of Tanzania, Schedule 18). The field trial is considered "confined" because it is conducted under planting conditions that limit the ability for the GE organism to escape from the site. Those conditions might include biological, physical, geographical, temporal, and/or chemical methods of confinement. It should be noted that the Kenyan Biosafety Bill defines "contained use" to include confined field trials, thereby combining the contained use and confined field trial categories into one.

If there is sufficient confinement, a confined field trial poses relatively little risk to human health or the environment because the chance of escape into the food supply or persistence into the environment is small. Thus, the regulatory system's review procedures for such applications should concentrate on analyzing the characteristics of the GE organism and matching those characteristics to a testing protocol with multiple layers of confinement. Thus, a risk assessment of the GE organism should be conducted but it might not be as extensive as the assessment performed for a commercial release, where the product will be sold to individuals to use without restriction. For a confined field trial, the risk assessment often only addresses risks and not benefits, as the benefits for the potential product are extremely speculative at the field trial stage. The assessment of the GE organism to approve a confined field trial application also may not need to include a food safety assessment. The nature of the field trial – its small scale and extensive confinement – can make the likelihood of impact on the food supply small.

Similarly, to the extent that a biosafety system is legally mandated to assess socio-economic considerations, such issues may not arise for confined field trials.

Tanzania, under Schedule 18 promulgated pursuant to the Plant Protection Act, recognized the need to treat confined field trials differently in the biosafety regulatory system and set up a streamlined process for reviewing and approving such experiments. Such a system could be copied by the other East African nations, leading to common procedures for such trials throughout the three countries.

Commercial Release. An application for the commercial release of a GE organism occurs when field testing is complete and a developer is ready to release the GE organism as a product sold to farmers. At that stage, the GE organism is expected to persist in the environment and interact with humans. Thus, it is this stage in the regulatory process where a full risk assessment is performed to ensure adequate protection of human health and the environment. That risk assessment should address all relevant environmental issues and could include an analysis of the potential benefits of the GE organism. If the GE organism is eaten by humans and/or animals, there should be a food safety assessment that follows the procedures and rules established by Codex. If a country's biosafety regulatory system requires an assessment of socio-economic considerations, the place for that analysis would be at the commercial release stage. Any analysis of those considerations, however, needs to be consistent with that country's international obligations. Thus, it may be prudent for such regulatory systems to restrict such an analysis to a small set of well defined issues that are directly the result of harms to biodiversity.

For commercial release applications, the regulatory system should ensure that the application and risk assessment are thoroughly evaluated. To do this, relevant government offices with expertise on the potential risk issues need to review the application and the risk

assessment and provide comments to the decision-maker. In addition, experts with scientific knowledge who do not work for the government should be consulted for their opinion on the issues raised by the application. The public should also be provided the non-confidential portions of the application and risk assessment and given an opportunity to provide comments relevant to the issues being decided by the government.

In deciding on the commercial release application, some risk management measures can be imposed with the approval of GE organism for commercial release. However, the fact that thousands of people may purchase the organism limits the types of measures that can be feasibly implemented. In developed countries, the types of risk management measures that have been implemented for commercial products include restrictions on planting the GE organism in certain geographic locations or the establishment of refuges to prevent insect resistance to the GE organism. (U.S. EPA, 2001). Finally, whatever decision is made on the application relating to a GE organism, the government should release to the public that decision as well the basis for the decision.

GE Organisms Used Only for Food, Feed or Processing. The final category of GE organisms are those organisms that are to be used solely for food, feed, or processing. An example of a GE organism that falls within that category would be GE grain that is imported as food aid. In that situation, the grain is not meant to be sold as seed that farmers will plant but will be used to feed humans and/or animals. In such a situation, two regulatory pathways are possible. First, the country can allow the GE organism to enter the country based on the risk assessments and approvals that were conducted in the country of export, as allowed for by the Protocol. In such a system, no new risk assessment is conducted in the importing country. Alternatively, the country of import can require its own review and approval process. If that path

is taken, the primary risks that need to be addressed are food safety issues. Thus, the data submitted by the applicant and the regulatory process should focus on conducting a detailed food safety assessment consistent with Codex rules. Any risk assessment involving potential environmental risks from the organism's introduction into the environment should be less extensive than what would be required under a commercial release application because the number of GE organisms that persist in the environment and reproduce would be a small fraction of what occurs in a commercial release situation.

Regional Risk Assessments for GE Organisms

When public or private developers are ready to commercialize a GE organism, that product may be of benefit to farmers not only in the country where it was developed and tested but also in its neighboring countries. Thus, the three East African countries could benefit from establishing a mechanism to assess GE organisms that may have a regional impact. Such a system could produce a mutually agreed upon risk assessment for a product that would form the basis for individual approval decisions in each country. It could establish uniform risk management measures for a GE organism, which may be important since ecosystems are not confined within national boundaries. Also, such a system could utilize the limited biosafety capacity in the region in an efficient manner by drawing upon scientists from the three countries to conduct one risk assessment on a particular application. Finally, a regional assessment system might result in a single mutually-agreed-upon decision on the commercial release of the GE organism for all three countries.

A regional risk assessment process for potential commercial GE organisms with markets in more than one East African country could be modeled similar to the system established for environmental assessments involving shared ecosystems. The East African Community has

developed Guidelines to be adopted within each country that address procedures for conducting trans-boundary environmental assessments in shared ecosystems in East Africa. (The East African Community, Environmental Assessment Guidelines). Under those Guidelines, projects that occur in one country but that may impact one or more of the other countries are required to produce a single EIA carried out by the developer. That EIA is submitted to the country of origin of the project as well as the affected countries and each is given the opportunity to comment on the EIA. Those comments are then taken into account in the decision by the country of origin. If the decision is not satisfactory to any one country, it can be appealed to the EAC Secretariat to try to resolve any dispute. (The East African Community, Environmental Assessment Guidelines).

If such a system were developed for GE organisms, an application for the commercial release of a GE organism could be submitted to one country, who would then share the application with the other two countries. Then, a regional science advisory board, composed of members of the different country NBCs and technical advisory bodies, could review the application, conduct the risk assessment, and propose any risk management measures. Each country, as well as the public, could have an opportunity to comment on the review by the regional body, who would finalize their recommendation taking into considerations relevant comments. Then, under one possible pathway, each country could take its own approval decision under its own legal authority. Such a system would allow for the possibility that the GE organism might be approved in one country but not its neighbor. It would also allow for individual countries to add their own additional risk management measures. A second option would be to have the legal authorities in the three countries meet and decide, based on the recommendation from the regional body, to jointly approve or deny the application for all the

countries. Whether or not the final decision is left to the individual country or determined jointly, a regional risk assessment procedure could provide tremendous savings of time and money and better utilize limited expert capacity within the region.

Even if a regional risk assessment system is not set up, at a minimum, the three East African countries could agree to use the same risk assessment procedures and risk assessment criteria for their individual risk assessments of a GE organism. A similar harmonization was successfully done with the phytosanitary rules, when the three countries all agreed to use the revised FAO Pest Risk Analysis procedures as the basis for issuing import permits (Seed Regional Working Group 2003). By using the same risk assessment criteria and procedures for GE organisms, there would be some standardization and predictability for developers in the review and approval process.

7. CONCLUSIONS

Kenya, Tanzania, and Uganda have been working the past few years to establish national biosafety regulatory systems so that safe GE organisms can become part of their agricultural system. While those regulatory systems are not yet completed, the framework for those future systems is set forth in different legal and regulatory documents that have been analyzed in this paper. Although the proposed biosafety regulatory systems differ in their details, their ultimate goal is the same – ensuring adequate protection of the environment and human health from activities involving GE organisms.

Through the detailed legal analysis of the current and proposed biosafety regulatory systems in East Africa, a number of issues have been identified that, if addressed, could improve those systems. Some of the major conclusions and recommendations from the analysis are as follows:

- Food safety is a necessary component of the biosafety regulatory system. Assessing the food safety of GE organisms could be conducted by a food safety regulator under a food safety law or it could be conducted when the environmental risks are assessed using legal authority granted under a Biosafety Act. The legal authority and procedures to assess and address potential food safety risks of GE organisms when they are released as commercial products should be spelled out in the national biosafety regulatory system so that they can be understood by all interested stakeholders.
- The biosafety regulatory system should set forth the legal standard and criteria upon which it will base its decision whether to approve or deny an application.
- Different activities with a GE organism should have different regulatory pathways to an approval that correspond to the potential risks of that activity. Different pathways should be established for contained use, confined field trials, commercial release, and use as food, feed, or processing.
- If socio-economic considerations are to be included in the assessment process for GE organisms, that process should only occur at the commercial release stage of development. The potential areas for analysis need to be explicitly set forth as well as how the analysis of those factors will affect the approval process. To try to achieve compliance with international obligations, any socio-economic analysis should be limited to impacts that are closely linked to biodiversity.
- GE organisms and not their products should be the focus of the national biosafety regulatory system. Products produced from GE organisms should be regulated under product-specific statute, not within the biosafety regime.
- Interim measures established in each country have allowed for some GE experimentation and begun the process of establishing institutional capacity in the area of biosafety. It is important that the knowledge and experience from those systems is incorporated into the proposed systems that will be implemented in the future.
- The role and value of Institutional Biosafety Committees should be assessed to determine if their actions increase the safety of GE organisms. If IBCs continue to be a part of the

national biosafety regulatory systems, countries might consider making them the primary regulator of contained use experiments.

- While each country is establishing its national biosafety regulatory systems, collaborative efforts at coordination and harmonization should be explored. Areas for cooperation, standardization, and harmonization might include the application forms and data requirements, the different regulatory pathways for different activities with GE organisms, and the risk assessment process. The three countries also might consider establishing a joint procedure that would provide for one risk assessment for a GE organism that is to be commercially released in all three countries.

The issue of biosafety in East Africa will increase in importance in the coming years as local scientists develop GE organisms that directly benefit agricultural interests in that region of the world. To be ready for those developments, Kenya, Tanzania, and Uganda need to continue to establish their national biosafety regulatory systems and turn them into functioning bureaucracies. By reviewing the conclusions in this paper and implementing some of the suggested improvements, those systems may become more comprehensive, understandable, workable, and fair.

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