Biosafety of GM Crops in Kenya, Uganda, and Tanzania

An Evolving Landscape of Regulatory Progress and Retreat

Author
JUDITH A. CHAMBERS

A Report of the CSIS Global Food Security Project

December 2013

CSIS | CENTER FOR STRATEGIC & INTERNATIONAL STUDIES

Biosafety of GM Crops in Kenya, Uganda, and Tanzania

An Evolving Landscape of Regulatory Progress and Retreat

Author
Judith A. Chambers

A Report of the CSIS Global Food Security Project

December 2013

CSIS | CENTER FOR STRATEGIC & INTERNATIONAL STUDIES

ROWMAN & LITTLEFIELD
Lanham • Boulder • New York • Toronto • Plymouth, UK

About CSIS—50th Anniversary Year

For 50 years, the Center for Strategic and International Studies (CSIS) has developed solutions to the world's greatest policy challenges. As we celebrate this milestone, CSIS scholars are developing strategic insights and bipartisan policy solutions to help decisionmakers chart a course toward a better world.

CSIS is a nonprofit organization headquartered in Washington, D.C. The Center's 220 full-time staff and large network of affiliated scholars conduct research and analysis and develop policy initiatives that look into the future and anticipate change.

Founded at the height of the Cold War by David M. Abshire and Admiral Arleigh Burke, CSIS was dedicated to finding ways to sustain American prominence and prosperity as a force for good in the world. Since 1962, CSIS has become one of the world's preeminent international institutions focused on defense and security; regional stability; and transnational challenges ranging from energy and climate to global health and economic integration.

Former U.S. senator Sam Nunn has chaired the CSIS Board of Trustees since 1999. Former deputy secretary of defense John J. Hamre became the Center's president and chief executive officer in April 2000.

CSIS does not take specific policy positions; accordingly, all views expressed herein should be understood to be solely those of the author(s).

ISBN: 978-1-4422-2805-4 (pb); 978-1-4422-2806-1 (eBook)

Center for Strategic & International Studies
1616 Rhode Island Avenue, NW
Washington, DC 20036
202-887-0200 | www.csis.org

Rowman & Littlefield
4501 Forbes Boulevard
Lanham, MD 20706
301-459-3366 | www.rowman.com

Contents

Acronyms

AATF	African Agriculture Technology Foundation
ABNE	African Biosafety Network of Expertise
ACTESA	Alliance for Commodity Trade in Eastern and Southern Africa
ASARECA	Association for Strengthening Agricultural Research in Eastern and Central Africa
AU	African Union
BecA	Biosciences East and Central Africa
BMGF	Bill & Melinda Gates Foundation
Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CFT	Confined Field Trial
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Center
COMESA	Common Market of Eastern and Southern Africa
COSTECH	Tanzania Commission for Science and Technology
CPB	Cartagena Protocol on Biosafety
DDPSC	Donald Danforth Plant Science Center
EAC	East Africa Community
EALA	East African Legislative Assembly
EU	European Union
FAO	Food and Agriculture Organization
FARA	Forum for Agriculture Research in Africa
GDP	Gross Domestic Product
GH	Greenhouse
GM	Genetically modified
GMO	Genetically modified organism
IBC	Institutional biosafety committee
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IFPRI	International Food Policy Research Institute
IITA	International Institute of Tropical Agriculture
ILRI	International Livestock Research Institute

ISAAA	International Service for the Acquisition of Agri-biotech Applications
KARI	Kenya Agriculture Research Institute
OAU	Organization of African Unity
OFAB	Open Forum on Agriculture Biotechnology
NARO	National Agriculture Research Organization
NBA	National Biosafety Authority
NBC	National Biosafety Committee
NCST	National Council for Science and Technology
NEPAD	New Partnership for Africa's Development
NGO	Nongovernmental organization
PBS	Program for Biosafety Systems
QUT	Queensland University of Technology
R&D	Research and development
RABESA	Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa
SADC	Southern Africa Development Community
SSA	Sub-Saharan Africa
S&T	Science and Technology
TR	Transformation
UNCST	Uganda National Council for Science and Technology
UNEP/GEF	UN Environment Program/Global Environment Facility
USAID	U.S. Agency for International Development
WEMA	Water Efficient Maize for Africa

Acknowledgments

The author wishes to acknowledge the contribution of content provided by the Program for Biosafety (PBS) and International Food Policy Research Institute (IFPRI) colleagues drawn from pending publications or personal communication used in the preparation of this report.

This publication has been prepared for the Center for Strategic and International Studies, made possible by a grant from the John Templeton Foundation. The opinions stated here are solely those of the author and do not necessarily reflect the policies or viewpoints of the IFPRI or John Templeton Foundation, neither of which peer-reviewed the paper.

Executive Summary

Against a background of rapid global adoption rates and two decades of safe use, the overly cautious approach to genetic modification (GM) technology in agriculture by African governments seems misplaced. To date, only three African countries are engaged in commercial production of GM crops, although others are experimenting with the technology. Among those African countries experimenting with the technology, several are proceeding along a path toward commercialization and reside geographically close in East Africa, where the potential for regional trade impacts and issues exist. An examination of their historical circumstance and experience with GM technology, and the resultant effects on regulatory policy, can offer some useful insights about the various factors that impact GM technology adoption in Africa, especially from the perspective of the biosafety policies enacted.

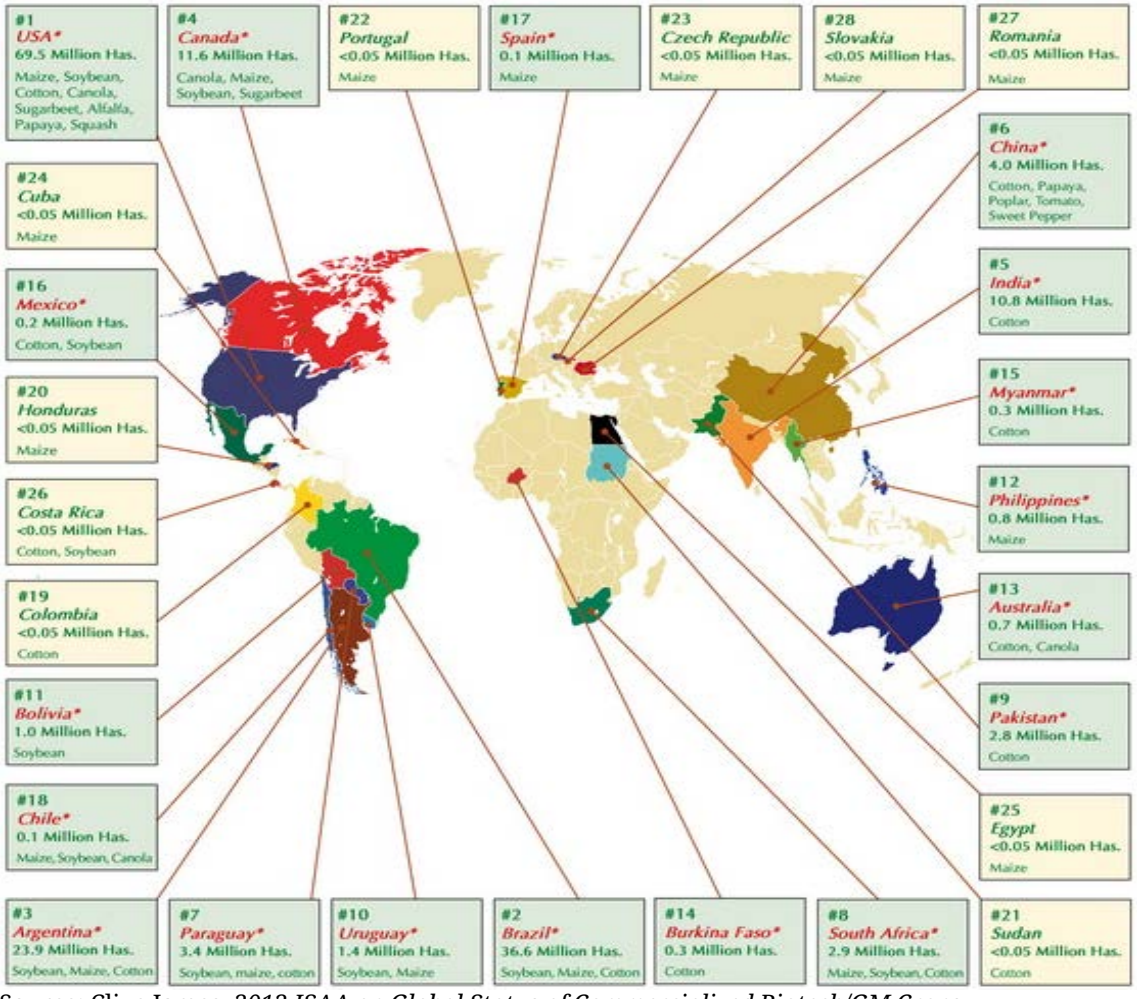
This report provides a situational analysis of the biosafety systems of Kenya, Uganda, and Tanzania and explores factors that contribute to common and disparate approaches to regulatory decisionmaking. The Cartagena Protocol process and African Model Law, opportunities for practical scientific experience with the technology, the role of capacity-building initiatives, the impact of coalitions, and the power of political will are examined for their eventual influence on the regulatory policy that has ultimately been formulated and implemented. Similarities in factors and experiences between Kenya and Uganda underscore their similar approach to biosafety regulation, which balances risk and benefits and follows a mostly “science-based approach.” By contrast, Tanzania’s risk-oriented regulatory system and the associated complication is poses for biotechnology adoption are explained from the perspective of its somewhat different history, experience, and capacity.

Finally, the report addresses recent trends that add to the complexities governing biosafety policy progress in East Africa and offers recommendations in support of science-based regulatory policy development for Africa in general.

1 | Background and Context

Nearly 25 years have elapsed since a seminal conference on agriculture biotechnology commenced in 1990 in Nairobi, Kenya.[1] According to the most recent data gathered by the International Service for the Acquisition of Agri-biotech Applications (ISAAA), global commercial cultivation of genetically modified (GM) crops increased a hundredfold, from 1.7 million hectares in 1996 to 170 million hectares in 2012, marking this technology as the most rapidly adopted agriculture technology in history (see Figure 1).[2]

Figure 1. Global Biotechnology Adopters

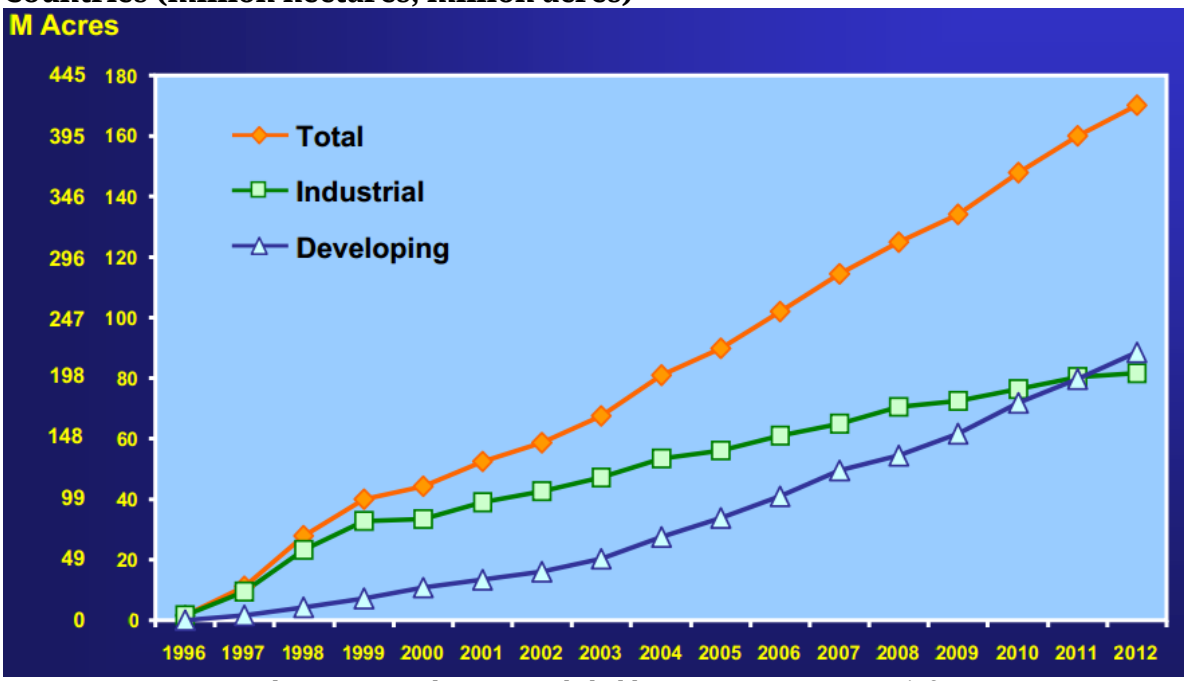


Source: Clive James, *2012 ISAA on Global Status of Commercialized Biotech/GM Crops*, www.isaaa.org/resources/publications/briefs/44/pptslides/default.asp.

[1] A.M. Mailu, J.O. Mugah, and P.O. Fungoh, *Biotechnology in Kenya: Proceedings of the National Conference on Plant and Animal Biotechnology* (Nairobi: Initiatives Publishers, 1990).
[2] Mariechel Navarro, Kristine Natividad-Tome, and Kaymart Gimutao, *From Monologue to Stakeholder Engagement: The Evolution of Biotech Communication*, ISAAA Brief 45, 2013, www.isaaa.org/resources/publications/briefs/45/.

While four crops (maize, soya, cotton, and canola) and two traits (insect and herbicide resistance) currently dominate adoption figures, trends point to the importance of this technology to address the future challenges of a food-insecure world, especially in countries poor in resources. Brazil has replaced the United States as the fastest global adopter (an increase in hectares planted to 21 percent in 2012), 90 percent of the farmers (17.3 million) are small-scale farmers from developing countries, and two new developing countries (Cuba and Sudan) were added to the ranks of adopting nations.[3] As Figure 2 shows, the percentage of global biotech crops planted by developing countries rose by an impressive 52 percent as compared to 48 percent for industrialized countries.[4]

Figure 2. Global Area of Biotech Crops, 1996 to 2012: Industrial and Developing Countries (million hectares, million acres)



Source: M. Narvaro et al., *From Monologue to Stakeholder Engagement*, ISAA Brief 45, 2013, www.isaaa.org/resources/publications/briefs/45/.

GM crops were first introduced into commercial agriculture in the mid-1990s. To date, there has been no *scientifically documented* evidence of human or environmental harm. Prior to the commercial release of a novel GM variety, independent experts in human and animal nutrition and toxicology, as well as specialists in environmental safety, review large volumes of data to ensure the safety of these crops. Some maintain that biotechnology is the most regulated technology in the history of agriculture. Many national and international scientific organizations have attested to the safety of GM technology, including those below:

- Food and Agriculture Organization
- World Health Organization

[3] Ibid.
[4] Ibid.

- Organization of Economic Cooperation and Development
- Asia Pacific Economic Cooperation
- Royal Society of London
- German National Science Foundation
- Brazilian Academy of Sciences
- Chinese Academy of Sciences
- Indian National Science Academy
- Mexican Academy of Sciences
- Third World Academy of Sciences
- National Academy of Sciences (United States)
- American Society of Microbiology

The extraordinary safety profile has even convinced some well-known anti-GM activists, such as Patrick Moore, the founder of Greenpeace,[5] and Mark Lynas, a renowned anti-GM activist,[6] to vocally and publicly recant their previously held negative stance on GM technology.

Despite this global track record of safety and consistently robust global adoption trends, African farmer access to these new varieties remains the exception rather than the rule and the voice of Africa on this technology persists as a confused cacophony of pro-GM advocates and anti-GM detractors. While most internationally recognized experts accept the safety of the technology, reports to the contrary persist in Africa. Questions about antibiotic resistance, allergenicity, toxicology, genetic pollution, pollen flow, loss of biodiversity, effects on nontarget organisms, increased "weediness," sterility, and obesity are consistently part of the African continent's dialogue on agriculture biotechnology.

The stagnant situation is particularly troublesome when one considers the reality of the agriculture sector in Africa. Most African countries derive at least 35 percent of GDP from agriculture[7]; more than 200 million people, mostly children, continue to be malnourished or undernourished; population pressures persist; and extensified versus intensified agriculture practices are prevalent, especially in more rural areas, placing added pressure on Africa's fragile ecosystems. Furthermore, climate change presents a real threat for Africa's marginal farming systems. As shown in Table 1, estimates of maize yields underscore the realities of the technology-starved African farmer.

[5] C.S. Prakash, "Greenpeace Founder Supports Biotechnology: Moore Criticizes Colleagues for Opposing Golden Rice," AgBioWorld, 2011, www.agbioworld.org/biotech-info/pr/moore.html.
[6] Mark Lynas, "Posts in Biotechnology," 2013, www.marklynas.org/biotechnology/.
[7] Calestous Juma, *The New Harvest: Agricultural Innovation in Africa* (New York: Oxford University Press, 2011), 7.

Table 1. Estimates of Maize Yields

Country	Yield (million tons/hectare)
United States	9.2
Indonesia	4.5
Kenya	1.5
Uganda	2.4
Tanzania	1.3

Source: Food and Agriculture Organization of the United States (FAOStat 2011).

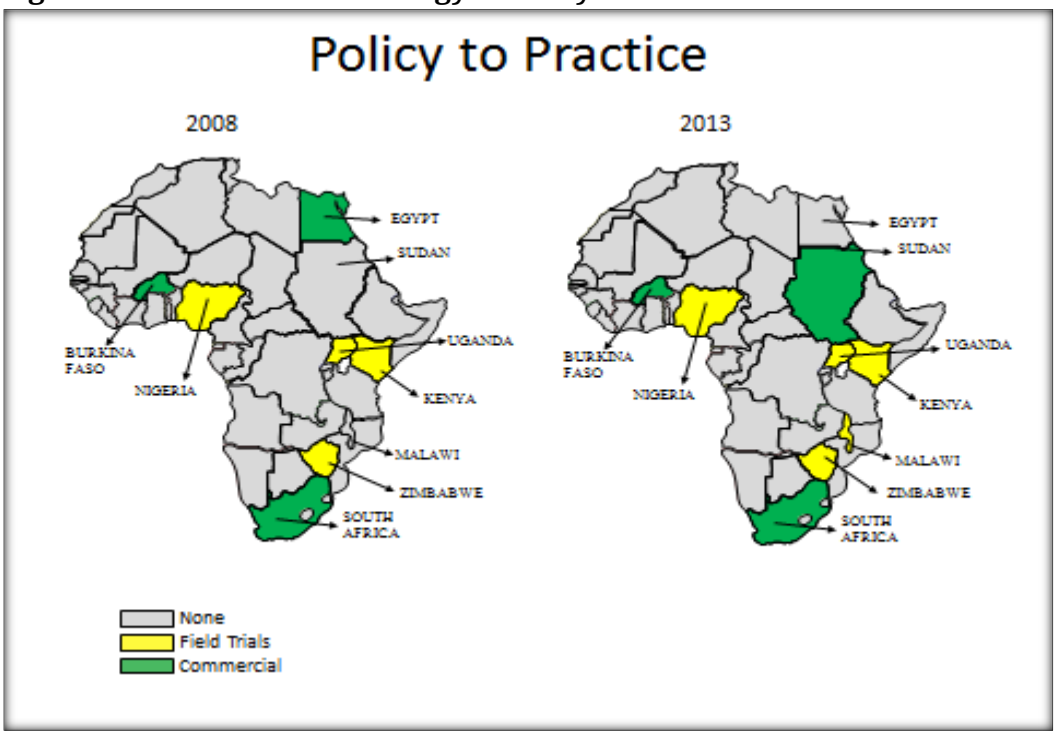
In his book, *Starved for Science*, Robert Paarlberg squarely attributes the anemic acceptance and adoption of GM technology in Africa to the ongoing polarized debate in the developed world.[8] The debate, according to Paarlberg, is focused less on science and evidence-based conclusions and more on the larger context of geopolitical concerns and issues around the global food system.[9] These concerns are often varied, cultural, and sometimes seemingly unrelated. They range from issues related to market function and globalization, to concerns about trade competition and retaliation, consumer angst and backlash about corporate control and domination of the food system, consumers' right to know, religious and cultural philosophies about "tinkering with life," and disparate understanding of complex scientific principles within and between countries. With much of the anti-biotech sentiment emanating from Europe, it is not surprising that the embroiled nature of the controversy has had a direct and profound impact on African attitudes about the technology. The situation becomes more perverse and insidious when one examines the impact on regulatory systems—the recognized "gatekeeper" of technology acceptance and adoption.

[8] Robert Paarlberg, *Starved for Science: How Biotechnology Is Being Kept out of Africa* (Cambridge, MA: Harvard University Press, 2008).
[9] Ibid.

2 | Rationale and Focus of the Study

A five-year snapshot of the evolving map of African biotechnology acceptance is revealing in its consistency and gives a window into the impact of the global biotechnology debate on regulatory policy across the continent. As Figure 3 demonstrates, unlike the global picture, the African picture of biotechnology activity for GM crops has remained relatively and alarmingly static over the past five years.

Figure 3. African Biotechnology Activity



Source: J. Chambers, IFPRI, and M. Karembu, ISAAA.

Only three African countries (South Africa, Burkina Faso, and Sudan) are commercially cultivating GM crop varieties. Egypt, which was a commercial adopter, recently issued a moratorium on GM crops and has ceased cultivation of insect-protected maize.[10] Only one new country—Malawi—has been added to the current group of those conducting confined field trials with its launch of a Bt cotton trial in 2012.[11] A few additional countries (Ghana, Kenya, Nigeria, and Uganda) continue to flirt with the prospect of commercial cultivation, but GM activity in these countries has primarily been relegated to an array of confined field trials often accompanied by regulatory stasis with regard to deregulation. The relative lack of progress of African regulatory systems mirrors the ongoing tensions emanating from Europe, leading to confusion among African policymakers about the "way forward" on agriculture biotechnology. Numerous capacity-building attempts have been initiated to address

[10] The New Ecologist, "Egypt Bans Import and Export of Genetically Modified Food," August 13, 2009, www.thenewecologist.com/2009/08/egypt-bans-import-and-export-of-genetically-modified-food/.
[11] Georgekalunwe' Blog, "Malawi to Finally Start Bt Cotton Tests," December 11, 2012, http://georgekalungwe.wordpress.com/2012/12/11/218/.

the situation, with various degrees of success (some to be discussed later in this paper). However, a more in-depth and critical examination of the current *methods, messages, messengers, and approaches* used to convey safety data to policymakers and the public will be required to change the current regulatory status quo.

A Critical Analysis of Three East African Countries

With this in mind, it is useful to perform a comparative study of the current biosafety situations in three neighboring countries in East Africa: Kenya, Uganda, and Tanzania. An in-depth analysis is useful in that it may reveal trends and tipping points that impact biosafety policy evolution, formation, implementation, and, consequently, adoption of GM crops in Africa. A focus on these three countries in particular is logical for a number of reasons. They are trade partners. All three countries are part of the East African Community (EAC); Kenya and Uganda are members of the Common Market of Eastern and Southern Africa (COMESA); and all share the European Union (EU) as a primary and influential trade partner. As compared to many other African countries, these three countries had early exposure to the technology and its accompanying biosafety issues. All were engaged at an early stage in the Cartagena Protocol process and had early experience with the UNEP/Global Environment Facility (GEF) capacity-building project on biosafety (1998 for Kenya and Uganda; 2003 for Tanzania). All were impacted to varying degrees by the African Union's (AU) Model Law on Biosafety. Finally, all three countries have a shared regional interest in a number of important GM crops, which have either been commercialized or are under development.

Table 2. GM Crops of Common Regional Interest

CROP	GM TRAIT
Maize	Insect, drought tolerant, nitrogen efficient
Cotton	Insect, herbicide tolerant
Cassava	Virus resistant, nutritionally enhanced
Banana	Disease resistant
Sorghum	Nutritionally enhanced
Sweet Potato	Virus resistant, weevil resistant

In addition, as shown in Table 3, R&D progress on the development and testing of many of these crops has already advanced (in Kenya and Uganda) and the lack of progress in Tanzania is illuminating for the chilling effects that its regulatory system has had on its biotechnology R&D status.

As with any analysis of this type, there is much to be gained not only from examining the historical perspective but also from discriminating between the similarities, differences, and resulting impacts. Accordingly, the paper will (1) look at the important timelines and events in each country that led to the current regulatory policy and framework in existence; (2) compare and contrast the key aspects of important regulatory principles and issues between all three countries; and (3) draw some common conclusions with respect to prospects for trade, harmonization, lingering issues and constraints, and GM technology acceptance.

Table 3. Current Biotechnology Product Releases

CROP	KENYA	UGANDA	TANZANIA
Banana		CFT	
Cassava	CFT	CFT	
Cotton	CFT	CFT	
Maize	CFT	CFT	CFT**
Sorghum	GH		
Sweet Potato	TR	GH	
Pigeon Pea	TR/GH		

Note: Transformation (TR), greenhouse (GH), confined field trial (CFT).
** Mock trial only.

3 | The Early Days: Biotech and Biosafety in Africa

Currently, the absence of functional, efficient, and technically competent regulatory systems throughout much of Africa is seen as a major rate-limiting constraint to the adoption of biotechnology and GM products on the continent, whether these products are generated internally or externally, by the private or the public sector. While Africa is not unique in this respect (notably, the EU's highly precautionary system has also stymied R&D progress and adoption of agricultural biotechnology in many member states), it has multiple challenges related to food insecurity, poverty, population growth, climate change, and natural resource degradation. These challenges place a sense of urgency on Africa to resolve its regulatory impasse in order to self-determine its path with respect to the adoption of biotechnology. This point was alluded to by the AU/NEPAD High Level Panel on Biotechnology in recommendation 12, which states, "Africa needs to develop its own scientific capacity to assess biotechnology-related risks through national, regional and continental institutions so that all biotechnology policy is informed by the best available research and knowledge."[12]

The Cartagena Protocol and Africa

The regulatory situation in Africa is currently plagued by difficulties, including:

- Lack of technical capacity leading to non-science-based approaches and policies and inefficient decisionmaking
- Lack of transparency and procedural rigor
- Lack of inter-ministerial agreement and role confusion
- Costly processes and requirements that negatively impact R&D and investment
- Systems that are overly influenced by politics stemming from historical trade relationships (EU) or traditional farming practices (i.e., farmer's rights)
- Absence of a market-driven agricultural system that, in turn, places extreme burden on public-sector entities (i.e., national governments, research institutes, and their regulatory systems) to address and guarantee food security

It is important to consider the historical relationship of Africa's regulatory policy against the backdrop of the Cartagena Protocol on Biosafety (CPB). There is ample historical evidence to indict the protocol process for the lack of regulatory progress and the current risk-averse stance exhibited by many African governments. The process and ensuing negotiation was, for Africa, a premature regulatory policy that preceded by many years the actual and practical experience of African governments with biotechnology R&D and the generation of actual new GM crop varieties. In the absence of firsthand experience with GM crops, the influence of the Cartagena Protocol became the driving regulatory force in Africa, setting the legacy and

[12] Calestous Juma and Ismail Serageldin, *Freedom to Innovate: Biotechnology in Africa's Development* (Addis Ababa and Pretoria: Africa Union and New Partnership for Africa's Development, 2007), 115.

standards for many national frameworks that still persist today. The regulatory policies of Kenya, Uganda, and Tanzania have all been impacted by the Cartagena Protocol to varying degrees.

The Cartagena Protocol was originally intended as an international trade agreement under the Convention on Biological Diversity to formalize biosafety assessments and a notification process as preconditions associated with the transboundary movement and trade of genetically modified organisms. Its stated objective was to ensure "an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements."[13] The process was initiated in 1996 with the formation of an open-ended ad hoc working group.[14] A formalized process began in 1999 with the first meeting of the parties in Cartagena.[15] The Cartagena Protocol was adopted on January 29, 2000, as a supplementary agreement to the Convention on Biological Diversity and entered into force on September 11, 2003.[16] To date, there are 166 parties to the protocol.[17] The European Union as a regional body was allowed representation as a single party, although countries within the EU also participate individually. Currently, non-parties include the major GM-adopting countries of Argentina, Canada, and the United States. The Cartagena Protocol is now being implemented (since 2003) and is recognized as a major driving force for the development of national regulatory systems throughout the world with a scope and impact that has far exceeded its original focus on biodiversity. Negotiations continue around the implementation of specific articles espoused in the Protocol agreement. A number of these, such as liability and redress, socioeconomics, and labeling continue to influence the African regulatory situation and are discussed in greater detail elsewhere in the document as they present unique challenges to the technology's adoption.

Early in the process, the EU introduced the concept of the precautionary principle as a guide for the ensuing negotiations over the objections of the major technology-adopting countries at the time (e.g., United States, Canada, and Argentina). The precautionary principle maintains that "if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is *not* harmful falls on those taking an action."[18] The EU adherence to the precautionary principle resulted in a persistent risk-averse approach that remained throughout the Protocol negotiations and influenced the Protocol's position on a number of key articles shown below.

---

[13] Wikipedia, "Cartagena Protocol on Biodiversity: Precautionary Approach," http://en.wikipedia.org/wiki/Cartagena_Protocol_on_Biosafety#Objective.
[14] Convention on Biological Diversity, "About the Protocol: History," http://bch.cbd.int/protocol/background/#history.
[15] Ibid.
[16] Convention on Biological Diversity, "About the Protocol: The ICCP Process," http://bch.cbd.int/protocol/background/#iccp.
[17] Wikipedia, "Cartagena Protocol on Biodiversity: Objective," http://en.wikipedia.org/wiki/Cartagena_Protocol _on_Biosafety#Objective.
[18] Wikipedia, "Precautionary Principle," http://en.wikipedia.org/wiki/Precautionary_principle.

Table 4. Key Issues Included in the Cartagena Protocol on Biosafety

- Assessment and review
- Capacity building
- Compliance
- Financial mechanisms
- Handling, transport, packaging, identification
- Information sharing
- Monitoring and reporting
- Risk assessment and risk management
- Public awareness and participation
- Liability and redress
- Socioeconomic consideration

Source: IFPRI, *A State of Affairs Assessment of GM Agricultural Technology for Africa*, unpublished report.

Discussions around these issues often resulted in divergent opinions between the EU and GM-adopting countries requiring multiple negotiating sessions in order to develop consensus or compromise. As Africa's major trade partner, the EU's position directly impacted the African position. More often than not, the African position reflected the position of the EU. During the process, an African "voting bloc" (commonly referred to as the African Group) evolved and eventually gave rise to the development of the African Model Law, which further impacted the regulatory "mindset" of many African countries.

The African Model Law

The African Union's (AU) African Model Law on Biosafety has been a significant guiding regulatory policy in Africa since it was first developed in an Organization for African Unity (OAU) workshop of experts in Addis Ababa (June 1999).[19] The first draft of the AU Model Law was based on a proposal submitted to the Convention on Biological Diversity (CBD) Secretariat during the third Conference of the Parties of the Biosafety Protocol in Buenos Aires in 1996 by the African Group.[20] The first draft was finalized by an OAU working group in Addis Ababa in May 2001, which brought together a diverse group composed of African governments, representatives of NGOs, scientific institutions, and the private sector, as well as representatives of the OAU and the UNEP/GEF.[21] The Model Law was presented at a meeting of the AU Executive Council held in Maputo in July 2003 by the AU Commission. The AU Executive Council, in its Decision EX/CL/Dec.26 (III) m, "urged AU Member States to use the African Model Law on Safety in Biotechnology as a basis for drafting their national legal instruments in biosafety."[22] As a result, countries throughout Africa have followed this advice in the development of their national biosafety frameworks and biosafety regulations.

The AU Model Law has been the subject of criticism by proponents of GM technology, who argue that it is an extreme interpretation of the Protocol's precautionary

[19] AU Biosafety Project, "African Model Law on Biosafety," http://www.africa-union.org/root/AU/AUC/Departments/HRST/biosafety/AU_Biosafety_2b.htm.
[20] Ibid.
[21] Ibid.
[22] Ibid.

principle and that its risk-oriented emphasis and non-science elements amount to a de facto regulatory ban on GM products. The AU Model Law establishes the following:[23]

- Uniform provisions for the import, export, transit, contained use, release, and placing on the market of any GMO and a product of a GMO, whether it is intended for release into the environment, for use as a pharmaceutical, food, feed or processing;
- Stringent regulation of GMOs in which decisionmaking is based on the precautionary principle;
- Strict regulation for GMOs imported for use as food, feed, processing, and food aid;
- Public participation;
- Identification and traceability, as well as labeling systems; and
- Liability and redress approaches.

Somewhat paradoxically, the AU has expressed a need to achieve a balanced approach to the assessment and use of the African Model Law by its member countries. Its website proclaims that "it is clear that African countries will generate modern biotechnology products and processes and will not be mere recipients. Therefore, the Model Law should not restrict investment in biotechnology, rather it is aimed that it acts as a facilitative instrument driven and informed by science to assist countries to maximize the benefits of biotechnology, while avoiding or minimizing the risks."[24]

The 2001 draft of the AU Model Law was subsequently revised in national and regional meetings in Africa. The Revised AU Model Law was introduced in the Africa-wide Experts Meeting in Lusaka, Zambia, in 2007 and a final revision was presented at the twelfth session of the African Ministerial Conference. The ministers endorsed the law and called on the AU Commission to provide biosafety leadership to ensure a harmonized African position. This draft Revised Model Law is still being revised based on the inputs from various regional and stakeholder discussions. It is expected that the Revised Model Law will eventually be presented to the ministers of trade and industry and ministers of agriculture at an undetermined point in the future.

While the passage of the AU Model Law has raised the profile of biosafety as an issue for GM crop introduction in Africa, it is clear that certain aspects of the law have the potential to actually limit progress for countries wishing to use GM technologies. For example, a "case by case" or "event by event" approach is not necessarily consistent with technical best practices in many adopting countries. Calls for regionally binding decisionmaking are at odds with some harmonization efforts (i.e., Common Market of Eastern and Southern Africa, COMESA) and some national regulatory positions. Interpretations of the Cartagena Protocol on Biosafety articles related to liability and redress and socioeconomics, especially as promulgated in the African Model Law, have had particular impact throughout Africa and have been applied differentially even among the three countries being considered here.

[23] Mariam Mayet, "Why Africa Should Adopt the AOU African Model Law on Safety in Biotechnology," June 2003, www.glow-boell.de/media/de/txt_rubrik_5/SuS_Mayet_CommentBiosafetyModelLaw.pdf.
[24] AU Biosafety Project, "African Model Law on Biosafety."

Liability and Redress

For some African countries, the inclusion of the liability principle recommended by the African Model Law is affecting progress in their application of biotechnology, even as they maintain a desire to use this tool to advance national interests. Article 27 of the Cartagena Protocol on Biosafety requires parties to adopt and implement international rules and procedures for liability and redress in connection with damage that may result from transboundary movements of GMOs.[25] The African Model Law interpretation of the Protocol espouses a system of strict liability (reserved for inherently hazardous activities) that confers responsibility and accountability to any entity or person engaged in the production process (from the developer to the manufacturer to the wholesaler to the retailer) if the product is deemed defective or harmful. This is in contrast to a fault-based, administrative system that seeks to apply, in a limited and specific manner, cause and remedial measures to an accountable and identified offending party.

In October 2010, at the fifth Conference of the Parties Meeting in Nagoya, Japan, a Supplementary Protocol on Liability and Redress (SP-NK) was adopted with an objective to "contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress to living modified organisms." The supplementary protocol pursues an administrative liability approach for addressing damage from GMOs and holds identified authorities ("competent authority") responsible for developer and operator actions undertaken in response to damage caused by GMOs.

The extent to which adoption and implementation of the supplementary protocol will negate the strict liability provisions in those African countries that have followed the AU Model Law recommendation is uncertain. However, the fact remains that many regulatory systems contain strict liability provisions that are hindering technological progress. Among the countries considered here, Tanzania is most affected by a strict liability approach.

Socioeconomic Considerations

Article 26.1 of the Cartagena Protocol raised the option of including socioeconomic considerations as part of the decisionmaking process. The implementation of this article is voluntary and has a scope limited to those factors affecting biodiversity and its value to indigenous and local communities. The Protocol does not require the inclusion of socioeconomic considerations in a regulatory decisionmaking framework; however, this is encouraged in the AU Model Law. Inclusion of socioeconomics in a risk analysis is complicated due to ill-defined parameters related to scope, risk-benefit, and identification of target populations, to name a few. Inclusion may lead to regulatory uncertainty, delay, elevated costs, and inefficiency. Yet, its consideration under the Protocol, with strong emphasis in the AU Model Law, has led to its inclusion in most regulatory systems and in all three countries under consideration here—Kenya, Uganda, and Tanzania.

[25] Convention on Biological Diversity, "Text of the Cartagena Protocol on Biosafety," Articles 1 through 40, http://bch.cbd.int/protocol/text/.

In general, the divergence of opinion about the value of the AU Model Law has led to its inconsistent application throughout Africa. While it has had expansive influence in Tanzania, decisionmakers in neighboring Kenya and Uganda have limited its influence to certain elements, while choosing to moderate the precautionary approach in favor of a more enabling regulatory scheme. Its deviation from internationally accepted regulatory norms and its varying application in Africa, even within the context of the East Africa Community, could potentially result in serious disruptions of trade and commerce for a continent plagued by porous borders and weak enforcement mechanisms. Continuing efforts are needed to obtain resolution on the content, scope, and impacts of the AU Model Law with an accompanying provision of scientifically sound, technical expertise to guide any revision process.

Regulatory Capacity-building Efforts and Impacts

The UNEP-Global Environment Facility (GEF) biosafety program was one of the early biosafety capacity-building efforts in Africa. In alignment with the Cartagena Protocol, the precautionary principle formed the basis for its early training approach and it typically focused its capacity-building efforts on ministries of environment. As a result, significant regulatory authority for biotechnology in Africa today rests with these ministries despite the cross-cutting nature of the technology. These ministries tend to favor the precautionary approach, which is often at odds with other ministries, such as agriculture or science and technology. Over time, the situation has evolved and countries have expanded their regulatory authority to include shared or primary responsibility with other ministries including higher education, science and technology, agriculture, health, trade, and industry. This has generally led to a more balanced approach to regulation. Nevertheless, confusion about intra-ministerial and inter-ministerial roles and responsibilities persists in most African countries as a result of the early UNEP-GEF influence. This has caused issues and regulatory delay in all three countries that are the focus of this report.

Ironically, although the UNEP-GEF capacity-building program was active in Kenya, Uganda, and Tanzania, regulatory authority rests within different ministries in each country. This may be the result of other capacity-building initiatives that influenced the eventual regulatory framework developed.

Other influential biosafety capacity-building initiatives that have been active in Africa are listed in Table 5. Nearly all have been or are currently active in Kenya, Uganda, and Tanzania.

Two programs, the Program for Biosafety Systems (PBS) and the African Biosafety Network of Expertise (ABNE), have been especially active in Kenya, Uganda, and Tanzania and have signed a memorandum of understanding to build better coordination and complimentary efforts. PBS is managed by IFPRI and is one of the oldest biosafety capacity-building programs still active on the continent.[26] Its objective

[26] Program for Biosafety Systems, “What is PBS?,” http://pbs.ifpri.info/.

Table 5. A Sampling of Biosafety Capacity-building Programs in Africa

Initiative	Key Players	Activity/Objective
UNEP/GEF	All African countries	Biosafety in conformity with the Cartagena Protocol
ICGEB	Sub-Saharan African countries	Strengthening and expanding biosafety systems
PBS	COMESA, Malawi, Kenya, Uganda, Nigeria, Mozambique, Tanzania	Integrated practical technical, legal, and outreach/communications expertise to assist African countries in the creation of functional biosafety systems and approaches
ABNE/NEPAD	All African countries	Empower Africans to develop and implement biosafety frameworks
BIO-EARN	East Africa	Biosafety for R&D
FARA	All African countries	Biosafety policy dialogue among diverse stakeholders at all decisionmaking levels: national, regional, continental

Note: ICGEB, International Centre for Genetic Engineering and Biotechnology; PBS, Program for Biosafety System; ABNE/NEPAD, African Biosafety Network of Expertise/New Partnership for Africa's Development; BIO-EARN, East African Regional Program and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development; FARA, Forum for Agriculture Research in Africa.

Source: Karembu et al., *Biotech Crops in Africa*.

is to empower African countries to develop, implement, and manage their own systems by providing training, technical and legal advice, and independent policy research for decisionmakers. Its approach provides a constant, in-country presence with an ability to directly interface with African governments. PBS helped to establish the early operational frameworks and field trials in Kenya and Uganda and has recently engaged in Tanzania.[27] ABNE is supported by the Bill & Melinda Gates Foundation in collaboration with Michigan State University and works under the auspices of NEPAD/AU.[28] It was created in response to the need to develop African capacity to assess *if*, *when*, and *how* biotechnology products may be adopted. It focuses on (1) building an African biosafety resource for regulators with an emphasis on members of the national biosafety committees, institutional biosafety committees, and plant quarantine agencies; and (2) providing long-term support to build functional regulatory systems.[29] ABNE is also active in all three focus countries. Both take a science-based approach to the regulatory advice and training provided, which has impacted the situations in Kenya and Uganda, in particular.

[27] Ibid.
[28] New Partnership for Africa's Development, "About ABNE [African Biosafety Network of Expertise]," http://www.nepadbiosafety.net/about.
[29] Diran Makinde, Luke Mumba, and Aggrey Ambali, "Status of Biotechnology in Africa: Challenges and Opportunities," *Asian Biotechnology and Development Review* 11, no. 3 (2009): 1–10.

4 | Comparative Biosafety Analysis: Kenya, Uganda, and Tanzania

General Considerations

According to Paarlberg, a sound legal framework is necessary to inspire trust in a government's ability to regulate biotechnology—to minimize the risk, maximize the benefit, and ensure public confidence. This is true not only for biotechnology, but for any new technology.[30] He states that many options exist for the creation of policies and structures that affect the introduction of biotechnology products. Regulation of biotech products could be done under an existing legal framework or a new system could be developed specifically, and that the approach eventually adopted is dependent on a number of factors, such as need, perception, and trade.[31] Paarlberg classifies regulatory approaches into four different categories, as shown in Table 6. Approaches vary along a gradient of opinion about whether or not the process of biotechnology is judged to be inherently risky or not; the gradient reflects basic principles about the product-versus-process debate.

Table 6. Biosafety Policy Options

Promotional	Permissive	Precautionary	Preventive
No careful screening, only token screening, or approval based on approvals in other countries	Case-by-case screening for demonstrated risk, based on intended use of product	Case-by-case screening for scientific uncertainties as well as demonstrated risks, owing to the novelty of the GM process	No careful case-by-case screening, biosafety risk assumed because of GM process

Source: Paarlberg, *The Politics of Precaution*.

A situational analysis of current regulatory policy, when considered against Paarlberg's regulatory policy options, for each of the three countries considered here, Kenya, Uganda, and Tanzania, is potentially illuminating. Their position on this regulatory continuum has been determined largely by a series of events, factors, and influences that shaped the evolution of regulatory history in the countries and that ultimately affected the composition of the regulatory policy that followed.

Kenya

Biosafety History, Context, and R&D Status

For nearly two decades, Kenya has been a leading vocal advocate among African countries for the use of modern biotechnology to address the continent's food-security challenges. This support has emanated from all aspects of Kenyan society and has

[30] Robert Paarlberg, *The Politics of Precaution: Genetically Modified Crops in Developing Countries* (Baltimore, MD: IFPRI/Johns Hopkins University Press, 2001).
[31] Ibid.

included a high degree of political will and government commitment, as compared to many African countries. In 1980, Kenya's Science and Technology Act established the National Science and Technology Council as the country's lead science authority with jurisdiction over its progress in biotechnology.[32] In 1990 progress continued as Kenya hosted one of its first national conferences on agriculture biotechnology.

Further support for biotechnology was evident with the 1991 launch of one of the first agriculture biotechnology public-private partnerships on the continent. This innovative partnership, which was funded by the U.S. Agency for International Development (USAID) and focused on the development of virus-resistant GM sweet potatoes, involved a research and technology transfer relationship between the Monsanto Company and the Kenya Agriculture Research Institute (KARI).[33] It was executed through the placement of a Kenyan postdoctoral fellow at the company's headquarters in St. Louis, Missouri, to conduct the actual research on locally important Kenyan varieties. Although the research had technical challenges, since this landmark activity, capacity for biotechnology R&D in Kenya continued to evolve. Currently, biotechnology research in Kenya includes tissue culture applications, marker-assisted selection, genetic engineering, and other advanced fields such as genomics and bioinformatics. Numerous scientists in public and private R&D institutions are engaged in advanced biotechnology R&D work.

KARI remains a leading national public research institution working on biotechnology and has established a center dedicated to biotechnology. It has a biosafety level II greenhouse and several laboratories. Efforts to strengthen and expand the human-resource base in biotechnology have been undertaken. Currently all public universities in Kenya are offering bachelors and postgraduate degrees in biotechnology and biosafety. Even several universities have cutting-edge facilities and research programs—an unusual occurrence among African universities. For instance, the University of Nairobi has the Center for Biotechnology and Bioinformatics (CEBIB) and Kenyatta University has a modern plant transformation facility and biosafety level II greenhouse. Kenya is also home for the Biosciences Eastern and Central Africa (BecA) regional hub located on the International Livestock Research Institute (ILRI) campus.[34] BecA has state-of-the-art facilities and laboratories for biosciences R&D in areas of crops and livestock.

GM crops are in the development pipeline, often through public-private partnerships formed under the auspices of the African Agriculture Technology Foundations (AATF), which is headquartered in Nairobi.[35] GM food crops under development include maize, cassava, and sorghum. The main traits being evaluated in current biosafety trials for these crops include insect and disease resistance, drought tolerance, and bio-fortification. GM cotton is also approaching commercial release. The sum of these efforts points to a nearly 25-year history of Kenyan involvement in modern biotechnology. Until recently, this has been a driving factor in the tone and technical content of the country's regulatory policy.

---

[32] National Council for Law Reporting, Laws of Kenya, "The Science and Technology Act: Chapter 250," 2009,www.kenyalaw.org/Downloads/Acts/SCIENCE%20AND%20TECHNOLOGY%20ACT(Cap.%20250).pdf.
[33] Author's personal communication.
[34] Biosciences Eastern and Central Africa, International Livestock Research Institute Hub, http://hub.africabiosciences.org/.
[35] African Agricultural Technology Foundation, "Who We Are," http://aatf-africa.org/.

Biosafety Policy Overview

Kenya's biosafety policy was developed against this backdrop of steady R&D progress. The enabling policy environment and legal framework was, in the author's opinion, a direct result of the early practical experience with the technology. Until recently, the policy has worked effectively in support of early-stage R&D activities and it has taken a science-based approach to decisionmaking.

Between 1995 and 1998, the National Council for Science and Technology (NCST) process (via ministerial decree) established a National Biosafety Committee (NBC) as its technical biosafety arm and issued working biosafety guidelines and regulations. Support for these efforts, as for many African countries, was initially provided by UNEP-GEF and was subsequently augmented by bilateral donors, most notably USAID. These actions positioned Kenya as an early leader, lagging only behind South Africa, in the development of a national, functional biosafety system. However, the system had recognized limitations related to the legal enforcement authority of the NBC and the lack of provisions governing commercial release and import/export/transit procedures and specifications. In 2000 Kenya became the first country to sign the Cartagena Protocol on Biosafety (CPB) and in 2003 the working guidelines were revised to ensure alignment with the Protocol's minimum requirements. During this time, momentum for the development of a biosafety law, to correct the deficiencies of the existing system, was building with the process beginning in earnest in 2002. A national biotechnology policy was approved in 2006.[36] The policy was a galvanizing document for pro-biotechnology interests in the country as it affirmed high-level government support for the technology. With numerous confined field trials underway (see Table 7) and plans for the first product commercialization (of Bt cotton) moving forward, stakeholder coalitions were formed to support the enactment of a formal Biosafety Law. After three changes of parliament and two general elections, the National Biosafety Act was passed and formally enacted in 2009.[37]

In 2010, in accordance with the new act, a National Biosafety Authority (NBA), with a board and operational secretariat, was created. Regulations on contained use, environmental release, import/export, and transit were formulated and published in 2011.[38] Eight regulatory agencies were designated to support the NBA's decisionmaking mandate. Technical guidelines and manuals to enforce compliance in conducting CFTs and other biosafety requirements have also been developed.

For Kenya, biosafety progress had advanced mostly under a climate of continued high-level political will and stakeholder support. In addition to the technical progress documented above, other evidence supports this assertion. In September 2008, as mandated by the National Biosafety Act, the government launched a five-year National Biotechnology Awareness Strategy (BioAWARE-Kenya) as a mechanism to improve public understanding and awareness of biotechnology.[39] The president has

[36] http://en.biosafetyscanner.org/pdf/doc/350_allegato.pdf.
[37] http://africasciencenews.org/asns/index.php/News/Latest/Kenya-finally-approves-Biosafety-law.html.
[38] National Biosafety Authority, "Environmental Release Regulations," www.biosafetykenya.go.ke/index.php?option=com_content&view=category&layout=blog&id=84&Itemid =498.
[39] International Service for the Acquisition of Agri-Biotech Applications, Crop Biotech Update, "Kenya Launches National Biotechnology Awareness Strategy," www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=3215.

Table 7. GM Field Trials in Kenya

Crop	Trait	Institutions Involved	Current Status
Maize	Drought tolerance (WEMA)	AATF, CIMMYT, KARI, Monsanto	CFT, currently in fourth season
	Insect resistance	AATF, CIMMYT, KARI, Monsanto	CFT application approved by NBA in 2012; first season completed May 2013
Cotton	Insect resistance	KARI, Monsanto	CFT phase completed; application for general release being prepared in anticipation of commercial release in 2015
Cassava	Virus resistance (mosaic disease, brown streak)	KARI, DDPSC	CFT, second season
	Enhanced micronutrient levels (vitamin A)	KARI, DDPSC, IITA, CIAT	CFT, second season
Sweet potato	Virus resistance	KARI, DDPSC	CFT, first season
	Weevil resistance	CIP, Kenyatta University	Lab and GH transformation approved by NBA in 2011; ongoing
Sorghum	Enhanced micronutrient levels	Africa Harvest, Pioneer Hi-bred, DuPont business, KARI	CFT, second season
Pigeon pea	Insect resistance	Kenyatta University, ICRISAT	Lab and GH transformation approved by NBA in 2011; ongoing

Note: WEMA, Water Efficient Maize for Africa; AATF, African Agriculture Technology Foundation; CIMMYT, International Maize and Wheat Improvement Center; KARI, Kenya Agriculture Research Institute; DDPSC, Donald Danforth Plant Science Center; IITA, International Institute of Tropical Agriculture; CIP, International Potato Center; ICRISAT, International Crops Research Institute for the Semi-Arid Tropics; CFT, Confined Field Trial; NBA, National Biosafety Authority.

Source: Global Status of commercialized Biotech/GM Crops: 2012. ISAAA Brief 44, 2012.

presided over several high-profile biotechnology events (e.g., the opening of biotechnology and biosafety facilities at KARI and BECA-ILRI biosciences hub). The prime minister has made numerous statements in support of the technology, and Minister William Ruto was a vocal African proponent at the 2010 Biosafety Protocol Conference of Parties in Nagoya, Japan.[40] Finally, in July 2011 in the midst of controversy, the cabinet approved importation of GM maize to mitigate the precarious food insecurity situation in Kenya.[41] All point to a history of consistent political support for biotechnology in Kenya with expected positive ramifications on biosafety

[40] Federal Ministry of Education and Research, "UN Conference Adopts International Liability Rules for Ecological Damage Resulting from Genetically Modified Organisms," http://dev.gmo-safety.eu/news/1233.conference-adopts-international-liability-rules-ecological-damage-resulting-genetically-modified-organisms.html.

[41] Daily Nation, "Cabinet Clears GM Maize Imports," July 14, 2011, www.nation.co.ke/News/Cabinet+clears+GM+maize+imports+/-/1056/1201488/-/14qeok5/-/index.html.

policy. Unfortunately the current situation, as will be discussed later, represents a departure from the past history of strong government support.

Uganda

Biosafety History, Context, and R&D Status

The trajectory for biosafety policy progress in Uganda is similar to that of neighboring Kenya. Like Kenya, Uganda was also a recipient of early UNEP-Global Environment Facility (GEF) capacity-building support, which was implemented from 1997 to 1998 and which catalyzed the beginnings of a national biosafety framework.[42] Influenced by the Biosafety Protocol negotiations, the focal point for the Protocol was established within Uganda's Ministry of Environment, while a practical arm for decisionmaking was housed under the Uganda National Council for Science and Technology (UNCST) under the Ministry of Finance. The country ratified the Biosafety Protocol in 2001 but guidelines to enable the first confined field trials were not promulgated until 2006, with the first field trial to evaluate disease-resistant GM banana commencing shortly thereafter, in 2007.[43] Subsequently, in April 2008, Uganda's National Biotechnology and Biosafety Policy was endorsed by the Cabinet and approved, which in turn led to the development of a draft biosafety bill that same year.[44] A general observation in comparing Kenya and Uganda timelines reveals Uganda lagging only one to two years behind Kenya in key biosafety policy accomplishments.

Perhaps even more so than Kenya, early achievements in Uganda's biosafety policy were facilitated by practical experience with a number of GM products coupled to steady progress, over the years, in both human and institutional capacity building in biotechnology. Approximately 50 people trained at the PhD level and 30 at the master's level have gained sufficient knowledge and skills to conduct biotech R&D in a variety of existing facilities, and three public universities have now established biotechnology-training programs at undergraduate levels, with over 100 students having graduated.[45] Research capacity exists mainly in Uganda's public institutions, with the National Agricultural Research System hosting two advanced laboratories and over 10 moderately equipped facilities. A few private commercial tissue-culture laboratories (focused on bananas, coffee, and pineapples) were also formed. As shown in Table 8, research is ongoing for five crops of key importance for food and income security in the country, including maize, cotton, bananas, sweet potatoes, and cassava. Tissue-culture technologies have been applied for bananas and coffee, while GM technologies are being evaluated through field tests for all mentioned crops except sweet potato (which is still in greenhouse containment). This high level of activity GM activity and field tests identifies Uganda as one of the leading countries in Africa with practical biosafety experience.

---

[42] Theresa Sengooba et al., *Analysis of the Biosafety System in Uganda: Regulatory Framework, Policies and Procedures*, February 2005, http://pbs.ifpri.info/files/2011/09/pbsugandacountrystudy.pdf.
[43] James A. Okeno, Jeffrey D. Wolt, Manjit K. Misra, and Lulu Rodriquez, "Africa's Inevitable Walk to Genetically Modified (GM) Crops: Opportunities and Challenges for Commercialization," *New Biotechnology* 30, no. 2 (January 2013).
[44] Ibid.
[45] Unpublished data, International Food Policy Research Institute.

Table 8. Pipeline Crops under Trial in Uganda

Crop	Importance	Trait under Testing	Stage	Partners
Maize	Food and income	Drought tolerance	CFT, second season	NARO, AATF
Bananas	Food	Bacterial wilt resistance	CFT	NARO, AATF, IITA
Bananas		Nutrition enhancement (Fe and Pro-vitamin A)	CFT	NARO, QUT
Cassava	Food	Virus resistance	CFT, second season	NARO, Danforth Plant Science Center, IITA,
Cotton	Income	Bollworm resistance and herbicide tolerance	CFT, third season	NARO
Sweet potatoes	Food	Sweet potato weevil resistance	Contained trials	NARO, CIP

Note: NARO, National Agriculture Research Organization; AATF, African Agriculture Technology Foundation; IITA, International Institute of Tropical Agriculture; CIP, International Potato Center.

Source: D. Wafula and T. Sengooba, personal communication; note: funding partners not shown.

Biosafety Policy Overview

Uganda's biosafety policy framework benefited from bilateral donor support in addition to that provided by UNEP-GEF. The USAID-funded Program for Biosafety Systems (PBS) project has been active in Uganda since 2004 and has been instrumental in strengthening the capacity of the NBC and Institutional Biosafety Committees (IBCs) since its inception to the present. As a result, scientists and regulatory authorities on the National Biosafety Committee (NBC) have the competency to evaluate field trial applications and to evaluate trial results as part of a science-based decisionmaking process for risk assessment. Biosafety inspectors for GM field trials have also been trained in assessing and monitoring regulatory compliance. The Program for Biosafety Systems (PBS) also assisted in the development of several manuals to guide field-trial research at the various stages of product development.

High-level political support has also been evident in Uganda throughout this time, although perhaps not with the same consistency and visibility shown by Kenya over a similar timeframe. For example, in 2003 President Museveni, while opening the National Biotechnology Center at Kawanda, proclaimed his support for biotechnology provided that safety concerns were addressed.[46] He and various ministers have made numerous endorsements since then.

Yet, despite the obvious political support, many GM field trials, movement of GM cotton toward commercial release, and a comparatively high level of R&D activity, the period from 2008 to 2010 marked a time of "legislative limbo" for the biosafety process. The reason for this was, in part, due to the lack of a well-organized coalition (similar to what existed in Kenya) that could drive progress of the Biosafety Bill from various constituent interests. After a meeting of stakeholders in late 2010, a path

[46] Gerald Tenywa, "President Museveni Okays Genetically Modified Organisms (GMO) Foods," August 25, 2003, www.mail-archive.com/ugandanet@kym.net/msg06483.html.

forward to advance the bill was defined and the need for an organized coalition was recognized. In April 2011 the Uganda Biotechnology and Biosafety Consortium (UBBC) was formed to "bring together stakeholders around a common cause of biotech science advancement."[47] It began an active education campaign to increase awareness about the pending Biosafety Bill. Since then, progress (as shown in Table 9) has been steady, with anticipated passage of the bill expected in late 2013 or early 2014.

Table 9. Timeline of Progress on Uganda's Biosafety Bill

Action	Date	Outcome
Legal advice to formulate draft bill; comparative analysis to other African biosafety policies	2003–2004; draft developed in 2008	Working draft bill developed as the basis of new legislation
Series of consultative stakeholder workshops	2008	Stakeholder awareness developed about bill and provisions
Workshop of stakeholders to identify constraints to movement of draft bill	2010	Strategy developed to further inform stakeholders and public about the bill and further progress
UBBC formed	2011	Organized coalition of biotechnology stakeholders
Education workshop for key implementing agencies	2012	Key agencies aware of bill provisions and their regulatory roles
UBBC meetings and outreach activities	2011 to present	Principles of bill developed (2012); Bill gazette and introduced to Parliament by Science and Technology committee (January 2013); Public comments incorporated and new draft developed (2012–2013); Second Parliament reading anticipated (late 2013)

Source: Program for Biosafety Systems, International Food Policy Research Institute.

Tanzania

Biosafety History, Context, and R&D Status

The biosafety situation in Tanzania represents a marked contrast to what has developed and exists currently in both Kenya and Uganda. First, actual policy development began much later. Tanzania did not ratify the Biosafety Protocol until 2003,[48] which was several years later than either Kenya or Uganda. While the UNEP/Global Environment Facility (GEF) project began providing assistance in 2003, unlike Kenya and Uganda, Tanzania did not benefit from the prolonged presence and advice of other biosafety service providers until much later in its policy development process. As a result, the eventual biosafety policy was largely dominated by negotiation of the Protocol and the African Model Law.

The legal framework for addressing biosafety issues was not articulated until the passage of the Environment Management Act of 2004, which provided a legal and

[47] Uganda Biotechnology and Biosafety Consortium (UBBC), "Welcome to UBBC," http://ubbconsortium.org/.
[48] Secretariat of the Convention on Biological Diversity, "Cartagena Protocol on Biosafety Ratification List," November 12, 2013, www.cbd.int/doc/lists/cpb-ratifications.pdf.

institutional mechanism for the regulation of GMOs.[49] This Act identified the Division of Environment in the Vice President's Office as the national biosafety focal point. In 2007, a National Biosafety Framework was finalized and in 2008 a National Biosafety Committee, also reporting to the Ministry of Environment, was given regulatory authority for GMOs.[50] Other institutions were given a supporting role. For example, a National Biotechnology Advisory Committee was established under the Ministry of Science and Technology to provide technical advice to the NBC. Nearly five years elapsed before biosafety-implementing regulations deriving from the Act were published (in 2009). The regulations identified procedures for field testing, risk assessment, release and commercialization of GMOs, and the parameters and actions related to liability for any damage caused by GMOs.

Tanzania's R&D capacity in biotechnology is also weaker than that of Kenya and Uganda. Tissue-culture applications dominate biotechnology R&D work in Tanzania, while research on GM technology is limited. The best capacity for more sophisticated biotechnology research exists at the Mikocheni Agriculture Research Institute, which has well-established capacity for tissue culture and micro propagation, plant disease diagnosis, DNA finger printing, and molecular-marker-assisted selection.[51] More limited capability exists at other institutes (Uyole, Horti Tengeru, Ukiriguru, Mlingano) and only a few universities (Sokoine University of Agriculture, and the Department of Botany at the University of Dar es Salaam).[52]

Biosafety Policy Overview

Strong political support for biotechnology is evident in its written policies. For example, the National Biotechnology Development Policy's mission statement commends the policy as a means to "create a strong infrastructure both for research, development and commercialization in biotechnology so as to ensure a steady flow of bio-products, bioprocesses and new biotechnologies for social and economic development of Tanzania."[53] However, the country's legal framework, in comparison to Kenya and Uganda, is prohibitive and preventive (by Paarlberg's definition and concurred by other internal and external stakeholders). Strict liability and redress provisions in the Act and accompanying regulations are a mainstay of Tanzania's biosafety policy and carry imposing penalties and fines for alleged perpetrators. Under this provision, whoever introduces the GMO would be automatically liable for any damage caused regardless of intent or circumstance. The approach to risk assessment is also problematic; it is not aligned with the product development cycle or in alignment with the currently accepted "best practices" of key adopting countries.

As a result of the current policy, internal and external stakeholders alike have argued that Tanzania's regulatory framework is a hindrance to biotechnology advancement in the country. The practical manifestation of this is a stalled approval process. An approval to conduct a confined field trial for a GM drought-tolerant maize variety,

[49] The Environmental Management Act 2004, www.dlist-asclme.org/sites/default/files/doclib/TZ%20EMA%202004.pdf.
[50] Ibid.
[51] Unpublished data, International Food Policy Research Institute.
[52] Ibid.
[53] United Republic of Tanzania, Ministry of Communication, Science and Technology, *National Biotechnology Policy*, 2010, www.tzonline.org/pdf/Biotecchnology_Policy_WEBB1.pdf.

whose development is funded by the Bill & Melinda Gates Foundation with technology donated from Monsanto, has not advanced due to the reluctance of developers and donors, who remain concerned about the strict liability provisions in the biosafety framework.[54] Accordingly, the lack of progress on this high-profile public-private partnership project has raised the level of concern to higher political channels. As a result, the government recently announced its intention to review the current regulatory framework.[55] This review and resulting decision is pending. The outcome of the decision is likely to have significant impact not only on Tanzania but, from a trade perspective, on the neighboring countries of Kenya and Uganda as well.

[54] TradeMark Southern Africa, "Pressure Mounts on Government to Review Biotech Policy," March 11, 2011, www.trademarksa.org/news/pressure-mounts-govt-review-biotech-policy.
[55] Orton Kiishweko, "Tanzania: Debate on Safety of GMOs Rages On," *Tanzania Daily News*, August 25, 2013, http://allafrica.com/stories/201308250158.html; author's personal communication.

5 | The Evolving Landscape: Attitudes, Actions, and Recent Trends

Issues and Impacts

Table 10 shows an annotated list of important biosafety provisions and their relative status in each of the three countries. Of the three, Kenya and Uganda are quite similar, while the policy situation in Tanzania differs in key areas, is more regressive, and represents a departure from an evidence-based system of regulation.

Table 10. Comparative Table of Key Biosafety Provisions

Provision	Kenya	Tanzania	Uganda
Lead Ministry	Science &Technology	Environment/VP Office	Finance
Precautionary Principle	No	Yes	No
Product Stage Risk Assessment	Yes	No	Yes
Mandatory Labeling	Yes	Yes	Not Specified
Liability and Redress	Yes, fault based	Strict	Fault based
Socioeconomics	Yes, not specified	Yes, with details	Yes, not specified
Food, Feed Safety	Yes	Yes	Yes
Products Thereof	No	Yes	No
Import Export	Yes	Yes	Yes
Public Awareness	Yes	Yes	Yes

As the chronological analysis for each country has revealed, the evolution of regulatory policy among these three countries resulted from a number of factors and historical realities. Chief among these was whether or not early practical experience with the technology was available to drive a science-based, results-oriented approach to biosafety. The ability to showcase the technology in action, through visits to field sites by political officials, media, and the public, has been instrumental in driving biosafety policy in Kenya and Uganda, which was rooted in practical “know how.” The “hands-on” experience by members of the scientific community in Kenya and Uganda also provided local credibility for the technology and resulted in better organization among scientists in support of the technology and an enabling biosafety policy. Where such practical experience has been lacking or was less robust (as in the case of Tanzania), a more risk-oriented policy was enacted.

The differential influence of capacity-building programs has also been a factor in the policies that emerged among these three countries. Although the UNEP-GEF program, which focused its activities on environment ministries and favored a process-based, risk-oriented training approach, was an early participant in each country, subsequent expertise provided to Kenya and Uganda (primarily through USAID, other bilateral programs, or foundation-funded initiatives) resulted in greater inter-ministerial influence, a focus on benefits, and an emphasis on product-based risk assessment. The Ministry of Environment continues to be the focal point for Tanzania’s biosafety

authority, while regulatory authority in Kenya and Uganda rests in the Ministries of Science and Technology and Finance, respectively. Furthermore, in Kenya and Uganda, the perspectives of GM-adopting countries and their donor agencies have had a mitigating effect on the influence of the Biosafety Protocol and the African Model Law. As a result, onerous provisions related to strict liability and socioeconomics are absent from Kenya and Uganda's policy, while highly prevalent and currently problematic in Tanzania's policy.

The relative experiences of the three countries also underscore the importance of organized and broad-based stakeholder support to drive and enact rational policy. Such support was instrumental in the passage of Kenya's biosafety bill and has been an important factor in the current progress of legislation in Uganda. Pro-GM advocates in Tanzania, by contrast, lack a formal mechanism to engage on policy reform and are operating via a more ad hoc approach to effect regulatory change.

Increased Activism and Political Will

Finally, political will has been evident to varying degrees in all three countries but has been important to the eventual policy result and continues to play an impactful role. It was a necessary component in the passage of Kenya's National Biosafety Act, will be critical for the passage of Uganda's biosafety law, and will ultimately determine the outcome of the Tanzania's reconsideration of its policy. However, it is a factor that cannot be taken for granted and is subject to change, as evidence by the developing situation in Kenya.

Despite strong political support, which led to a science-based and enabling biosafety policy, the current regulatory situation in Kenya can be described as "concerning" at best, with several recent developments pointing to a lack of political fidelity and "back sliding" of regulatory progress. Political change resulting from the recent election process and escalating activism by anti-GM forces has led to increasing political interference in regulatory decisionmaking. Several recent decisions are worth noting.

Despite broad stakeholder consensus on Kenya's labeling provisions, guidelines were issued that did not reflect the consensus position. The labeling guidelines mandate a 1 percent threshold for all packaged and unpackaged foods and lack guidance with respect to detection methods and parameters.[56] The current guideline is considered unworkable and unenforceable by many stakeholders and regulatory practitioners

Similarly, a second journal report by Seralini et al.,[57] although widely discredited by the global scientific community, led to an impromptu pronouncement of safety concerns by the minister of health during a cabinet meeting. This was followed by a subsequent cabinet ban of GMOs that was issued in November 2012.[58] Currently, attempts are underway to reverse this ban by several key parliamentary committees

[56] National Biosafety Authority, "Labeling Regulations," www.biosafetykenya.go.ke/index.php?option=com_content&view=article&id=163:biosafety-labeling-regulations-2012&catid=84&Itemid=498.
[57] Gilles-Eric Seralini et al., "Long term Toxicity of a Roundup Herbicide and a Roundup Tolerant Genetically Modified Maize," *Food and Chemical Toxicology* 50, no. 11 (November 2012): 4221–31.
[58] Emily Willingham, "What You Need to Know about GM Foods Is Half the Story," *Forbes*, December 7, 2012, www.forbes.com/sites/emilywillingham/2012/12/07/what-you-need-to-know-about-gm-foods-is-half-the-story/.

(health, agriculture, and science and technology) on the premise of illegality since the cabinet decree was not published in the *Kenya Gazette*. However, the ban remains in effect.

Finally, a revision of the Kenya Biosafety Act is under consideration to bring it into alignment with the new constitution. Some provisions contemplated in the new Act are potentially problematic. For example, GMOs are characterized within a broad scope of hazardous biological materials and infectious agents, thereby ignoring a track record of almost two decades of safe use.

This reversal of political sentiment, in a country where regulatory policy in the past was driven by strong political support, is having a negative effect on biotechnology progress in the country and the region. Commercialization plans for Bt cotton are uncertain, the status of other products in the regulatory process remains unclear, and Kenya's reputation as a biosafety leader in the region is becoming precarious and could potentially influence the pending course of events in Uganda and Tanzania.

Impacts of Regional Efforts on Country Policies

In addition to political will, the pursuit of harmonized regional biosafety policies can potentially alter the course of regulatory policy in East Africa with either positive or negative consequences. Regulatory harmonization is listed as a key recommendation in the AU/New Partnership for Africa's Development (NEPAD) high-level policy report on biotechnology.[59] Most experts agree that harmonization efforts could contribute to greater regulatory efficiency for biotechnology decisionmaking overall, but will likely not substitute for the development of strong national systems. Rather, they are intended as a means to promote trade and commerce and to minimize any potential negative trade effects that might result from cross border flows of GM products and technologies among countries with differing biosafety status and policies.

In recent years, a number of regulatory harmonization efforts have been launched in Africa. These efforts have been designed to provide uniform rules and procedures that would allow for regional trade in GMOs and to simplify the approval processes for GMOs by eliminating the need for every African country to establish de novo national biosafety regulatory systems. Harmonization activities have raised the profile of biosafety issues at regional and national levels throughout the continent and have contributed to biosafety capacity building.

The following is a summary of African regional biosafety initiatives currently underway that are relevant to Kenya, Uganda, and Tanzania. Some initiatives have progressed further than others but no initiative has progressed to a completed product. Even without a consensus document that is implementable, provisions established in the harmonization process may still offer models of policies that could be adopted by individual countries at the national level.

[59] Juma and Serageldin, *Freedom to Innovate*.

Common Market for Eastern and Southern Africa

Beginning in 2003, the Common Market of Eastern and Southern Africa (COMESA) ministers of agriculture endorsed the Regional Approach to Biotechnology and Biosafety Policy in Eastern & Southern Africa (RABESA) project with a goal of establishing mechanisms for managing biosafety issues at the regional level. Both Kenya and Uganda are COMESA member countries. The key partner institutions supporting COMESA in the implementation of RABESA have been the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), the Program for Biosafety Systems (PBS), and the International Service for the Acquisition of Agri-biotech Applications (ISAAA). In 2009, the Alliance for Commodity Trade in Eastern and Southern Africa (ACTESA) was created as a specialized Agency of COMESA, and in 2010 this entity became the focal point for the harmonization activity.

The COMESA approach, from the outset, was consultative and limited in scope. Three areas for a regional harmonized approach on biosafety were identified: (1) the commercial planting of GM crops, (2) trade in GM products, and (3) emergency food aid with GM content.[60] Regional experts and country representatives met to draft policies and guidelines for each of those three areas. The commercial planting guideline established a regional committee to carry out a regional risk assessment for cultivated GMOs that can then be used by individual national biosafety regulators to make approval decisions. The trade in GM products policy identifies how different GM products should be treated by COMESA countries depending on whether they originated from a country within or outside the COMESA group of nations. Finally, the emergency food aid portion of the guidelines articulates procedures to be used by COMESA countries to review and approve emergency food aid that may contain GM content coming from both COMESA and non-COMESA countries.

A COMESA ministerial meeting in Sudan in 2007 endorsed the drafting of regional biosafety policies and guidelines around the three areas of focus identified by stakeholders. The ministers also recommended the formation of a Panel of Biotechnology and Biosafety Experts to serve as a technical advisory body of COMESA; this took effect in December 2008. The drafting of regional biosafety policies and guidelines started in 2008. The documents were subjected to several rounds of technical review. A regional workshop of COMESA member states was held in Nairobi in April 2010 to discuss and review the document.

The third meeting of COMESA ministers of agriculture and environment and natural resources, held in July 2010 in Zambia, resolved that national consultative workshops on the three draft regional biosafety policies and guidelines should be conducted in all of the COMESA countries. The draft biosafety guidelines were presented to most COMESA countries in consultative meetings for their comments and endorsement in 2010 and 2011. By July 2011, 14 workshops had been held in Uganda, Rwanda, Ethiopia, Egypt, Sudan, Swaziland, Kenya, Zimbabwe, Seychelles, Burundi, Zambia, Democratic Republic of Congo, Eritrea, and Malawi. A final consolidated document was prepared and was recently endorsed at the fifth Joint Meeting of Ministers of Agriculture, Environment and Natural Resources in September 2013, marking a major

[60] International Service for the Acquisition of Agri-biotech Applications, "COMESA in Pursuit of Regional Harmonization of Biosafety Policy," www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=5914.

achievement in the process.[61] Upon final approval, the guideline will offer a more consistent path for regulatory approval of GMOs in COMESA member countries and will provide a basis for uniform treatment for regional trade involving GMOs, both with seed and grain (including emergency food aid). Both Kenya and Uganda have been active participants and interested stakeholders in the COMESA process.

Southern Africa Development Community

A 2003 Council of Minister's directive of the South Africa Development Community (SADC) established an advisory Committee on Biotechnology and Biosafety (SACBB) of the 15 representative countries. Of the three countries considered in this report, only Tanzania is a SADC member. The focus of the committee was to consider a regional harmonization effort focused on policies related to the handling of food aid, biosafety policies and regulations, capacity building, and public awareness.[62] Recommendations developed for biosafety were highly precautionary, and included language derived from the AU Model Law. The effort has faltered in recent years, plagued by widely polarized viewpoints of member states and an inability to achieve consensus. To date, the initiative still lacks traction and is not a current factor on Tanzania's regulatory situation.

East African Community

The East African Legislative Assembly (EALA) of the East African Community (EAC) recently announced plans to develop a harmonized law that would supersede member states' biosafety legislation.[63] Kenya, Tanzania, and Uganda are members of the EAC but they have varying status with respect to their biosafety situation and are at variance on some key issues. The course of this initiative is currently uncertain. It has the potential to move the policy of Tanzania into closer alignment with the policies of Kenya and Uganda (which are more similar in intent and specific provisions). Alternatively, it could give rise to renewed debate and influence by anti-GM activists that may affect the national policy situation in both Kenya and Uganda.

Global Acceptance and South-South Collaboration

While current regulatory status in Kenya, Uganda, and Tanzania has been largely defined by the past—the historical relationships to the Biosafety Protocol process, trade with Europe, and policy recommendations developed under various capacity-building initiatives—future policy considerations will likely by driven by the biosafety and biotechnology status of other emerging economies (Brazil, Argentina, China, India, and Indonesia, for example). Most of these countries have already commercialized several GM crops and are developing others that may have particular relevance to East Africa (rice, beans, sugarcane, and bananas). They are developing regulatory policies that dovetail with their R&D interests. Many are investing in Africa

[61] International Service for the Acquisition of Agri-biotech Applications, "COMESA Undertakes National Consultations on Draft Biosafety Guidelines," www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=6720.
[62] Margaret Karembu, Faith Nguthi. and Ismail Abdel-Hamid, *Biotech Crops in Africa: The Final Frontier* (Nairobi: ISAAA AfriCenter, 2009).
[63] The People in Farming, "Common EAC Law on GMO Coming Soon," September 12, 2013, www.thepeople.co.ke/20394/common-eac-law-gmo-coming-soon/.

or represent new avenues of global trade for African countries and some, like Brazil and China, are pursuing joint agriculture R&D partnerships and donor relationships on the continent. These “south-south” opportunities offer a new and interesting dynamic to build and fine-tune regulatory policy outside the boundaries of Africa’s traditional partners and donors.

6 | Conclusions and Recommendations

The development of biotechnology regulatory policy in Africa is a complicated undertaking. It is compromised by the lack of scientific capacity, historical trade relationships with Europe, and the pervasive influence of the Cartagena Protocol and African Model Law that served as de facto regulatory frameworks early in the process. Nevertheless, a situational analysis of the biosafety policy in Kenya, Uganda, and Tanzania offers a number of insights for biotechnology adoption in Africa.

Of chief importance is the need to reposition the role of the Cartagena Protocol and to reconcile the AU African Model Law with a growing number of progressive national regulatory policies. By virtue of its encompassing status as an African-wide example, the AU Model Law exerts significant influence on African governments and is particularly influential in cases where a national policy vacuum exists. Some current provisions of the law are at odds with global best practices and biotechnology's 20-year safety record. Expertise should be provided to assist AU/New Partnership for Africa's Development (NEPAD) in the revision of the model law in accord with regulatory "best practice" and global norms.

Similarly, the regulatory role of the Cartagena Protocol should be grounded in an appropriate national context and repositioned in light of other regulatory standards and requirements that are needed to address the cross-cutting nature of biotechnology applications. To this end, expanded outreach and education to ministries beyond environment and agriculture is needed to ensure that the full potential of biotechnology is addressed from a position of strategic, national priorities and interests.

Long-term, science-based regulatory capacity has provided beneficial impacts for rational decisionmaking in Kenya and Uganda. Such efforts should be supported and expanded, as experience has shown that even enabling policy climates are subject to negative influences and misinformed political interference.

Experience, in the case of Kenya and Uganda, has demonstrated that policy is best formulated from a position of practical experience with the technology. While interesting R&D and technology transfer initiatives exist (e.g., Water Efficient Maize for Africa and bio-fortified sorghum), they are too few to provide an effective policy catalyst in the East African region, and especially continent-wide. Additional support for such initiatives will help to ensure the development of regulatory policies that are grounded in an appreciation for product-development principles and are tested for functional efficiencies.

Adoption of biotechnology products, robust R&D pipelines, and functional regulatory systems in many newly emerging economies (Brazil, China, Argentina) offer another example for African governments, whose trade concerns and national interests are becoming increasingly tied to these new investors and donors. Efforts to establish "south-south" regulatory training initiatives should be pursued, in addition to capacity-building initiatives with more traditional partners.

Finally, harmonization efforts are underway in Africa, some of which may directly impact the three focus countries of this report. Real prospects for regional trade of GM products exist and could be better facilitated by technically sound, harmonized regional biosafety policies. However, caution should be exercised; harmonization is a complex endeavor and could easily result in a less-than-desirable outcome as the process attempts to reconcile regional efficiencies with national goals and interests. In addition, the current discrepancies in regulatory policies, even between Kenya, Uganda, and Tanzania, argue against a policy that is expansive and binding. An advisory approach, such as that undertaken by the Common Market of Eastern and Southern Africa (COMESA), may offer the best alternative in the near term.

About the Author

Judith A. Chambers holds a PhD in molecular biology from the University of Pennsylvania, where she studied animal models for retrovirus gene action. She now leads the Program for Biosafety Systems at the International Food Policy Research Institute in supporting partner countries in Africa and Asia in the responsible development and use of biotechnology. The program brings an integrated approach to the application of biotechnology that helps countries make informed decisions about biosafety. Dr. Chambers completed her postdoctoral study at Ecogen, Inc., where she focused on the molecular analysis of Bt genes for plant pesticide applications and the molecular characterization of CryIF Bt toxin gene and protein (1987–1989). She has served as a senior adviser for biotechnology and government relations at the U.S. Agency for International Development (USAID) and codeveloped the first USAID public-private-sector program on agricultural biotechnology, which focused on smallholder farmers in developing countries, the management of biotechnology and biosafety issues for various public- and private-sector organizations, and the development of programs that focus on an integrated approach to biotechnology.

CSIS | CENTER FOR STRATEGIC & INTERNATIONAL STUDIES

1616 Rhode Island Avenue NW | Washington, DC 20036
t. (202) 887-0200 | f. (202) 775-3199 | www.csis.org

ROWMAN & LITTLEFIELD PUBLISHERS, INC.
Lanham • Boulder • New York • Toronto • Plymouth, UK

4501 Forbes Boulevard, Lanham, MD 20706
t. (800) 462-6420 | f. (301) 429-5749 | www.rowman.com