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BEYOND BIOSAFETY REGULATION: IMPLICATIONS FOR PUTTING BIOTECHNOLOGY RESEARCH INTO USE IN A DEVELOPING COUNTRY CONTEXT

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Abstract

The objective of biosafety regulation is to enhance safe and responsible use of new biotechnologies, thus optimise benefits and reduce risks. This seemingly narrow focus of regulation for development is challenged by the need to look at factors that drive innovation in totality. To this end, all aspects of biosafety regulation implementation that could hamper the process of putting biotechnology research into use need to be given critical thought. Using *Bt* Cotton as illustration, this paper explores the dynamics involved in the implementation of regulations associated with biotechnology in a developing country context towards putting research into use. It seeks to bring to the limelight the underlying issues that complicate the process of identifying and building pathways to sustainability in complex, dynamic, social-ecological-technological systems. It finds that addressing the regulatory issues is a prerequisite to biotechnology development but does not guarantee uptake of products for development. The paper concludes by suggesting an integrated approach to deal with the multiple challenges that have delayed the translation of biotechnology research products into use in Africa.

KEY WORDS: Biotechnology, Regulation, *Bt* cotton**,** Africa

JEL Codes: L26, L31, L33, N5, N57, O13, O19, O31, O32, O33, O34, O55, P48, Q12, Q13, Q16, Q28

RIU DISCUSSION PAPER SERIES

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LIST OF ACRONYMS

AATF	-	African Agricultural Technology Foundation
ABNE	-	African Biosafety Network Expertise
ABSF	-	African Biotechnology Stakeholders Forum
ACTS	-	African Centre for Technology Studies
ASARECA	-	Association for Strengthening Agricultural Research in Eastern and Central Africa
ATPS	-	African Technology Policy Studies Network
BIOEARN	-	East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development
Bt	-	Bacillus thuriengiensis
CABE	-	Centre for African Bio-Entrepreneurship
CABI	-	CAB International (Formerly Commonwealth Agricultural Bureax)
CBD	-	Convention on Biological Diversity
CFT	-	Confined Field Trial
CGIAR	-	Consultative Group on International Agricultural Research
CODA	-	Cotton Development Agency
COMESA	-	Common Market for Eastern and Southern Africa
CRT	-	Central Research Team, RIU
DFID	-	Department for International Development, UK
FAO	-	The United Nations Food and Agriculture Organization
GDP	-	Gross Domestic Product
GMO	-	Genetically Modified Organism

GTZ	-	Deutsche Gesellschaft für Technische Zusammenarbeit, now called the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)
IAASTD	-	International Assessment of Agricultural Knowledge, Science and Technology for Development
IDRC	-	International Development Research Centre
IFPRI	-	International Food Policy Research Institute
ILRI	-	International Livestock Research Institute
IPM	-	Integrated Pest Management
IPR	-	Intellectual Property Rights
IRM	-	Insect Resistance Management
IRMA	-	Insect Resistant Maize for Africa
ISAAA	-	International Service for the Acquisition and Application of Agri-biotech
KGT	-	Kenya Gatsby Trust
KNFU	-	Kenya National Farmers Union
LINK	-	Learning INnovation Knowledge
MDGs	-	Millennium Development Goals
NBA	-	National Biosafety Authority
NBC	-	National Biosafety Committee
NBF	-	National Biosafety Framework
NEPAD	-	New Partnership for Africa's Development
NGOs	-	Non-Governmental Organisations
PBS	-	Program for Biosafety System
R&D	-	Research and Development

RIU	-	Research Into Use
S&T	-	Science and Technology
SARI	-	Savanna Agricultural Research Institute
SIDA	-	Swedish International Development Cooperation Agency
STEPS Centre	-	Social, Technological and Environmental Pathways to Sustainability Centre
UK	-	United Kingdom
UN	-	United Nations
UNEP-GEF	-	United Nations Environment Programme Global Environment Facility
UNU-INTECH	-	United Nations University Institute for New Technologies
UNU-MERIT	-	United Nations University Maastricht Economic and Social Research Institute on Innovation and Technology
USA	-	United States of America
USAID	-	United States Agency for International Development

1. INTRODUCTION

The Research into Use (RIU) programme — funded by the UK's Department for International Development (DFID) — has been debating over the question of how to better put agricultural research into use for developmental purposes. Based on emerging strands of evidence from RIU's experiments — through projects in Asia and country programmes and 'Best Bets' efforts in Africa — it is now becoming clear that the process of transferring agricultural research products to end users is a complex one.

In the case of the biotechnology sub-sector, in particular, the research-into-use process is pegged not only to appropriate regulatory policies, but also to institutional configurations that enable or hinder it (Hall, 2005). Moreover, biotechnology innovation is embedded in a complex and dynamic system that is constantly changing due to the impacts of globalisation, which further confounds development endeavours (Tait et al., 2006). This scenario calls for a need to identify structures for sustainability in order for the poor to benefit from these technologies.

Regulation, more generally, helps to shape technology development by influencing investment decisions, market structures, access to and distribution of costs, risks and benefits through "steering the flow of events and behaviour" (Braithwaite et al., 2007:3). Biotechnology regulation, in particular, is poised to bring about safe and responsible application of biotechnology products and has been debated widely. It is now understood that biosafety regulation is a key device available to governments interested in shaping governance of biotechnology to promote public interest. In developing countries, for instance, biotechnology regulation paves the way for consumers' health and environmental protection and at the same time leaves room for harnessing its potential benefits (FAO, 2004). Since the initiation of biotechnology research in Africa, efforts have gone into building the requisite regulatory capacities to manage this technology. These efforts have involved developing biosafety regulatory systems and concentrating on improving their capabilities to allow for the deployment of these technologies (Falck-Zependa et al., 2009).

The interface between biotechnology development, on the one hand, and biotechnology regulation, on the other, brings about interesting dynamics that need to be understood and unpacked in order to ultimately foster meaningful innovation — what programmes such as RIU are ultimately interested in.

Surprisingly, analyses of debates around these intertwined subjects seem to have advanced from a narrow perspective, without much effort to probe questions around what happens after such biosafety systems are in place — particularly in a developing country context. For instance, would regulation automatically lead to biotechnology development and consequent adoption?

Using empirical data, this paper explores this subject further in an African context in order to contribute to research around biotechnology regulation and how it can be re-oriented in order to specifically benefit the poor. It uses *Bt* Cotton as an illustration to examine the issue of regulation and the study is supported by a desk review, followed by interviews with key stakeholders in the cotton value chain across countries in Sub Saharan Africa.

The paper is organised as follows: Section 2 briefly explores the trends in biotechnology development and regulation. This is followed by a presentation of the methodological approach adopted in this paper in Section 3. Section 4 summarises our findings based on the perspectives of respondents, revealing a number of regulatory and non-regulatory challenges to biotechnology transfer. A brief discussion section explores ways to implement biosafety regulation that is effective and integrated. The paper concludes with a few recommendations for policy and practice.

2. EXPLORING THE DEBATE AROUND BIOTECHNOLOGY AND ITS REGULATION

This paper proceeds with the understanding that biotechnology development must be accompanied by a concurrent development of requisite regulatory systems. In most countries in Sub Saharan Africa, for instance, the two developments have progressed in tandem (Mugwagwa, 2008).

Progress and Challenges in the Delivery of Biotechnology Products

It has been consistently noted that countries that have embraced biotechnology — in the developing world in particular — have both increased spending in the research and development of *Bt* (Bacillus thuringiensis) crops as well as areas under production (Clives, 2009). According to Makinde (2010), three countries in Africa are currently engaged in the commercial production of *Bt* crops: South Africa (maize, cotton & soya bean), Burkina Faso (cotton) and Egypt (maize). Many others are conducting trials in contained environments as well as field trials and support for such tests is gaining momentum in other countries rapidly. Examining the dynamics involved in the development and adoption of these technologies is likely to yield some insights into how to make this process smoother and quicker.

There are several studies that examine the benefits associated with the application of new biotechnologies and their potential to contribute to the challenges that face mankind (Paarlberg, 2008; FAO, 2004; Cohen, 2005). Indeed the FAO (2004) report categorically argues for biotechnology as one of the tools to confront food security issues in developing countries. However, there is also an ongoing debate that questions how realistic this discourse is for pro-poor innovation (Hisano, 2005). As a follow-up, FAO conducted an electronic discussion over the failures and successes of agricultural biotechnologies in developing countries over the last two decades (FAO, 2010). The report that emanated from this discussion focused on learning experiences and reveals some interesting findings (FAO, 2010). It shows that the process of research and development of a biotechnology and its expected adaptation to a local context is “more complex, with performance depending on

the hybrid background, growing conditions and institutional context" (pp. 2). This analysis was based on a number of case studies in different countries — notably the *Bt* cotton experience in India. Experiences with GM soybean in Argentina, on the other, indicate both substantial economic benefits and some undesirable correlated environmental impacts. The latter, it has been argued, was caused primarily by failure to incorporate appropriate planning and policy interventions. The FAO report identified four main reasons for failures of agricultural biotechnologies in developing countries:

- The lack of or inadequate human and infrastructural capacities, including facilities and trained professionals
- Brain drain, which further weakens national capacities
- Behavioural research practices of researchers that comes in the way of considering the needs of citizens, described as "socially valuable applied R&D" (pp. 20)
- A lack of political will and failure of governments to support research through an enabling policy environment

Suggestions for increasing the chances of successful adoption of agricultural biotechnologies in the future revolve around taking an integrated approach that involves key partners in public and private sectors, including farmers. This approach also involves improving the capacities of institutions concerned with transferring knowledge and information from research to farmers. According to the FAO report regulation appeared to impact negatively on product adoption due to huge costs and delays associated with approvals. The only positive attribute of regulation appeared to be to facilitate the commercial release of biotech products.

This is a very simplistic way of looking at regulation, considering that the Cartagena Protocol on Biosafety provides a broader interpretation that takes cognisance of both technical and socio-economic aspects of regulation (CBD, 2000). According to this report, successes and failures in agricultural biotechnologies have both been recorded, thus warranting a further empirical investigation with a view to harness practical lessons that can move the debate to a higher productive level.

Prospects for *Bt* Cotton in Africa

Cotton is an important crop for several smallholder farmers in many African countries, where it contributes both to the Gross Domestic Product as a foreign exchange earner and to farmers' livelihoods (Poulton et al., 2004). The cotton sub-sector is unique because in many countries, particularly in Sub Saharan Africa, it has been liberalised. This implies that there are many players who dominate different aspects of the production value chain. For instance, private operators dominate input supply, crop buying, ginning and selling. Increased competition has resulted in increased demand for sector coordination (Tschirley et al., 2010). The industry has, however, also had its share of common challenges, including high quality requirements for cotton lint; fragmented channels for delivery of inputs to smallholder producers; weak research systems for continued provision of improved seed varieties; general pest management and control issues, among others (Poulton et al., 2004: 520). Despite these challenges (further complicated by global market price fluctuations), cotton production has continued to increase — fact that has been attributed in part to the worldwide adoption of *Bt* cotton (Tschirley et al., 2010). *Bt* cotton is different from conventional cotton in that it contains a gene from a common soil bacterium, *Bacillus thuringiensis* (*Bt*). This gene confers a degree of protection against a family of pests that generally attack cotton, called bollworms.

Of the countries in Africa only Burkina Faso and South Africa are currently engaged in the commercial production of *Bt* cotton, implying that this technology has not benefited as many smallholder farmers in the region as was expected. Regulatory hurdles have been blamed for this slow technology transfer but perhaps it is now time to take a critical look at this claim. This rethink is partly triggered by two competing strands of research; one claiming that *Bt* cotton has significantly impacted on the socialeconomic welfare of poor farming communities (Vitale et al., 2010) and the other arguing that the benefit claims have been overemphasised. In the latter group, scholars such as Glover (2009, 2010) have argued that Genetically Modified technology may have not have benefited poor farmers because the impact of this technology depends on a complex socio-economic context, appropriate institutional frameworks and agro-ecological factors. This paper looks at both claims, seeking to understand the dynamics involved in order to start thinking about post-

regulatory implications. It takes cognisance of the fact that high investments have gone into developing a research and development infrastructure, including the institution of biopolicy regulatory frameworks (Atanassov et al., 2004; Karembu et al., 2010).

Regulatory milestones: A pathway for biotechnology transfer

The importance of biodiversity conservation as well as biosafety cannot be underestimated in an African context. All the countries in Sub-Saharan Africa (with the exception of Somalia) are contractual parties to the Convention on Biological Diversity (CBD, 1992). CBD has a provision for an international framework for the safe transfer, handling and use of living modified organisms resulting from biotechnology, which may otherwise have adverse effects on the conservation and sustainable use of biological diversity — referred to as the Cartagena Protocol on Biosafety (CBD, 2000). To date, many African countries have signed and ratified the Protocol. This notwithstanding, national biosafety systems in many countries have evolved over the years in response to regulatory challenges and compliance with global requirements. This process has largely been driven by a global urge to create an enabling environment for biotechnology transfer. Eighteen countries in Africa, for instance, have benefited from the initial United Nations Environmental Programme-Global Environment Facility (UNEP-GEF) support pilot project on implementing national biosafety frameworks (UNEP, 2004). Through this support, many countries have been able to initiate National Biosafety Frameworks (NBFs) that encompass various components namely:

- *Biotechnology policy*
- *Regulatory regime (legislation and regulations)*
- *A system for handling notifications or requests for authorisations of GMOs*
- *A mechanism for monitoring and inspection*
- *Approaches for public information and participation*

Using these components as an analytical framework, a study by the African Agricultural Technology Forum (AATF) categorises African countries into four groups, noting that they are all at different levels in terms of setting up National Biosafety Frameworks (Nang'ayo, 2006). The AATF report notes that as of December 2006, only five countries (Burkina Faso,

Mauritius, South Africa, Sudan and Zimbabwe) in Sub-Saharan Africa appear to have met the basic obligations of the Cartagena Protocol on Biosafety, which is linked to the cumbersome process of implementing the requirements of the Protocol. The situation is changing, however, and Kenya is one of the countries that has since attained a functional NBF after approval of the Biosafety Act, 2009 (Nang'ayo, 2010).

Concurrent with national efforts to establish regulatory frameworks, Africa has also been the setting of a few international efforts to help build systems on biosafety. After identifying gaps that the UNEP-GEF programme failed to address, the United States Agency for International Development (USAID) came up with the Program for Biosafety Systems (PBS, 2007-2010) project, specifically focused on building functional biosafety systems through various capacity building efforts. The programme views a functional system as one that ensures adequate safety but allows the country to test potentially promising products and deploy them to end users. It, thus, considers various developmental stages of biotechnology products (contained trials, field trials, deliberate release and post release) as critical decision points in attaining such a system. The programme has concentrated its efforts more on building capacity for implementation of Confined Field Trials (CFTs), harmonising operations of the implementing regulatory structures in preparation for commercialisation of biotechnology products, and, more recently, communicating information on biotechnology science (see www.pbs.org or www.ifpri.org). PBS operates in a number of African countries, including Kenya, Uganda and Tanzania.

Another programme, the Eastern African Research Network on Biotechnology and Biosafety (BIO-EARN) project funded by the Swedish International Developmental Cooperation Agency (SIDA), which ran from 1998- 2009, focused on human and infrastructural capacity building in biotechnology research and development. Consequently, biosafety and biotechnology policy-making were identified as key challenges towards achieving this goal. Thus, the programme sponsored awareness workshops for scientists, policy-makers and the private sector aimed at stimulating collaborations within Eastern Africa institutions (Mugoya, 2007: 9).

Biosafety regulatory capacity building initiatives have also received paramount attention at the regional level through the African Biosafety Network of Expertise (ABNE). The ABNE initiative was conceptualised and established by the AU-NEPAD Agency in 2007 with the sole aim of strengthening the capacity of African regulators and contributing to the building of functional biosafety systems in Africa. It aims to do this through empowering African regulators and policy-makers with knowledge and skills to make informed decisions on biosafety and biotechnology issues (ABNE Newsletter, June 2010; www.nepadbiosafety.net). Its activities are supported by the Gates Foundation.

The regulatory milestones discussed above are largely aimed at creating a pathway for biotechnology transfer in Africa. In some ways, these are positive moves towards preparing different stakeholders for the implementation of requisite biotechnology regulatory requirements. However, these efforts have also been criticised on different fronts as being simplistic while others see them as part of technology determinism approach, which assumes that technology takes a pre-determined pathway (Jasanoff, 2002; Levidow, 2007). Others have argued that this approach is "closed down" as it embraces harmonised structures (van Zwanenberg et al., 2008). These scholars also feel this sort of an approach is too narrow as it pays a lot of attention to the regulation of bio-physical risks (biosafety) while ignoring other non-biophysical social factors that are context-specific. It is, therefore, not surprising that the FAO (2010) report discussed elsewhere recognises "local context" as a key determinant of success or failure of biotechnology innovation in developing countries. It is important to note that this conclusion is based on experience in implementing biotechnology regulation in developing countries and that most of the participants in the online discussion were scientists who understand biotechnology science.

Other scholars have also appealed for embracing the broader considerations of biosafety regulation towards innovation governance. Scholars in the "Beyond Biosafety" project at the STEPS Centre[2], for instance, have demonstrated how this might be achieved through embracing pathways that reflect local realities under which different innovations manifest

[2] The STEPS Centre is an interdisciplinary global research and policy engagement hub, funded by the Economic and Social Research Council (ESRC), and aims to develop a new approach to understanding action and communication on sustainability and development (see http://www.steps-centre.org/aboutus/index.html)

(Brooks, 2010; van Zwanenberg, 2010; Brooks et al., 2009). A key fundamental recommendation from these studies includes involving local actors in framing biosafety regulation and re-aligning institutions (e.g., organisations, practices, local policies, etc.), given the significant role they play in effecting social and institutional change, which is pertinent for meaningful innovation to occur. According to governance theorists, in reality, such recommendations may be challenging to implement, considering the complexity of enforcing a flexible, evidence-based and legitimate governance system in new biotechnologies (Lyall, et al., 2009; Tait et al., 2006).

The scholars who promote an integrated approach to biotechnology regulation, however, fail to recognise that the contextual factors that influence institutional aspects are dynamic and tend to change with experience and incremental learning (Hall, 2005). This is particularly true for an institutional setting embedded in the knowledge-intensive biotechnology research and governance field. Drawing insights from these scholars, this paper explores “beyond biosafety regulation” from an integrated learning perspective to understand the dynamics involved and the implications for putting biotechnology research into use.

3. CONCEPTUAL APPROACH AND METHOD FOR DATA COLLECTION

One way to broaden the biotechnology regulation debate is to focus on biosafety regulation (such as regulatory procedures, categories of risk, types of evidence, etc.), as has been the practice, but go beyond this to look at non-biosafety aspects that include but are not limited to socio-economic concerns (Brooks, 2010). This is actually provided for in the Cartagena Protocol on Biosafety, but details of how this should be done are left to the member parties to decide. This leaves room for manoeuvre in order to embrace the context and the local realities of a nation that constitute supposedly complex systems (Leach et al., 2007).

However, perhaps the best way to understand biotechnology governance is through the lens of an innovation system framework. Proponents of this framework tell us that institutions, actors, and linkages and interactions between them are very significant components that determine how innovation contributes to requisite development (World Bank, 2006). The framework further tells us that through the diverse forms of interactions and the embedded learning, knowledge is exchanged and put to use in a manner that brings about social and institutional change. This framework helps us rethink a number of issues relevant to biotechnology regulation and, in particular, implementation. These include, for instance, the gaps in the value chain; the question of how to engage different actors in the value chain based on institutional mandate, roles, skills and resources, including expertise; the question of where to focus efforts and attention based on the gaps identified in the value chain (e.g., R&D investment, incentives, trade interests, capacity building at different levels, education and awareness, etc.). The framework has been applied in providing policy and practice guidance in biotechnology capacity building in an African context (Hall, 2005). This makes it possible to identify what sorts of capacities would be needed to take account of integration of scientific knowledge and resources with the biotechnology economy and regulation and, consequently, make this work for the benefit of the poor (Chataway, 2005). This integration goes beyond the level of biotechnology research to accommodate many other key actors in the innovation process.

This paper is largely informed by empirical data generated from interviews with key stakeholders in the agricultural sector, particularly those involved in the biotechnology regulation debate across the African continent. These include senior policy-makers, knowledge developers, development policy and academic researchers, nongovernmental organisations (NGOs) in the biotechnology sector, regulators in biosafety and cotton development agencies, *Bt* cotton farmers and the media. These respondents were drawn from a number of African countries, namely: Burkina Faso, Nigeria, Ghana, Togo, Malawi, Kenya, Ethiopia and Uganda, who were involved in a "seeing is believing" tour of *Bt* cotton farms in Burkina Faso. This tour took place from November 8–12 2010 and was organised by the International Service for the Acquisition of Agri-Biotech applications (ISAAA)-Africenter. Other comments were solicited from participants in a biosafety workshop organised by the Centre for African Bio-Entrepreneurship (CABE), Future Agricultures Consortium and the STEPS Centre, University of Sussex on November 15–16′ 2010, in Kenya. Other isolated interviews were conducted between June and October 2010, mainly in Nairobi, Kenya and some in Ethiopia during the Science with Africa conference held in Addis Ababa from June 23–25, 2010.

The aspects that the respondents consider to be a motivation and/or hindrance for exploitation of *Bt* technology potential and sustainability were sometimes subject to interpretation. *Bt* cotton was considered for illustration due to the fewer food safety controversies it attracts when compared to food-oriented biotechnologies. In addition, most countries have made progress in considering *Bt* cotton as a measure of reviving the textile industry (Vitale et al., 2010).

Data obtained from the interviews was complemented by secondary material around biosafety implementation and biotechnology governance in Sub Saharan Africa.

4. BEYOND BIOSAFETY REGULATION: WHAT ARE THE PERTINENT ISSUES?

The analysis presented in this section is guided by empirical data emanating from a wide range of interviews and views of different actors in the *Bt* cotton value chain. The issues identified by interviewees are presented in two complementary ways; first, thematically, and secondly in tabulated and diagrammatic forms. These presentations guided the discussion and conclusion that follow.

Respondents identified a number of regulatory and non-regulatory issues that have been grouped into overlapping themes below.

i) Consensual role of regulation

There appears to be no argument among respondents that putting regulatory systems in place was paramount before biotechnology research could be successfully put into use. Apart from Ethiopia, the African countries represented in this study are not opposed to the commercialisation of transgenic crops. Most, for instance, cited *Bt* cotton as a motivation for the revival of the textile industry, which has collapsed in many countries.

> *Bt cotton is being pushed to revamp the cotton industry, so motivation to adopt Bt is to revive the cotton industry* (A member of Parliament, Ghana, November 10, 2010)

This implies that tapping the benefits of biotechnology is intrinsically tied up to issues of biosafety regulation. Political support needed to enhance regulatory systems development was identified as the main reason why Burkina Faso was ahead of other African countries in this regard. Burkina Faso, South Africa and Egypt are the only African countries that have commercialised biotechnology products. This may perhaps be the reason why the "seeing is believing" tour invited a considerable number of politicians from different countries to attend, as it is believed that policy-makers need to be convinced to play an advocacy and lobbying role on order to get relevant legislation passed by the government. One respondent, a member of the House of Representatives in Nigeria and chairman of the

Federal House Committee on Agriculture, championed the passing of the biosafety bill in his country's Lower House of Representatives. After attending the "seeing is believing" tour, he planned to lobby for the passing of the same bill by the upper house.

Although some respondents didn't appear to be considering the broader ramifications of the issue — as in what transpires after regulations are in place and what else is needed to be done to get biotechnology research into use — they felt the transfer process needed to be given much more thought. As one respondent emphasised:

> *"We need to connect what we are doing today and what we will be doing tomorrow"* (CABE staff, 15, Nov 10)

Clearly as this narrative seems to suggest, biosafety legislation is important but is not the only determinant of biotechnology uptake.

ii) Context for technology transfer

This sub-section summarises the issues raised by respondents with regards to what they considered pertinent in regulation implementation and what might hinder biotechnology transfer.

- **Multiple actors with multiple agenda**

  The transfer of *Bt* technology involves many players beyond just researchers and regulators. From the Burkina Faso experience, the *Bt* cotton transfer process apparently involves a multitude of actors along the entire cotton value chain, including farmers, producers and cotton societies, researchers, technology developers (such as Monsanto and its partners), political decision-makers, civil society actors, regulators, users of cotton and its by-products and ginners (see Vitale et al., 2010). Arguably, all these players have differing skills and functions that they articulate in the cotton value chain. This may bring about conflicts of interests, as well as tensions associated with mandates and the sharing of benefits.

- **Control of the industry by the private sector**

  Commercialisation of biotechnology products is led by private sector actors such as Monsanto. In Burkina Faso, for instance, *Bt* cotton production is controlled by Monsanto, which has designated agents to manage formal contract channels according to the various cotton production zones. These agents are responsible for the management of cotton production from planting to harvest of both cotton lint and seed cotton (Vitale et al., 2010). Although so far this form of contract farming appears to work in Burkina Faso, the situation may be different in other African countries.

- **Uncertainty in sustainability of farmers' access to *Bt* technology**

  Liberalisation of the textile industry has made the cotton sector very volatile, largely due to to poor and informal marketing systems that have affected the quality of seeds resulting from admixtures. In addition, according to the respondents, most cotton farmers in African countries are small/medium-sized, with no access to credit and with no access to commercial markets (this is the case in Ghana, Nigeria, Kenya, Uganda, Burkina Faso and Malawi, for instance). Based on the Burkina Faso experience, the price of *Bt* cotton seeds is higher than that of conventional varieties and the same is presumed to be the case in other countries. Most small-scale farmers cannot afford or access credit for certified GM seeds and may not re-use their own seed because they do not own cotton gins. The cotton seed supply is actually in the hands of few ginneries. This means that even if farmers are organised into groups, their bargaining power is limited.

iii) Regulatory and enforcement challenges

Respondents from Ghana, Kenya and Uganda identified regulatory challenges as key hindrances to biosafety regulation implementation and consequent technology transfer to users. In Africa, donor funding has been the norm in setting up existing regulatory systems. This being the case, respondents argued that mechanisms were needed to sustain these systems beyond the point where such funding ceased.

Although *Bt* products have not been commercialised in these three countries, there are concerns that regulators do not have the capacity or potential to accommodate the requisite flexibilities that should accompany *Bt* transfer. Kenya, for instance, is still grappling with challenges of putting up an operational mechanism to allow approval of commercial applications one and half years after the Biosafety Act was first enacted. Participants in the Biosafety workshop cited regulatory challenges linked to monitoring of seed trade in volatile systems such as in Kenya, where both informal and formal seed systems co-mingle. The former is largely controlled by farmers' day-to-day practices of exchanging seeds after selection while the latter is controlled by government regulatory agencies and the private sector. The informal seed trade is likely to dominate because of the expected high cost of *Bt* seeds. This is particularly worrisome to civil society actors who represent farmers as they feel that local farmers may have to legally pay for this practice, citing possible breach of intellectual property rights and private contracts (member of a civil society, November 16, 2010). The informal seed trade challenges the sustainability of quality seed and enforcement of contracts. Luckily for Kenya, the Kenya Gatsby Trust (KGT) is offering to look into the sustainability and viability of the cotton value chain through competitive one season contractual agreements (KGT staff, November 11, 2010). In Uganda, the Cotton Development Agency (CODA) plans to take up this role (CODA staff, November 11, 2010).

In Ghana, researchers are concerned about the *Bt* gene management strategy in terms of monitoring as noted by a senior plant breeder at the Savanna Agricultural Research Institute (SARI):

> *I don't think the researcher and regulatory services are adequately resourced to monitor actors in the whole country to monitor efficacy of the gene and admixture.*
>
> (10 November 2010)

He argued that the solution to admixture would be zoning of *Bt* growing areas, which has been possible in Ghana where zoning has been based on companies providing services in different areas. However, he felt that effective zoning should be based on variety. Another member of parliament from Nigeria concurred with the idea of zoning and argued that

"sustenance of quality seeds can be achieved through zoning which is easy to implement in Nigeria due to the concurrent governance system" (10 November, 2010).

The biosafety workshop participants in Kenya also raised the issue of refugia management[3]. As Kamau (2010) emphasises, farming communities are worried about how this will be implemented post-*Bt* crop release. Generally, the objective of this practice is to delay or prevent likelihood of resistance development to the *Bt* toxin(s) by the targeted pests, thus ensuring that farmers maximally exploit the pest protection potential provided by *Bt* crops. Refugia management is key in curbing the risk of contamination — particularly for cross-pollinated crops such as maize — and in the enforcement of co-existence measures (especially for smallholder farms) and against increased threats to biodiversity and the genetic base (Kruger et al., 2009). *Bt* cotton has to co-exist with non-*Bt* cotton and measures for co-existence have not been designed, despite the complexity of the mixed cropping farming systems (Kamau, 2010). In sub-Saharan Africa, research has shown that sustainable deployment of *Bt* technology for economic development must be accompanied by sustainable insect resistance management (IRM) strategies (Kruger et al., 2009; Hillocks, 2005:139). Similarly, in Kenya researchers involved in the Insect Resistant Maize for Africa (IRMA) project have consistently stated that sustainable IRM strategies will be required to enhance maximum exploitation of *Bt* maize potential (IRMA quarterly newsletters).

This is an issue that technology developers consider to be important. For instance, training on refuge management is being planned post-*Bt* cotton release in Burkina Faso (regulatory affairs manager, Monsanto, Burkina Faso). In Kenya, training on refuge management was popularised under the IRMA project (phases I & II) as part of *Bt* maize technology stewardship (Mulaa et al., 2008). The discourse around refugia management brings to the fore pertinent social and technical issues that relate to implementation, which should not be ignored.

[3] Refugia refers to a reservoir for non-resistant pests that mate with emerging resistant target pests rendering them susceptible and economically non-viable. It is derived from management strategies that require input of farmers and entails a non-*Bt* crop growing nearby a *Bt* crop to act as a refuge for the target pest (Gould, 2000).

The Biosafety workshop participants also identified lack of trust in government systems when it comes to enforcing the labelling requirements for biotech products, including seeds. Kenya was identified as an example where GM seeds have entered the country despite the presence of responsible regulatory government agencies to oversee such an event (Daily Nation, 2010). With commercialisation of biotechnology products, most civil society actors cite fears linked to regulators' inabilities to detect unapproved accessions, which might compromise quality assurance and safety.

Despite these challenges, many respondents agreed that there is more beyond biosafety regulation in order to attain the desired level of development:

> *Overall, for biotech products to contribute to development, the key fundamental issues must be addressed in a holistic manner and not in a compartmentalised manner. Biosafety legislation must proceed concurrently with approaches to address these fundamental issues.* (A former Member of Parliament, Nigeria, 10 November 2010)

Practically, it still remains unclear what roles different actors and organisations will play post the approval of *Bt* crops under different contexts, particularly after environmental release. The role of regulators in Burkina Faso seemed to be minimal and the active private sector players were the ones providing necessary technical and extension services. This may or may not be replicated in other African countries.

iv) Public engagement, awareness and biosafety education

"What are the top priority issues for Kenya's regulation"; this question, posed by a participant from the Futures Agricultures Consortium during the biosafety workshop, generated interesting findings. It emerged that many technology users have not been sensitised on the implications of implementing biosafety regulation. Thus, public engagement and awareness were ranked top among key priority needs if biotechnology is to benefit farmers. In reference to Kenya, issues that the civil society cited as having not received enough attention in terms of awareness creation include: refuge management, operations of GMO seed contracts and the role of farmers in negotiation of terms,

implementation of a weak Biosafety Act that could not save farmers from GM maize import scandal in March 2010 (Daily Nation, 2010), poor transparency in biosafety matters and public representation, risk and liability, imbalanced debate between GMOs and food security, which is largely pegged to hunger discourse (see also Kamau, 2010). Thus the different civil society groups represented urged for speedy engagement of the public in biosafety implementation to safeguard against possible rejection or failure of technology due to non-technological reasons.

In summary, the realities on the ground for many African countries are complex and may present a challenge in implementation of regulations in a manner that can help technology transfer.

Table 1 below summarises the underlying context linked to the 'beyond biosafety' regulatory era associated with *Bt* technology. The diverse challenges affecting different stakeholders hinder technology transfer in various ways, as illustrated. These challenges call for different policy options in order to enhance translation of *Bt* biotechnology to innovative products.

Table 1. Regulatory and Non-Regulatory Challenges to the Use of Biotechnology

Challenges	Key bottleneck	How these prevent use	Key actors/ stakeholders	Policy and practice options to address these challenges
Many stakeholders with different roles	Reconciling the interests of all stakeholders	Slows the process of farmers as key beneficiaries accessing the technology	Farmers, technology developers (Monsanto), cotton ginners, farmers associations, researchers, government agencies, regulators, politicians	Some form of brokerage by the government to leverage productive use of resources
Regulation enforcement	Inadequate regulatory capacity from the government agencies' front	Novelty of the product may be compromised due to admixtures and failure of the technology to deliver expected benefits.	Regulatory agencies, farmers associations, extension officers, research scientists	-Governments to design appropriate training strategies that incorporate a wider stakeholder e.g., the extension arm of the government and civil society -Governments to intensify training of regulators and farmers
	Lack of capacity by the public/farmers to enforce the management and monitoring requirements			
	Regulatory enforcement			

	mechanisms lacking public trust Lack of clarity on what post *Bt* release regulatory requirements entail			up to the grassroots level -Mechanisms to build trust and educate stakeholders that incorporate evidence based dialogues about risks and benefits
Inadequate biosafety/biotechnology awareness by the public	Weak mechanisms to educate public hindering implementation of post release regulation	Affects stakeholders trust that would promote faster decisions leading to uncontested technology uptake	Government, civil society, scientists and farmers	Sustainable awareness programs spearheaded by the government that take cognisance of the gaps & local needs

***Source**: Interview data*

Figure 1 below highlights the interconnectedness between biosafety and post-biosafety regulatory phases. In the former, the dynamics involved reflect less involvement of the technology recipients with concerns largely being around biosafety. In the latter, social, economic and regulatory factors dictate the scope of the stakeholders (see Table 1).

Figure 1. Interconnectedness between Biosafety Regulation and Beyond Biosafety Regulatory Phases

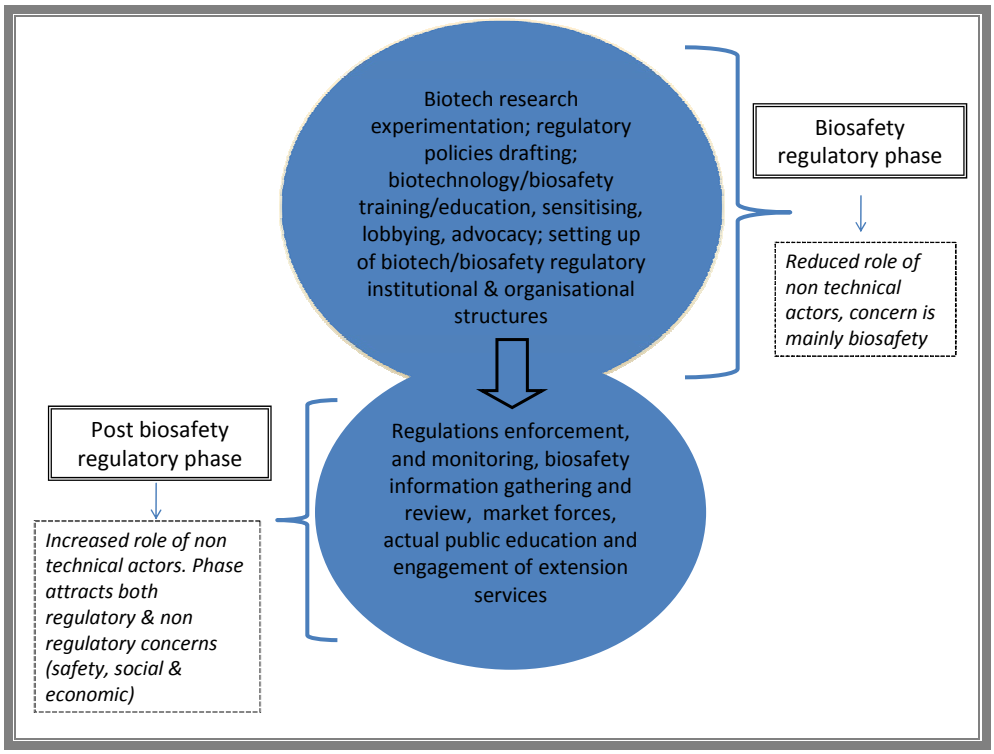

Table 1 and Figure 1 clearly show the complex process embedded in the translation of biotechnology products into use. They also clarify the relationship between the two phases, bringing to the limelight dynamics and activities that interplay to impact this process.

5. DISCUSSION

As noted by many respondents contacted for this study, the potential benefits from *Bt* cotton are profoundly evident. They also agreed that regulatory policies are a prerequisite to biotechnology development and its related benefits. This notwithstanding, there are underlying regulatory and non-regulatory challenges that are critical to the transfer of *Bt* cotton and the sustainability of the sector's profitability. One challenge relates to reconciling the non-technical interests of the many stakeholders within the cotton value chain. These interests are social and economic in nature, unlike the biosafety concerns linked to the controversial regulation of biotechnology (Kingiri, 2010). Depending on how this challenge is approached, conflicting interests are likely to slow the process of *Bt* cotton technology transfer to poor farmers, with perhaps the interests of technology drivers overshadowing the interests of the farmers. Another challenge relates to difficulties in enhancing capacities and sustaining a credible 'beyond biosafety' regulatory enforcement and monitoring system, both on the part of the government and the technology recipients. The weak structures for public awareness and education on matters of biotechnology and biosafety are in a way a challenge that curtails faster decision-making relating to biotechnology uptake by farmers. One interesting finding in this paper is the interrelationship between the biosafety regulation and beyond biosafety regulation phases. The *Bt* cotton case has empirically shown that some activities associated with the latter phase actually start off early during the former phase. The "seeing is believing" tour, for instance, is actually a lobbying and advocacy endeavour to influence adoption and marketing dynamics later on (see Figure 1 in the preceding section). It may not be immediately clear how this overlap impacts the biotechnology transfer process but it may negatively affect trust among players promoting different viewpoints (Kingiri, 2011). This notwithstanding, the bottlenecks created by these challenges call for appropriate policy and practice actions that are explored briefly in the conclusion.

These findings show that the process of biotechnology transfer is not a straightforward endeavour. In a number of aspects, the exposed dynamics resonate with the views of scholars at the STEPS Centre, who seek to understand more generally the underpinning

issues that link environmental sustainability and poverty reduction (for details see Leach et al., 2007). According to them, these processes are intertwined in complex systems defined by the context in which they occur. Context relates to the understanding of the environment (social and economic) in which the system is set and the subjective framings of the system. The latter is based on the perspectives of different actors who constitute the system (*Ibid*: 5). Looking at biotechnology in particular, van Zwanenberg et al. (2008) and van Zwanenberg (2010) argue that debates about transgenic agri-biotechnology elevate regulation of bio-physical risks (biosafety) above other non-biosafety regulatory factors. They argue that this has implications as it tends to mask the underpinning local context and realities. For instance, based on empirical research in Argentina and China, van Zwanenberg (2010) found that informal and formal seed regulation complicates the *Bt* cotton seed market, including seed quality controls. He proposes flexible regulatory actions that respond to local realities while "opening up" debates to embrace the non-biosafety aspects of regulation.

There are still gaps, including inadequate understanding of how "opening up" might be achieved in practice towards a pro-poor innovation goal, particularly in Africa. This is because of the context-specific nature of agri-based innovation systems (World Bank, 2006) and the political economy of agri-biotechnology (Fukuda-Parr, 2006). Arguably, these scholars who advocate for flexibility need to consider the intricate relationship between the regulatory context and embedded politics, and the potential impact on anticipated development. This calls for rethinking policy and practice options geared towards influencing a progressive and productive 'beyond biosafety' regulatory phase. For instance, it would be important to understand upfront the institutional framework that constitutes the cotton value chain and the embedded operations to address socio-economic contexts. Examples include formal or contract-based systems under which *Bt* cotton is managed in African countries and the informal systems that characterise farmers' farming practices (e.g., seed handling). These issues cannot be ignored and may be dictated by local context, history and learnt practices. Secondly, the regulatory and non-regulatory capacities to make the *Bt* cotton industry take off and thrive and, thus, impact innovation need to be strengthened at all levels.

6. CONCLUSION

This paper has shown that biosafety regulation is important for putting biotechnology research into use but it has also established that regulation is not the only determinant of research uptake by users. Lessons from *Bt* cotton suggest that there is a need to approach the 'beyond biosafety' regulatory phase or post-*Bt* cotton release regulatory phase with caution, by instituting policy and practice measures to address the practical challenges alluded to before. This is critical because many countries in Africa are preparing to commercialise *Bt* cotton. Thus, they should be guided by policies that take into consideration both regulatory and non-regulatory issues. The latter includes, for instance, the social and economics problems and constraints that farmers face, as well as the local practices linked to cotton production and marketing.

The challenge of reconciling diverse interests of stakeholders may require the intervention of respective governments who should act as disinterested brokers. This implies that all resources associated with this sector value chain can be appropriated according to the stakeholders' interests. The challenge linked to weak public awareness mechanisms, again, requires government intervention. Respective government agencies will be required to appraise public awareness needs and consequently initiate appropriate awareness programs that address the gaps. Capacities to implement the post-*Bt* release regulatory requirements are paramount for sustainable transfer and adoption of biotechnology products. Consequently, strategies to engage actors in line with their institutional mandate, skills and expertise must be devised and directed towards areas where capacities are lacking. Capacities may be strengthened through engagement of a wider stakeholder group, including extension agents who arguably have established links with farmers at the grassroots level. Other players whose involvement needs scaling up include civil society actors, who should be encouraged to participate in the process based on expertise and resources. Capacity building initiatives must at all times be guided by evidence-based social and technical information.

Suggestions have been made over how capacity building may be approached from an integrated front. Chataway (2005) and Hall (2005) have implicitly explored how biotechnology might benefit the poor through redirecting efforts towards innovation capacity building. This implies that endeavours to build regulatory capacities should include not only development of human capital and R&D infrastructure but should also encompass building capacity to use knowledge associated with regulation productively. The latter is what this paper advocates for through strategies that take cognisance of 'beyond biosafety' regulation challenges. Debatably, it may be productive to delink the controversies associated with biosafety regulation and what actually happens after biosafety regulation. This would ensure that the needs of stakeholders and local realities, including diverse farming systems into which *Bt* technology is being deployed, are taken into account. This would further strengthen trust amongst value chain actors. Other factors that would enhance trust include encouraging actors to be reflexive and flexible in order to accommodate the needs of value chain actors.

REFERENCES

Atanassov A.A., Bahieldin, A., Brink, J., Burachik, M., Cohen, J., Dhawan, V., Ebora, R., Falck-Zepeda, J., Herrera-Estrella, L., Komen, J., Chon Low, F., Omaliko, E., Odhiambo, B., Quemada, H., Peng, Y., Sampaio, M., Sithole-Niang, I., Sittenfeld, A., Smale, M., Strisno, Valyasevi, R., Zafar, Y. and Zambrano, P. (2004). To Reach the Poor. Results from the ISNAR-IFPRI Next Harvest Study on Genetically Modified Crops, Public Research, and Policy Implications. EPTD Discussion Paper 116. Washington, DC: International Food Policy Research Institute. http://www.ifpri.org/divs/eptd/dp/eptdp116.htm. Accessed 5 April, 2011.

Braithwaite J., Coglianese C. and Levi-Faur D. (2007). Can regulation and governance make a difference? *Regulation and Governance*. 1(1):1-7.

Brooks, S. (2010). Biosafety Regulation: Opening up the Debate. Lessons from Kenya and the Philippines. A presentation during the Biosafety workshop organized by CABE, Futures Agricultures and STEPS Centre in Nairobi Kenya, 15-16 November.

Brooks S., Thompson J., Odame H., Kibaara B., Nderitu S., Karin F., Millstone E. (2009). Environmental change and maize innovation in Kenya. Exploring pathways in and out of maize. STEPS working paper 36, Brighton, STEPS Centre.

CBD (2000). Secretariat of the Convention on Biological Diversity. Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes. Montreal, Canada.

Convention on Biological Diversity (CBD) (1992). Secretariat of the CBD. Text and Annexes. Montreal, Canada.

Chataway, J. (2005). Introduction: is it possible to create pro-poor agriculture-related biotechnology? *Journal of International Development*, 17: 596-610.

Clives, J. (2009). Global status of commercialized biotech/GM crops. ISAAA publication.

Cohen, J. (2005). Poor nations turn to publicly developed GM crops. *Nature Biotechnology*, 23 (1): 27-33.

Daily Nation (2010). Puzzle of GMOs import. Article by Gatonye Gathura, April 15, 2010.

Falck-Zepeda J., Cavalieri A., Zambrano P. (2009). Delivering Genetically Engineered Crops to Poor Farmers. Recommendations for Improved Biosafety Regulations in Developing Countries. International Food Policy Research Institute (IFPRI). Washington, DC USA.

FAO (2010). Learning from the past: Successes and failures with agricultural biotechnologies in developing countries over the last 20 years. Summary Document to Conference 16 of the FAO Biotechnology Forum (8 June to 5 July 2009). http://www.fao.org/biotech/logs/C16/summary.htm. Accessed 30 Oct. 2010.

Food and Agriculture Organisation (FAO) (2004). The state of food & agriculture. Agricultural biotechnology: meeting the needs of the poor? FAO, Rome, Italy.

Fukuda-Parr, S. (2006). Introduction: Global actors, markets and rules driving the diffusion of genetically modified (GM) crops in developing countries. *International Journal of Technology and Globalisation*, 2 (1/2): 1-11.

Glover D (2010). Is Bt Cotton a Pro-Poor Technology? A Review and Critique of the Empirical Record. *Journal of Agrarian Change*, 10 (4): 482–509.

Glover, D. (2009). Undying Promise: agricultural biotechnology's pro-poor narrative, ten years on, STEPS Working Paper 15, Brighton: STEPS Centre.

Gould, F. (2000). Testing *Bt* refuge strategies in the field. *Nature Biotechnology* 18:266-267.

Hall, A. (2005). Capacity development for agricultural biotechnology in developing countries: an innovation systems view of what is and how to develop it. *Journal of International Development*, 17: 611-630.

Hillocks, R.J. (2005). Is there a role for *Bt* cotton in IPM for smallholders in Africa? *International Journal of Pest Management*, 51(2): 131 – 141.

Hisano, S. (2005). A critical observation on the mainstream discourse of biotechnology for the poor. *Tailoring Biotechnologies*, 1 (2): 81-106.

Insect Resistant Maize for Africa (IRMA) updates quarterly newsletters (IRMA phase I & II, 1999 – 2008). http://www.cimmyt.org/english/ Accessed 01 Oct. 2009.

Jasanoff, S. (2002). New maternities: reimagining science, technology and development. *Environmental Values*, 11 (3): 253-276.

Kamau, W. (2010). Opposition or Engagement? Civil society perspectives on biosafety regulation in Kenya. A presentation made during a Biosafety workshop organized by Centre for African Bio-Entrepreneurship (CABE), Future Agricultures Consortium and the STEPS Centre, University of Sussex on 15 – 16th November, Nairobi, Kenya.

Karembu, M., Otunge, D., & Wafula, D. (2010). Developing a Biosafety Law: lessons from the Kenyan experience, ISAAA AfriCenter, Nairobi, Kenya.

Kingiri, A. (2011). Underlying tensions of conflicting advocacy coalitions in an evolving modern biotechnology regulatory subsystem: Policy learning and influence of Kenya's regulatory policy process. *Science and Public Policy Journal* (forthcoming).

Kingiri, A. (2010). Experts to the rescue? An analysis of the role of experts in biotechnology regulation in Kenya. *Journal of International Development*, 22: 325-340.

Kruger M., Van Rensburg, J.B., Van den Berg, J. (2009). Perspective on the development of stem borer resistance to Bt maize and refuge compliance at the Vaalharts irrigation scheme in South Africa. *Crop Protection*, 28: 684–689.

Leach, M., Scoones I., Stirling A. (2007). Pathways to sustainability: an overview of the STEPS Centre approach. STEPS Approach Paper, Brighton, STEPS Centre.

Levidow, L. (2007). European public participation as risk governance: enhancing democratic accountability for agbiotech policy? *East Asian Science, Technology and Society: an International Journal*, 1: 19-51.

Lyall, C., Papaioannou, T., Smith, J. (eds.) (2009). Governance in action in the life sciences: some lessons for policy. In Lyall, C., Papaioannou, T. and Smith, J. (Eds.). *The limits to governance. The challenge of policy-making for the new life sciences*, pp. 261-273. Farnham, Ashgate.

Makinde, D. (2010). The Transformed NEPAD and the Role of ABNE in Building Functional Regulatory Systems in Africa. Training Workshop for East Africa Regulators July 14-16, 2010, Nairobi Kenya.

Mugoya, C.F. (2007). Status of biotechnology policy-making, regulations and development in Eastern Africa. In ICTSD and ATPS. *Biotechnology: Eastern African Perspectives on Sustainable Development and Trade Policy*, pp. 1-17. ICTSD, Geneva, Switzerland and ATPS, Nairobi, Kenya.

Mugwagwa, J.T. (2008). Supranational organizations and cross-national policy convergence: the case of biosafety in Southern Africa. PhD Thesis, Development Policy and Practice, Faculty of Mathematics, Computing and Technology. The Open University.

Mulaa, M.A., Bergvison, D., Gethi, M., Muli, B., Ngeny, J., Mugo, S. (2008). Screening crop varieties and fodder species and varieties for their suitability for use as refugia in Mugo S., et al, (eds.). Book of abstract of the "Consolidating Experiences from IRMA I and II: Achievements, Lessons and Prospects", IRMA Project End-of-Phase II Conference, 28-30 Oct 2008, Nairobi, Kenya: IRMA Document No. 35: KARI and CIMMYT.

Nang'ayo, F. (2010). GM technology in Kenya with a focus on Potential Risks. Training Course on GMOs Detection for regulators. KEPHIS Headquarters, Karen, Kenya. 1-5 Mar.

Nang'ayo, F. (2006). The status of regulations for genetically modified crops in countries of Sub-Saharan Africa. African Agricultural Technology Forum (AATF).

Paarlberg, R. (2008). *Starved for science: how biotechnology is being kept out of Africa*. Harvard University press: Cambridge, MA.

Poulton, C., Gibbon, P., Hanyani-Mlambo, B., Kydd, J., Maro, W., Nylandsted, Larsen, M., Osorio, A., Tschirley, D., Zulu, B. (2004). Competition and coordination in liberalized African cotton market systems. *World Development*, 32 (3): 519–536.

Tait, J., Chataway, J., Lyall, C., Wield, D. (2006). Governance, policy, and industry strategies: pharmaceuticals and agro-biotechnology. In Mazzucato, M. and Dosi, G. (Eds), *Innovation, growth and market structure in high-tech industries: the case of biotech-pharmaceuticals*, pp. 378-401. Cambridge University press: Cambridge.

Tschirley, D.L., Poulton, C., Gergely, N., Labaste, P., Baffes, J., Boughton, D., Estur, G. (2010). Institutional diversity and performance in African cotton sectors. *Development Policy Review*, 28 (3): 295-323.

UNEP-GEF (2004). Projects on implementation of national biosafety frameworks. http://www.unep.ch/biosafety/development/devdocuments/Toolkit. Accessed 8 Mar. 2007.

van Zwanenberg, P. (2010). Regulatory harmonization: lessons from comparative studies of the design and implementation of biotechnology regulations in different national contexts. A presentation during the Biosafety workshop organized by CABE, Futures Agricultures and STEPS Centre in Nairobi Kenya, 15-16 Nov.

van Zwanenberg, P., Ely, A., Smith, A. (2008). Rethinking regulation: international harmonisation and local realities. STEPS Working Paper, 12, Brighton: STEPS Centre.

Vitale, J.D., Vognan, G., Ouattarra, M., Traore, O. (2010). The commercial application of GMOs crops in Africa: Burkina Faso's decade of experience with Bt Cotton. *AgBioForum*, 13(4): 320-332.

World Bank (2006). Enhancing Agricultural Innovation: How to go beyond the Strengthening of Research Systems. Economic Sector Work Report. The World Bank: Washington, DC, pp. 149.

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