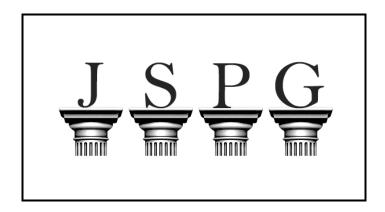# The Journal of Science Policy & Governance

POLICY ANALYSIS:

MANAGING KNOWLEDGE FOR DEVELOPMENT: LESSONS FROM KENYAN MODERN BIOTECHNOLOGY REGULATORY PROCESS

BY

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Executive Summary

This paper shows how challenges linked to modern biotechnology[1]-related knowledge management[2] contribute to the slow pace of biotechnology development in a developing country context. It draws lessons from Kenya's experience in instituting regulatory structures to manage biotechnology research and development (R & D). Kenya stands among the few African countries to embrace modern biotechnology to enhance agricultural productivity and production. However, its two-decade experience of introducing biotechnology has been full of controversies, turns and twists. To date, R & D efforts in biotechnology in Kenya have not resulted in successful products or services.

The study informing this paper relates to empirical analysis of the engagement of different stakeholders in the various regulatory activities leading to biotechnology development (elsewhere referred to as regulatory process). This analysis exposes context-specific factors, like interest-driven role of knowledge actors, particularly the scientific communities that negatively impacted knowledge management and biotechnology governance. This contributed to among others impacts, the slow adoption of biotechnology R & D alluded to previously. This analysis brings to light the potential problems and challenges associated with different types of knowledge contributing to regulation. Consequently, there are key policy and practical lessons that can be learned from Kenya's experience. First, there is a need to rethink the regulatory context under which knowledge associated with biotechnology is managed. Rethinking the conditions and dynamics under

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[1]This involves application of genetic engineering (GE) technology which is manipulation of living organisms to produce goods and

[2] This concept is used in this paper to denote concerted efforts and practices used by organizations and individuals to identify, create, accumulate, re-use, apply, and distribute knowledge related to biotechnology R & D including regulation (insights from Hartwich *et al.*, 2007).

which knowledge communities strategically manage knowledge need to be considered for negotiation of meaningful biotechnology governance that would benefit the poor. Second, there is a need for behavioral change associated with biotechnology regulation to accompany technological and institutional changes. Kenya's experience suggests that there are benefits in following an evidence-based, transparent and more inclusive approach to biotechnology governance and knowledge management. Moreover, there is a need to acknowledge the social construction of science in the development of biotechnology information and its influence in Kenyan regulatory processes.

Keywords: Modern agricultural biotechnology; regulatory practice; knowledge actors; Kenya.

Introduction

Knowledge management in a contemporary agricultural system refers to exchange of knowledge, information and skills between those who produce it and users (Hartwich *et al.*, 2007). However, recent studies have shown that the activities that entail knowledge management in a dynamic system, like agriculture, have become more integrated and inclusive due to the changing roles of actors in the process of creating and using knowledge (van Leeuwen *et al.,* 2007). Consequently, new ways of managing knowledge have emerged to encompass new practices like participation, collaboration, joint learning between and among actors, capacity building efforts, brokering and advocacy (Hartwich *et al.,* 2007; van Leeuwen *et al.,* 2007).

In the biotechnology subsector, knowledge management has been analyzed from an innovation perspective focusing on knowledge flow between high-tech firms and universities in industrialized countries (Alvarez, 2003). In the agricultural biotechnologies subsector, particularly in developing countries, knowledge management has not been given critical thought away from the controversies associated with biotechnology trade conflicts (see Aerni, 2005; Bernauer, 2005). It is important to consider that this subsector has regulatory demands (e.g. biosafety, intellectual property rights, trade) that are global in nature but which must be considered alongside efforts to use biotechnology knowledge for development endeavors (Fukuda-Parr, 2006). Questions thus arise as to how knowledge, linked to regulatory requirements, may be productively integrated into the overall biotechnology R & D process. The problem relates to how information and knowledge is solicited, shared, applied towards biotechnology regulation, and on its consequent development. This process is highly politicized, often value laden and therefore subjective (Kingiri, 2010). Some scholars have analyzed the polarized political dimension of biotechnology development and the extent to which the associated controversies have permeated developing countries (Paarlberg, 2008; 2001; Newell, 2002). Paarlberg for instance argues that the politics of biotechnology regulation have slowed the process of the poor African farmers benefiting from biotechnology applications.

Compared to other continents, Africa lags behind in terms of adoption of biotechnology applications. Only South Africa, Burkina Faso and Egypt have commercialized biotechnology products totaling approximately 2.65 million hectares in total of area under maize, cotton and soybean cultivation; although much of the science remains at research

stage (Makinde, 2010; Clive, 2011). However, significant milestones have been made in the development of regulatory structures to manage potential environmental risk exposed by application of these products (UNEP, 2003). In many African countries, respective governments hope to exploit the benefits of biotechnology exposed through experimentation while also considering safety aspects (Mugwagwa, 2008). The rapid adoption of biotechnology implies a parallel development of government oversight of biotechnology R & D. This is because the institutional and organizational revolution that accompanies adoption of biotechnology is growing faster than governance and the risks involved (Tait *et al.,* 2006). This revolution although influencing learning and knowledge production terrain in an unprecedented way has not received critical attention, especially in the context of a developing country which stands to gain from biotechnology development.

Despite the regulatory milestones, the benefits of biotechnology have not been realized fully in Africa. One of the major reasons for slow pace of using the benefits from biotechnology R & D relates to the (mis)management of knowledge associated with biotechnology, which a number of scholars link to the presence of multiple actors sometimes with conflicting interests (Philips, 2007; Smith, 2009). Considering the value-laden nature of biotechnology regulatory process, there is a need to rethink knowledge management in the context of biosafety regulation. This would enhance an evidence-based process that promotes social desirability of policies (Lyall *et al.*, 2009). Investigating the underpinning dynamics related to knowledge in a contemporary and regulatory setting becomes a pertinent subject when addressing a multi-faceted and multi-actor subsector

like agricultural biotechnology. This puts to test the traditional scientific approach to knowledge use and decision-making processes that are expected to ultimately lead to uptake of technology by users for economic development (Harsh, 2008). It however presents opportunities to study new policy and practice aspects like focusing on regulatory practices that impede or facilitate knowledge use in a way that would promote economic development of the intended beneficiaries.

This paper seeks to analyze how biosafety regulation[3] (which includes instituting a biosafety system[4]) affects the use of knowledge associated with biotechnology development. It does so by tracking the ways in which regulatory processes shape traditional knowledge production practices hitherto associated with scientific communities. This is intended to inform a viable technological and regulatory process where knowledge is managed effectively towards a productive public policy process. It further contributes to knowledge management literature by examining dynamics and processes when knowledge actors (e.g. scientists, policy makers, and public) engage in controversial public policy making, in this case biotechnology regulation.

Kenya is interesting as a case study because of its two-decade experience in managing biotechnology R&D. The initiation of biotechnology R&D activities in the 1990's[5] paralleled

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[3] Under the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD), biosafety regulation refers to the legal actions that an importing country is entitled to take with the aim of protecting the biological diversity of its conventional plants and animals against the risk of contamination through imported varieties or species consisting of so-called Living/Genetically Modified Organisms (LMOs/GMOs) (CBD, 2000).

[4] A biosafety system or framework is defined as "a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of LMOs 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" (UNEP-GEF, 2006).

[5] Thereafter, the number of research trials being undertaken has steadily gone up (see Kingiri 2011a for details).

the establishment of the requisite regulatory process, providing a good opportunity to investigate the dynamics around knowledge production with both technological and regulatory orientations. Critical analysis of this process helps to track down the dynamics involved, including the role played by knowledge actors. This helps us understand critical areas of knowledge management that include, but are not limited to, expert/scientific knowledge production, coordination of regulatory process, sharing of information amongst different policy coalitions, and embedded policy learning and influence experienced by different communities of practice. The paper uses empirical evidence generated through interviews with over 42 knowledge actors affiliated to different organizations between 2006 and 2011. The study was conducted as part of doctoral and post-doctoral research by the lead author of this paper.

For the purpose of this paper, knowledge actors denote the wide range of players in scientific, policy and public arena who are (or claim to be) stakeholders in governance of biotechnology development. They include both individuals (e.g. scientists and non scientists), corporate (e.g. donors and development agencies), and civil society actors. Interviewees' points of engagement in the regulatory activities and decision processes are seen in the context of effort to provide knowledge (e.g. information, expertise and other resources) and/or to influence regulatory policy outcomes. Consequently, the data analysis captures the different ways knowledge is articulated in regulatory processes (captured during the evolving regulatory phases) and what factors come into play. Unless otherwise stated, codes are used to report information cited in this paper in order to guarantee anonymity of some of the interviewees as requested. Where PS, GP, NSS and NS are used,

they refer to policy scientist, genetic engineering practitioner, non-state scientist and non-scientist, respectively. For instance, NGOco-NS4 refers to a non-scientist interviewee from a nongovernmental organization (NGO) or a civil society organization. Interview-based evidence was complemented by observation carried out during different scientific and public workshops in biosafety and biotechnology held during the study period, and analysis of relevant secondary documents.

The paper is structured as follows: in the next section the concept of knowledge is explored from perspective of biotechnology and the embedded biosafety regulation. This is followed by an empirical exploration of Kenya's regulatory practice and context tracked through four different regulatory Phases. Drawing insights from this empirical case, subsequent sections analyze and conclude the paper by looking at implications of knowledge dynamics in a regulatory context.

Uses of biotechnology related knowledge in debates on biosafety regulation

Defining knowledge management

Different typologies of knowledge have been described in the literature. Nonaka *et al.* (2000) define explicit and tacit knowledge where the former is described as codified, expressed formally through data and scientific illustrations and is easy to handle. Tacit knowledge is described as personal, not easy to express, not tangible and is linked to "actions, procedures, routines, commitments, ideals, values and emotions" (*Ibid*). Hartwich *et al.* (2007:22) describe knowledge as both information and skills acquired within an organization or a learning community, or from outsiders adapting it to local context

through trial and error as well as individual experience. Regardless of its typologies, knowledge is a product of intense social interaction amongst knowledge actors (individuals and organizations) with the emerging tacit and codified knowledge complementing each other (Nonaka and Takeuchi, 1995). The integrated and collaborative nature in which knowledge is produced and used in agricultural innovations attests to the complementarity and commingling of both tacit and codified knowledge (Hartwich *et al.*, 2007; van Leeuwen *et al.,* 2007).

Nearly two decades ago Gibbons, Nowotny and colleagues introduced the concepts of Mode 1 and Mode 2 to describe the ways in which knowledge is generated and used (Gibbons *et al.*, 1994). The Mode 1 practice mimics a linear knowledge transfer process from a traditional knowledge source, like a research institute or university, to a policy body or industry. The Mode 2 practice however is more integrated in nature with knowledge produced largely reflecting increased flexible collaborations between players with interest in a particular problem. Mode 2 practice is also perceived to be consultative and adaptable to societal needs, and can therefore increase the practical relevance of research and reduce public risk (Nowotny *et al.*, 2001, 2003). Mode 2 more generally exposes the behavior of knowledge actors in the process of managing knowledge as they navigate the complex knowledge production terrain (Gibbons *et al.,* 1994).

However, what entails knowledge management is not easily conceptualized through the application of these concepts. Hartwich *et al.* (2007:22) puts this into perspective by defining knowledge management as "concerted efforts and practices used by organizations

and individuals to identify, create, accumulate, re-use, apply, and distribute knowledge".

This process is complicated by the fact that knowledge dynamics have been impacted by the changing roles of knowledge actors in interactive activities like capacity building, brokering, and participation among others (Hartwich *et al.,* 2007; van Leeuwen *et al*., 2007). In the science policy arena, the policy-making process also entails diverse groups coming together in a trans-disciplinary working environment to co-produce knowledge (Mode 2 practice) in their attempt to ensure research relevance and applicability (Swan, 2009). In the context of developing countries' agriculture, the conventional linear and supply-led approach to knowledge production and use has changed to a more holistic, demand-led, multi-stakeholder approach (World Bank, 2006). This approach recognizes the importance of using not only the scientific knowledge for technological development, but also different skills and resources embedded in different sources, processes, and cultures that ultimately promote social and economic development (Hall, 2005). This holistic view of knowledge is crucial for moving agricultural products to be used for the benefit of the intended poor in developing countries thereby improving their livelihood.

Biotechnology and knowledge management

For a long time science was considered to be objective providing solutions to societal problems (Haas, 2004; Jasanoff, 2003). This has however been questioned by scholars in science policy literature. Jasanoff (2003) for instance argue that science and related scientific research are heavily value laden since they are products of a technical and sociological process that involves both objective and subjective decisions especially in framings about safety or risk. This supposedly narrow approach to use of knowledge fails to account for policy issues that have political connotation. For example, managing

knowledge related to biotechnology R & D, as well as regulation, has been challenged by the embedded political dimension. In this subsector, knowledge is influenced by the new institutional infrastructure (structures, mechanisms, norms and regulations) governing behavior of multiple actors who have different perceptions about regulation and embedded biosafety risk (Tait and Levidow, 1992; Philips, 2007; Fukuda-Parr, 2006). Moreover, the multi-actor biotechnology regulation attracts many challenges that include dealing with the tensions emanating from the diverse views of different governance actors, while upholding transparency and accountability (Lyall *et al.*, 2009). Consequently, if we question what regulation means to different players, and the role of different players in decision processes associated with safety of biotechnology, we begin to understand the place of knowledge in regulation (Kingiri, 2011b). This consequently complicates the role of experts as knowledge producers and users in decision-making processes pertaining to biotechnology regulation (Kingiri, 2010).

In Europe for instance, biotechnology regulation takes cognizance of experts' knowledge primarily to harmonize risk assessment and facilitate decision-making (Levidow and Carr, 2005). Soliciting knowledge from experts was intended to instill public confidence in regulatory decisions (Levidow *et al.*, 2005). Based on European experience, reliance on expert knowledge in biosafety regulation has questioned the legitimacy of the approach to knowledge due to the "great burden placed on science as the basis for societal choices about agri-biotechnology" (*Ibid:* 274). In Africa, few empirical studies have attempted to explore the dynamics involved in biosafety regulation in terms of knowledge. In Kenya for instance, studies show that technical expertise was solicited primarily from biological

scientists to guide in regulatory policy deliberations as biotechnology was perceived as a new and highly technical science (Kingiri, 2010).

This paper uses different typologies of knowledge to understand and characterize knowledge management in the context of biotechnology regulation using Kenya's experience in generating regulatory systems for biotechnology development.

Dynamics of knowledge articulation in the evolution of biotechnology and biosafety regime in Kenya: empirical exploration and analysis

This section analyses the four distinct regulatory Phases that paralleled biotechnology subsector R & D between early 1990's and 2011. The analysis is aided by key identifiers namely institutional structures, mechanisms and norms, and the dynamics amongst knowledge actors.

Phase 1: Initiation of the regulatory process (1990-1998)

The National Advisory Committee on Biotechnology Advances and their Applications (NACBAA) was formed in early 1991 by the Ministry for Research, Science and Technology under the National Council for Science and Technology (NCST) to advice on matters pertaining to national priority setting on biotechnology applications that "could resolve productivity constrains of conventional agricultural methodologies" (Sander, 2007:23). The NACBAA emphasized the need for multi-actor cooperation to enhance the use of resources (mainly finances and technical expertise) towards biotechnology deployment. The NCST was to offer the requisite coordination of skills and resources emerging from the many

knowledge actors becoming an active focal point on matters of biotechnology and later biosafety policy (Thitai *et al.*, 1996).

Using funding from the United States Agency for international Development (USAID), Kenya Agricultural Research Institute (KARI) scientists initiated two projects: the rinderpest vaccine and the transgenic sweet potato. Realizing the need for regulation to guide biotechnology R&D, the Dutch government, through the Directorate General International Cooperation (DGIS), funded the drafting of regulations and guidelines in 1998 (RoK, 1998). Consequently, technological development efforts paralleled the institution of a requisite biosafety regulatory regime.

As regulatory capacity development ensued, debates focused around biotechnological benefits and biosafety needs. At the beginning, research scientists provided technical information that explained the different applications of biotechnology and how they could tackle persistent challenges affecting agricultural sector in Africa like pests, diseases, and drought (Wambugu, 1996). In contrast, early policy makers that were not participating in the actual biotechnology R & D, argued for safe deployment of biotechnology, appealing for consideration of public views through an appropriate biosafety policy. They stressed the need to look at both the benefits and safety aspects of the proposed and purportedly new science (Mbaratha, 1998). Debatably, this exposed two contrasting views of knowledge, researchers on the one hand, and policy makers on the other.

It is important to see the different roles played by pioneers or early players in biotechnology development and regulation arena. These roles include policy stewardship, capacity building, and awareness creation among others. First, irrespective of professional arena or domain, the scientific community was seen to be articulating two roles as scientific or technical advisors and as policy advisors unified by one goal, to develop a regulatory structure for biotechnology R&D. Second, donors primarily USAID and DGIS provided financial resources to support technological development and to develop regulations. Third, development agents (NGOs) backstopped these two initiatives in terms of logistics and intermediation.[6]Although the regulatory process and biotechnology research proceeded in tandem at this phase, the objective for all these actors was to enhance biotechnology development through scientific opportunities for both KARI and the government (NCST) as opposed to enhancing safety in application of biotechnology products (Sander, 2007:42). This implies that the interests of KARI as a public research institute were not in conflict with the government interests (to enhance R & D for), while the interests of non-state actors were not directly regulatory policy related. Finally, the role of the public is conspicuously absent at this phase. This may imply that any form of expertise emanating from the public or non-scientific side may not have been considered by the government in their decision making process.

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[6]-Kenya Agricultural Biotechnology Platform (KABP), later Biotechnology Trust Africa (BTA) working closely with DGIS in spearheading the process of biosafety regulations development.
-Agricultural Biotechnology Support Program (ABSP Phases I & II) working closely with USAID pursued several roles: research and scientific assistance; and also policy brokering to ensure a positive environment for scientific and social economic opportunities like modern biotechnology.

Despite these contentions about role of actors and impacts, some interviewees noted that the collaborative effort of donors and development agencies contributed to learning through knowledge exchange. Some argued that this resulted into shift of NCST developmental policy agenda to biosafety policy.

"If there was no KARI or research institution trying to push, the priorities of NCST would have been different because their work is not exclusively GMOs. What they [KARI scientists] were doing created need for regulations to be developed. It was a need-based initiative. KARI as a research institute was vital in defining the priorities of NCST with regards to GM research." (RSIn-GP9, research scientist, international intermediary organization, Nov. 2007)

Phase 2: Biotechnology governance under interim regulatory instruments (1998-2005)

In Phase 1, the interim regulatory instrument (RoK, 1998) had been drafted to provide regulatory guidance in biotechnology research activities. This instrument provided an institutional structure constituting of the National Biosafety Committee (NBC) and Institutional Biosafety Committees (IBCs) to oversee its implementation. These committees were made up of technical experts in the biological sciences arena. Phase 2is therefore characterized by implementation of this instrument that some interviewees considered to be inadequate as a regulatory benchmark for it did not provide for post R & D handling of biotechnology products.

"So far at least they [regulations of 1998] allow researchers to perform confined trials within the research centers (…) but now when you want to go to the next step [beyond research stage], you cannot complete the research process"(RSPu-GP1, research scientist, PRI, Jan. 2008).

Consequently, challenges encountered during this phase energized knowledge actors who include scientific communities, regulators and the non-scientific communities to become proactive in the regulatory policy process.

In particular the following institutional actors were actively involved in the initiation of the regulatory process, and were intricately linked to multiple actors through complex knowledge links and interactions that led to the development of R&D activities and implementation of new technologies (?).

The Eastern African Research Network on Biotechnology and Biosafety (BIO-EARN) project. It was funded by the Swedish Developmental Agency (SIDA) in 1998 with capacity building (human and infrastructural) in biotechnology R&D being the main focus. Biosafety and biotechnology policy-making were identified as key challenges towards achieving this goal. Thus, the program sponsored awareness workshops for scientists, policy makers, and private sector aimed at stimulating collaborations (Mugoya, 2007: 9) and other initiatives that resulted into policy materials (BIO-EARN, 2003-resource book for biosafety implementation in East Africa). One key factor to note is that activities under BIO-EARN largely involved biological scientists in the academic and policy arena, and the information

resources materials were intended to impact policy change: *"The main goal of the resource book is to provide a tool for regional guidelines in biosafety implementation to biosafety assessors."* (BIO-EARN, 2003: i-ii)

It is however claimed that BIO-EARN did not directly impact policy change and the only tangible output was training of PhD students from academic and research institutes (Sander, 2007).

The UNEP-GEF Biosafety Enabling Activity project. Kenya was one of the countries that benefited from this project that was implemented in two phases. Phase I of this project commenced in 1997 as a pilot biosafety-enabling project, and Phase II in 2002 signaling the commencement of development of national biosafety frameworks (UNEP-GEF, 2003). Phase II, which is of relevance to this paper, aimed at securing adoption of a national policy and law through the establishment of a regulatory regime. It supported the development of an institutional and legal biosafety framework with the goal of establishing a sustainable and an effective biosafety management system, and strengthening the capacity and national infrastructure for handling GMOs in the country. A National Coordinating Committee (NCC) was formed and launched in September 2002 to support the implementation of this latter phase. The NCC consequently formed various working groups and taskforces, among them the legal taskforce which drafted the following policy documents: Revised Regulations and Guidelines on Biotechnology and Biosafety, National Biotechnology Development policy (RoK, 2006) and early draft versions of the biosafety bill, 2005.

Sander (2007) claims that the NCC minimized the role of research scientists in the policy process because its members were drawn from the NBC and the IBCs provided for in the interim regulatory instrument, the RoK (1998). Contrasting this view, Kingiri (2010) suggests that, in activities outside of NCC, research scientists were actively involved as policy and scientific experts. For instance, scientists who were biotechnology specialists participated actively in public awareness initiatives some of which were funded by UNEP-GEF.

The Program for Biosafety System (PBS). A renewed initiative launched in 2003 by USAID to support the national biosafety policy and institutional capacity development (see http://pbs.ifpri.info/). According to some interviewees, PBS was meant to address the pocket gaps left by the UNEP-GEF project, particularly capacity building of the key regulatory agencies. Early PBS activities were coordinated through NCST and focused mainly on building Kenya's Plant Health Inspectorate Service (KEPHIS) capacity to enhance the regulation of field trials and training of KARI's IBC and the NBC members. PBS also engaged technical consultants to backstop the review of the 1998 interim regulations that were in use, which resulted into a revised application for Confined Field Trials (CFTs). These capacity building efforts were aimed at enhancing transparent, proportionate, risk-based regulatory reviews and an efficient regulatory approval process (Jaffe, 2006). Some interviewees supporting the role of PBS claimed that, conflicting roles between regulatory agencies and research institutes undertaking biotechnology research, as well as regulatory non-compliance suspicions, tended to slow regulatory approvals. According to some

interviewees, PBS was stepping in to harmonize regulatory operations in order to enhance faster regulatory approvals. PBS later got involved aggressively in biosafety regulatory policy process through lobbying and advocacy for the enactment of the biosafety bill towards biotechnology development (see Phase 3).

A critical analysis of dynamics under this phase suggests that the increased activities of knowledge actors, including donors focused on regulatory policy, was a reverse of what occurred in Phase 1. Financial support, learning and knowledge used in Phase 1targeted technology development, while in this phase endeavors were oriented towards policy learning and influence (see also Kingiri, 2011a). Consequently, the corresponding scientific activities integrated policy related activities with majority of scientists assuming policy roles.

The main players in [biosafety policy formulation process] were the scientists in the biotechnology industry who showed more interest than the broader section of the Kenyan society [public]." (JO-NS6, journalist, a local daily, Apr. 2008)

This sparked off a sharp conflict between scientific knowledge purportedly used to influence regulatory process by scientific communities in both policy and research arenas, and public knowledge that was sidelined (see also Harsh, 2005; Kingiri and Ayele, 2009; Kingiri, 2010, 2011a, b).

Phase 3: height of the controversies (2005-2009)

This phase characterizes what can be perceived to be a crash between knowledge and politics. It constitutes the climax of controversies surrounding the legalization of biotechnology research (or technical knowledge), and the interim biosafety regime characterized by a mix of technical and non-technical knowledge. Controversies were experienced during the public and parliamentary debate of the different and evolving versions of the draft biosafety bill. This debate exposed an unprecedented proliferation of pro-biotechnology and anti-genetic engineering activist groups (NGOs) who adopted opposing stances.

In a recent study, Kingiri (2011a) explains that opposing stances were primarily fuelled by different belief systems that enhanced formation of advocacy coalitions, which proactively defended and advanced the shared beliefs of each coalition group. Two main actors deserve mentioning due to their relevance in exposing the knowledge management context pursued in this paper: The Kenya GMO Concern Group (KEGCO) that evolved to Kenya Biodiversity Coalition (KBioC) after its membership increased from 12 in 2004 to over 30 in 2008is comprised of NGOs who were opposed to either the biosafety bill or against GMOs. Another participating group is the Kenya Biosafety Coalition (KBC, sometimes referred to as Kenya Biotechnology Coalition) that ceased to exist after the bill became law. Critical to knowledge management tasks were the nature of coalition members and interests that motivated them, causing them to support a particular belief system. Moreover, the institutionalized method by which they engaged in advocacy could have influenced knowledge. KBC articulated its goals and interests through a wide range of

institutionalized policy and scientific networks [e.g. The Open Forum for on Agricultural Biotechnology in Africa (OFAB) and the government coordinated NBC]. KBioC on the other hand was more proactive through public and media avenues (see Kingiri, 2011a for a detailed account). Information was eventually disseminated to different recipients and the nature of engagement that may be tantamount to coercion and influence of the overall process and outcome.

USAID which has been mentioned previously as a donor organization is a key institutional actor in this phase. Its activities, unlike in Phase 2, are coordinated through two organizations: NCST and the International Service for the Acquisition of Agri-Biotech applications (ISAAA)-Africenter. USAID appropriates funds through PBS (described in phase 2 above) and International Food Policy Research Institute (IFPRI). PBS in collaboration with NCST has been undertaking an activity intended to harmonize the regulatory institutions operations in Kenya, thereby streamlining and enhancing their capacity for efficient deployment of GMOs including GMOs food (see www.biosafety.ke). IFPRI collaborates with ISAAA-Africenter in coordinating the biotechnology awareness and communication component of PBS. Under this component, the policy makers, regulators, and media are actively sensitized to make a case for biotechnology, while emphasizing the need for a Biosafety Law (see Karembu *et al.*, 2010). Journalists, researchers, regulators, and politicians interviewed in this study admitted receiving training and exposure to "seeing is believing" GM field trials locally and abroad through ISAAA.

"We organized for "seeing is believing" tours so that policy makers can appreciate the facilities and preparedness that we have as a country to manage and contain this technology" (ABp-PS14, technological & biosafety policy advisor, MOA, Feb. 2008).

Interviewed members of the civil society agreed that farmers were sidelined in these sensitization efforts.

One significant difference between this phase and the others is the increased utilization of resources, notably information and finances, for the counter and rhetorical activities articulated tactfully to influence policy process. Another key observation to make is the division among parliamentarians between pro-biotechnology and anti-biotechnology groups (AG-chambers, 2008; Daily Nation, 2008). The media became the sphere for expression of opposing standpoints. Just like Phase 2, it seems like activities in this phase were highly politicized with a temporary merger between science and politics on the one hand, and public and politics on the other. It is difficult to establish with certainty how logical and objective knowledge may be utilized in such a polarized environment to influence a productive regulatory policy.

The most significant outcome of this phase is the approval of the biosafety bill to become an Act (RoK, 2009), ushering in an era of technology transfer through commercialization of GMOs. Debatably, different conflicting roles of knowledge, incremental policy learning and outcomes spurred by diverse interactions and linkages tended to intensify controversies associated with biotechnology regulation. This reveals that managing knowledge in a

regulatory environment can be rather problematic which may work against the intended developmental objective.

Phase 4 (beyond 2009, post enactment of Biosafety Act, 2009)

This phase may be perceived to have started after the biosafety bill received presidential assent in Feb. 2009, laying a legally binding regulatory structure for biotechnology research trials approval, risk assessment (RA), and eventual deliberate release of products of GE technology into the environment. The Biosafety Act provides different ways of managing knowledge through requisite decision-making processes that entail public education, public comments, RA, and mechanisms for monitoring and enforcement. Three key regulatory instruments have been drafted to operationalize the Act (RoK, 2011). These instruments became effective on July 1st, 2011 and regulate different stages of genetically modified materials, namely contained use; import, export and transit; and environmental release. It however, remains unclear how all these provisions will be implemented in terms of biosafety information generation, synthesis, and eventual decision-making. In addition to these regulatory instruments, the National Biotechnology Awareness Strategy (BioAWARE) has been put in place to enhance participative biotechnology regulation and development (RoK, 2008).

Since February 2009, very few activities that relate to knowledge management can be cited. These include a few applications approvals to conduct biotechnology research, the drafting of the mentioned supporting regulations and their publication legalizing the Biosafety Act operation in Kenya. Perhaps signifying transparency, the draft regulations were posted on

the Science and Technology website (www.scienceandtechnology.go.ke) for perusal by interested parties. A stakeholders' workshop was eventually held on 12th April 2011 to discuss emerging concerns (NBA, 2011). During this workshop, concerns that were raised related to modalities of regulations implementation vis-à-vis meeting the expected level of safety of biotechnology products. Other concerns relate to whether the scientific community in their quest for knowledge transfer may deviate from ethical research practice (remarks by honorable John Mututho, the chair of Agriculture parliamentary committee present during the meeting). However, legitimacy of these concerns cannot be ascertained at this point in time.

The controversy behind biotechnology application is evident in this phase. On February 14th 2011, the Kenyan cabinet made a political pronouncement that approved immediate importation of GM maize to avert a looming food crisis. This generated a heated debate and reactions with civil society members staging public protests (see Opiyo, 2011; Omondi, 2011; Kinuthia, 2011). The proponents who include scientists did not oppose the importation, citing scientific evidence that has demonstrated GM products to be safe for human consumption. The opponents expressed skepticism citing unconfirmed risks posed by these products to human health. These fears are largely disseminated through media and arguably subsequently become source of information to the public (see Kingiri 2011a detailing how media is an avenue for information dissemination). The controversy suggests that the debate surrounding biotechnology clearly remains polarized making it harder for scientists to deliver products to the public, and the public to endorse them as beneficial and safe products. The political dynamics exposed in this Phase may compound efforts to

manage knowledge appropriately because of uncertainty of safety of GM products even with availability of regulatory instruments. Arguably, a way has to be sought of dealing with the inherent politics without interfering with use of evidence-based knowledge for biotechnology development. This is revisited in the conclusion.

Discussion

Analysis of the Kenyan case brings to light different potential problems and challenges associated with different knowledge strands contributing to regulation. Arguably, how actors input knowledge into the regulatory process has implications for knowledge management. This is influenced by different factors that relate to how institutional structures were set up to govern biotechnology R & D, the mechanisms and norms that guided in this process, and eventually how this influenced the dynamics of knowledge actors.

It emerges from analysis of the above narrative that the government's pro-development agenda in Phase 1led it to consider biotechnology research as a tool for development. This influenced subsequent government approaches to regulation. In order to achieve and sustain this developmental endeavor, the other three Phases took a different direction. In Phase 1, biotechnology research agenda seems to have made knowledge actors primarily focus on development. However, the need to put up institutional regulatory structures to manage biotechnology research takes precedence. In Phase2, the regulatory instrument (RoK, 1998) developed in Phase 1failed to adequately meet the regulatory interests of majority actors. The main goal of this instrument was to regulate biosafety and at the same

time facilitate the advancement of biotechnology research. This dual role sparked unwarranted controversies surrounding governance of biotechnology R&D. The main factor causing this may be linked to the circumstances under which biosafety regulation was found necessary; to facilitate biotechnology development. Another factor relates to the role of the increased number of non-public actors (particularly donors and technology developers) whose regulatory agenda was arguably geared towards influencing biotechnology policy outcome. The policy side had to adjust to accommodate these non-state actors represented by mainly biotechnology technical experts who aligned themselves with scientific communities in the research, policy and NGOs circles. The mechanisms put in place through the NCST to enhance the regulatory process seem to have resulted in a low-key involvement of the public and overreliance on scientific expertise. This suggests a biased knowledge articulation supposedly from limited categories of stakeholders if the public views' aspects of regulation (non technical) are largely ignored.

In Phase 3, regulatory capacity building efforts intensified, but again the engagement mechanisms used by NCST seems to have excluded non-scientific stakeholders in what may be considered to be a key public policy endeavor. Consequently, we see a strong opposition from the civil society purportedly representing the non-scientific public. Arguably, knowledge is articulated in a highly polarized and political environment that was exacerbated by the food crisis that brought the controversy to a wider and intense public debate. This being the case, values and interests are likely to take root unabated where knowledge actors align themselves with different groups perpetuating opposing standpoints (see also Kingiri, 2011a). The regulatory process shifts from being objective to

subjective. Repercussions on part of knowledge management include questionable quality of resources used to inform the regulatory policy process (Gibbons *et al.*, 1994). In addition, inadequate public representation in decision-making process may have compromised quality of emerging regulatory tools and instruments related to GMOs governance. Public participation is meant to bring in diverse views and understanding about the problem at hand, thereby enlisting support for implementation of policy and increase trust in governance (Haas, 2004). With regards to biotechnology, this would lead to accepting rules and processes by which this technology is being developed and ultimately used. It may not be immediately clear the level of impact this may have on deployment of biotechnology for development. However, deliberate efforts might be needed on the part of the government to consider diverse actions and viewpoints.

The controversies in Phase 4 make us ask pertinent questions about how politics can be managed in order for knowledge emanating from biotechnology to benefit the targeted beneficiaries. In the Kenya's case, it would be key to establish the cause of the controversies sparked by GM foods importation and how a consensus can be reached. Some recommendations are highlighted in the conclusion.

From the perspective of knowledge theorists, the dynamism portrayed and actualized in Phase 3reflects a redistribution of knowledge from the innovation communities who comprise of research fraternity (who previously were perceived to be experts in their own right) and the technology suppliers, to policy makers and the public (Gibbons *et al.*, 1994). It mimics the integrated mode of knowledge generation and flow, and adaptation

characterized by changing knowledge relations and the emergence of new networks of knowledge users and producers (Mode 2 practice). From this perspective, the overlaps between science, policy and public represent an empirical example of changing knowledge-based relationships. This has implications for scientific practice evidenced by changing social identities and creation of tension that puts strain on behavior of actors particularly scientists (Guston, 2001). It also poses a fundamental question related to quality of knowledge "co-produced" to suit a particular context (Jasanoff, 2004; Waterton 2005). Moreover, scholars advocating for socially desirable knowledge that takes cognizance of public participation in biosafety matters have warned against the decreasing credibility of scientific knowledge in informing environmental policies (Levidow, 2007).

Evidence from this paper augments the work of governance scholars who have shown that biotechnology development and regulation attract complex political, social and economic challenges. Lyall *et al.* (2009) for instance argues that these challenges invariably expose the difficult terrain that characterize the institutionalization of biotechnology science where diverse interests and values inevitably drive the decision making process associated with knowledge management. Some policy-based recommendations on how some of these challenges may be addressed based on Kenya's context are discussed next.

Conclusion and Recommendations

This paper points towards a need to rethink the regulatory context under which knowledge associated with biotechnology R & D is managed to consider the value laden nature of the embedded regulatory practice. This is the only way to reveal the conditions and dynamics

under which knowledge communities manage knowledge. However, efforts should be geared towards creating a platform for meaningful deliberations that can enhance application of biotechnology products for the benefit of the poor. Two interrelated recommendations are proposed. First, for contested technologies like biotechnology, practitioners and policy makers need to be more pro-active in terms of capturing knowledge from different stakeholders. This is important in order to legitimize knowledge emanating from regulatory processes. This being the case, policy and regulation designers and implementers need to rethink the seemingly rigid scientific practice towards an inclusive and more pluralistic practice (Ayele, 2007). In practice this would mean that major actors, with different preferences, need to be involved in a regulatory process to bring about collective ownership of, and accountability for action. Considerations of the different viewpoints and social, professional and sectoral interests in a regulatory process provides not only better opportunities for understanding the issues involved, but by enlisting trust in regulatory process, it also creates better opportunities to successfully develop biotechnology products that serve the poor (*ibid*). In Kenya, the National Biosafety Authority (NBA) under the provisions of the Biosafety Act has a role to play through weighing and analyzing the types of knowledge that inform the regulatory decision making and implementation process. The objective would be to ensure that socially desirable knowledge informs the final policy outcome (Nowotny *et al.*, 2001; Nowotny, 2003).

The second recommendation is a call for reflexivity towards behavioral change on the part of all actors involved in the knowledge management chain. This should accompany the technological and institutional changes linked to biotechnology regulation. The increased

integration and collaboration (Mode 2 practice) necessitated by biotechnology R & D as well as regulation challenge certain behavioral aspects related to knowledge management. Reflexivity therefore encourages knowledge suppliers to agree with knowledge users (Gibbons *et al.*, 1994). However, the different types of knowledge that go into the regulatory process need to be debated without interfering with science development. To achieve this, the government through the NBA must take up a broader consultation role to enhance a balanced articulation of policy relevant knowledge.

If regulation is to promote biotechnology development as desired by many African governments it should be approached from a participatory, all-inclusive, and socially responsive process. In the Kenya's biotechnology subsector, there is a positive re-conceptualization of the role of the public through the BioAWARE public awareness strategy (RoK, 2008) that is being implemented by the National Council for Science and Technology (NCST). In addition, there is now a legal framework under the provisions of the Biosafety Act (RoK, 2009) where all players have been empowered. It has mechanisms for public participation and education. The scientists can undertake research while the public can demand proper public education. The implementing agency (NBA) must use this platform to constructively engage of all stakeholders in the biotechnology products implementation phase. It is this kind of public awareness and an all-stakeholders dialogue that must lie at the centre of an effective regulatory process, which encourages the interrogation of scientific claims, and ensures a more inclusive form of debate on issues pertaining to biotechnology and its potential to spur economical growth in the Kenyan agricultural sector (see Kingiri, 2011b). This must be done on the premise that decisions on

biotechnology regulation cannot be done on the basis of sound science alone (Newell, 2002).

Acknowledgements

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