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Biotechnology regulation in a developing country context: the role of scientists

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ABSTRACT

Scientists for a long time have been associated with the role of generating the evidence-base and reliable knowledge that ultimately informs public policy with a view to ensure evidence-based and/or research-informed policy decisions. However, recent demands for accountability in management of controversies associated with biotechnology have created a new platform for experts in biotechnology research and regulation. This has challenged the previously undisputed knowledge production role with the public demanding to be part of the biotechnology governance and policy decision-making process. The role of scientists in biotechnology regulation in practice is investigated using Kenya Biosafety Act formulation process and implementation as a case study. Based on interview data solicited from different stakeholders who participated in the process, this paper exposes challenges that exist when scientists get entangled in public policy formulation process due to the underlying value based practices. It appeals for reflexivity in order for the process to accommodate different values and interests towards a biotechnology development for the benefit of the poor.

Keywords: *Biosafety Act Kenya, reflexivity*

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Introduction

New advanced biotechnology applications involving genetically engineered (GE) technology particularly in agriculture are poised to revolutionalize the sector through transformation of specific traits to increase productivity, manage pests and weeds as well as enhance nutritional value of products (FAO, 2004; 2010).). Despite this progress, the focus on ensuring effective technology transfer pathways has generated scepticism regarding the process of technology transfer to contribute to significant social and economic impact, especially considering the fact that process of developing transgenic crops and subsequent adoption has been very slow (FAO, 2010). Some of the factors that have contributed to this slow progress are linked to the political economy of biotechnology governance and particularly biosafety regulation (Paarlberg, 2008). Governance is a contested subject both in theory and practice. It has been applied in public policy-making to reconcile the role of multiple actors in debating, defining and achieving policy goals where the role of the respective governments becomes that of coordinating and steering (Lyall *et al.*, 2009a: 4). Indeed in new biotechnologies, there is a clear call to engage a wide range of stakeholders in regulatory policy-making (Tait *et al.*, 2006). Analysis of governance is thus heavily anchored in the decision-making approaches that broadly define governance based on the rules, institutions, practices and power that shape the behaviour of different actors (Harsh and Smith, 2007:252).

Biotechnology regulation has been debated widely and it is now understood that regulation is a key device available to governments interested in shaping governance of technology to promote the public interest. At the global level, this regulation is provided through the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD secretariat, 2000). Regulation of biotechnology allows consumers' health and environmental protection and at the same time leaves room for harnessing the potential benefits (FAO, 2004). However, regulation implementation is multifaceted involving very many players at different levels (Fukuda-Parr, 2006). This complicates the process of arriving at a consensus since these multiple actors have different views around how this process should be advanced. The scientific communities are caught up in this and their viewpoints have become a subject of debate in public policy making.

This paper looks at the renewed role of scientists as experts in the context of the political environment under which they operate and disseminate policy relevant knowledge in biosafety regulation and implementation. The term 'expert' is understood from the perspective of expertise that denotes the mechanism by which problems are framed whereby experts are called upon to respond to these problems. In the process, they incorporate scientific judgments and basic social, political and cultural predispositions and commitments (Nowotny *et al.*, 2001: p. 215). The expertise advanced in the process therefore, captures technical knowledge in both scientific and non-scientific domains (Nowotny, 2003). The paper seeks to bring to the limelight the dynamics around biotechnology regulation and how this can be brought to bear on productive practice for biotechnology development. It is informed by experiences of Kenya in developing requisite regulatory structures for management of biotechnology research and development (Kingiri, 2010).

Research context and methodology

Kenya presents an excellent case to investigate the dynamics associated with modern biotechnology in terms of regulatory policy environment and context. This is because the initiation of biotechnology research activities that commenced in 1990's paralleled the establishment of the requisite regulatory process providing an exemplary context to investigate the dynamics around knowledge production with both technological and regulatory orientations. This parallel process engaged communities in research, policy and public arenas in an iterative manner bringing about interesting biotechnology and institutional innovations. Secondly, policy initiatives like the strategy for revitalising agriculture (RoK, 2005) and the Vision 2030 embraces an integrated approach to innovation towards economic development.

This context created a conducive environment to undertake qualitative in-depth semi-structured interviews with over 50 individual knowledge actors who had (or claimed to have) a stake in decisions pertaining to biotechnology as researchers, policy makers, employees of nongovernmental organisations (NGOs) and members of the public (mainly consumers and farmers). The research period was between 2006 and 2010. This was complemented by observation carried out during different scientific and public workshops in biosafety and biotechnology held during this period, and analysis of relevant secondary documents. 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) to influence policy outcomes. Consequently, the data analysis captured the different ways knowledge is used in the regulatory processes and what factors come into play.

In some cases, codes are used to report information cited in this paper in order to guarantee anonymity of some of the interviewees as requested.

Milestones in Kenya's biotechnology sector

Modern biotechnology has revolutionised many sectors including agriculture and embraces a wide range of applications including tissue culture, markers assisted selection and genetic engineering (GE) also referred elsewhere in this paper as modern biotechnology. All these are being applied in Kenya, but the latter is the focus of this paper. Just like many African countries, GE is relatively new, but GE products have been handled indirectly through trade in form of food aid (Kagundu, 2008).

Actual work involving advanced GE commenced in 1991 when Kenyan scientists went to USA and in collaboration with scientists there, engineered a virus resistant sweet potato (Odame *et al.*, 2003). Thereafter in 1998, the transformed plants required regulatory approval for this research to continue in Kenya. However, actual process of regulatory process and implementation had commenced prior to 1998.

To date, over six GE research initiatives have been evaluated in public institutions in conjunction with local and international partners (see Kingiri and Ayele, 2009). These activities include Bt maize and Bt cotton engineered for resistance to insect pests, cassava for resistance to viruses and sorghum for resistance to striga weed. The recombinant rinderpest vaccine initiative targeted control of rinderpest disease in cattle and other viruses in small ruminants. Other initiatives are in the pipeline for example the sorghum fortified with nutrients funded by the Bills and Melinda gates foundation through the Africa Harvest Biotechnology Foundation International (see www.africaharvest.org). Since the approval of the first transgenic crop- the sweet potato in 1998, no product has reached the farmers and the furthest the biotechnology activities have gone towards a product is the confined field testing. It is hoped that with the establishment of a functional biosafety framework, the situation will change.

Biosafety regulatory mechanism

Biosafety encompasses the regulatory mechanisms that the government has put in place for the governance of GE activities. Article (8g) of the Convention on Biological Biodiversity (CBD, 2000) and Article (16) of the Cartagena Protocol provide for establishment of appropriate mechanisms to regulate, manage and control risks associated with Living Modified Organisms (LMOs). The protocol emphasises on risk assessment (RA) and risk management, and provides guidelines to achieve this (Annex III).

At the early stages of biotechnology research activities, Kenya opted to use the existing infrastructure, the Science & Technology Act (RoK, 1980) to institute regulatory mechanisms through the drafting and adoption of the *Regulations and Guidelines for Biosafety in Biotechnology in Kenya* (RoK, 1998). Thereafter, in an effort to legalise the regulations as well as the biotechnology activities, the *National Biotechnology Development Policy* was drafted and later approved in 2006 (RoK, 2006). This was followed by different versions of the biosafety bill which became Biosafety Law in Feb. 2009 (RoK, 2009).

Kenya signed and ratified the Cartagena Protocol in May 2000 and January 2002 respectively. This further obligated the government to put up regulatory structures to operationalise it. This Biosafety Act therefore primarily seeks to operationalise the Protocol. The controversial developments surrounding its formulation over the years are at the centre of this paper where different actors were proactively engaged particularly between 2002 and 2009.

Previously, all the involved government actors and other nongovernmental players involved in biotechnology governance were brought together as a Committee (NBC) under the umbrella and coordination of the National Council for Science and Technology (NCST) that acted as a boundary organisation overseeing the management of biotechnology research through regulation. This role has since been taken over by the National Biosafety Authority (NBA) formed under the provision of the Biosafety Act.

Theoretical framework

To analytically situate the discussion in sound theoretical debates, this paper draws upon insights from science policy literature in particular governance debates on the policy formulation process (see for instance Lyall *et al.*, 2009a; Tait and Lyall, 2005). These scholars try to explain the changing role of science in policy deliberations and the changing integrated knowledge production architecture prompted by new technological developments (Gibbons *et al*., 1994). In the case of biotechnologies, this brings about governance challenges linked to biosafety regulation imposed to promote technological competitiveness and encourage public acceptance of these new technologies (Lyall, 2007).

Dynamics associated with biotechnology regulation: implications for knowledge production

In this section, practical reasons why and how scientists got entangled in Kenya's regulatory process is explored and the kind of reactions this generated. This helps us understand the controversies and challenges associated with biotechnology and how this may hamper a productive regulatory process that may lead to pro-poor biotechnology development.

Scientists' proactive role in regulatory process

The section tracks empirically the Kenya's regulatory trajectory paying attention to the involvement of scientists in this process, and exposes the tensions that this generated. It is important to note that many interviewees desired a regulatory environment that would enhance deployment of products of GE science. Biosafety bill was a gateway towards achieving that goal. Media reports analysed during field work confirm some activism by the scientific and non scientific communities in support or against the biosafety bill. Biosafety formulation process as a pertinent step in legalising the regulatory regime engaged the scientific community intensely. Scientists collectively educated policy makers and journalists, sensitizing them on GE thus making *"a case for biotechnology"* as well as persuading them to support it (interview with RSIn-GP2, Dec. 2007). This was however viewed with suspicion by some interviewees, who were concerned with what they viewed as biotechnology promotional agenda and associated politics. Several documents obtained during field work and numerous media reportage by both proponents and opponents seemed to confirm this pro-activeness.

Scientists as experts

Empirical data revealed different roles played by the scientific communities in the policy, academic and NGOs arena under the umbrella of experts and advisors. The scientists' early involvement in drafting and steering the regulatory process was not disputed because as argued by one of the members, they had the needed technical capacity to understand the purportedly technical and complex science:

> *"The constitution of the first team that wrote the guidelines was predominantly scientists. It was historical in that capacity of other groups such as consumers and other groups was limited in understanding the science behind the development of biotechnology."* (Interview with a technological & biosafety policy advisor, Public University, Nov. 2007)

Research scientists from Kenya Agricultural Research Institute (KARI) were instrumental in shaping the Kenyan regulatory process and were widely mentioned by both scientist and non scientist respondents as having pushed for the drafting of the first regulations and guidelines. KARI's role actually revolutionized the government operations and priorities. Consequently, the NCST actually shifted its focus from general science and technology to the establishment of a regulatory regime in order to support GE research (Sander, 2007). A respondent undertaking biotechnology research explained how this occurred:

> *"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 GE. 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."* (Interview with a research scientist, international intermediary organisation, Nov. 2007)

The key policy scientists interviewed in this study claimed that they were relied upon extensively to advise the Ministry of Agriculture and regulatory agencies on both biotechnology and regulatory issues. Consequently, this advisory role impacted upon the regulatory process trajectory.

Additionally, in the formulation of the Biosafety Act (2009), the scientific communities were actively involved in various capacities namely; technology experts, regulatory experts and advisors as well as lobbyists (this is clearly demonstrated in Karembu *et al.*, 2010). The nature and role of the ensuing

relationships formed around the formulation of the bill were consequently interpreted in different ways as collaborations, facilitation or activism, lobbying and advocacy, spurred by different factors.

Scientists' role and implications

National efforts to establish a legally binding regulatory regime in compliance with Cartagena Protocol engaged stakeholders in various ways. One of the roles of the NBC according to RoK (1998) was to draw policies and procedures to govern biotechnology. In this regard, this gave NBC the legal powers to spearhead the policy-making process. However, NBC coordination role in the biosafety bill formulation process was perceived to be blurred by the activism of other actors, a view shared by both scientists and non scientists. Arguably, the scientists and their allies became the main drivers of the bill formulation process:

> *"The main players were the biotechnology industry, and the scientists make much of the industry. The whole process was supposed to be an initiative of the government but the interest was with people from the biotechnology industry than what we would call the broader section of Kenyan society."* (Interview with JO-NS6, journalist, local daily, Apr. 2008)

NBC was also largely made up of scientists representing different organisations with two representatives from the civil society. This being the case, it can be concluded that scientists and their affiliated institutions played vital roles as technical experts. This role is however threatened by perceived motivations and interests likely to bring about conflicts of interest. It was a concern of non-scientists from the civil society that technical information used in risk assessments (RA) and consequent decision making pertaining to GE trials was solicited by scientists from technology developers who are interested parties. The relationships established around the regulatory process in the Kenyan context were mutual in that the participating players expected to benefit. Scientists and the government were for instance receiving financial support from non-state actors and donors. These relationships and partnerships were perceived by many interviewees to have positively enhanced the regulatory process. Further, some interviewees were in agreement that the government has inadequate capacity to support the regulatory process, so these other supporting parties were filling in that gap. From these accounts, resources and in particular financial support was a key incentive cementing these relationships (for a detailed account of the role of scientists and controversies this generates, see Kingiri, 2010).

Despite the potential conflict of interests, scientists were perceived to be key players in regulatory process as facilitators, and through their active involvement provided a regulatory mechanism through which the biosafety institutional regime could operate.

Conclusion and recommendations

From the foregoing, it is clear that the roles played by the scientists directed the regulatory process without any contestation. The paper suggests that scientists are not disinterested actors in the regulatory instruments formulation process, and are inspired by different motivations and interests. This has an impact on the ensuing regulatory practice prompted by the unprecedented biosafety revolution. This leads to a compelling urge to reconsider how policy and regulatory formulation processes are conceptualised and articulated. Biotechnology regulation, if it is to achieve greater effect in reconciling the governance agenda of modern biotechnology on the one hand, and role of actors in providing evidence-based expertise into the process; it must factor into the process the different inspirations.

In addition, effective policy and regulatory processes must first acknowledge the potential of experts to influence policy directions. Consequently, strategies should be devised that encourage a reflexive and responsive behaviour (Lyall, et al., 2009b: 261). This may enrich how policies are implemented considering that cultural practices in biotechnology are linked to values and interests (Laurie et al., 2009).

In conclusion, the paper appeals to the policy, public and scientific communities to adopt a reflexive approach to biotechnology regulation in order to enhance convergence of knowledge for sustainable pro poor biotechnology development.

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References

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

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

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

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.

Gibbons, M.; Limoges, C.; Nowotny, H.; Schwartzman, S.; Scott, P. and Trow, M. 1994. The new production of knowledge: the dynamics of science and research in contemporary societies, London: Sage.

Harsh, M., and Smith, J. 2007. Technology, governance and place: situating biotechnology in Kenya. *Science and Public Policy*, 34 (4):251-260.

Kagundu, A.M. 2008. Risk assessment mechanisms for genetically engineered plant products at official entry points in Kenya. A paper presented in the *1st all Africa congress on biotechnology*, September 22-26, 2008. Nairobi, Kenya.

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

Kingiri, A., and Ayele, S. 2009. Towards a smart biosafety regulation: the case of Kenya. *Environmental Biosafety Research*, 8: 133-139.

Kingiri, A. 2010. An analysis of the role of experts in biotechnology regulation in Kenya. Journal of International Development, Vol. 22: 325–340.

Laurie, G., Bruce, A., and Lyall, C. 2009. The roles of values and interests in the governance of the life sciences: learning lessons from the "ethics+" approach of UK biobank. In Lyall, C., Papaioannou, T. and Smith, J. (Eds.), *The limits to governance. The challenge of policy-making for the new life sciences*, pp. 51-77. Farnham, Ashgate.

Lyall, C. 2007. Governing genomics: new governance tools for new technologies. *Technology Analysis & Strategic Management*, Vol. 19 (3): 369-386.

Lyall, C., Papaioannou, T., and Smith, J. (Eds.). 2009a. The challenges of policy-making for the new life sciences. In Lyall, C., Papaioannou, T. and Smith, J. (Eds.), *The limits to governance. The challenge of policy-making for the new life sciences*, pp. 1-17. Farnham, Ashgate.

Lyall, C.; Papaioannou, T. & Smith, J. (Eds.) 2009b. 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.

Nowotny, H. 2003. Democratising expertise and socially robust knowledge. *Science and Public Policy*, 20 (3): 151-156.

Nowotny, H., Scott, P., and Gibbons, M. 2001. Re-thinking science: knowledge and the public in an age of uncertainty. Polity Press, Cambridge, UK.

Odame, H.; Kameri-Mbote, P. and Wafula, D. 2003. Governing modern agricultural biotechnology in Kenya: implications for food security. IDS Working Paper, 199, Institute of Development Studies (IDS), University of Sussex, Brighton, UK.

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

Republic of Kenya (RoK). 1980. The Science and Technology Act. Government printer, Nairobi, Kenya.

RoK. 1998. Regulations and Guidelines for Biosafety in Biotechnology for Kenya. NCST: No. 41.

RoK. 2005. Strategy for Revitalising Agriculture (SRA): 2004-2014. (Short version), Feb 2005.

RoK. 2006. National Biotechnology Development Policy. Government Printer, Nairobi, Kenya.

RoK. 2009. The Biosafety Act, 2009. Kenya Gazette Supplement No. 10 (*Acts No. 2*), Government Printer, Nairobi, Kenya, 13 February, 2009.

Sander, F. 2007. A construction of Kenya's Biosafety Regulations and Guidelines. How international donor agencies interact with regulatory innovation actor-network. Msc. Thesis. Science and Technology Studies, Faculty of Social and Behavioural Sciences, University of Amsterdam.

Tait, J., and Lyall, C. 2005. A new mode of governance for science, technology, risk and the environment? In Lyall, C. and Tait, J. (Eds.), *New modes of governance. Developing an integrated policy approach to science, technology, risk and the environment*, pp. 177-188. Aldershot, Ashgate.

Tait, J., Chataway, J., Lyall, C., and 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: Cambridge University press.