

International Journal of Technology and Development Studies
Volume 2, Issue 1 (2011), pp. 64-86
[URL:www.ijtds.com](http://www.ijtds.com)
ISSN: 2211-0313

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The Contested Framing of Biosafety Regulation as a Tool for Enhancing Public Awareness:

Insights from the Kenyan regulatory process and
bioAWARE strategy

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Keywords: Biotechnology, biosafety regulation, public awareness

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ABSTRACT: *Innovations in modern biotechnology have governance issues that demand appropriate regulation. Regulation is therefore a tool for managing some of the controversies but there are various interpretations on how this may be achieved. In this paper, I seek to provide an overview of how the recently approved Kenyan public awareness strategy for biotechnology (BioAWARE strategy) might best approach its future developmental objectives through developing an understanding of what biotechnology regulation means to different implementing stakeholders. As such, it seeks to highlight that programmes such as BioAWARE need to avoid simplifying the consultation process to one by which scientists present science to the public without recognition of its social significance. I recommend that instead the governance actors involved should see such social values as integral to the development of, and implementation of regulations, rather than an afterthought. The intention is not to de-rail the science progress, but highlight that it cannot be assumed that either more science will inevitably lead to conformity, or that social values are inevitably anti-science.*

INTRODUCTION

Modern biotechnologies involving application of genetic engineering (GE)² can potentially improve human wellbeing for example through enhancement of agricultural productivity. There are however concerns about potential risks that these technologies may pose to biological diversity and human health. An international mechanism referred to as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD, 2000) was negotiated by countries to regulate and facilitate safe deployment of biotechnologies. Thus, 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. In developing countries for instance, regulation of biotechnology allows consumers' health and environmental protection and at the same time leaves room for harnessing the potential benefits (FAO, 2004).

Provisions of Article 23 (public participation and awareness) of the Cartagena Protocol require that public be involved in decisions and activities involving safe transfer, handling and use of living modified organisms. There are, however, challenges in implementation of this article that go beyond simplistic engagement of public on technological matters. These challenges include the disagreements on how stakeholders should be engaged (Glover, 2003) but they also relate to the contested nature of risk or biosafety regulation. Lessons from agribiotech regulation in Europe show that biosafety regulation is confounded by inability to deal with the social and value laden uncertainty paradox linked to

² The term GE or GM is used to mean the manipulation of living organisms to produce goods and services useful to human. But I make distinction between traditional (or conventional) and modern biotechnologies. The traditional approach allows the development of new products (such as seed varieties) by the process of selection from genetic material already present within a species, while the modern (transgenic) approach develops products (such as seed varieties) through insertion of genetic material from different species into a host plant).

potential risks (van Asselt and Vos, 2008). Clearly, there are alternative views of what constitutes biosafety risk and different views of how risk should be addressed with regard to biotechnology. These alternative views complicate the task of risk governance efforts and democratic public engagement (Levidow, 2007). Article 23 brings two intricately intertwined roles of regulation; addressing the safety aspects (biosafety regulation) and engagement of public through requisite awareness strategies. Achieving a harmony between the two has been proved to be a contentious issue (as alluded to above in reference to Europe). This situation is further aggravated by the fact that biosafety regulation implementation is multifaceted and involves very many players at different levels who are interested parties (Fukuda-Parr, 2006). These multiple actors have different views around how a regulatory process should be advanced.

In Africa, the Cartagena Protocol has been domesticated by many countries through the institution of appropriate national biosafety frameworks (NBFs). Indeed, many countries are in the process of establishing functional NBFs to regulate risk (biosafety³ regulation) linked to modern biotechnology (Makinde, 2010). However, the process of institutionalising biosafety has been advanced from a narrow perspective, primarily to promote biotechnology transfer (Hisano, 2005; Falck-Zependa *et al.* 2009). Interestingly, how the respective NBFs could be utilised to improve public awareness for smooth biotechnology transfer and delivery is not well addressed. This paper explores this subject through the lens of the Kenya's regulatory process (Harsh, 2005; Kingiri, 2010) and the recently approved BioAWARE strategy (RoK, 2008). The BioAWARE strategy seeks to serve three main aims; firstly it provides a platform for biotechnology education and awareness creation in order to raise the level of understanding and appreciation of biotechnology. Secondly, it is perceived to be a national compliance with Article 23 of the Cartagena Protocol and thirdly, it fulfils the public awareness requirement under the National Biotechnology policy (RoK, 2006). Both the strategy and the regulatory process provide an excellent context for interrogating how the regulatory framework can enhance public awareness which is the objective of this paper. Consequently, the paper looks at the way regulation may create an opportunity and space for negotiation in biotechnology governance. I point at the need to rethink regulation in the light of how this can be improved to enhance public awareness. To support this objective, I use qualitative data primarily generated through interviews with different governance actors in Kenya involved in biotechnology regulation. Alongside other factors, Kenya was considered as a case study country because the process of developing a NBF has been co-evolving alongside biotechnology transfer endeavours (for accounts of this co-evolution process, see Harsh, 2005; Kingiri, 2010). In respect to this context, the paper attempts to provide a broad picture of:

³ Biosafety is the avoidance of risk to human health and safety, and the conservation of the environment as a result of the use of products of GM (CBD, 2000).

- How different stakeholders conceptualise biosafety regulation and the dynamics linked to a controversial regulatory process;
- What lessons can be learnt from a proactive regulatory process in the light of effective implementation of innovation policies through public awareness strategies like BioAWARE;
- How regulation can be enhanced to promote productive public awareness.

The paper is structured as follows. The next section situates the paper in context by looking at theoretical debates around regulation as a tool for promoting public awareness. This is followed by a brief discussion of the methodology and context that empirically support the narrative pursued in the entire paper. Thirdly the context under which regulation implementation occurs in Kenya based on respondents' description is explored. Next is a discussion of the implications of this context for implementation of BioAWARE strategy. The paper concludes with some recommendations informed by emerging issues in the light of how this can productively inform innovation based public awareness initiatives like BioAWARE.

RETHINKING ROLE OF REGULATION AS A TOOL FOR NEGOTIATION IN BIOTECHNOLOGY GOVERNANCE

Regulation as a tool for governance in biotechnology in developing countries has been approached from a very narrow perspective. The key objective has been to enhance safe and responsible use of new biotechnologies, thus optimize benefits and reduce risks (FAO, 2004). Consequently, efforts have gone to building the requisite national biosafety regulatory capacities to manage the technology and its deployment (Falck-Zependa *et al.* 2009). One aspect that has constantly been neglected is the role of the public in regulatory processes and has at times contributed to controversies and tension (see in reference to Kenya Harsh, 2005; Kingiri, forthcoming). Harsh (2005) notes that the public had been marginalised in the debates about biosafety regulation with the nongovernmental organisations (NGOs) taking up the public space. This is however in line with the cited challenges that confound governance of modern biotechnologies that include the tensions emanating from the diverse views of different governance actors who sometimes hold conflicting belief systems and interests (Laurie *et al.* 2009) and the increasing necessity for scientific and social evidence to guide the decision-making processes (Lyll *et al.* 2009). Despite these challenges, governance takes cognizance of the important role participation plays in reconciling the diverse needs of different players. This is important because processes that fail to recognise the different public demands associated with biosafety regulation are likely to lack credibility and legitimacy (Glover, 2003, Glover *et al.* 2003).

To augment debates that have so far been advanced by governance theorists, it is important to reconsider how regulation and in particular the national regulatory frameworks can serve as a space for public awareness towards better and negotiated public understanding of biotechnology science. Scholars in science policy domain describe this role through conceptualisation of regulation as a boundary object or a social instrument intended to bridge between scientific and social controversies (Guston, 2001; Jasanoff, 1987). Guston describes boundary objects as tools for stabilising science and non science, which are seen as two different social worlds. He gives examples like patents, model research agreements and regulations to illustrate this function. Boundary objects are perpetuated through boundary organisations which primarily try to bridge between politics and science through for instance provision of incentives, enlisting participation of actors from science and non science worlds and professional mediation (Guston, 1999, 2001). The arguments are largely based on case studies in technologically advanced countries like USA and Europe but in a developing country context, the concept of boundary object or organisation has not been explored. Arguably, these studies show that the framing of risk and the practices of the actors involved particularly the scientific communities in policy deliberations differ from country to country based on political cultures (Jasanoff, 1995).

This paper draws insights from the scholarly material briefly alluded to in this section to inform how a productive implementation of a public awareness strategy like BioAware might be achieved. The objective of doing this is to enhance a feasible communication awareness strategy that takes cognizance of the social and value-based aspects of biosafety regulation, made visible during a proactive regulatory process. The basic idea is to avoid pitfalls that may limit the possibility of such public awareness tool from reaching its intended innovation objectives.

DATA COLLECTION AND STUDY CONTEXT

This paper is based on research conducted in Kenya between 2006 and 2010. The rationale for selecting Kenya as a study area was based on several factors. Firstly, there is a significant body of literature on the Kenyan regulatory policy process that reveals that the establishment of the Kenyan biosafety regulatory regime had become controversial (Sander, 2007; Harsh, 2005). Secondly, Kenya is perceived to have advanced both in terms of biotechnology research and development (R & D), and progress made towards establishment of a functional biosafety regulatory regime (Nang'ayo, 2010). The latter aspect presents an excellent innovation-policy model that makes it possible to analyse the science policy controversies in an empirical setting. The process of instituting a regulatory regime for management of biotechnology involved among other activities the development of biosafety regulations. Thus, "biosafety regulations

implementation” was perceived to be an invaluable process through which rich data could be generated. This process involved a wide range of stakeholders making it possible to randomly select the 42 respondents who were interviewed in this study. These interviewees have been involved in biotechnology research and biosafety policy making in their various capacities as biological scientists and non-scientists. They were affiliated to organisations that have (or claim to have) a stake in modern biotechnology and biosafety arena ranging across researchers, policy makers, academics and nongovernmental organisations (NGOs) in both pro-biotechnology and civil society arenas (see Appendix 1 for details).

Most of the interviews were conducted at the height of controversies involving legalisation of biotechnology activities in Kenya through formulation of a Biosafety Law. Interviews were structured in a way that yielded detailed understanding around the dynamics that shape the process of biotechnology regulation including regulatory policy making. The subjective views of the interviewees related to implementation of regulations, why they hold these perspectives and their behaviour related to regulatory process were the topic for interpretation. The qualitative data generated this way were analysed against secondary data linked to role of actors in the Kenya’s biosafety regulatory process between 1998 and 2009 (cf Appendix 2; Harsh, 2005; Kingiri 2010; Kingiri and Ayele, 2009). Direct observations were made during numerous biotechnology and biosafety forums held between 2007 and 2009 at the height of debate around formulation of the biosafety bill.

THE STATE OF BIOTECHNOLOGY REGULATION IN KENYA: AN OVERVIEW

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). 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). It is this product development initiative led by scientists that triggered the need for regulations (Sander, 2007). To date, several GE research initiatives have been evaluated in public institutions in conjunction with local and international partners. The crop 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 include the transgenic sorghum and cassava fortified with nutrients and the water efficient maize for Africa (WEMA). 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 trials (CFTs).

At the early stages of biotechnology research activities, Kenya opted to use the existing infrastructure, the Science & Technology Act (RoK, 1980) under the National Council for Science and Technology (NCST) to institute regulatory mechanisms through the drafting and adoption of the *Regulations and Guidelines for Biosafety in Biotechnology in Kenya* (RoK, 1998). 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. In an effort to institutionalise 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 draft versions of the biosafety bill which eventually became Law in February 2009 (RoK, 2009). This process was controversial based on the way participation of different stakeholders was advanced. It was a protracted process between the public represented by the civil society on the one hand, and the scientists backed by the government and pro-biotechnology NGOs on the other. Harsh (2005) and Kingiri (2010) also note that the process was largely driven by the scientific communities and the private sector which brought about resistance from the civil society and public representatives. The scientific communities and the non scientific groups used different avenues to present and advance their viewpoints, with the media being utilised by both groups extensively (see Appendix 2 for selected media reports).

THE BIOAWARE STRATEGY

The National Biotechnology Awareness Strategy (BioAWARE Kenya) was launched on 22 Sep 2008 as a culmination of about two years work and consultation. It can be said that it is partly a national compliance with the public participation and awareness components of the Cartagena Protocol (Article 23) and the National Biotechnology policy (RoK, 2006). Its objective is “to provide a participatory mechanism for awareness creation and raise the level of understanding and appreciation of biotechnology” (Preface). Its launch ushered in the biosafety regulation implementation phase targeting public awareness of a wide stakeholder through open and transparent information and knowledge sharing, for informed decision making processes. Ultimately, this is expected to benefit the Kenyan citizenry. Its core values and functions embrace both innovative and social aspects, as well as strategies that embrace participation and needs of the government, research scientists, extension service providers, farmers, teachers/lecturers/students, mass media, industry, civil society, consumers and faith-based leaders. These groups are also to act as champions through which a wider public can be influenced (RoK, 2008: 11-13). Different dissemination channels and venues are targeted. I want to argue that this is a very good strategy paper but its implementation and success will entail careful rethinking of engaging the targeted stakeholders. Indeed, during the launch of the strategy the chief executive of the Kenya Federation of Agricultural Producers (KENFAP), a farmers association, and the Director of Agriculture

appealed for a radical and strategic change in attitude in order to reverse the purportedly scientific and industry led biotechnology approach. This, they argued would lead to a process that recognises participation of technology users like the farmers (recorded speeches during the launch at Kenyatta International Conference Centre, Nairobi, Kenya). These remarks put to perspective the need for a more participative governance approach to biotechnology regulation (Lyll and Tait, 2005). Moreover, because debates about biotechnology are fuelled by risk and diverse perceptions, risk communication is critical. A key factor to consider is how to appeal to public through consideration of their viewpoints. In the present paper, insights from experiences and lessons from the implementation of Kenya's biosafety regulatory process are explored with a view of informing a productive implementation of this strategy.

ISSUES EMERGING FROM KENYA'S REGULATORY PROCESS

The respondents interviewed for this study expressed their views about biosafety regulation based on the underlying context under which biotechnology was being introduced in Kenya, and the triggered biosafety regulatory process outlined in the preceding section. This being the case, different aspects of biosafety legislation formulation constitutes the regulatory process. Other aspects include risk assessment and related decision making approaches adopted by the policy government organ, the then National Biosafety Committee (NBC). Contestations and varying interpretations emerged alongside particular themes explored next in line with two distinct communities of practice, the scientists and non scientists (see Appendix 1).

WHAT SHOULD INFORM A REGULATORY PROCESS?

Many interviewees from the scientific community were of the view that biosafety regulatory process at all times should be informed by sound scientific judgements. Anything that could not be justified empirically or scientifically qualified as "social" or "value based". Some scientists were of the opinion that scientific issues needed to be deliberated separately from social and ethical issues. To some, failure to respect this creates room for politics by anti-biotechnology critics who were in many instances linked to Europe and its precautionary style of biosafety regulation:

We should not allow social issues that cannot be regulated to block [biotechnology] science. Unfortunately most of social issues are exported from Europe to Africa. We cannot allow the politics of Europe to be exported to Africa (Scientist from a pro-biotechnology NGO).

Probing this further, the same respondent argued that social regulation fails to take note of unique food security needs that confront Africa, thus regulations should be flexible enough to enhance economic competitiveness.

In contrast, respondents from the non scientific community were concerned more with consideration of the wider social and economic factors that broadly affect the `public as voiced by a representative of civil society:

What we want as civil society is a policy framework that is very comprehensive, that captures aspects of economic development, ensures food security in the long run and attends to social, cultural and environmental aspects to safeguard our environment. Anything that falls short of this is not acceptable to us.

Non scientists from civil society did not approve of the seemingly science based approach to regulation advanced by the scientific community. Some labelled scientists as being restricted only to a “scientific” approach, and lacking the broader understanding of the social issues that affect the public as another representative of civil society explains:

Scientists do not even acknowledge that there could be a problem. Our scientists are not willing to or are not inclined towards addressing GMOs and public fears. The policy documents that “they” drafted took a very scientific approach without looking at the social, economic and environmental aspects. It was purely a commercial thing. It was like someone drafting a business proposal and then giving it to you (public) and you do not have to question it.

Some members of the civil society further claimed that social-economic issues were not strongly considered as they ought to in processes that are social in nature. One representative of the farmers referring to the drafting of the biosafety bill commented:

I could read clearly that the bill is scientists’ work. I do not blame the scientists because to them they see things that way. They say they want to improve the farmer’s life but at the same time I think they are really not looking at the issues from the farmers’ perspective.

Perhaps to discredit the purportedly scientific regulatory process and expose the difficulties of implementing a science based process, a policy scientist who was then a member of the decision making organ, the NBC, made the following comment:

All I would say is that NBC uses scientific reasoning. 90% of the people from NBC will think from a science base, but (biotechnology) is an area of science whereby the scientific reasoning is very varied. Some people are liberal, some are still conservative. Because Kenya does not have a (regulatory) guideline, it still gives you the liberality to quote any scientific information that you have.

This shows the value-laden nature of the decision making process associated with biosafety regulation. These arguments clearly show that it is not practical for science alone to guide the regulatory process. Social aspects of biosafety regulation and value based judgements cannot be ignored.

PURPOSE OF REGULATION

The scientific communities were in agreement that regulation aims at providing a technological and innovation space for biotechnology research and deployment. This is through creation of the much needed legal framework for any biotechnology work. The scientists in policy and academic arena noted that regulation basically enhanced confidence amongst the players in biotechnology sector including the public. One academic scientist referring to the interim regulations and guidelines of 1998 noted;

Within Kenya....there is raised confidence evidenced by biotechnology research which would not have come up without the regulations and guidelines that have been put in place.

Perhaps because of their pro-development role as government agents, policy scientists were of the opinion that regulation serves a role of attracting investment (the biotechnology policy approved in 2006 supported development of biotechnology as a tool for poverty reduction). In this regard, lack of a legal statute to regulate biotechnology research was acting against this pro-innovation policy goal as one policy scientist noted;

Lack of this legal instrument (biosafety bill) has affected and hindered research and promotion of biotechnology in this country.

In contrast, the purpose of regulation from non scientists' perspective is to holistically regulate GMOs, capturing social aspects alluded to above, and safety. To achieve this objective, they felt that efforts to come up with a biosafety law should be preceded by adequate public awareness as emphasised by a consumer representative speaking on behalf of a coalition of civil society members (the Kenya Biodiversity Coalition):

To have (structures for biosafety) regulation is important but for me and as a coalition we felt that involvement of the public was our number one key issue, the fact that we are bringing in a technology that Kenyans know very little about. Public awareness and education is fundamental for us. More should be done to educate people about what biotechnology is before embracing it.

Analysis of the foregoing narrative suggests that scientists primarily view regulation as functioning to support the development and promotion of biotechnology, and to build confidence in the sector, thus ultimately attracting investment. The non scientists on the other hand have a broader view of regulation which should encompass not only technological development, but also social regulation aspects of biotechnology.

NATURE OF ENGAGEMENT IN BIOSAFETY REGULATORY PROCESS

An all-inclusive and representative process was preferred by many interviewees irrespective of whether scientists or non scientists. There was no dispute that implementation of biosafety regulation should involve all stakeholders including all citizens like farmers. Referring to participation in the biosafety bill development, non scientists from the civil society perceived the process to be imbalanced and selective. They cited inability of the government to steer a transparent process, excluding the critics who were purportedly advancing the interests of the public:

We (civil society) believe that the drafting process of the biosafety legislation was mainly a boardroom process with inadequate representation of stakeholders (a representative of a farmer's organisation).

They were wary of manipulation of the process to accommodate certain vested commercial and scientific interests:

We need some legal instruments within which people should operate from, including the scientists themselves because they have vested interests; the institutions they represent have vested interests and the multinationals have vested interests; after all they are the ones who fund such biotechnology research (NGO staff from an organic farmers' association).

It was recognised particularly by scientists from the policy arena that biotechnology as a science was technical in nature thus attracting participation of a relatively large number of scientist actors. However when considering biosafety regulation, engagement of all citizens is important as expressed by a senior policy executive in a research organisation:

The regulations are paramount and are not the responsibility of an organization like Kenya Agricultural Research Institute (KARI) or scientists; it is an overriding issue and is a concern of all citizens.

In conclusion, the preceding arguments seem to point out that the regulatory process was lacking in scope by failing to consider major concerns around public participation, representation and potential manipulation by interested players.

COMMUNICATING REGULATORY ISSUES TO THE PUBLIC

Communication of risk is paramount and this is not easy in the cases of uncertainty linked to biosafety regulation as revealed by both scientists and non scientists. One scientist involved in biotechnology research noted:

The problem in (biosafety regulation) is with the understanding of the risk. It is important that once a product is out there (in the public domain) and there are issues that are identified as risky, then this should be communicated to stakeholders. But if (scientists) have not been able to quantify that risk, it is

still a problem because you will still be talking about the possible or potential risk.

Communication also needs to articulate all issues that concern the public in a holistic and transparent manner as argued by a journalist:

The issue of safety and the issue of benefits need to be brought to public debate. If something is not explained fully, I tend to develop some fear about that product. Kenyans are not quite sure whether the GM products are good or bad.

With respect to scientists communicating science to the public, there is a problem as noted by many respondents. Majority of the non scientists for instance noted that scientists often don't see the need to communicate or are ineffective in communicating aspects of biosafety regulation to the public.

Scientists may not be the best communicators and we need those who can communicate all aspects including risks and benefits, by getting the information from the scientists, balance it, and consequently inform the public effectively. Majority of the scientists are not very good at this (Journalist from a local daily newspaper).

The content of the message that eventually reaches the public was a contested issue. Majority of the interviewed scientists claimed that some environmental groups who are against GE technology, were fighting biotechnology introduction into Africa using non factual information. However it was claimed that the inability of science to counter propaganda was blamed on scientists' poor communication skills as argued by a journalist from a local daily newspaper:

Usually the local (Kenyan) scientists are not quite aggressive enough to explain the pros and cons of GM products. The problem is, as a journalist I have read so much especially from other organizations that are anti GM products like the Greenpeace. They are quite aggressive in making their positions and their stands known seizing every opportunity where they suspect that GE products have been counterproductive to the consumers.

This shows how polemic debates about biotechnology governance confound effective science communication. Thus, there was an appeal for scientists and the media to work together in order to enhance a balanced and evidence-based reporting that is beneficial to technology development and to the satisfaction of the public.

I think there is a gap between the scientist and the media which needs to be bridged. There is need for scientists and media to work closely together so that media reporting is accurate and well informed as opposed to just reporting for the sake of reporting which might be misleading (Journalist from a local newspaper).

In conclusion, the public debate surrounding biosafety regulation may be seen as characterised by an imbalanced debate caused by many factors ranging from

uncertainty about risk, transparency and politics.

EMERGING REGULATORY IMPLEMENTATION ISSUES AND IMPLICATIONS FOR BIOAWARE STRATEGY

Based on the findings of this paper, there are many challenges in implementation of a productive public awareness strategy as well as other public policies that aim to promote pro-poor innovations. The ones that have been brought to the fore in the preceding section include; *the role of science and social aspects of biosafety regulation in biotechnology governance, public engagement in the regulatory process and communicating biotechnology science to the public*. These issues pose fundamental challenges to the implementation of BioAWARE strategy and are discussed next.

Contested role of science and non science aspects in regulation

It emerged from this paper that scientists and non scientists have contestations over the value of science in a regulatory context. Basically, different interpretations of regulations show that in practice regulatory process is largely a social process. Perhaps oblivious of this fact, the scientific community argues for science based regulatory process geared towards biotechnology development. The non-scientists on the other hand, perhaps challenging the role of science argue that regulatory process should be guided by consideration of the broader non scientific issues which are sometimes social in nature. This reveals the political nature of biosafety regulation.

Scholars in science policy domain have tried to illuminate the tension that emanates from controversial undertakings within the boundary between science and policy. According to Jasanoff (2004), in regulatory policy making, policy makers use science to legitimise the regulations (or regulatory process) to enhance objectivity. Consequently as social issues inevitably emerge in the policy making process, policy makers re-configure the scientific facts to balance the science and social concerns. It has also been noted that it is not unusual for scientists to struggle between science and politics in an endeavour to uphold the cognitive authority of science among scientists and outside this group (Gieryn, 1995:434-435). This may explain why the scientists in Kenya would want social issues to be left out of a purportedly scientific process. This may be interpreted as narrow focus of regulation when compared to the broad focus preferred by the non scientists from the civil society. Arguably, a broad focus of regulation embraces public awareness and puts emphasis on social economic and other non-technological aspects of biosafety regulation as revealed by this paper.

But perhaps the most important point emerging from the Kenyan case is the uniqueness in the way regulations are framed by players who fit within two distinct categories. This context may have an impact on regulation

implementation, including public awareness. For instance, this may create mistrust between the public on the one hand, and the policy makers on the other who seem to align themselves with the seemingly scientist actors who are perceived to have vested interests. Context for regulation and the underlying framing by different stakeholders largely influences the regulatory trajectory particularly in developing countries (van Zwanenberg *et al.* 2008). It is paramount therefore for local context to inform how a public awareness strategy like BioAWARE is implemented.

Public engagement

The role of the public in the regulatory process was another contested issue. From the perspective of the civil society, the public was marginalised particularly in regulatory policy making. This is in agreement with other reports that also show conflicts brought about by an imbalance in stakeholders' engagement in biosafety regulation (Harsh, 2005; Kingiri, 2010). Controversies in governance of biotechnology have been widely reported in respect to Europe and there are useful lessons that can inform a productive public engagement towards a convergence strategy in biosafety regulation. The early development of regulations in Europe around 1990's was marred by contestations due to lack of initial participation by public who had concerns on potential risk related to agri-biotechnology. We see the proactive push by the biotechnology industry to have permissive regulations elevating the public suspicion of the technologies. This led to a strong opposition by the public towards agro-biotechnologies (Tait *et al.* 2004). Levidow (2007) further demonstrates how in Europe there has been a stalemate in agri-biotechnology governance due to conflicts associated with biosafety regulation and related public engagement.

Value based controversies and conflicts may have long term future ramifications in a poor economy like Kenya which hopes to benefit from agricultural biotechnology (RoK, 2006). An all inclusive regulatory process implementation is desired if long term benefits of biotechnology are to be realised and contribute to food production challenges in developing countries (FAO, 2004). This is important for implementation of BioAWARE strategy since it would be embraced positively leading to a more widespread public acceptance of biotechnology.

Communicating biotechnology science

This paper has revealed the importance of effective communication of regulatory aspects of biotechnology to the public which would promote a better and evidence-based public awareness strategy. The non scientific community that constitute the public has little understanding about potential benefits and risks related to biotechnology. This lack of awareness is not helped by the polemic debates that are often played out in the media when reporting on modern

biotechnology (see Appendix 2 in reference to Kenya). Efforts to verify certain negative or positive claims about biotechnology have been a relatively slow process compounded by poor communication links between scientists and the public. Unfortunately, the media – which could play an important role facilitating communication, has become platform for pro and anti hype around biotechnology. Furthermore, the internet allows information and misinformation to travel fast (there is a lot of information, factual and non factual, that is uncontrollably circulating related to biotechnology). This, one may argue supersedes the speed by which science or scientists are building up empirical evidence that may be accessed from peer reviewed publications. Moreover, it is difficult to know the intentions of different actors, whether proponents or critics. For instance, in the Kenyan case, some pressure groups are perceived to be deliberately misinforming the public and others appear to want to deliberately derail the regulatory process.

Communication of regulatory aspects of biotechnology may have negative or positive ramifications on progressive public education and awareness creation. Careful thought should therefore be given to the content and mode of communication, and the objective this is intended to achieve. There is a possibility of misinformation or overemphasis of particular value-based viewpoints that may result to different interpretations and impacts. A balanced and transparent debate however is likely to yield better results.

CONCLUSION

Both the non scientific and scientific communities are not in agreement over interpretation of biosafety regulations in the light of regulatory needs and by extension, the wider public awareness needs. Thus, different perceptions of regulatory process reveal controversies surrounding the framing and implementation of regulation. The regulatory context exposed here helps to inform how a productive public awareness strategy may be enhanced in Kenya.

As stated previously, the objective of this paper was to look into how regulation can serve as a negotiating tool between science and politics through an enhanced and productive public awareness strategy. This implies going beyond satisfying safety requirements of the public for the sole reason of enhancing internal economic growth, as has been the norm (cf FAO, 2004). However, because of the political economy of biotechnology (which has been noted in the Kenyan case and also in Europe), and the appeal for evidenced-based social and scientific decision making (Tait, *et al.* 2006; Tait and Lyall, 2005), effective regulation needs to meet certain key objectives. The economic aspect for instance should be given careful thought since as much as there might be a general appeal to economic benefits, many farmers who are poor and who might benefit from this technology need to see the value in investing in it. The safety aspects are also governed by complex value-based social factors that cannot be ignored.

Regulation therefore should extend beyond dealing with biophysical risks (biosafety) with the sole purpose of technology transfer to encompass the context under which regulation occurs. This context brings to the fore the underlying issues associated with regulation implementation including ambivalences from all actors in the regulatory process. As this paper has revealed, science itself will not solve wider social issues. Tools like BioAWARE could enhance the positive re-conceptualisation of the role of the public in understanding the social aspects of biosafety regulation. It should further encourage the interrogation of scientific claims and ensures a more inclusive form of debate on all issues pertaining to modern biotechnology, and its potential to spur economical growth in the Kenyan agricultural sector. This must be done on the premise that decisions on biotechnology regulation cannot be implemented on the basis of sound science alone (Newell, 2002). This kind of public awareness and an all-stakeholders dialogue makes us perceive the broader role of regulation as a negotiation tool that promotes science as well as public interests.

There are different suggestions on how a legitimate and all inclusive regulatory process might be achieved in Kenya, which is also applicable for developing economies that are lagging behind in biotechnology revolution in Africa. Firstly, the government needs to solicit experts who understand the different framings of regulations and identify what might be productive frames. Secondly, the government needs to take lead in implementation of the BioAWARE strategy in compliance with the public awareness component of the Biosafety Act (RoK, 2009). Thirdly, the government should coordinate and steer the actions of all governance actors in biotechnology regulation (Tait et al. 2006). Lastly, to avoid the repercussions of overreliance of donor funds as has been the case in Kenya's regulatory system development (cf Sander, 2007); the government should endeavour to work with supra-regional organisations⁴.

Effective communication strategies are integral to the success of biotechnology development. This may be a challenge for BioAWARE as success of its effective implementation is pegged to effective communication of biotechnology science as it develops, and related biosafety issues as empirical data become available. In Kenya, much of the biotechnology work is at research stage and therefore not much empirical data is there to convey in terms of communicating about biotechnology based on local context. However, there is a need to appeal to empirical evidence – that is the value of the scientist. There is a perceived need to focus upon facilitating through bringing actors together (especially users), and helping them understand risk. The only way to do this is through proper and transparent communication. This is because it is not acceptable for scientists simply to continue their work for their own benefit without taking note of public interests.

⁴The New Partnership for Africa's Development (NEPAD) of the African Union (AU) has been in the forefront in providing policy direction with regards to biotechnology innovation and governance (cf Juma and Serageldin, 2007).

As a final note, any awareness strategy intended to embrace governance principles needs to avoid simplifying the consultation and communication process to one by which scientists present regulatory science to the public without recognition of its social significance. Instead, they should see such social values as integral to the development of, and implementation of regulation, rather than an afterthought.

ACKNOWLEDGEMENT

This paper is based on research conducted in Kenya over the period 2006-2010 funded by the Open University, UK, the UK Economic and Social Research Council (ESRC), Innogen centre and partly by the DFID-Research into Use program. The author gratefully acknowledges this support. The views expressed in the paper do not necessarily reflect those of the Open University, ESRC Innogen centre and DFID. The author also acknowledges the invaluable comments on the first draft of this paper by Dr. Simon Outram, previously of Innogen centre.

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APPENDICES

Appendix 1: Research participants

| | Categories of participants | Participant code | Institutes/org | No. |
|--------------|--|--|---|-----------|
| 1 | GE Practitioners (GP) are (or have previously) engaged in GE activities. Some in the interviews claimed to be passionate about GE work. The professional profile information supports this claim as well as institutional documents. | RSPu-GP1, RSPu-GP2, RSPu-GP3, RSPu-GP4, RSAC-GP5, RSPo-GP6, RSPu-GP7, RSPu-GP8, RSPu-GP9 | Public research, public universities and international organisations. | 9 |
| 2 | Policy Scientists (PS) are either senior government officials, biological scientists in the NBC and/or IBC and regulatory institutions. The senior government officers are (or have been heads of government institutions or ministries). The scientists in the NBC and IBC are generally from public academic institutions, regulatory agencies and one international research organisation. Some of them are affiliated to other professionally related institutions. Participants in this group are all connected to GE research in one way or another. | BIp-PS1, ARp-PS2, ATp-PS3, PRp-PS4, ATBp-PS5, RSPu-PS6, RSPu-PS7, RSPu-PS8, ARp-PS9, PRp-PS10, BIp-PS11, FSp-PS12, BIp-PS13, ABp-PS14, ENp-PS15, ARBp-PS16 | Government ministries, public universities, international research institutes, regulatory agencies and public universities. | 16 |
| 3 | Non State Scientists (NSS or NGOs) belong to non-governmental organisations with a stake in biotechnology activities. They are backed up by their biological science background. | TAR-NSS1, TAN-NSS2, TRTp-NSS3, TAN-NSS4, EPA-NSS5, TAD-NSS6 | International & regional organisations, NGOs & donor agencies. | 6 |
| 4 | Non-Biologists Scientists & Non-Scientists (NS). Participants in this category are spread out in civil society, lawyers, journalists, biotechnology industry and funding organisations and include social scientists. | NGOf-NS1, NGOf-NS2, NGOcs-NS3, NGOco-NS4, NGOco-NS5, JO-NS6, JO-NS7, LABp-NS8, LAEp-NS9, TAI-NS10, TAD-NS11 | Government legal arm, civil society, farmers & consumer associations, media, industry and donor agency. | 11 |
| Total | | | | 42 |

Appendix 2: Selected media reports showing the controversies surrounding Kenya's biotech regulatory process

| Source and date | Activity/ Media report title | Summary of issue/s | Remark/Writer |
|--|---|---|--|
| Sunday Nation (SN), August 28, 2005. | "Government halts research on maize" | Open <i>Bt</i> . Maize trial site at Kiboko erroneously sprayed with insecticide. | Article created tension between scientists and the government. |
| SN, 1 Jan, 2006. | "Permanent secretary sees no conflict in his role and directorship in GM food body" | Role of former Kenya Agricultural Research Institute (KARI) director, currently a senior official in the Ministry of Agriculture) questioned as an advisor to a biotechnology programme. Public worried about conflict of interest. | The newspaper correspondent, opinion and analysis. |
| The People Daily, 9 Jan 2007 | "Cotton research critical phase" | Meant to inform public about <i>Bt</i> cotton trials in Mwea, KARI. | H. Wahinya |
| Daily Nation (DN), 22 Oct 08 | "Biosafety bill to regulate modern biotechnology activities" | The government through the policy body, the National Biosafety Committee (NBC) issues a statement countering anti-GMOs media reports regarding the biosafety bill 2008. | Statement endorsed by 19 NBC institutional members. |
| DN, 8th Dec 2008 | "Intense lobbying of house set to debate GMOs" | Two camps in the Kenyan parliament openly support or oppose the biosafety bill. | Article written in relation to scientists' open support for biotechnology. |
| SN, 23rd Nov 2008 | "Scientists endorse gene altered foods" | | G. Gathura, food production column. |
| People Daily, 24 Nov 08 | "University lecturers endorse GMO bill" | | P. Mutuma, national record column. |
| Sunday Times, 23 Nov 08 | "Embrace biotechnology use, say dons, experts" | | N. Chepkemoi |
| The East African, 26 May - 1 June, 2008. | "How Africa's media is pushing GM crops" | Article claims that pro-biotechnology reports have increased, fronted by scientific organisations and funded by biotechnology industry. | J. Mbaria, special correspondent in the Focus column. |
| SN, March 23, 2008 | "Farmers planting maize that poses threat to humans" | | J. Mbaria |
| Science Africa magazine on Science, Innovation & Development (SAM on SID) Nov 6-Dec 6, 08 issue. | "Enact biosafety bill 2008 now" | An exclusive interview with a former member of parliament sensitized on <i>Bt</i> cotton locally and abroad. | C. Osodo |
| | "Biosafety: former Member of Parliament (MP) first-hand experience" | | |
| | "This time MPs must enact Kenya's Biosafety Bill 2008" | The editor beseeches the MPs in the 10 th parliament to enact the bill 2008. | Editorial |
| | "Opposition to biosafety bill misleading" | - | D. Wafula & D. Otunge |
| | "Biotechnology offers opportunities to tackle | Article talks about the biotechnology potential and the need for a | F. Nang'ayo |

| | | | |
|--|--|---|---|
| | food insecurity” | biosafety law to regulate it. | |
| | “Scientists root for greater maize yields to tackle food insecurity in Kenya” | Articles records two scientists’ views regarding the Bt Maize IRMA project and its potential to address food insecurity. | N. Mwaura |
| (SAM on SID magazine, 15 Sep- 15 Oct 08 issue. | “African scientists’ time to wake up” | Article writes on African scientists and implies that they are not doing enough to solve problems facing Africa today. | |
| DN, 8th Dec 2008 | Draft code of practice for handling GMOs (foods). | Kenya Bureau of Standards (KEBS), a government regulator prepares to adopt GMOs food. | Remark by KEBS director |
| 25 Sep 2008 | Government launches BioWARE. Hon. W. Ruto, Minister for Agriculture as the guest of honour and flanked by senior officers from the Ministry of Higher Education, Science & Technology (MOHES&T). | Minister for agriculture publicly supports biotechnology & biosafety bill. He emphasises that as a scientist, he understands biotechnology science. | The speeches recorded and transcribed. |
| 22 Sep 2008 | 1 st All Africa congress on biotechnology in Nairobi, Kenya, officially opened by an Assistant minister, Ministry of Agriculture. | The assistant minister in his off speech remarks vowed to support the biosafety bill in parliament together with other ministers. | |
| | | Key note speech by Prof. S. Abdulrazak, NCST chief executive, and he appeals for support to have the bill enacted. | |
| | 1st all Africa congress on biotechnology in Nairobi, Kenya. The forum officially closed by Dr. K. Mweria, assistant minister, MOHES&T. | The assistant minister in his off-speech remarks said that the ministry was keen in providing a regulatory framework for biotechnology deployment. | |
| SN, 7 Dec 2008 | “To our Kenyan MPs. The biosafety bill 2008 before parliament. What is wrong with the biosafety bill 2008” | Open letter to MPs by civil society citing anomalies in the bill 2008, claiming that it seeks to sell public to multinationals. | Article appears in the Africa News column. |
| | Press statement by National Council of Churches of Kenya (NCCK). | NCCK issues a press statement on matters of national concern one of which is the GMOs. It claims that government is in a hurry to adopt GMOs without giving the public freedom to decide for or against them. | Statement prepared by the executive committee in 3-4 Dec 2008 & endorsed by Rev. Dr. C. Kibicho (Chairman) and Rev. Canon P. Karanja (General Secretary). |
| AG-chambers, 10 June 2008 | Parallel bill “the biotechnology and biosafety bill, 2008” & accompanying comparative analytical report of both the government & civil society bills. | The civil society under the Kenya Biodiversity Coalition (KBioC). | The bill proposed in parliament by Hon. S. Ruteere, an opponent of GMOs. |
| DN, 25 Nov 08 | “Biosafety bill 2008. Kenyan MPs selling the country?” | Civil society under KBioC publishes weaknesses perceived to be inherent in the bill and proposes a way forward to address the weaknesses. | Article endorsed by 66 members of the complainant umbrella body- KBioC. |

| | | | |
|---------------|--|---|--|
| DN, 23 Dec 08 | "Farmers' union asks President Kibaki not to sign the biosafety bill 2008" | Farmers organised by KBioC, a consortium of over 60 farmers organisations protest in the streets in Nairobi demanding that the president desist from signing the controversial biosafety bill which had just been approved by parliament. | K. Kibiwott in the National News column. |
|---------------|--|---|--|

Source: Various secondary sources including media reports in local newspapers and records of selected workshops related to biotechnology regulation.