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SCIENCE AND GOVERNANCE OF MODERN BIOTECHNOLOGY IN SUB-SAHARAN AFRICA—THE CASE OF UGANDA

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Abstract: Science policy, particularly as it applies to biotechnology and biosafety, has no single 'correct' approach to follow. An objective approach to biotechnology policy however requires three essential components: scientific advice, the engagement of a range of stakeholders in policy dialogue, and effective governance at a systemic level, in an 'innovation systems' sense, forming closer interaction between organizations and personnel to ensure that knowledge flows are maintained at all times. The article discusses the governance of modern biotechnology in Uganda. It shows that some progress is being made on interactivity among scientific organizations—many of whom are on the threshold of a capacity to become involved in gene transfer with potential application to the national needs. Interactivity, however, does not appear to be strong amongst governance bodies. Similarly the development of national policy, while strong in inspirational terms, seems in practice to be rather *ad hoc* and piecemeal, with uncertainty about who makes decisions and how these are to be implemented, monitored and evaluated. So, from an 'innovation systems' standpoint the governance of modern biotechnology in Uganda still has some way to go. Copyright © 2005 John Wiley & Sons, Ltd.

1 INTRODUCTION

African governments are increasingly confronted with complex issues associated with the development, application, importation and commercialization of genetically modified crops. Many of these issues have scientific and technical underpinnings, and so the need for decision-makers to seek and acquire scientific advice has grown. Recent controversy over genetically modified food aid to countries of southern Africa has demonstrated that in the absence of legitimate and authoritative science advisory systems biotechnology policy-making in Africa will continue to be torn between anti-technology activism and

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foreign influence. At the same time from the standpoint of public policy there is considerable uncertainty as to what exactly is the standing of biotechnology and how it is to be administered in many parts of Africa. This study was conducted in Uganda during July and August 2004. It was designed to elicit contemporary practice and benefited from interviews held with senior scientists, legal experts and policy makers. Among the organisations assisting the enquiry were the Kawanda Agricultural Research Institute (KARI), Makerere University (Crop Science Department), Food Science and Technology Research Institute (FOSRI), the Uganda National Health Research Organization (UNHRO), the Uganda National Council for Science and Technology (UNCST) and the National Environment Management Authority (NEMA). Relevant literature on science and governance of modern biotechnology in Uganda has been cited to augment the views and perceptions of the respondents. Also a list of organizational acronyms is appended at the end of the text.

However, in order to set the Uganda experience in context the article begins in Section 2 with a summarized discussion of science policy, particularly as it applies to biotechnology and biosafety. Issues of governance are still being explored and elaborated in many parts of the world and there is no one correct approach to follow. What is becoming clear though is that an objective approach to biotechnology policy requires three essential components. One is that scientific advice is fundamental and relevant institutions need to be consulted at all levels. A second is the need to engage all stakeholders in policy dialogue, including especially civil society organs. Most important, however, is the need to engage governance at a systemic level. That is mechanisms are needed to ensure that organizations and personnel maintain close interactive contact to ensure that effective knowledge flows are maintained at all times. It is in this *'innovation systems'* sense that interaction is needed in order for governments to come to sensible decisions in a field that is evolving rapidly both scientifically and in terms of public acceptability. We shall see that in Uganda that ambition is still some way from being realised.

The article then goes on to concentrate on three broad issues. Firstly Section 3 reviews the general status of biotechnology in Uganda. It shows how considerable developments have taken place in the past five or so years, particularly in institution building for governance. This section also summarizes the main organizations active in biotechnology R&D. It pays close attention to how well inter-organizational linkages have been developed since lack of such integration is a key problem raised in much of the contemporary literature. While some considerable progress has been made it is clear there is still some way to go. Section 4 covers the regulatory framework with a focus on biosafety issues. It documents the measures Uganda has begun to put in place to deal with these issues, which have recently taken on considerable importance. Section 5 then summarizes aspects of more general measures being made to develop biotechnology policy and integrate policy with civil society. Again the processes are still very much at an embryonic stage but nevertheless there is considerable achievement generated. Finally Section 6 draws the paper to a conclusion and suggests policy initiatives that might be considered by the Ugandan Government.

2 BIOTECHNOLOGY POLICY AND GOVERNANCE

As the new millennium begins it has become clear that the one of the main determinants of its progress will depend upon the search for and the use of scientific knowledge. In a very real sense sustainable economic development now depends fundamentally upon the use and abuse of knowledge. And yet 'policy towards science' is still a relatively unexplored aspect of public policy despite a broad recognition of its importance over the closing decades of the last millennium. But while resource allocation to science is often at bottom an economic question, the role of the scientific community and how it conducts itself is also of fundamental importance. In addition, science policy analysis is unusually complex. This is so because those who concern themselves with science policy issues come from widely different disciplinary backgrounds, with differing appreciations of what constitutes legitimate scholarship, how problems may be defined and tackled, what is the most appropriate technical language for communicating ideas, and so on and so forth. The area is, therefore, essentially 'interdisciplinary' and from a policy point of view 'interdisciplinarity' is hard to handle. The problem is twofold. Scientists are normally trained in a regime of disciplinary excellence and very often their interests (and capacities) do not go beyond this tight boundary. Policy makers on the other hand (and the problems they deal with routinely) require more subtle and rounded guidance. But they often do not know how to benefit from the knowledge that would simplify their task. Both 'estates' would gain from interaction. The issue is, however, how best can this be brought about?

These issues have come to a head in recent years in the context of biotechnology and biosafety policy. In developing countries it is now clear that applications of biotechnology have the potential to transform socio-economic possibilities for large sections of disadvantaged peoples, especially in health and agriculture. But at the same time there are widely felt risks to human health and to environmental sustainability. How then should African countries respond to these opportunities and challenges posed by genetic engineering? Perhaps the primary area of policy concern is that of risk but here there is much disagreement. For example, within the more specific field of biotechnology and biosafety policy Wint (2005) has shown that there are big differences in country approaches. The US sees regulation as a purely 'scientific' issue. It views biotechnological products, as being little different from their traditional counterparts and as not requiring new regulatory legislation. Australia, on the other hand, attempts to take account of science, ethics and community under one (regulatory) umbrella and so has built public acceptability directly into its legislation. The UK takes a similar view to Australia while other EU countries tend to place much more emphasis on public acceptability taking a more distanced attitude to traditional scientific criteria.

Within scientific communities similar disagreements occur. For example, many scientists still argue that governments can handle issues of risk by the use of standard probability calculus. Thus risks are computable in the sense that values may be assigned to them. Decision-makers then combine standard estimates of contributions to welfare with such risk values before making final policy recommendations. However, this view has increasingly come under criticism on both scientific and ethical grounds. On the former it is argued that much of modern experimental science is based on the view that the system under investigation is relatively stable. This then allows it to be subject to experiment and characterisation in the sense that its parameters are computable. Once we know these, we can predict with some certainty how it will behave in future periods, in other words, we can assign probability values to future behaviour based upon how the system has behaved in past. On the other hand if the system in question is evolving in terms of its underlying structure, then such a procedure is flawed simply because its parameters are no longer stable. This becomes a serious problem in a field such as biotechnology that is subject to very rapid technical change. Here assigning probability values to, say, the impact of a

GMO becomes impossible simply because the future ‘states of nature’ are unknown. We live genuinely in a state of ignorance about the future system in question.[1]

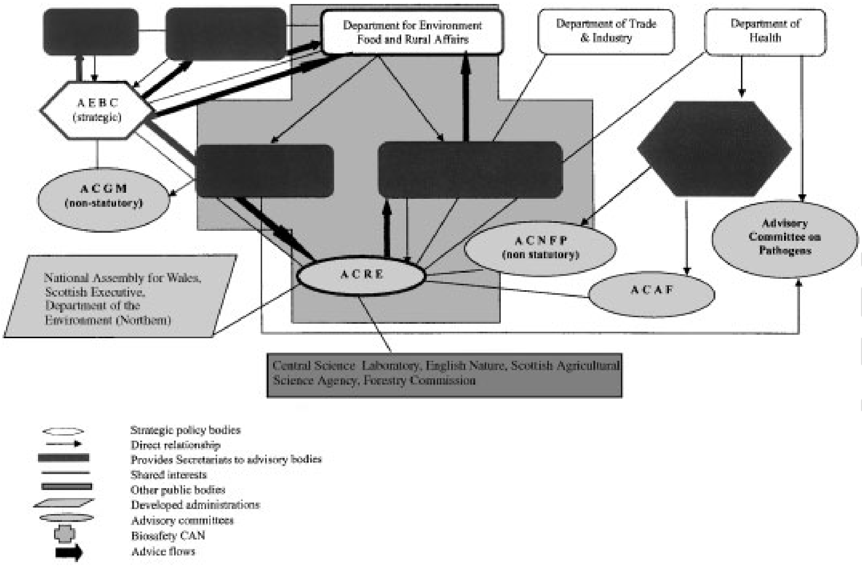
The ethical criticism is equally important. For even if formal risk analysis could show that an intervention is likely to be relatively harmless there may still be important issues associated with values and ethics. Thompson (2000, p. 24), for example, shows how in the context of the GM controversy consumers became ‘deeply resentful of a marketing approach that denied them the opportunity to give or withhold consent. Even consumers who thought of themselves as potentially benefiting from GM foods nevertheless insisted upon the right to decide for themselves whether to eat it or not’. Tait (2001) shows how throughout the 1990s there arose increased resistance among many sections of European public opinion to the use of biotechnology to modify crop production. Some of this resistance may have been ‘irrational’ in the formal scientific sense but by no means all. The impact of ‘mad cow’ disease in the UK did great damage to public trust of government regulation. It also called in question the relative inability of science to provide a coherent impartial judgement of such issues. The early attitude of industry also did not help. Although much of the agro-biotechnology industry has now come to realise that a more inclusive strategy is probably necessary to deal with such issues, a great deal of damage has been done to their corporate interests.

It was for reasons such as these that the notion of the *Precautionary Principle* began to emerge as an important conceptual organiser in relevant policy analysis as a general injunction to decision-makers to postpone action where human health and the physical environment at are at risk. But as Common (1995, p. 214) points out ‘it does not offer much in the way of guidance as to how the problem should be dealt with. To say that a lack of certainty should not inhibit measures to protect the environment from serious and irreversible damage does not indicate what should be done and how it should be done. Nor does the principle suggest how one might set about answering such questions’.

Nevertheless it is clear that in many countries the Precautionary Principle is having practical influence. Tait (2001) for example, shows how many European countries have now begun to take a much more cautious approach to biotechnology policy, especially with regard to the advent of GM crops. Her view is that the time has come to take the precautionary principle much more seriously than has been the case in the past. But this cannot be done through the simple application of the old risk-based formulae for the simple reason that we are now dealing with future events and our perceptions of such events and their implications. It is a political and ideological world, not often acknowledged by industry, science or government. Tait calls for a constructive dialogue among all interested parties so as to clarify the issues and reach a social consensus on all the underlying problems. This does not mean abandoning science. Rather it implies the need to recognise the limitations of science in a field that is developing very fast indeed.

But how should this be done? The first step is to recognize who the interest groups are and what factors influence their views. In particular Tait identifies environmental pressure groups (ENGOs), consumer organizations (CNGOs), multinational companies (MNCs), small-scale industry (SMEs), farmers and farmer organizations (FOs), the public research system (and the scientists that work in it) and government ministries and secretariats. Each of these interest groups generally view issues of biotechnology risk quite differently even

[1]Again more rigorously, a distinction should be made between ‘uncertainty’ and ‘ignorance’. In the former future states of nature are known. In the latter they are not, in which case the assigning of objective probabilities becomes impossible. In the case of biotechnology change the level of ignorance is certain to be considerable. Clark and Juma (1992) explore these issues in respect of technology more generally. See Chapters 1 and 9.



Source: Wint (2005)

Figure 1. [Q2]Regulatory structure for biosafety in the United Kingdom Q2

where the presenting evidence appears to be very similar. But their views are neither static nor homogeneous. Paarlberg (2000) shows how agricultural and scientific ministries are usually much more promotional to biotechnology than environmental ministries. And, as mentioned above, the views of European CNGOs have certainly changed from a neutral position to a much more hostile position over the 1990s as trust in regulatory authority has dissipated (Tait, 2001). When it comes to governance itself the complexities are no less as Wint (2005) has recently pointed out. Figure 1 illustrates the current regulatory structure for biosafety in the United Kingdom. It may easily be seen that decisions on biosafety policy require the integrated involvement of several government departments, laboratories and a host of advisory committees from different stakeholder groupings.

It is largely to deal with these complexities that the notion of an *innovation system* has been developed in the science policy literature (cf. Hall, 2004). The essential feature of such innovation systems is that they comprise the integrated activity of many stakeholder groups. Where such interactivity is strong and knowledge flows are allowed to take place across institutional boundaries, then economic and technological development can take place rapidly with the full concurrence of all interested parties. Where on the other hand interactivity is weak or is prevented by poor governance or vested interests, the opposite is liable to be the case. Notice that science is only part of an innovation system and even here there is need for the various disciplines to be allowed to interact freely including across organisational boundaries. This is particularly so with innovations in biotechnology where many disciplines are normally necessary. For example, returning to the UK practice in biosafety management, Table 1 illustrates the range of disciplines (well over 20) felt to be necessary for the Advisory Committee on Releases into the Environment (ACRE).

In short the management of biotechnology and its attendant risks is a complex business. What is clear is that mechanisms are necessary to ensure the incorporation of scientific advice from a wide range of expertise, often coming from separate organisations. At the

Table 1. Scientific Expertise represented on ACRE 1996–1999 and 1999–2002. (in alphabetical order)

1996–1999	1999–2002
Agricultural botany	Biodiversity and conservation
Biological sciences	Biochemistry
Biotechnology	Plant Ecology—plant herbivore interactions
Crop research	Entomology—pollination ecology, integrated management of oilseed rape pests
Epidemiology	Farmland ecology
Food research	Farming practice
Insect-plant interaction, agriculture	Food safety—GM foods
Molecular genetics	Molecular biology, microbiology—bacterial genetics, microbial ecosystem function, soil microbial ecology
Molecular biology	Plant biology
Public health	Plant breeding
Terrestrial ecology	Plant physiology—plant primary metabolism, environmental stress
Veterinary pathology	Plant virology—molecular biology of plant viruses
	Weed ecology—population dynamics, biological control of weeds
	Sustainable agriculture and rural development—sustainable agricultural systems
	Genetics

Source: For details see Wint (2005).

same time however, representatives from civil society need to be assured that decisions on biosafety are acceptable to different popular constituencies. These are difficult issues to resolve. Even industrially advanced nations are struggling. Many do not agree with each other and most are still experimenting with relevant institutional forms. The question for this paper is how well does Uganda measure up in this difficult task?

3 STATUS OF MODERN BIOTECHNOLOGY R AND D IN UGANDA

3.1 Overall Trends

Uganda's existing comparative advantage and economic potential is heavily concentrated in agriculture. This is attributed to the favourable soil conditions and climate that has contributed to the country's agricultural potential. Efforts aimed at promoting agriculture in Uganda have been characterized by both institutional and policy changes. Institutional changes include developments that have paved way for consolidation of all bodies dealing with agricultural R and D. Until the late 1980s, agricultural research was scattered under different government ministries and departments. In 1987, the process of consolidating all the agricultural research activities under one organization was initiated. This process culminated to the establishment of the National Research Organization (NARO) in 1992 as the apex body with the mandate to undertake, promote and coordinate research in all aspects of crops, fisheries, forestry and livestock, and ensuring dissemination and application of research results. NARO is the largest sectoral body in Uganda with a total of nine research stations. This was followed by the Plan for Modernization of Agriculture (PMA), which was finalized in 2000. PMA reflects a major policy shift in the orientation of the agricultural sector in Uganda. It aims at achieving the broader objective of poverty eradication. The target of the plan is to transform subsistence agriculture to commercial or market oriented production.

With the increasing and growing potential of biotechnology, the Ugandan government is beginning to recognize and appreciate that biotechnology provides opportunities that must be fully explored and utilized to contribute to sustainable food production, improved health care and environmental protection. In addition, the government of Uganda has pronounced that, for the country to benefit maximally from this new technology, it will establish an adequate, workable and transparent national biosafety framework, which will be implemented in consultation with relevant stakeholders so that all biotechnology applications are done in a scientific manner.

Biotechnology and Biosafety developments in Uganda are governed in the context of international instruments and regulations. The country signed and ratified the Cartagena Protocol on Biosafety on 24th May 2000 and 30th November 2001 respectively. The National Environment Management Authority (NEMA) represented the government in the negotiations leading to adoption of the Biosafety Protocol. The Ministry of Environment continues to participate in the Conference of Parties. It is the designated focal point and reports to the secretariat of the Convention on Biological Diversity. On the other hand, the Uganda National Council for Science and Technology (UNCST) under the Ministry of Finance, Planning and Economic Development is the designated competent authority for the purpose of domesticating and implementing provisions of the Cartagena Protocol on Biosafety. The council advises the Ugandan government on matters of science and technology including biotechnology. The National Biosafety Committee (NBC) established in 1996 is the technical arm of the UNCST delegated with the responsibility of reviewing applications and implementing biosafety guidelines and regulations.

Uganda is currently free from GMOs. Applications to introduce Bt. cotton and Bt. maize were submitted to UNCST in the year 2000 but none was approved for research trials. There are divergent explanations as to why the two were not considered. According to the UNCST, approval was not granted because of procedural technicalities. The council as the competent authority felt that Uganda was unprepared to handle GM crops because of lack of an overall policy framework and biosafety regulations. In addition, Uganda lacks confinement and containment facilities where trials of GMOs can take place. Monitoring and enforcement mechanisms are yet to be put in place. Other reports reveal that there was lack of consensus between the National Agricultural Research Organization (NARO) and UNCST. NARO submitted application for Bt. cotton after engaging Monsanto in consultations. The possibilities of having the trials conducted at Serere Agricultural Research Institute in Soroti, eastern Uganda, had been explored.

It seems that NARO did not elicit the participation of UNCST right from the beginning. Subsequently, when questions of intellectual property ownership and liability arose, the UNCST requested the application to be submitted by Monsanto.[2] Lack of consensus between the two bodies emerged later at a national stakeholders' workshop on biotechnology and biosafety in Kampala, where there were polarized exchanges between UNCST and NARO scientists. The UNCST scientists (including the executive secretary) were not satisfied with NARO's explanation about the risks that may be posed by cottonseeds. Other concerns regarding Bt. cotton were voiced by the Uganda Cotton Growers Association, which expressed fears that European buyers would refuse to buy cotton from Uganda if genetically engineered. The major issue was that Bt. cotton produces short-staple lint

[2]Visit http://allafrica.com/stories/200308280241.html[Q1] Q1

while conventional cotton grown in Uganda is long staple. On the basis of this information, it was believed that introduction of Bt. cotton would affect the quality of cotton produced. The long staple one commands a premium price in the European markets (New Agriculturalist, 2002).

In addition Uganda lacks containment and confinement facilities for evaluation of GMOs. This is a major limitation given that biosafety regulations require evaluation of genetically modified products to be done in a contained greenhouse facility prior to evaluation in the field. This is hindering importation of materials for testing. For instance, no application to test transgenic (Cavendish) bananas has been presented to the UNCST, despite the fact that this banana cultivar is functionally a self-contained system, due to its male sterility. Another constraint is the low understanding of IPR issues among researchers and scientists in Uganda. As a result, loss of biological resources, which are eventually patented, has grown to become a critical concern.

3.2 Key Organizations

None of the institutions in Uganda are working on GMOs but the capacity to handle GMOs in terms of laboratory infrastructure and human resources capacity in various fields of biotechnology is being developed and accumulated. This includes gene mapping, transformation and regeneration. The key institutions involved in biotechnology work in Uganda include both public sector bodies and the private industry. In the public sector domain, a number of departments at Makerere University are involved in biotechnology R and D. They include departments of Crop Science, Biochemistry, Animal Science, Veterinary Parasitology and Microbiology, the Institute of Environment and Natural Resources, Food Science and Technology Research Institute and the Medical School at Makerere University. Under NARO, biotechnology is predominantly taking place at the Kawanda Agricultural Research Institute (KARI). The private sector is represented by two key institutions. These are the Med-Biotech Laboratories (MBL) and the Agro-Genetic Laboratories (AGL).

For example, the Makerere University Crop Science Department has laboratory infrastructure for basic molecular biology and tissue culture work. Molecular biology work includes diagnostics and marker assisted breeding while tissue culture applications revolve around banana improvement. Genetic engineering work is being explored through partnerships with the International Network for Improvement of Banana and Plantain (INIBAP) and NARO. The Catholic University in Leuven, Belgium (KUL) is another partner that the department collaborates with in banana improvement initiatives.

Support for research at the department comes from the Rockefeller Foundation, the East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN) European Union, United States Agency for International Development (USAID) and the Belgian Government. The diverse sources of assistance are taking care of both equipment and money for running projects. Fellowships from the Rockefeller Foundation have enhanced the human resources capacity in the department, while BIO-EARN is highly acknowledged for provision of equipment that has enabled modernization of the laboratory to a molecular biology category. Although the department's capacity to undertake transformation and advanced biotechnology work is growing, the actual transformation has been put on hold by lack of a national biotechnology and biosafety policy which is pending debate and approval by parliament.

The main national institution is the Kawanda Agricultural Research Institute (KARI). KARI is one of the nine institutes under the leadership of NARO. Tissue culture work at KARI started in 1994 after a tissue culture laboratory was built to produce coffee and banana planting materials on commercial basis. By the time the project ended in 1996, the anticipated commercialization had not taken place. At some point, it was decided that banana research should be separated from coffee research. This led to the creation of a full-fledged Coffee Research Institute (CORI) located at Mkono.

Banana is dominating tissue culture work in Uganda because of the high importance attached to it as a staple and food security crop. Banana projects are of high priority and command national support and ownership. Significant financial support comes from the national banana programme, which is substantially funded by the Ugandan government. For instance, the molecular biology laboratory at KARI was an initiative of the banana programme and was largely funded by the government. In addition, the government has budgeted US $500 000 annually for the banana programme. It seeks to improve Uganda's East African Highland Bananas by genetically engineering resistance to black sigatoka, banana weevil and nematodes. The international banana programme is co-ordinated by INIBAP whose head office is in France. The regional office for Eastern and Southern Africa is located in Kampala. Scientists at KARI acknowledge that collaborating with INIBAP has been beneficial in terms of facilitating access to genes and reinforcing Kawanda's position to solicit for funding from other sources other than the national banana programme supported by the government (Sengooba *et al*., 2001).

In recent years, the BIO-EARN programme, supported by SIDA, has instigated human resources capacity building. The programme is currently supporting three students at PhD level, all of whom are focusing on aspects of banana transformation. Bananas cannot be best improved by conventional breeding. Inability to form seeds makes them safer for transformation. Genetic transformation equipment is available but the work has not started. Researchers at NARO have also been attempting to develop tissue culture and regeneration methods, with the ultimate goal of enabling transformation. Cell suspensions—this is an advanced genetic engineering technique. Kawanda has successfully developed cell suspensions, which will be passed on to the molecular biology laboratory for transformation.

3.3 Institutional Linkages

The institutional linkages between the Crop Science Department at Makerere University and NARO institutes are relatively strong. The department is recognized as a training centre for scientists who are eventually recruited to work for NARO. A number of institutes under NARO send their employees to the Crop Science Department for training. For instance, KARI sends its technicians and research assistants for short courses. Apart from training, the university and NARO are engaged in collaborative projects. A good example is the marker assisted breeding for maize project between the Crop Science Department and the national maize-breeding programme, which is under the leadership of NARO. University students in the department work on research projects directed at answering key questions of the programme.

Scientists from research institutions teach at the university and enjoy unrestricted access to laboratory facilities. In areas where NARO lacks scientific expertise, they seek advice from university scientists. While noting that these linkages are concrete, surprisingly there are no formal agreements or arrangements that guide interactions between these institutions. The Crop Science Department at the university has enjoyed significant support from BIO-EARN. Students taking their PhDs under sandwich arrangements between BIO-EARN and Swedish universities are co-supervised by lecturers in the Crop Science Department and have access to laboratory facilities in the department when working on their research projects.

The linkages between private industry and the NARO institutes are also strong. For instance scientists at Kawanda have access to laboratory infrastructure at Med-Biotech laboratories although there are no formalized instruments like MOUs to outline the terms and conditions of such partnerships. It is also very interesting to note that the Agro-Genetic Tissue Culture Laboratory (AGL) was established with technical support from KARI scientists. While KARI is concentrating on research aspects of tissue culture, AGL is focusing more on commercialisation. In this regard, when KARI has a shortage of clean banana planting materials, farmers are advised to buy them from AGL.

FOSRI collaborates with the department of food science and technology under the Faculty of Agriculture at Makerere University. With financial support from NORAD, the department is putting up a laboratory for R&D that FOSRI will have access to. The Director of FOSRI lectures in the Departments of Food Science and Technology and Zoology. In contrast to the above, weak linkages were noticed between FOSRI and organisations that it should be working with in the areas of food biotechnology and safety. Such organisations include UNCST, the Ministry of Health and the Uganda Bureau of Standards. Similarly, the Uganda National Health Research Organization (UNHRO) should be concerned about and involved in health-related issues touching on GM food standards and their safety. There was no evidence of strong interaction between these bodies.[3]

However, the lack of mechanisms to facilitate transfer of technologies from laboratories to the market place is still a major concern. In particular, mechanisms to promote transfer of technologies from research institutions to enterprises that can commercialize them are lacking. For example, Makerere University does not have a technology transfer office to handle the commercialization of technologies developed by its faculty. This is constrained further by absence of a policy to reward university scientists for discoveries that might eventually become commercially valuable. Intellectual property rights and technology transfer policies are the least developed elements of Uganda's biotechnology system. This may be a limitation to developing a biotechnology-based industry in the country simply because many of the advances in biotechnology cannot be protected.

4 RISK ASSESSMENT AND REGULATORY REGIMES

The UNCST is the competent authority with the mandate to approve GMOs. All the applications for introduction of GMOs are first forwarded to UNCST, which screens them for completeness and after sending acknowledgement to the notifier, the request is forward to NBC for risk assessment evaluation and review. Risk assessment is expected to be done by the applicant. The obligation of NBC is to review risk assessment dossiers and draft

[3]From 1987 Uganda initiated a process of consolidating research institutes, NGOs, the private sector and universities in the area of health to form an umbrella body-the Uganda National Health Research Organization (UNHRO). This is an apex body under the Ministry Of Health and its responsibilities will be to co-ordinate, catalyze and disseminate research findings in the areas of health in a manner similar to what NARO does.

report advising the UNCST appropriately. The final verdict rests with UNCST after taking into consideration views from the public, line ministries and other stakeholders. The membership of NBC is broad based made up of representatives from over 19 institutions including the scientific community, relevant ministries, farmers' organizations and the private sector. Recently, the Ministry of Defence has been co-opted given the transboundary nature of GMOs. The public have an opportunity to comment also.

According to one interviewee, monitoring and risk management of GMOs if approved in future will be done by existing inspectorate bodies. For example, if UNCST makes approval for a GM crop, it will be the responsibility of the Ministry of Agriculture to undertake the monitoring. A memo will be released from UNCST directing the ministry to monitor the trials. A wide array of inspectorate bodies will be expected to play a role in monitoring and enforcement of biosafety regulations including Customs, NARO, agricultural research centres and several ministries.

Most inspectorate bodies have experience in handling inspections for conventional crops but have limited experience and capacity for handling GMOs. Given that this limitation has already been noted, training courses on transboundary movement of GMOs have been planned to train members of NBC and inspectors for ministries of Health, Environment, Agriculture and Ugandan Bureau of Standards. This will provide them with insights on the nature of the inspection capacity required for Uganda. At least two selected laboratories in Uganda will be equipped, certified and assigned for detection and identification of GMOs in the context of inspections.

There are no institutional biosafety committees in Uganda's biosafety system. If one wishes to introduce a GM crop, the application is submitted directly to UNCST, which in turn forwards it to NBC for expert review. While there are no institutional biosafety committees working with NBC, some research institutions such as Makerere University and KARI have in-house measures and procedures to guide internal operations and ensure safety handling of materials and products that they work on.

However, the UNCST has developed a National Biosafety Framework, which includes regulations and guidelines for recombinant DNA work in the laboratory, contained greenhouse, and contained field settings. The guidelines and regulations were first drafted in 1988. Development of the biosafety framework was described as a spontaneous process that was internally driven as opposed to being driven by external forces. The Ministry of Finance, Planning and Economic Development was responsible for the development of the framework (Nyiira, 2000). The drafting of the framework was done by a task force from the council. The process is said to have been participatory and inclusive. Key ministries were involved and agencies such as NEMA were represented. Civil society organizations such as the Uganda Consumer Protection Association (UCPA) and consumer education advocacy groups were brought on board as well. The private sector was represented by Med-Biotech laboratories. These institutions were selected based on the cross-sectoral nature of GMOs and future roles that they are likely to play in biotechnology and biosafety related issues. For instance, NEMA was represented by the technical committee on biological resources and is expected to play a leading role in environmental impact assessment for GMOs.

After a draft was produced, workshops were held to reflect on the framework and revise it accordingly. While noting that the biosafety guidelines and regulations were first drafted in 1988, they are currently under revision with financial support from the United Nations Environment Programme–Global Environment Facility (UNEP–GEF) project on the implementation of the biosafety frameworks. A working group formed by the National

Co-ordinating Committee has been constituted to review the draft regulations. The finalization of the regulations will be followed by a workshop that will be organized for stakeholders to create awareness on the regulations and the implementation process. Implementation is being done under the aegis of the UNEP–GEF project on the implementation of the National Biosafety Framework. This project started in September 2002 and will end in September 2005. A National Co-ordinating Committee (NCC), with a broad membership, oversees the project.

The objective of the draft regulations is to ensure the protection of the environment, including humans, in the use of GMOs. Approval for introduction of GMOs will be done under a permit system. That is, an applicant will be issued with a permit to introduce a GM crop or product by the UNCST after meeting the stipulated biosafety conditions and requirements. The future regulatory regime for biosafety in Uganda is embodied in the biosafety regulations. The regulations will be enacted under sections 3 and 32 of the Uganda National Council for Science and Technology Statute (1990). The statute empowers UNCST to formulate policies and strategies in all fields of science and technology including biotechnology and biosafety. It is not clear if the statute has specific provisions to address biotechnology research. One of the areas of controversy in designing a regulatory regime was whether or not Uganda should use the existing legislation (UNCST Statute) or enact a new piece of legislation to govern biosafety issues. While some members of parliament have been pushing for new legislation, UNCST is content that biosafety issues for the time being can be accommodated by the existing legislation.

5 POLICY FORMULATION

A draft biotechnology and biosafety policy has recently been developed and handed over to the Ministry of Finance and Planning under which NCST falls. The task force that drafted the policy was constituted by UNCST under the leadership of the head of policy division at the council. Representatives from key were involved. While support for the development and implementation of the biosafety framework came from UNEP–GEF and donor agencies such as USAID, the policy process was entirely supported/sponsored by the government. In contributing to the policy process, Uganda was open in terms of borrowing key elements and tenets of a biotechnology policy from countries such as Kenya, Zimbabwe, South Africa, Namibia and the European Union.

Upon completion of the draft policy, consultative workshops of stakeholders were held to discuss and review it. In total about four consultative workshops were held. USAID, Association for Strengthening Agricultural Research in astern and Southern Africa (ASARECA) and BIO-EARN experts participated in the workshops. Participation from parliamentarians was also high. On aggregate, a total of about 90 MPs attended the workshops. The attendance was dominated by legislators sitting on the committees on agriculture and natural resources. The broader civil society was represented by consumer groups. NGOs such as Advocates Coalition for Development and Environment (ACODE) have been instrumental in contributing indirectly/independently to specific dimensions of the policy such as the liability and redress regimes suitable for Uganda.

Uganda has also developed a wide range of strategies for public information and public participation in the implementation of the national biosafety framework, including district workshops, an information database, and translation of biotechnology and biosafety information into four local languages.

UCPA is the most active and vibrant civil society group in Uganda. UCPA is engaged in consumer protection and advocacy activities. The activities of the association seek to realize socio-economic justice, consumer safety, fair trade, sustainable and healthy environment plus good governance. Issues of food safety and security are a key focus for the association. The concern of the UCPA is to ensure that consumers in Uganda are amply represented in discussions on developments in the area of biotechnology. Towards this end, UCPA has been fully engaged in decision-making processes on biotechnology in Uganda. For instance, when the guidelines on biosafety were being drafted, UCPA and other civil society organizations firmly placed on the agenda the need for clear labelling of all imported products with GM content. It has also been instrumental in providing advice on best approaches in disseminating information and eliciting public participation in issues of biotechnology and biosafety. Although UCPA sits on the NBC, its mandate is constrained by lack of technical capacity in biosafety issues. Because of a lack of scientific capacity and infrastructure, civil society organizations including UCPA have often been forced to seek guidance from public sector scientists. This raises questions about the objectivity and credibility of the advice given (BIO–EARN, 2002).

From the standpoint of technical advice there are very few science advisory bodies in Uganda. The Uganda National Academy of Sciences, which is expected to be a major scientific body, was formed recently and has not yet engaged in rendering scientific advisory services. UNCST mainly solicits for advice from independent advisory bodies such as ACODE, ASARECA and BIO–EARN. Scientific advice from the private industry largely comes from Med-Biotech laboratories. The National Biosafety Committee is chaired by the Director of Med-Biotech laboratories. This is a strong indicator of the private industry's involvement in decision-making on biosafety issues in Uganda. The UNCST also makes use of *ad hoc* expert bodies. A roster of scientific experts has been compiled and from time to time *ad hoc* expert bodies are convened to deliberate on specific issues.

Similarly the role of the university as a source of scientific advice is an idea that has not precipitated in Uganda. Owing to its size as one of the largest universities in sub-Saharan Africa, Makerere University has a pool of experts in diverse fields of science. However, it has not yet received explicit recognition as a hub of scientific advice. There are no formal mechanisms to approach university departments for advice by bodies such as UNCST. University scientists are engaged in decision making as individuals and not as university delegates. To a large extent, this is determined by their experience, the level of recognition that they command and the prominent positions that they hold in national and regional bodies. For example a senior professor in the Crop Science Department is consulted quite frequently by UNCST and ASARECA. However, he is not involved in biotechnology and biosafety decision making processes as a representative of the university, but is his own personal capacity and by extension as the chairman of the ASARECA biotechnology group.

5.1 The Case of GM Food

It may readily be seen therefore that much is in the process of being planned. However, the current reality is rather different. In 2003, the President of Uganda approved the importation of processed GM products when opening a research laboratory at the Kawanda Research Institute. This decision was received with mixed reactions among lawmakers, scientists and civil society groups. According to two senior scientists, this decision was not a 'science blind' policy since the relevant presidential decree was informed by scientific advice. But the advice seems to have been quite narrowly based. The President constituted a small committee that advises him on the implications of allowing GM foods in Uganda. The advice in this case was simply based on the positive history of GM foods in other parts of the world and lack of concrete evidence so far to demonstrate that they might pose risks to human health. However, given that the country has no capacity to monitor environmental consequences of GM crops, the approval strictly permits processed foods and not seeds or anything that can be planted or released to the environment.

Varied reactions to the presidential pronouncement suggest, however, that the composition of the committee and decision-making process was not representative and consultative enough. Divergent reactions from legislators indicate that this issue lacked political support from some quarters. This could be explained by failure to engage MPs in discussions leading to the approval. For instance, MPs sitting on the parliamentary agriculture committee argued that Uganda had no food insecurity problems and therefore there was no justification to allow importation of GM foods. Conversely, those supporting the idea argued that the President only allowed importation of GM foods from a country (the US) that exhibited some of the highest environment standards in the world (*Biotechnology Monitor*, 2003).

In addition key institutions were excluded in the process. For instance, bodies such as the Uganda National Bureau of Standards whose mandate entails setting standards for both GM and non-GM food and screening were not consulted. The fact that GM foods can generate ethical and cultural issues cannot be overstated. However, there was no attempt to involve consumer groups and religious bodies that defend and articulate interests and concerns of the wider public. Reactions from the NARO secretariat scientists attest to the fact that the agricultural body was not part and parcel of the course of action. For instance, a report reacting to Museveni's decision from the NARO secretariat warned that Uganda lacked the capacity to distinguish between GM and non-GM products and therefore this will make the country vulnerable to an influx of GM products. The NARO secretariat recommended that a law should be enacted in Uganda to guide the use of GM products before such products are granted entry. The existing pieces of legislation are deficient. In particular, the Food and Drug Act handles standards for food and drugs, but does not cover biosafety concerns regarding GMO foods and drugs, and the labelling of foodstuffs, feeds or pharmaceutical products for the consumer. FOSRI, a research body expected to look into issues of food safety and food biotechnology in the near future was not involved.

6 CONCLUSIONS

What then can we say about Uganda's progress in biotechnology development? The evidence is patchy. On the purely scientific side it does seem that some progress is being made on the degree of interactivity among scientific organisations. And biotechnology capacity more generally has made considerable progress. Not only are there are a number of competent organisations involved but many are on the threshold of a capacity to become involved in 'third generation' gene transfer with potential application to primary national needs. On the other hand there is little evidence of spin-off to a nascent private sector to date. And interactivity does not appear to be strong amongst governance bodies like the NARO and the NCST. Similarly the development of national policy, while strong in aspirational terms, seems in practice to be rather ad hoc and piecemeal, with uncertainty about who makes decisions and how these are to be implemented, monitored and evaluated. For example, there seems no good reason why biosafety and broader biotechnology policy should not be established in a co-ordinated fashion but this does not seem to have happened. The scientific community itself is still not well organized from a policy standpoint with the results that decisions appear often to be reached on the basis of short term political criteria. In addition the degree of consultation with broader stakeholder groupings, while progressing in a general fashion, leaves much to be desired. And so from an 'innovation systems' standpoint there is still some way to go.

Having said this, however, it is perhaps easy to be unduly critical. We have seen that international experience shows how hard it is to develop public policies that can strike a balance between the risks and benefits of biotechnology. Not only is the precautionary principle difficult to handle itself. In addition there are difficulties in achieving the sorts of institutional reform needed to ensure accountability to civil society while at the same time ensuring that scientific advice is given its due place in decision-making. In the case of Uganda what is probably now needed is some special initiative designed to rationalize public policy in this area. Measures along these lines should ensure that Uganda could soon provide a lead to the whole African region in this important area of technological development.

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