

Regulatory Cooperation, Using Information, Regional Policies, and National Expertise

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(eds.)



Proceedings of an East Africa
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The Partnership

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We appreciate the contribution of the National Councils of Science and Technology of Kenya, Uganda and Tanzania, ASARECA and UNEP-GEF for their contribution to the program formulation and in selecting participants. Members of PBS including John Komen and Adriane Massey and Isaac Minde of ECAPAPA are commended for their critical and repeated review of the program and guidance to the overall structure of this meeting. Many thanks to Moses Osiru of Makerere University who efficiently tracked and recorded all proceedings.

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Thank you to all participants for the open discussions, constructive comments and guidance to the follow-on actions.

List of Acronyms and Abbreviations

ABSAC	Agricultural Biosafety Scientific Advisory Committee
ABSF	African Biotechnology Stakeholders Forum
ACODE	Advocates Coalition for Development and Environment
ACTS	African Centre for Technology Studies
AIA	Advanced Informed Agreement
BCH	Biosafety Clearing House
BL	Biosafety Level
CA	Competent Authority
CBD	Convention on Biological Diversity
CBI	Commercial Business Information
CFT	Confined Field Trials
COP	Conference of Parties
COSTECH	Commission for Science and Technology
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic Acid
DVS	Department of Veterinary Services
EAC	East African Community
EASTC	East African Science & Technology Council
EMA	Environmental Management Act, 2004
FAO	Food and Agriculture Organisation
GCLA	Government Chemist Laboratory Agency
GEF	Global Environment Facility
GMO	Genetically Modified Organisms
HEPA	High Efficiency Particulate Air
HV	Host-Vector
IBC	Institutional Biosafety Committees
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
JET	Journalists Environmental Association of Tanzania
KARI	Kawanda Agricultural Research Institute, NARO
KBIC	Kenya Biotechnology Information Centre
KEBS	Kenya Bureau of Standards
KENFAB	Kenya National Farmers Bureau
KEPHIS	Kenya Plant Health Inspectorate Service
LMO	Living Modified Organisms
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries, Uganda
MAFS	Minister for Agriculture and Food Security

MARI	Mikocheni Agricultural Research Institute
NARO	National Agricultural Research Organisation
NBAC	National Biotechnology Advisory Committee
NBC	National Biosafety Committee
NBFP	National Biosafety Focal Point
NBF	National Biosafety Framework
NBS	National Bureau of Standards
NCST	National Council for Science and Technology
NEMA	National Environment Management Authority
NEMC	National Environment Management Council
PBS	East Africa Program for Biosafety Systems
PCPB	Pest Control Products Board
PEAP	Poverty Eradication Action Plan
PHS	Plant Health Services
PMA	Plan for Modernisation of Agriculture
rDNA	Recombinant Deoxyribonucleic acid
SPS	Sanitary and Phytosanitary Agreement (FAO)
SRI	Sugarcane Research Institute
STAK	Seed Trade Association of Kenya
SUA	Sokoine University of Agriculture
S&T	Science and Technology
TACRI	Tanzania Coffee Research Institute
TASTA	Tanzania Seed Trade Association
TBS	Tanzania Bureau of Standards
TFDA	Tanzania Food and Drug Authority
TFNC	Tanzania Food and Nutrition Centre
TOSCA	Tanzania Official Seed Certification Agency
TPRI	Tropical Pesticides Research Institute
TRIT	Tea Research Institute of Tanzania
TTA	Tanzania Tea Authority
UDSM	University of Dar Es Salaam
UNCST	Uganda National Council for Science and Technology
UNEP	United Nations Environment Programme
VPO	Vice President's Office
RF	Rockefeller Foundation
USAID	United States Agency for International Development
WTO	World Trade Organisation

Overview and Roundtable Executive Summary

Can regional approaches help biosafety regulation in East Africa?

What is the rationale for regional collaboration in biosafety regulation? For East Africa, national biosafety frameworks, policies, and legislative development take precedence over sub-regional approaches. This cumulative national experience and capacity building, together with regional associations, and international agreements presents a distinct opportunity for sub-regional dialogue and action on biosafety. Making alliances a reality now helps countries prepare for future collaboration, exchange and use of regulatory data and information, able to use common forms, and inform one another of biosafety developments for the sub region.

In geographic regions where farmers grow the same staple crops, battle similar pests and diseases, and face common environmental constraints such as drought or poor soils, some genetically engineered crop varieties will be appropriate and beneficial to countries across the region. Within the region, however, countries may be at vastly different stages in developing their national biosafety systems. Some countries may be at the earliest step of raising awareness of biotechnology among government leaders. Others may have established biosafety committees and drafted legal instruments to regulate the use of products derived through modern biotechnology. Indeed, some countries simply may not have the technical and financial resources to support a biosafety system, given numerous pressing national needs and priorities.

Considering regional efficiencies¹ among neighboring countries facilitates the safety, testing and review of transgenic crops of interest. This would mean that key elements in the various national regulations are comparable. Such commonalities among national regulations help create a more consistent regulatory environment in a region, which in turn supports limited national capacity available for regulators, as they review biotechnology applications, meet regulatory requirements for importation, understand confined field trials, and eventually, approve decisions regarding use.

Information for biosafety decision-making in one country is often applicable for neighboring countries as well, although rarely used as such. Regulators assess safety based on sufficient data, properly collected and interpreted. This can include data for food and feed safety, molecular characterization, socio-economic needs, efficacy and biosafety data from field trials, and in many cases, environmental impacts. It is generally accepted that food and feed safety information required of genetically modified (GM) crops is universal. GM food and feed safe for human and animal consumption in one country is likely to be safe for humans and animals elsewhere.

Environmental safety is best assessed in the environment in which a GMO is to be used. As such, environmental safety data from countries on one continent provide part of the data needed to assess impacts of GMOs in distant countries. Neighboring countries share common habitats, and environmental risk assessments in one country can be applicable in part or entirety to adjoining countries. Environmental safety assessments benefit from regional collaboration and can increase effectiveness of the limited regulatory capacity available in developing countries.

¹ By efficiencies, we mean increasing capabilities among regulatory systems having limited: human capacity, technical know how, confidence for document review, and competent decision-making.

Exchange and use of data provides benefits including: sharing: costs of reviews, regional expertise with similar crops and events, regional capacity, applications for approval and processing for applicants, ways to avoid duplication, information collection and dissemination, results of regionally specific biosafety research, and responsibilities with international biosafety platforms

However, such exchanges are not common practice among countries in East Africa. Therefore, three East African countries, relevant sub-regional research organizations, and the Program for Biosafety Systems (PBS) organized a policy roundtable to explore specific regional approaches, deterrents and policies for congruent and more efficient regulation. Specific policy and regulatory matters were presented, including modified confined field trial applications forms, regional opportunities consistent with the Cartagena Protocol on Biosafety, regulatory review of national systems in Kenya, Uganda, and Tanzania, and a comparative analysis of these systems. Examining role of plant protection and quarantine, presenting working regional models as examples, and designing communication strategies were also reviewed.

What is happening regionally in Africa?

Regional planning for biosafety is taking place among countries in West and Central Africa. Many countries of this sub-region are developing national approaches for biosafety that protect national sovereignty and decision making. They do not however, benefit from knowledge and experience gained by other countries, and it presents a risk of formulating inoperable regulations. One opportunity to overcome inoperable regulations and learn from others is approaching biosafety regionally.

The Ministerial Conference on Agricultural Science and Technology held in Ouagadougou, Burkina Faso in June 2004 was a landmark event. Four heads of state — from Mali, Burkina Faso, Niger and Ghana — and sixteen Ministers participated in the meeting. They unanimously endorsed recommendations to raise public awareness about biotechnology, create a regional biotechnology center of excellence, and to organize a second ministerial meeting on the adoption of a regional biotechnology action plan and regional harmonization of biosafety systems. In another important development, ECOWAS agreed to associate itself with the regional biotechnology and biosafety program being developed under the leadership of CORAF/WECARD.

Increased attention and effort by West African countries to develop biosafety frameworks is being catalyzed by two recent developments: first, entry into force of the internationally binding Cartagena Protocol for Biosafety; and second, testing and adoption of genetically engineered crops in the region. Transgenic insect-resistant cotton is in its second year of field testing in Burkina Faso, and continued commercial production in South Africa. West African countries including Ghana, Benin, Mali, Chad, Nigeria, Côte d'Ivoire, Senegal and Niger have indicated interest in testing GM cotton, cowpeas, cassava and/or crops of regional importance.

The East Africa Community (EAC) has also recognized the need for an efficient biosafety system to guide the development of biosafety and biotechnology in its region. In that regard the EAC's Council of Ministers established a Technical Committee of Experts to address biosafety issues and come up with an EAC regional policy on Genetically Modified Organisms. Concerned

experts and dates for the meeting have already been identified. The Community has also already taken concrete steps on institutional and policy issues including:

1. Conclusion of Common Agriculture and Rural Development Policy and Agriculture and Rural Development Strategy. The formal approval of the two instruments will be made at the next EAC Committee of Ministers Meeting in May 2005.
2. Preparation of Protocol in Environment and Natural Resources Management is ready and under scrutiny through relevant technical evaluation before consideration and adoption. The Protocol contains provisions related to biotechnology issues that will guide investments, trade and operations in biosafety frameworks and establishes an East African Science and Technology Council.

Regional activities in the context of the Cartagena Protocol on Biosafety.

National biosafety frameworks are key components of the UNEP/GEF program supporting capacity building and compliance with the Cartagena Protocol on Biosafety. As many countries develop their frameworks, an opportunity is presented to emphasize regional information sharing, sharing regulatory procedures and documentation. This is recognized by the UNEP/GEF project itself (UNEP/GEF, 2001).

The GEF Council, in November 2000, adopted an *Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety*. The main objectives of this initial strategy are to: assist countries in the establishment of national biosafety frameworks and promote information sharing and collaboration, especially at the regional and sub-regional level. To begin this work, the 10th meeting of the GEF Council, held in Washington, DC on 4-6 November 1997, approved a Pilot Biosafety Enabling Activity project of US\$ 2.7 million. The National Level Component of the project aimed at assisting eighteen eligible countries to prepare National Biosafety Frameworks (US\$ 1.9 million), with the Global Level Component aiming at facilitating the exchange of experience at regional levels.

As no country is isolated from its neighbors, the UNEP/GEF recognizes that there is a clear need to strengthen regional ties between countries, either by assisting in setting up regional networks or by helping to set up systems with the necessary authority to oversee the development of modern biotechnology within the region. Co-operation at sub-regional and regional levels is key to the successful implementation of the objectives of the Protocol. Support for sub-regional and regional co-operation will facilitate development of the following aspects:

- Human resources/relevant expertise pertinent to issues of biosafety at national, sub-regional and regional levels;
- National and sub-regional capacities to assess and manage risks associated with living modified organisms that may have an adverse impact on the environment; Guidelines, methodologies and procedures for rapid assessment and management of risks and benefits of living modified organisms and review of applications for field trials and field releases;
- Networks for supply and exchange of biosafety information

East Africa and PBS Policy Roundtable

Countries in East Africa have called for meeting and sharing information regionally, preparing for cooperation and exchange of information, comparison of policies, and human capacity building, and recognition of application assessments. **To examine such information and**

possibilities, an East African Biosafety Policy Roundtable was held in conjunction with the Program for Biosafety Systems (PBS) in April 2005.

The Program for Biosafety Systems (PBS), implemented through a consortium of public, international, regional, and local organizations in developing countries, was initiated in response to the numerous challenges facing less developed countries such as:

1. The need to foster an efficient regulatory environment characterized by transparency and stability
2. How to provide an effective system that ensure accountability and stakeholder participation, thus building public confidence in decision making
3. How to better rationalize biosafety regulations with other on going strategies and frameworks for food safety, seed and phytosanitary regulation, importation, and other relevant laws and/or regulations, and,
4. The need to develop acceptable criteria to weigh risks/benefits while considering agricultural productivity, environmental, and human health concerns.
5. The need to improve implementation of the Cartagena Protocol on biosafety at national and regional levels.
6. How to respond to the other needs for biosafety at international level (CODEX, SPS, IPPC)

The topics presented in this first roundtable featured discussions from Kenya, Uganda and Tanzania, while allowing for perspectives from various stakeholders. The primary audience for the roundtable included the Chairs of national biosafety committees, members of the NBCs, members from national plant protection and quarantine offices, representatives from the UNEP/GEF speaking on the Cartagena Protocol on Biosafety, and environmental ministries.

The main topics discussed included:

- International/regional regulatory comparisons, contrasts, and collaboration
- National approaches and international agreements
- Plant protection and quarantine mandates and operations as related to national biosafety systems
- Experiences with other regional, collaborative approaches
- Strategic approaches to regional communication for biotechnology and biosafety
- Stakeholder perspectives and recommendations.

Key Recommendations and actions

Discussions indicated that countries were ready to work together on some aspects of their regulatory systems while other areas needed more dialogue and more progress needed to be achieved at the national level before exploring regional approaches. It was apparent that sharing information and conducting regional studies posed no controversy.

However, it is also recognized that not all agree with setting regional precedence for regulation, nor for countries making more efficient the limited capacity they have in-country. Doing such is also seen as a way to foster easier routes of approval for multinational companies, seeking to move proprietary material into key agricultural regions of Africa. Thus, any type of regional acceptance of data and decisions would make the approval process all that easier for them, and allow them to move in haste through national biosafety procedures.

Not to negate this scenario, for it was voiced in our discussions, and, it was also the case that not all issues could come to an agreement, as some proved that further dialogue and research were needed. Common findings were distilled from roundtable presentations, dialogue, workshop reports and stakeholder presentations that led to recommendations and actions for the countries:

Information sharing.

- information shared must be of value, and for the purpose of using, allowing additional data for informed regulatory decision making

Sharing of experience and policies within region will help to:

- speed up implementation; there is need to share experiences through visits by NBC members, exchange programs, and by bringing the NBC members together on a periodic basis
- bring countries closer together by sharing practical experiences of countries using biosafety processes
- identify entry points for regional cooperation; after pointing out that countries are at various levels/understanding
- improve interactions across counties to understand what is going on in each of the countries to encourage knowledge spill-over in specific areas of need for each country and save each country from trying to re-invent the wheel
- share knowledge of science, technologies, and regulations across countries.
- track movement of GMO materials from one country to another and this will benefit from harmonized policies, inspection and administrative procedures and manuals.

For capacity building the following were noted:

- countries need to be brought to equal footing and this often means starting from the basics
- more defined ways to build capacity and examine its cost
- logical to look at the possibility of using trained personnel in the region rather than individual countries having to account for all personnel they require
- the inter-university council could be used to screen training materials to ensure that it contains no propaganda
- From the ASARECA-ECAPAPA experience with seed policy harmonization, it is seen that it is not necessary to wait for all countries in a region to be at the same level when beginning regional practices

On confined field testing the following were noted

- confined field testing is justified by the need to see performance at multiple locations, to confirm product efficacy, as there can be much genotype by environment interaction
- focusing on confined field trials is also a way to build capacity to inform on later critical areas in the processes towards open release

Environmental issues for confined field trials and commercial/open release

- Ex-ante data analysis on pests and predators
- Proactive monitoring and evaluation of environmental impacts
- Harmonization on development, import and export authorization
- Stakeholder information and consultation programs

- Risk assessment coordination
- Analysis of risk mitigation issues

Recommendation on Communication included:

- Scale up on-going stakeholder sensitization programs and dialogues
- Explore information materials available and effectively disseminate them
- Media awareness and training in the area of biotechnology enhanced to enable more effective communication;
- Scientist should initiate joint Media-scientists communication programs; bring scientists from understanding of confined field trials to open release
- Communication facilitator to get the message across in the different languages
- Prepare a glossary of terminologies and how they can best be used
- Help stakeholders to appreciate how the regulatory regime (i.e. competent authorities) operate

Cartagena Protocol on Biosafety

- LMOs destined for commercial use should have nationally set standards and procedures in place
- Need for parties to the Protocol to expedite completion of biosafety legal framework
- Need for Cartagena Protocol on Biosafety regulators to work with other relevant regulators to build supportiveness
- Regional arrangement should not lead to less protection than that outlined in the Protocol.

Actions

The report from the roundtable, as well as recommendations will be passed to the East African Regional Advisory Group for Program for Biosafety Systems for review. Priorities will be set for immediate action steps which PBS should implement.

From the meeting, and recommendations, some actions can be seen of immediate value:

- Setting schedule and agendas for periodic meetings of the NBCs and their chairperson, with focus on particular documents, evaluations, and so forth
- Establishing similar group for the plant production and quarantine offices
- Regional review of common documents needed for the regulatory process
- Specialized workshops on confined field testing, to understand what they are, and are not, and the type of approvals needed.
- Convening country experts for regional communication strategy design
- Special attention in capacity building to bring countries towards an even level of knowledge so that each country can make the most of the regional meetings
- Special attention to analysis and completion of policies and legal instruments.

Observations and Implications for future Policy Research Issues

- 1) Biotechnology and poverty alleviations: Focus back on the end-user
- 2) Creative ways to finance R&D in appropriate biotechnology
 - a. Commodity groups financing R&D through voluntary fees and production check-offs based on sales
- 3) Regulatory objectives, structures, scope and development
 - a. Multiple institutions and stakeholders
 - b. Institutions and human capacity building
 - c. Awareness

- d. Differentiation between stages of regulatory process: Confined versus contained
- 4) National and regional integration of biosafety and biotechnology policies into national development plans and policies
- 5) Internal and external consistency of laws and regulations
- 6) Biotechnology as a tool versus end-result
- 7) Cost, benefits and risk/safety assessments: When? How? By Whom?
- 8) Governance of biosafety and biotechnology policy and the need to establish competent authorities to regulate

Policy Research ideas

1. Gap analysis in terms of human, financial and infrastructure resources. Sense that there is the need to bring all countries to the "same" level.
2. A trade/learning model for East Africa. We have three players, one innovates and is considering approval for commercialization (i.e. Kenya and Bt maize), Uganda and Tanzania are not considering approval, but plant maize in their own countries. What is the innovator strategy? What is the other two countries' reaction? For Kenya questions regarding biotechnology and biosafety may be:
 - a. Why should I invest in biotechnology and biosafety when I know that my product would flow to other countries? Uganda and Tanzania will benefit from the spillovers of my investments.
 - b. Mirror question for Uganda and Tanzania is: Why should I invest in B/B when Kenya my neighbor will invest in biotechnology?
 - c. What is the effect of the level of learning (capacity to do biosafety) of all countries?
3. Cost of regulation derivatives.
 - a. Assume that full biosafety authorization/approval is done in each and every country. Estimate the cost of regulation for a similar set of biosafety processes for the portfolio of technologies and under different regional scenarios. Output should provide some initial leads as to the benefits of regionalization approaches.
4. Examine the harmonization efforts completed for seed and Plant Protection Quarantine (PPQ) in East Africa. How did this harmonization effort happen? What are the conditions that lead to this outcome? Phelix Majiwa explanation is that at the top there was a regional requirement to do so (Need to find out what was the arrangement) and at the bottom, there was a set of laws (traced to Colonial times) that were basically very much the same. For biosafety there does not seem to be anything at the top or bottom.
5. Paper clearly establishing the differences in between PPQ and CFT, in terms of existing capacity in countries.
6. Under what conditions cost of biosafety processes may decrease over time? Greg Gaffe paper indicates that the lag of approval of pharmaceuticals has increased over time, presumably the cost has increased
7. Consequences of different levels of biosafety capacity, legislation and implementation plans in terms of:
 - a. R&D policy
 - b. Approval in one country and posterior dissemination
8. Pathways to biosafety development and implementation. Does one need a law in place before initiating discussions and implementation plans and efforts?
9. Practical approaches to biosafety decision making processes. How does one separate between commercialization of products for planting versus importation for food/feed consumption?

5.1 Status of Biosafety Frameworks In The Three Countries

Issue	Kenya	Uganda	Tanzania
a) Biosafety Guidelines	1998 Draft approval and operational	2002-2004 (Operational)	Draft (not operational) 2002 - 2004
b) Biosafety Framework	(+) 2003	(+) 2003	(+) 2004
c) Agencies involved in biosafety regulation defined	(+)	(+)	(+)
d) Draft law/ Regulatory regime Existing/New	(+) Draft law NEMA (+)	(+) Draft regulations	(+) Draft regulations EMA 2004
e) Policy (biotechnology and biosafety)	(+) Draft	(+) Draft	(+) Draft
f) Existing legal body g) New	NEMA Biosafety Authority?	S&T	S&T Act EMA 2004
Exchange of information	BCH; ABSF; KBIC; ACTS	BCH; ABSF*; ACODE**	BCH; ABSF*; ACTS**JET
Ministries	Agriculture, Industry and Trade, Health, Education, Constitutional Affairs Environment Livestock, Fisheries	Finance, Environment Agri, Trade and Industry, Health, Fisheries, Livestocks, Constitutional Affairs	Ministry of Science, Technology & Higher Learning VPO-Environment MAFS, Industries and Trade, Natural Resources (Wildlife, Fisheries & Forest), Ministry of Justice & Constitutional Affairs, Livestock and Water
Regulatory Agencies	KEPHIS PCPB KEBS NEMA NCST PHS DVS	NEMA NBS UNST Plant Quarantine	TPRI TBS TFNC TFDA COSTECH GCLA TOSCA/NEMC
R & D Institutions	Universities, KARI	Universities NARO	Universities Directorate of Research & Development
Farm organizations	Kenya seed STAK KENFAB	Uganda Farmers Federation	Consumer TASTA TTA
Private Sector	(+) STAK	Med-Biotech	TACRI TRIT
Authority	NBC IBC	NBC IBC Inter-Sectoral Committee	NBC IBC CA (NBAC, ABSAC) NBFP
Application of RR	Applied for approval Crop and animal vaccine	HIV vaccines Bt Cotton	None

OPENING SESSION

Background to the Program for Biosafety Systems Round Table (Theresa Sengooba; PBS)

Background

The East Africa Biosafety Policy Round Table meeting was hosted by the Program For Bio-safety Systems in collaboration with NARO and the National Council of Science and Technology. Other partners who contributed to shaping the meeting included ASARECA, ECAPAPA and different institutions in charge of biosafety aspects in Uganda, Kenya and Tanzania. COMESA, Members of UNEP-GEF project and biosafety focal point institutions / persons also provided vital contribution to the round table through their participation. Other invitees included biosafety regulatory officials who are in the driving seat for biosafety policy proposals, policy interpretation and implementation. In addition a range of experts within and outside PBS components with special skills in biosafety policies for developing countries participated in this round table.

The principle behind the round table was that no one person can claim monopoly of good ideas when it comes to regional approaches for biosafety systems because there are complex variables involved. Hence the meeting brought various experts together to look at commonalities across the three countries of East Africa and find out what aspects of biosafety could be shared for the benefit of individual countries and the region as a whole. The round table set to explore opportunities for the countries of East Africa to work together and help one another for an efficient and effective biosafety policy and regulatory system.

Purpose and objectives

The overall purpose of the round table was to identify regulatory efficiencies leading to collaborative approaches, enhanced biosafety decision-making, and regional implementation. While the desire to have some regional approaches for biotechnology regulation may be apparent there are questions that may have to be answered and issues to be analyzed regarding the value of regional collaboration on biosafety. There are also modality factors. Hence the specific objectives of the round table included:

1. Seeking agreement among partners for policy research, information, and case studies to be covered by country, external experts, and PBS
2. Presenting and discussing new methodologies, findings, research and experiences leading towards greater cross border efficiencies for biosafety
3. Incorporating stakeholder suggestions in formulating and drafting sub-regional regulatory models
4. Introducing and analyzing implications of new regulatory models for regional efficiencies

The meeting was structured to have plenary and working group discussions. At the start of the technical session international regulatory systems that have an impact on biosafety and how these are directly or indirectly influencing pertinent decisions were examined. This was followed by discussions on national systems for biosafety regulation and plant quarantine and a touch on how the regulatory environment is impacting public research investments and products. Experience on regional approaches that are already in place for example the seed policy and on communication for biotechnology and biosafety advancement was highlighted.

Expected output from the round table

1. Regional plans or concepts for consideration by relevant regional bodies, ministries, institutes and other stakeholders and
2. Individual plan of action for specific topical focus

PBS Components

1. PBS Policy Component

The policy work is designed to promote science-based decision-making and policy development with information and recommendations that will help policy makers choose between regulatory options and tradeoffs. The program is supporting existing systems, while providing opportunities to examine alternative models for sub-regional and regional consideration. Through research the program is supportive of evaluation of biosafety policies and objectives for their implications for agricultural growth, trade, and food security. Potential tradeoffs and complementarities between these goals, costs of systems, and levels of safety are examined.

Proposed and on-going policy activities include: a) regionally focused discussions on alternative models for biosafety that were initiated through the round table; b) regulation and costing determinations to characterize national approaches; c) an analysis of economic and trade implications to the adoption and non adoption of transgenic plants. The discussions from the meeting were expected to generate more ideas about relevant and priority biosafety policy studies.

2. Environmental Risk Assessment and Risk Management Research

Scientific knowledge on the nature of biodiversity/ecological risks and strategies to manage such risks should be the foundation for biosafety decision-making. When knowledge is lacking, assessments can be subjective and methods for risk management arbitrary. Therefore, in consultation with local authorities and partners priority research areas are identified and some of these funded through a competitive research system. East Africa has actively participated in this competitive grant project of PBS and any successful outcome should enable researchers to generate information that will be useful for risk assessment and risk management. Specific training on concepts and up to date methodologies for risk assessments research has been provided by PBS to a number of scientists and regulators.

3. Assistance with Regulatory Packages

The PBS component that is responsible for assistance with regulatory packages consulted widely at the start of the program and with partners identified regulatory capacity as a critical need in national biosafety systems. Hence various training workshops that targeted regulatory institutions have been conducted to enhance capacity for evaluation of application for confined field trials of genetically modified plants. In both Kenya and Tanzania efforts have been devoted to establishing documents necessary for introduction, handling and evaluations of transgenic plants that are introduced or produced in country. The documents that have been reviewed/produced in collaboration with PBS include regulations/schedule/directive for confined field trials, review of application form for use when introducing plants for research under confined conditions, inspectors' manuals and a number of biology documents. Training of potential applicants has also been initiated.

4. Communication, Outreach and Capacity Building

Communication, outreach and capacity building are fundamental for a biosafety system to be effective and transparent and form the fourth component of PBS. Effective and targeted communication strategies with a consistent national/regional approach have been initiated. The project activities under this component include:

- a) workshops to develop communication skills among key policy makers and scientific leaders;
 - b) supporting communication and outreach activities for other biotechnology stakeholders.
- Capacity building – This is cross cutting and includes a) enabling authorization and safe conduct of experimental field trials; b) policy development seminars, including results from BBI research;

c) consultative guidance to regulators and scientists for the development of regulatory packages; d) environmental and food safety risk assessment and risk management training.

Partnership

PBS foundation is based on partnerships as biosafety cuts across several institutions. At the conceptual level, the original proposal that won the grant was put together by a consortium of professionals and institutions with skills and expertise in biosafety and policy development. This consortium has remained a dynamic group originally led by ISNAR and presently IFPRI. The consortium members include CGIAR centers, Universities, NGOs and private consulting groups all brought together by a common interest and specialized skills in biosafety for developing countries.

At the operational level the consortium of experts is working with partners at national and regional levels to implement the project. PBS is currently operating in Asia and in Africa where projects are on-going in West Africa, Southern Africa and East Africa. The major partners in Africa include but are not limited to ASARECA, BIOEARN and COMESA for Eastern Africa and CORAF for Western Africa.

As resources are always limiting, PBS is not able to work in all countries of the regions covered by the regional partners. Hence in the case of Eastern Africa PBS has so far decided to focus on three countries including Uganda, Kenya and Tanzania. These countries were selected largely on a basis of

- Indicated interest and investments in modern biotechnology
- The status of the development of biosafety policy and regulations
- The human resource involved in Biotechnology and Biosafety policy and regulatory framework.
- Whether biosafety concerns have been identified as priority area within the government plan

Within the individual countries PBS is working with a range of partners from government and private organizations including councils of science and technology, agricultural research systems, crop inspection departments, ministry of health, national bureau of standards, Universities and others that may have a biosafety regulatory responsibility. While PBS is working in specific countries strategies are being developed to enable other countries in the region benefit from the presence of PBS.

Country/Regional Advisory Groups

The program is guided by **Country/Regional Advisory** Groups that include mostly members of biotechnology/biosafety advisory committees. The Advisory Groups provide input on identifying priority areas that should be addressed; they advise on implementation strategies and they approve the annual work plans. The contribution of the Advisory Groups is critical for PBS as a mechanism to ensure that national needs are addressed and that there is no duplication of activities already successfully addressed by other national or regional programs.

Sponsor

The Program for Biosafety Systems is an award from a competitive grant funded from USAID Washington. The program was launched in May 2003 and since then it has been growing through grants and mission buy-in. Both Uganda and the Kenya USAID missions are supporting the program.

**Keynote Address: Agricultural Biotechnology: A case for Developing countries
(W. Kisamba-Mugerwa, ISNAR-IFPRI)****Summary**

Agricultural biotechnology can contribute to increased food security and household incomes in African countries by way of greater agricultural productivity whilst conserving the natural environment. For that to happen, it is critical that biotechnology be viewed as one part of a comprehensive, sustainable poverty reduction strategy, not as a technological "quick fix" for Africa's hunger and poverty problems. It is also essential that the necessary innovations and investments be made in institutions to build the necessary capacity. What is particularly critical is that there be national and regional consensus for the advancement of biotechnology. Indeed, the greatest risk for Africa is to do nothing, allowing the biotechnology revolution to pass it by. This may happen if capacity strengthening at all levels is not addressed and effectively backed with coordinated regulatory systems in form of biotechnology policy and bio-safety regulations. This requires that there be a comprehensive communication strategy in creating awareness among stakeholders to eliminate mistrust.

1. Introduction

According to the Food and Agriculture Organization of the United Nations, the number of chronically undernourished people in developing nations has risen in recent years to 798 million. Proponents of biotechnology argue that it offers the best prospect for helping less developed nations feed their hungry citizens by improving plant and animal genetics to increase yields, in the same way that improved rice and wheat varieties led to the Green Revolution beginning in the 1960s. Farm productivity growth is lagging in Africa because the continent missed the benefits of the Green Revolution that swept through most of Asia and Latin America in the 1960s and 1970s. Plant breeding breakthroughs at diverse research centers in China, Mexico and the Philippines in the 1950s and 1960s gave many farmers the opportunity to increase crop yields (Paarlberg 2001; Omamo and von Grebmer 2005). It is estimated that because of the high yielding varieties of the Green Revolution the productivity of an average farm worker in China increased from US \$ 161 up to US\$ 307 in real terms between 1980 and 1997. In Thailand productivity increased from US\$ 634 up to US\$ 932. In South Korea agricultural productivity increased from US\$3,800 per farm worker up to US\$ 11,657. However, during the same period average agricultural value added per farm worker was actually declining in Africa, from \$418 down to \$379. The social welfare consequences of this farm productivity failure in Africa have been devastating in terms of famine, hunger, and malnutrition and food insecurity.

It is common knowledge that the vast majority of Africans about 75 percent or more get their employment and income from farming. As such any lag in agricultural growth translates directly into poverty, and hence hunger. Lagging productivity on small farms is the chief reason why 30 percent of children in Africa are still chronically malnourished. For Africa more than any other region, the problem of inadequate food consumption grows directly from an unsolved farm productivity problem. All these lead to poverty, hunger, and nutrition insecurity (Paarlberg 2001).

The state of affairs in Africa has been reflected in several different ways but all in common indicate poverty due to deteriorating food production and poor environment trends. According to Thirtle, McKenzie and Wiggins (2001) half of all Africans earn less than \$1 a day; three fourths earn less than \$2 a day. A one percent increase in yields would help six million more people raise their incomes above one dollar per day. In 2000, Africa had 44% of the world's hungry; if present trends continue, the number may be 73% by the year 2015. Africa is the only region in which the actual numbers of hungry people are increasing, Conway (2003). The rapid increase in population nearly 3 percent annually causes even greater pressure on the available natural resources.

If, to feed Africa's ever growing population, more and more acreage must be turned over to food production and with the current low resource practices, environmental damage will significantly increase. The land brought into cultivation for increased agricultural production will be more fragile and more easily damaged. Much of it will have to be obtained by clearing forests, jungles, and wetlands. It is envisaged that if present agricultural practices continue, the increase in chemical inputs fertilizers and pesticides will contaminate wider areas of land and water, and may simply maintain, not necessarily increase, productivity.

Africa urgently needs answers and solutions to the myriad of problems and challenges facing it. The scientists claim that biotechnology can assist developing countries by reducing the major constraints to sustainable production of food and cash crops. The claim points out that agricultural biotechnology offers the opportunity of lifting people out of poverty, hunger, and malnutrition and food insecurity while controlling natural resources and environmental degradation. However, for agricultural biotechnology to be successful in increasing productivity and growth in Africa requires that the many challenges related to technology transfer strategies, policy and regulatory issues in Africa be confronted and overcome.

Few African countries conduct biotechnology research on their own. However, all have a keen interest in food security, reducing hunger and malnutrition and the safeguard of their agricultural comparative advantage. Like the rest of the world, Africa appears to be divided on the issues of biotechnology. Sincere concerns and passions characterize the public debate but incomplete knowledge, lack of information, poor communication, weak policy and regulatory mechanisms seem to dominate it.

In this paper it is recognized that a lack of policy and regulation related to agbiotech have an effect on public understanding of the technology which can limit public acceptance and confidence in biotechnology derived products. Policies and regulatory procedures are vital for the successful implementation of biotechnology led food and agricultural development. The potential of agbiotech in Africa is further constrained by insufficient capacity at all levels with respect to human resources and infrastructure. A lack of a comprehensive communication strategy in creating awareness among all stakeholders has led to widespread mistrust and limited the dissemination of biotechnology products. The available knowledge is not collectively assessed by each institution and stakeholder tailored to a common objective. This leads to policy-maker receiving mixed messages which leads them to delay the formulation of policies and regulations related to biotech applications

2. Agricultural biotechnology Insights

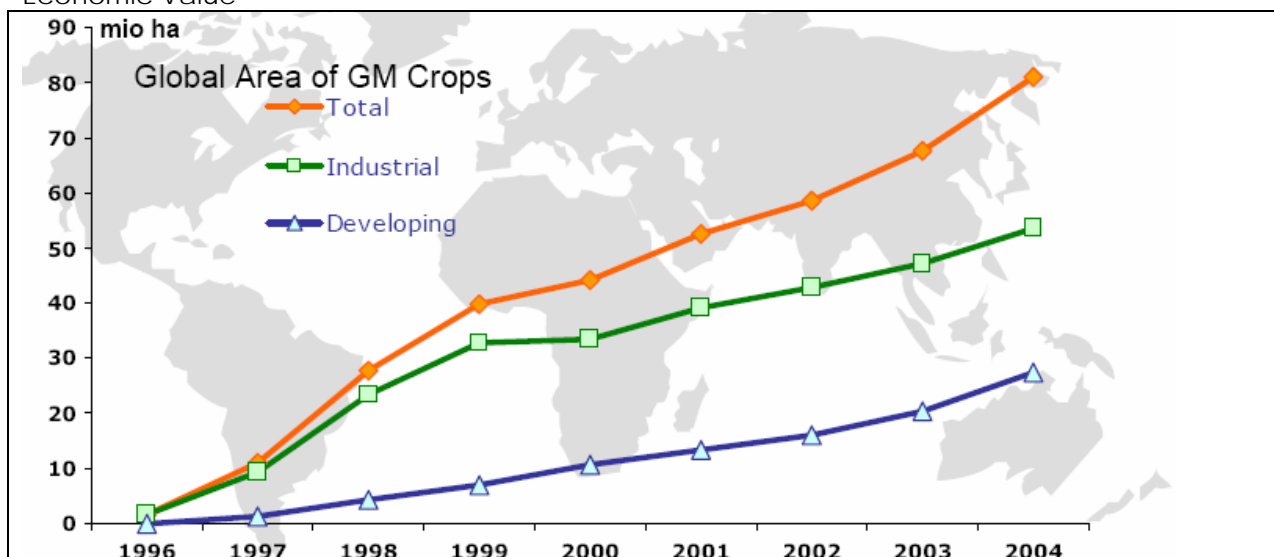
Agricultural biotechnology development is intended to address some of the challenges faced by farmers. These challenges include threats to crop yields from diseases, pests, weeds, and weather, and lack of critical growing inputs such as nutrients and water. Farmers in Africa need crops which have disease resistance qualities to viruses, fungi, bacteria and insect effects; together with environmental stress resistance such as heat, drought, and salinity. They also include quality improvement in respect of nutritional improvement, increased yield, and reduced post-harvest losses.

Furthermore, if a farmer could reduce intensive irrigation by using a crop variety modified for drought resistance, this could lower the cost of production in areas with high irrigation costs or enable productions with minimum irrigation in areas that lack sufficient water. The potential of biotechnology to increase yields or improve nutrition is also highly associated with environmental benefits which could be realized. Higher yields from land already under cultivation also may make it possible to avoid the conversion of biologically diverse natural habitats such as rainforests, wetlands, or grasslands to farmland. Insect-resistant crops also could reduce the use of more persistent or toxic pesticides. Higher yields may obviate the needs to cultivate steep hillsides or wetlands critical for watershed protection, flood control, and soil retention. On the

other hand, however, some argue that the increased ability to use marginal lands that would otherwise be unsuitable for cultivation acts as a disincentive to critical conservation efforts (de Janvry et al. 1999; The Pew Initiative 2004).

Whatever the case may be the available literature shows that the value of the global market in transgenic crops grew from U.S. \$75 million in 1995 to U.S. \$1.64 billion in 1998 (Persley and Siedow 1999). Global use of biotechnology is growing as shown in Figure 1 & 2 and Table 1. It has been also recorded that transgenic crops have delivered large economic benefits to farmers in some areas of the world (FAO, 2004).

Figure 1. Evidence of Global Increase in Biotech Crops: Rapid Adoption a Testimony to Economic Value



Source: James, ISAA 2004

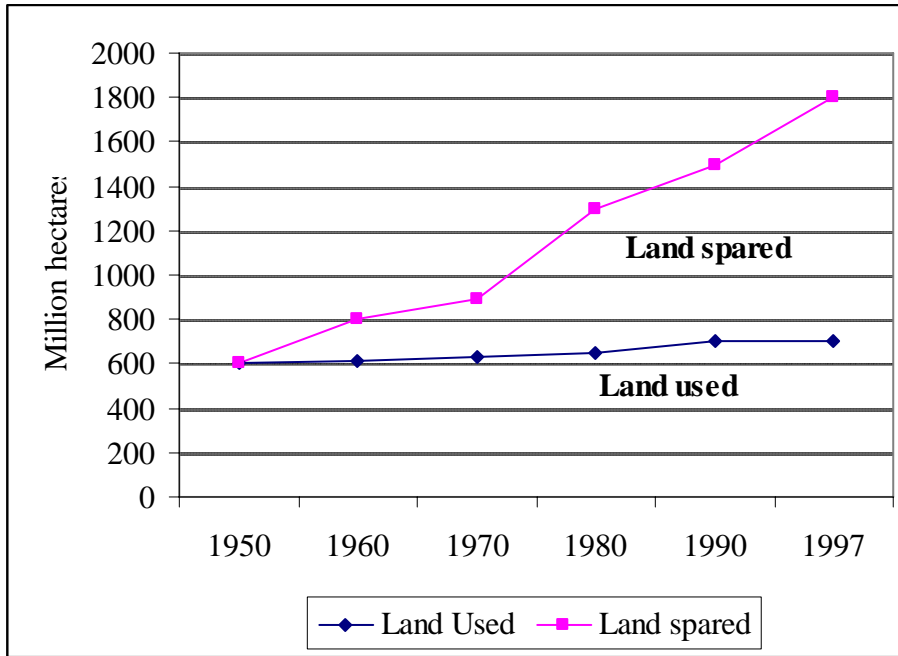
According to Borlaug a huge arable land was saved through adapting biotechnology between 1950 and 1997. In 1960 in the U.S., the production of the 17 most important food, feed, and fiber crops was 252 million. It is important to note that the 1999 harvest was produced on 10 million fewer acres than were cultivated in 1960 (Table 1)

Table 1. Biotechnology - A Contribution to Sustainable Agriculture

<u>Economic</u>	<u>Environment</u>	<u>Society</u>
Enhancing Efficiency	Reducing environmental impact	Safeguarding food supply
Improving competitiveness	Saving resources	Promoting nutritional & health benefits

Source: James, ISAA 2004

Figure 2. World cereal production –area saved through improved technology, 1950-1998



Source: Borlaug, 2000

If it was tried to produce the harvest of 1999 with the technology of 1960, it would have had to increase the cultivated area by about 460 million acres of land of the same quality which the United States didn't have.

In areas with slow transportation or inadequate storage facilities, the ability to preserve a harvested crop on its way to market could provide considerable economic value. Research regarding ways to delay ripening or provide post-harvest pest resistance through genetic modification could mitigate current barriers to food distribution in developing countries. For example, altering a fruit's production of the ripening agent ethylene could reduce rot by extending shelf life and increasing the amount of time the fruit could spend in transportation. Researchers have accomplished this in tomatoes; development is underway for delayed ripening raspberries, strawberries, bananas, and pineapples (The Pew Initiative 2004).

As previously discussed, because pest-resistant GM crops may decrease the need for pesticides, the occupational exposure of farmers and their family members to these chemicals could be reduced.

3. Agricultural Biotechnology Policy and Regulation Experiences in EU and US

GMO Policy of the European Union - Regulations

Since the mid-1990s, crops, foods, and food ingredients developed through recombinant DNA technologies commonly referred to as GM-seeds, GM-crops, or GM-foods have entered the markets of the United States, Japan, and several other industrialized countries on a massive scale. Controversies over whether and how to regulate this new technology have concentrated on the approval of GM-crops and GM-foods, and on the labeling of such products.

By 1997, the EU's GMO approval policy was in disarray. Since April 1998, there has been a de facto moratorium on new approvals. The strongest supporters of this moratorium are Denmark, France, Greece, Italy, and Luxembourg. These countries have taken the position that they will not approve any new GMOs until strict labeling and tracing regulations are established. Belgium,

Sweden, Austria, Portugal, the Netherlands, Finland, and Germany have adopted a somewhat more moderate position. They have emphasized the precautionary principle and have stated that no approvals of new GMOs should take place unless companies can demonstrate that GMOs for which approval is sought do not have adverse effects for the environment or human health. Only the United Kingdom, the Netherlands, and the EU Commission have opposed a formal moratorium (Bernauer 2002).

In summary, the European Union has moved from a situation of no regulation of agricultural biotechnology in the mid-1980s to very stringent regulations on the approval of GM-crops and GM-foods, and to increasingly stringent and harmonized labeling requirements. As a result, very few GM-crops and GM-foods have been approved for commercialization, the number of field trials has remained low, and virtually no GM-crops are commercially grown in the EU. Moreover, because of strict labeling laws there are extremely few labeled GM-products on the European market, suggesting that consumer demand for GM-products is almost non-existent (Bernauer 2002).

GMO Policy of the United States - Regulations

US regulatory policy on GMOs has been built on the assumption that biotechnology implies innovation in how food is produced, but does not lead to substantially different properties of food products themselves, compared to what would be obtained with conventional methods. Following this product-orientation, the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) have approved most industry requests for field testing and commercialization of GM-seeds and GM-foods. Over 50 GMOs have been approved for commercialization. GM-crop acreage in the United States has increased dramatically between 1996 and 2001. In 2001, one third of US all corn crops and more than half of all US soybean crops were produced from GM-seeds. Around 60 percent of all food in US grocery stores contained GMOs. The FDA does not require labeling of GM-foods. Proposals by the US Environmental Protection Agency (EPA) to establish GMO-related process regulations for environmental protection purposes have not been adopted (Bernauer 2002).

In summary, US regulatory policy on GMOs has focused almost exclusively on products. It has operated within pre-existing legislation and generally assumes that genetic engineering per se does not pose a particular risk that requires specific regulation of this production method. Approval of new GM-crops and GM-foods by the USDA and the FDA respectively has been relatively swift and uncomplicated. The EPA has, on several occasions, proposed process-oriented regulations for pest-resistant GM-crops, but these proposals have not been adopted. The majority of US consumers appear to favor mandatory labeling of GM-foods. NGOs have taken legal action in pursuit of this cause, and two bills on labeling have been introduced in Congress. So far, the FDA has not given in to this public pressure. It has maintained its permissive approval and no-labeling policy (Bernauer 2002).

4. AGRICULTURAL BIOTECHNOLOGY AND AFRICAN COUNTRIES

While biotechnology has advanced agricultural productivity growth in some of the more developed countries, it has had little actual impact so far in most developing countries, particularly in the farming systems of Africa. While we acknowledge ethical and precautionary concerns regarding the use of some particular techniques of biotechnology, it should be kept in mind that failure to develop and capture this potential could further increase the income gap between developed and developing nations and could be a serious setback in the struggle to reduce poverty, hunger and malnutrition in African.

It is widely recognized that macroeconomic stability, good infrastructure availability, good governance, absence of conflict and security of land tenure systems, and access to markets must be in place to advance economic growth in developing countries. With respect to agriculture however, all these would just create an enabling environment for the sector to grow.

Agriculture, unlike a housing industry or a transport sector, has a biological element which must be activated to increase productivity besides the conducive atmosphere. Unless this is scientifically addressed agricultural growth will lag behind the fast growing rate of human needs. Therefore, investment in agricultural research and innovations should be given full attention to provide solutions to the persistent problem of food insecurity in sub Saharan Africa.

Developing countries have an opportunity to increase agricultural productivity and agriculture's contribution to economic growth by acquiring (importing) agricultural biotechnologies from the North. However, this requires developing and adopting appropriate biosafety and food safety regulations, and intellectual property protection (IPP), each of which is increasingly governed by international law (Oehmke, Maredia and Weatherspoon 2001).

Concerns to biotechnology development

Despite incidence of famine in many parts of Africa genetically modified crops have been on some occasions rejected or reluctantly received. In some instances as was the case in Zambia GM crops were reluctantly accepted as long as corn was milled for flour and was not used as seed. The fears of the states and the general public are not entirely misplaced. It is the sole responsibility of any government to protect the lives of the people and their property. Unfortunately the mixed messages tend to induce the states to take an overly precautionary approach and reject anything related to biotechnology and genetically modified crops.

The dilemma however, emerges in instances when the desire to protect the citizens is not backed with the capacity to verify the available scientific evidence. Logically, it is impossible to take any viable decision without an established policy, food safety regulations and even laboratories and technological know how to analyze the ingredients of imported food. Several countries do not have comprehensive food and nutrition policies. As a result, the formulations of regulations safeguarding the citizens from the risks of suspected GM are not even in place.

Another related issue is the lack of protection of intellectual property rights in Africa that hampers the development of new technologies, profitable inventions and investments, and initiatives by entrepreneurial African biotechnologists. Biosafety regulations and legislation are in place only in a few countries of Africa, and such limitation constitutes a serious constraint that impairs the use, evaluation and release of genetically modified organisms.

A serious deficit of skilled human resources in the fields of biotechnology and intellectual property rights is evident in Africa. Related to this is the serious loss of skilled personnel who have received training in developed countries and have added to the brain drain and attrition. Furthermore, Africa does not have adequate laboratory facilities and equipments for biotechnology operations. Basic infrastructure and facilities even for the simplest tissue culture techniques such as micro-propagation are not available. Modern communication systems, telephones, fax and access to email and internet are also lacking in large areas of Africa which seriously hamper the acquisition of relevant and necessary knowledge, and the application of plant biotechnology which is a rapidly changing and developing field. Again, unreliable power supply in many African countries is a serious constraint for the efficient biotechnology application of even basic tissue culture techniques. In short, the enabling infrastructure is simply not available and requires investments to refurbish existing laboratory facilities, provide new facilities and equipments.

The building up of such knowledge and development of human resource capacity is necessary to produce improved varieties through use of biotechnology as well as to handle imported GM crop varieties that also demand changes in agricultural management.

Many government authorities in sub-Saharan Africa are sandwiched between the dilemma of hunger and the need to have access to global markets for their agricultural produce and

products. This is made worse due to varying perception between Europe and America on the approach towards biotechnology. The EU moratorium on GM crops is having a serious consequence for Africa in terms of loss of collaboration links, loss of research links, lost trade and diminished funding of biotech research.

In light of mixed messages about biotechnology and insufficient capacity plus insufficient infrastructure, decisions are taken without sufficient evidence known to the countries in SSA. In view of threats that African countries might lose market access to the EU if they engage themselves in GM produces, it may seem wise to many countries to totally reject biotech crops. However given that in many cases there is not a single product to export to those markets meeting the needs of starving people at home should be paramount. It is because of this quandary that SSA countries have not yet maximized the potential of the available technology-particularly in respect to biotechnology.

Public Attitudinal change

While capacity strengthening with respect to human and infrastructure remains crucial, there is urgent need of attitudinal change as well. The message about biotechnology has been misdirected, misinterpreted and often borders on scare-mongering by its critics and naïve optimism by its proponents. A communication strategy that brings all stakeholders together is lacking. For example, very often scientists at all levels tend to work in isolation and talk amongst themselves, wondering why the civil society, the policy makers and government leadership do not appreciate these innovations embedded in science and technology that would save thousands of children from malnourishment and millions of people from hunger.

Even with the availability of a regulatory framework that can help developing countries safely deploy genetically modified plants and animals, it is proving difficult to establish the required policies and regulations amidst misconceptions and misleading messages. Very few scientists are members of regulatory bodies especially at the national level as policy makers. Their writing remains too technical and abstract. That being the case, the message is often unintelligible to those who spearhead policies and regulations. In many countries food and nutrition policies are missing. Where they have been formulated no implementation action plan is in place. Biotechnology policies and bio- safety regulations are generally delayed.

All these just indicate that there is a need for a comprehensive communication strategy. Due to the international debate on GM crops, certain civil society and non-governmental organizations (NGOs) in developing countries in the name of protecting the consumers complicate the situation by conveying misleading information to policy makers and government authorities. Any suggestion that genetically modified crops may be approved for commercialization is often met with hostility and demonstrations on the street.

The environmentalists also differ in their view on the benefits genetically modified crops and animals. Failure to collectively work on a common mission, they tend to monitor environment from a protection perspective. This makes the debate even worse. In absence of joint analytical mission on biotechnology issues, the population becomes confused while the policy makers are hesitant to take any steps that may be construed to be supporting receipt of biotech products. This causes paralysis.

According to Kent (2004, p. 65) Forty-eight of the 53 countries in Africa have not yet created official regulations governing the commercial release and distribution of transgenic seeds. None of the large international seed companies that own commercial biotechnology products (Monsanto, Pioneer, Syngenta, Bayer, etc.) is willing to sell these products in countries that do not have a regulatory system in place to confirm their environmental and food safety. This is dictated by good business practice and concerns over liability. Many African countries are currently drafting regulations and legislation, but enactment has been slowed by the

controversial nature of transgenic crops. In Asia and Latin America, the situation is more promising—several countries have enacted biosafety regulations over the past decade, including the large countries of India, Brazil, and China. Other countries are working on it.

Table 2. Some examples of the status of biosafety regulations and biotechnology policies or laws in eastern and southern Africa, 2004

Country	Status of biosafety regulations	Status of biotechnology policy	
		Policy	Law
Angola	None	None	None
Botswana	None	None	None
Ethiopia	None	Draft	None
Kenya	Guidelines developed by National Biosafety Committee	Draft	Draft
Lesotho	Biosafety Committee established 2001	None	Present
Malawi	National Biosafety Committee established	None	Present
Mauritius	GMO bill for National Biosafety Committee	None	None
Mozambique	None	None	None
Namibia	None	Present	None
Seychelles	None	None	None
South Africa	Present—Act 1997	Present	Present
	Legislation enacted	None	None
Swaziland	None	None	None
Tanzania	National Biosafety Committee established	Draft	AMA#20, 2004 + Draft regulations
Uganda	Guidelines or draft regulations written	Draft	None
Zimbabwe	Guidelines established by the Biosafety Board	None	None

Source: Omamo and von Grebmer, 2005

Table 3. Some example of the status of intellectual property rights (IPR) in southern and eastern Africa, 2004

IPR instruments in place or under way		
Country	Patent or industrial property law	Plant breeders' rights
Ethiopia	Available	Not available
Kenya	Available	Available –international Union for the protection of New varieties of plants (UPOV) 78
Lesotho	Available	Not available
Malawi	Available	Not available
Mauritius	Available	Not available
Mozambique	Available	Not available
Namibia	Being developed	Not available
Swaziland	Available	Not available
Tanzania	Available	Not available
Uganda	Available	Not available
Zambia	Available	Not available
Zimbabwe	Available	Available national

Source: Omamo and von Grebmer, 2005

Table 2 and 3 show, deficiencies in biotechnology policies and little application of GM technology and hardly any policies on it in most of southern and eastern Africa countries. Apart from Kenya, Malawi, Uganda, and Zimbabwe, where national draft policies on biosafety exist, South Africa is the only country with advanced biotechnology policy strategies and the only country in Africa today growing GM crops on a commercial scale. Only a few African countries have institutionalized laws for the protection of plant varieties (Table 3) (Omamo and von Grebmer, 2005).

Policy and Regulatory Challenges

There are a number of policy and regulatory challenges that hinder the development and application of biotechnology in many countries of Africa:

- o Lack of clear priorities and investment strategies in research for development.
- o Short-term and low level financing of biotechnology in research for development in many African countries.
- o The role of intellectual property protection and its impact on the acquisition, development and diffusion of biotechnology.
- o Institutions for administering industrial property rights particularly patents are still in their infancy.

Intellectual property rights (IPRs) have been important in all developed countries and in some developing countries in providing incentives to invest in research and development (R&D) in the private sector. They are especially important for the agricultural and agribusiness sectors, which will be one of the earliest sectors to develop many counties. The purpose of intellectual property management is to protect local inventions and enable access to technologies developed elsewhere. Trade-related intellectual property rights (TRIPs) are a matter of ongoing concern within the World Trade Organization. The present patent system favors those countries that have a strong innovation base. Despite much effort, no satisfactory system exists to recompense traditional owners and improvers of germplasm. The lack of intellectual property protection also constrains private-sector investment in developing countries (Persely and Doyle 1999).

While a good number of the countries have established patent offices, the utility of these as sources of scientific and technological information has not been adequately exploited. In many countries of the region intellectual property laws are in a state of flux with increasing demand

from the international community, particularly the World Trade Organization (WTO) to revise them to meet requirements of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

5. Conclusion

5.1 Promoting Multi-stakeholders Dialogues

African government should promote multi-stakeholders dialogues at all levels in the development of national, regional and continental Agricultural biotechnology regulation and policy formulation process. Strategies which bring on board everybody at early stage and collaborative action such as policy makers, environmentalist, NGOs, human right activities, legislators, research institutions and donors can help the safe use of agricultural biotechnology to revamp agriculture and to reduce hunger and children's malnutrition. Groups of African nations working together can save money by pooling expertise to develop regionally appropriate systems. They should encourage full and candid discussions on biotechnology, aimed at determining how best to address problems while building achievements. It is important for the stakeholders to own the regulation and policy formulation processes. This should be one of Africa's government development plan priorities.

The issue of Africa feeding its own growing population and to compete internationally should not be just a matter of international conferences. It should be conspicuously embedded in the local authority and national development policies and annual budgets. In this respect Africa will have to adopt Agricultural biotechnology for production in their development programs as a priority. As generally accepted the biggest risk for Africa would be to do nothing, allowing the biotechnology revolution to pass the continents by like the green revolution. If that happens, Africa will miss the opportunities to grow its economy and reducing the level of food insecurity, hunger, and child malnutrition and see the agricultural productivity gap with industrial countries widen.

5.2 Strengthening the required capacity at all levels

Establishing a regulatory regime for the safe use of biotechnology is generally hindered by the lack of human and infrastructural capacity even at national level. In this context, it is crucial to support institutional capacity building, increase the number of scientists and the accommodation of new knowledge and experience in the regulatory and policy decision making processes. In Africa underinvestment in agricultural research has been singled as a critical problem. In 1995, for example, developing countries had fewer than 100 agricultural researchers per million economically active people in agriculture, compared with 2,500 researchers in the industrial countries. But Sub-Saharan Africa, desperately in need of productivity increases in agriculture, had only 42 agricultural researchers per million people engaged in agriculture. African Countries need to enhance its researchers and human resources capacity in agricultural biotechnology.

5.3 Reengineering an Effective Communication Strategy.

The fact that genetically modified produces are highly stigmatized, Africa needs to adopt a strategy that may minimize mistrust and clear misconceptions. A critical issue in evolving agricultural biotechnology policy and biosafety regulations is lack of reliable information to those who may be responsible to address policy and regulatory issues. In the absence of reliable policy oriented information, the dialogue that help multi-stakeholders to achieve agreements on it and decision making becomes more difficult.

The key information on Agricultural biotechnology for policy makers is crucial to establish the policy and pertinent regulations in any country. Such information on the Agbiotech itself, information on how to increase the public awareness and participation, and improve information sharing among its national, regional and continental partners as may be required.

This calls for an effective comprehensive communication strategy to promptly respond to various queries in simplistic terms and constantly address emerging issues targeting different groups of stakeholders at all levels. This would build greater awareness and understanding of the issues and facilitate accords of making sound regulatory and policy process at national, regional and continental levels.

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INTERNATIONAL REGULATORY COMPARISONS, CONTRASTS AND COLLABORATION

Biosafety Research and Regulatory Policy in East Africa: Emerging Trends and Implications (Charles Mugoya, ASARECA)

Background

Two approaches are currently being used in tandem (1) The "ISNAR" Conceptual Framework For Implementing Biosafety and (2) The UNEP/GEF approach. The "ISNAR" Conceptual Framework for Implementing Biosafety focuses on 4 elements: (1) National Policies and Strategies, (2) Knowledge, Skills and capacity base, (3) Development of regulations and (4) Regulatory implementation

The UNEP/GEF Approach on the other hand has five main areas:

1. Policy on Biosafety/or Biotechnology
2. Regulatory regime
3. System to handle requests
4. Monitoring and inspections
5. Public Information and Public Participation

Policies on Biosafety

- a. Covers both biotechnology and biosafety
- b. Brings on board national interests
- c. Strikes a balance between benefits and risks
- d. Ensures accountability
- e. Ensures transparency
- f. In step with local (ie. nat. dev. plans) and international trends (MDGs, NEPAD)
- g. Emphasizes regional collaboration

Key considerations on the regulatory regime for Biosafety are its objectives, scope and structure. Regulatory objectives are based on the National Policy on Biosafety and Biotechnology & other international obligations such as CBD, CPB, WTO, IPPC, TBT,SPS, Codex Alimentarius, etc. The main elements of regulatory scope are contained use, releases, placing on the market, import, and export. In terms of regulatory structure two key questions arise:

1. Do we use an existing regulatory regime or develop a new regime?
2. Do we set up one competent authority or more?

Main features of emerging regulatory regimes are general provisions, operational provisions and other/final clauses. General provisions normally include objectives, definitions, scope, institutional arrangements and general obligations among others while operational provisions focus on contained use, release into the environment, placing on the market and import/export.

Other Clauses are:

1. Information requirements –Public Information, Confidentiality
2. Enforcement, Compliance
3. Review mechanism
4. Entry into force, Transition period

Key international influences on regulatory policy in Biosafety

1. The Convention on Biological Diversity (CBD)
2. The Cartagena Protocol on Biosafety (CPB)
3. The WTO Agreements
4. The SPS Agreement
5. The TRIPS Agreement
6. The Codex Alimentarius

7. The IPPC
8. The OIE

The Convention on Biological Diversity is the preserve of environment ministries of respective countries. The convention contains provisions for access to genetic resources including international transfer of biotechnology; the conservation of and sustainable use of biodiversity; fair and equitable usage of biodiversity and establishment of regimes for the management and regulation of biotechnology (biosafety).

The Cartagena Protocol on Biosafety is also mainly under ministries of environments and provides countries the opportunity to obtain information before new organisms are imported. The Protocol also acknowledges each countries right to regulate bio-engineered organisms subject to international obligations and creates a framework to help improve the capacity of developing countries to protect biodiversity. This is the main agreement for Biosafety regulatory systems.

The Sanitary and Phytosanitary Measures Agreement (SPS) is a WTO agreement. The agreement is usually under respective ministries of agriculture and covers measures taken by countries to ensure the safety of foods beverages and feedstuffs from additives, toxins or contaminants or for the protection from spread of pests and diseases. It requires that measures regulating imports be based on sufficient scientific evidence and that countries operate regulatory approval procedures. In addition, it brings in inspections & enforcement aspects of Biosafety

The WTO Trade Related Intellectual Property Agreement (TRIPS) is mainly under ministries of trade. This agreement enables private ownership of living matter through the granting of patents. Presently, this form of protection is only mandatory for microorganisms. It also brings in Socio-economic aspects of Biosafety

The Codex Alimentarius is an international standard setting body and joint initiative of the FAO and WHO. It is also mainly under ministries of trade. The body is represented by 167 countries and recognized by the WTO SPS Agreement. Its role is to develop food safety standards so as to protect public health and promote fair trade in food. It deals with food hygiene, processing, storage, labeling, quality and packaging and establishes principles for the risk analysis of foods derived from modern biotechnology and gives guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants and micro-organisms

The IPPC and the OIE are International Standards Setting bodies mainly under ministries of Agriculture. They are recognized by WTO SPS Agreement. The International Plant Protection Convention (IPPC) focuses on preventing the spread and introduction of pests in plants and plant products. The Office of International Epizootics (OIE) performs a similar function for animal health).

Implications for better Regulatory Development in East Africa

1. Multiple Institutions - Need to improve coordination within governments for better policy formulation and implementation.
2. Multiple disciplines/stakeholders and decision making - Need intensify efforts geared at policy harmonization at regional level and forging of partnerships.
3. Institutional and Human Resources Capacity building -Need for capacity building and technical assistance.
4. Awareness - Improve access to information.
5. Focus on the end users - Aim at the small scale farmer.

Comparative Analysis of Biosafety Regulatory Systems (Gregory Jaffe, Center for Science in the Public Interest)

Genetically engineered (GE) plants and animals have the potential to benefit both developed and developing countries. To reap the benefits from those products, they must be found safe to humans and the environment. To ensure those products are safe, it is essential to have a strong, but not stifling, biosafety regulatory system that independently reviews and approves each product for safety before it is released into the environment or ingested by humans.

Some developed countries (such as the United States, Canada, New Zealand, and the European Union) established regulatory systems to address safety issues surrounding genetically engineered organisms a decade or more ago. More recently, some developing countries (such as China, Argentina and South Africa) have put in place biosafety regulatory systems while others have put in place interim measures to address limited applications of the technology (such as Egypt and Kenya). In addition, the Cartagena Biosafety Protocol came into force on September 11, 2003. It sets forth international legal requirements for the transboundary movement of living modified organisms and is probably the single-most important reason countries are establishing biosafety regulatory systems.

As more countries move to establish interim and more permanent biosafety regulatory systems, those countries can learn from the biosafety systems already in place. Based on a comparison of existing biosafety regulatory systems, this paper sets forth the important components of different biosafety regulatory systems. It also identifies how the legal requirements of the Biosafety Protocol intersect with a country's domestic biosafety regulatory system. Finally, the paper provides some thoughts on what countries in East Africa can do while they are putting in place a biosafety regulatory system.

Components of a Biosafety Regulatory System

A good biosafety regulatory system should be understandable, workable, equitable, fair, adaptive, and enforceable. A review of existing biosafety regulatory systems from around the world find that countries achieve those characteristics in very different ways. Those systems reflect, among other things, the type of government in the country, the politics of that country, the country's view on the relative safety of genetically engineered organisms, and the country's regulation of food, agriculture, and the environmental issues. Through an analysis and comparison of different biosafety regulatory systems, however, one can identify key components needed in a good biosafety regulatory system. Those components are set forth below:

1. Adequate Legal Authority

The biosafety regulatory system needs sufficient legal authority to subject each GE product to a thorough food-safety and environmental approval process before the food is marketed and or released into the environment. The system must make government oversight mandatory to ensure safety and put the public at ease about the new products.

To ensure that there is adequate legal authority for the biosafety regulatory system, most countries need to decide whether they can establish their system using existing laws or whether they need to pass new biosafety-specific legislation. There are advantages and disadvantages to both options. The advantages of using existing laws is that the regulatory structure is quicker to implement and using established agencies and practices allows for the efficient use of existing expertise. It also allows for establishing interim measures under other related regulatory systems while new regulations and guidances are being drafted and announced for public comment. A disadvantage of using existing laws is that those laws are usually not biosafety-specific, may not comply with international obligations, and may require convoluted legal reasoning in order to apply to biotechnology products. Also, adapting existing laws to

agricultural biotechnology may involve the use of multiple laws and agencies, resulting in a complex, inefficient, and not easily understandable process. If a country uses existing laws, there is also a concern that some products may be under- or over-regulated (based on their relative risk), while other products may fall through the cracks and avoid regulation altogether. An example of a country that used existing laws for its biosafety regulations is the US, which put together a coordinated framework involving numerous laws and several agencies to regulate engineered products.

Many countries, such as the European Union, South Africa and New Zealand, have established new laws to specifically address agricultural biotechnology products. Those new laws have been tailored specifically to biotechnology, and address special issues specific to regulating that technology. One disadvantage of establishing new laws is that it takes a long time to enact laws and that moratoriums preventing the release of GE products may be required until the law has been passed and regulations are put in place. In addition, it is not particularly efficient to establish a new law for each new technology that comes along. If a country does decide that a new law is needed, it is important to establish interim policies and procedures to address biosafety while the law is being passed by the legislature and its regulatory system is being established. Tanzania, Kenya, and Uganda have all established such interim biosafety procedures and they have allowed for the technology to move forward in a safe manner while a more permanent system is authorized.

2. Comprehensive

A good biosafety regulatory system needs to be comprehensive. It should cover all the different stages of development for a GE product. It should address GE organisms used in a laboratory or other contained facilities, releases into the environment as confined and unconfined field trials, the transport or movement of GE organisms within the country, the release of products into commerce, and consumption of GE organisms by humans and/or animals. Second, the regulatory system should address all the potential safety issues associated with each particular stage of development. The regulatory system should not only address the environmental and biodiversity issues highlighted in the Protocol but also food-safety issues and any other potential safety questions. Finally, the regulatory system's scope should include all potential organisms that could be engineered and the different products that they might produce. The regulatory system should address not just engineered plants used for food or feed but plants engineered to produce non-food substances, non-food crops such as trees, and engineered animals.

3. A Clear Safety Standard

A biosafety regulatory system should establish safety standards for its approval processes. Those safety standards need to set forth what level of safety must be satisfied to approve an application and what factors the government will consider before making a decision. A safety standard sets forth both what baseline should be used to analyze the safety of the new product and determines the level of protection that is desired. For the biosafety regulatory system to be transparent and predictable, all interested parties must know and understand that standard and any government decisions must apply that standard in a uniform and fair manner.

Different types of regulatory decisions can have different safety standards depending on what types of risks those systems may be addressing. In many countries, the safety standard for determining if a product is safe for human consumption is a fairly onerous standard that only looks at risks and does not factor potential benefits into the determination. For example, EU Regulation 258/97 states that the food safety standard for GM foods is that they must not "present a danger to the consumer." Similarly, in the US, when the Food and Drug Administration approves a food additive, it must determine that the substance presents "a reasonable certainty of no harm." Although some biotech foods may be found to be a food additive, to date, biotech crops have been reviewed under a different standard that ensures that the crops are "substantially equivalent" to their conventional counterparts. That safety

standard acknowledges that crops may have some inherent food-safety risks and one should ensure that the biotech variety does not either add new risks or increase the existing risks.

For some regulatory systems, a safety standard can often require a balancing of the benefits and risks of a product. Many environmental safety standards do in fact balance both risks and benefits since products or technologies (both new and existing) have positive and negative effects on the environment. In the US, FIFRA states that a pesticide (which includes plants engineered to produce a pesticide) should not cause "unreasonable adverse effects on the environment." That standard has been interpreted to require a review of both benefits and risks during the risk assessment process. Similarly, the HSNO Act in New Zealand states that an application can be denied where the adverse effects outweigh positive effects.

4. Proportionate Risk-Based Reviews

A good regulatory system looks at each application individually and assesses its potential risks to human health and the environment through a scientific risk-based analysis. The system should have the flexibility to treat products differently depending on the potential risks and concerns raised. It should prioritize the applications based on the potential risk and give the most scrutiny to products with the most risk while allocating less resources and time to products that raise less concern. All products should still be required to be reviewed and approved and they all must still meet the applicable safety standards. The procedures and the data needed to meet that standard, however, should vary depending on the nature of the product and its potential risks so that the risks match the regulatory procedure.

An example of a proportionate risk-based review system is the approval process at the US Department of Agriculture for the deliberate release of GE crops. In that regulatory system, there are two different paths to the granting of government approval for a release into the environment, a permitting process and a notification process. The notification process is a streamlined approval process for engineered crops whose release poses minimal risk while the permitting process is reserved for engineered crops where the potential risks are significantly greater. The determination as to which procedure is followed for a given crop depends on the particular crop that is being released, the characteristics of the gene introduced into the crop, and the confinement conditions that will be imposed on the field trial. Thus, introducing a herbicide resistant gene into a soybean plant might qualify for the notification process but introducing a gene that produces a pharmaceutical into corn would require going through the permitting process. To date, there have been over 11,000 field trials in the US, with approximately 1,000 of them getting approval through the permitting process and 10,000 through the notification process. The system allows the regulators to tailor the regulatory process to the riskiness of an engineered crop and allocate its limited resources to the crops which pose the most potential risk. Another example of a proportionate system are the processes established under the Biosafety Protocol (see Protocol section below).

The key to establishing a proportionate risk-based review process is to provide flexibility to address particular products differently depending on the nature of the product (the organism and the added gene), and the use of the product (a confined laboratory experiment, a field trial or a commercial release). For example, a confined field trial does not require the same detailed risk assessment and governmental review and approval procedures as a commercial release of that same product; the confined trial is released under specific conditions, limited in duration, and designed to have minimal impact on the environment while the commercial release may not be controlled and will remain permanently in the environment. Thus, it is important for the biosafety regulatory system to allow for proportionate risk-based reviews both to function effectively and to minimize the cost and expense to safe products with minimal risks.

5. Transparent and Understandable

An important component of a biosafety regulatory system is transparency. It is essential that the public has access to information about the regulatory system and the products that go through it because with that information the public will have confidence in the decisions made by the regulatory process.

In order for a biosafety regulatory system to be open, transparent, and understandable, that system must provide to the public:

- details about the regulatory process, including the steps, data requirements, and time lines for the applicant (a roadmap of the process and what is expected of the applicant);
- standards that set forth what data will be made available to the public from the applications;
- a clear discussion of how the agency will conduct its review, what criteria and standards it will use, and who will be the accountable public officials;
- a clear opportunity to participate in the regulatory process before a decision is made, stating where, when and how the public can be involved; and
- a document setting forth how the agency conducted its analysis of a particular application and the reasoning behind its decision.

With that information, all interested persons should be able to understand how the regulatory system will process applications, the information the public will have access to, the opportunities for the public to participate in the process, and the basis on which a decision will be made.

Although transparency is an essential component of a good biosafety regulatory system, achieving transparency involves numerous trade-offs and the balancing of competing interests. For example, making information available to the public can be expensive and time consuming. The government must balance the additional costs to the system from making more information available as well as the time added to the regulatory process from informing the public and collecting their input. Less transparent systems (where less information is available and there is minimal opportunity for public involvement) can reach decisions quicker and at less expense but may not achieve the same public acceptance that might result from a more transparent process. Similarly, the regulatory system must balance the competing interests of the applicant, who may want to keep some information confidential for business purposes, with the public's need and right to know about the products being reviewed. A regulatory system with no protection for trade secrets and proprietary information could be completely open and make all applications submitted completely available. Such a system, however, might not receive any applications because private enterprises would not be able to successfully market a product if certain information is not kept confidential. Finally, the more open, transparent and understandable a regulatory system, the less able that system is to provide flexibility and adaptability to new and different products. A regulatory system with known regulatory pathways sometimes cannot provide a different process for a new or different product without losing its transparency.

6. Participatory

Public participation in the regulatory process is essential for consumer trust in that process. Public participation includes the opportunity to provide information and comments on regulations, guidance documents, and product applications. It also includes the opportunity to provide oral and/or written testimony at public hearings. That system should also respond to any comments in its decision-making documents to assure the public that its concerns were seriously considered.

Unless a biosafety regulatory system is transparent, public participation is difficult. The biosafety regulatory system must provide the public with timely information about any opportunity to

participate in a regulatory decision as well as necessary background information (such as portions of the product application) to make that participation meaningful. Government agencies need to make a special effort to educate interested stakeholders about the issues and then solicit facts, opinions, and expert advice from those stakeholders to ensure that all points of view are heard before the regulatory decision is made. Although it is relatively easy to write regulations and rules that allow for public participation, it is much more difficult to provide the public with the knowledge about the issues and the information about a particular application to make their participation meaningful. Financial constraints, language barriers, and the lack of communication vehicles can sometimes make reaching segments of the population with a stake in the issue difficult.

7. Post Approval Oversight

A good biosafety regulatory system does not stop its oversight once a product has been approved for a deliberate release field trial or as a commercial product. The system continues to ensure human and environmental safety after the product is released into the environment or enters the market. At a minimum, the post approval activities should include post-approval monitoring for adverse environmental or health effects and monitoring and enforcement of the regulatory decisions.

Post approval monitoring is important to understand what effects result, if any, from the approval and release of the engineered product. Where there is some likelihood that a release of an engineered product could have an effect on the environment, humans, animals, or biodiversity, monitoring by the applicant and/or the government should be considered. Such monitoring will require not just experiments and data collection designed to identify whether a particular change has occurred but also information about the baseline before the introduction so that a fair comparison can be made. For example, many countries that have approved the commercial planting of plants engineered with a pesticide have identified monitoring that must be conducted to identify if resistant insects are developing.

The other post-approval activity essential to the biosafety regulatory system is compliance monitoring and enforcement. Lack of assurance that regulatory restrictions are complied with can shatter public confidence in the system. Thus, compliance monitoring and enforcement is needed to uphold the integrity of the system and instill public confidence. To do this, the regulating agency needs adequate authority to carry out enforcement activities, such as conducting inspections, sampling food products, recalling unsafe products, limiting environmental problems that might arise, and taking legal actions against violators of permit conditions. Through a combination of applicant self-monitoring and government oversight through inspections, the system must ensure that permit conditions are complied with and any violations are dealt with in an appropriate manner.

8. Adaptable

Biotechnology is a rapidly changing and one may or may not be able to fully anticipate the range of future applications. Thus, if a country is setting up a biosafety regulatory system to address the potential risks that might arise from biotechnology, that system needs flexibility to adapt to new evidence on risks and benefits, and new types of products.

There are several ways in which a biosafety regulatory system needs to be flexible and adaptable. First, it needs laws, regulations, and guidance that can accommodate not just the products being proposed today but products that might be developed ten or twenty years from now. Definitions of products covered by the regulatory system and the procedures established in that system must be broad enough to allow review of such products in a way that addresses their particular benefits and risks. Non-flexible systems tend to either not have the authority to regulate new products or resort to moratoriums while they put new laws, regulations, and procedures in place to address them. Second, the regulatory system should be able to learn

from its experiences regulating products and adapt accordingly. As the system regulates more products, it should become more familiar with the benefits and risks of particular applications, allowing some applications with low risk to get a streamlined review process while increasing regulatory scrutiny for products that are similar to previous high-risk applications.

Building flexibility and adaptability into a biosafety regulatory system, however, requires balancing those attributes with other important characteristics, such as transparency and understandability. A flexible system usually gives more discretion to the regulatory agency to modify and change regulatory pathways to suit new products. When that happens, there is less certainty about the system for both the users (developers) of the system and the observers (stakeholders and the general public) and the system becomes less transparent and understandable. The ideal system balances both the need for transparency, certainty, and equity (treating similar products in a similar manner using established criteria and standards) with the need to provide regulatory agencies the flexibility to adapt as the technology changes. This can be done by bounding the discretion given to the agency and requiring public pronouncements whenever procedures are changed to accommodate a new product or a new risk issue.

The Biosafety Protocol

The Cartagena Biosafety Protocol is a binding international treaty specifically addressing biosafety. It is extremely important and influential to the establishment of national biosafety regulatory systems in both developed and developing countries. While the Protocol comprehensively addresses a number of biosafety issues, its scope and intent is sometimes misunderstood. In addition, it leaves unresolved several critical issues that must be resolved by individual countries when they establish their biosafety regulatory regime. Those issues are discussed below.

What the Protocol Does and Does Not Do

While the Biosafety Protocol addresses many aspects of biosafety, the treaty addresses only small portions of a country's biosafety regulatory system. First, the Protocol addresses the **transboundary** movement of living modified organisms (LMOs). The Protocol does not cover LMOs that have been developed domestically and that will be used domestically. Second, the Protocol focuses on the **first** introduction of the LMO when it is either released into the environment or imported for food, feed, or processing. Transboundary movement of LMOs that are to be used in contained facilities or that transit through the country are covered by the Protocol but they are exempted from the consent procedures it sets up. Third, the Biosafety Protocol is to be interpreted as being consistent with other international agreements. It is not subordinate to other international obligations nor does it trump those obligations. Also, while the Protocol anticipates that countries will implement its obligations through a domestic biosafety regulatory system, the legal authority for that domestic system is not dictated by the Protocol. A country can use existing laws or pass new laws.

Finally, one strength of the Protocol is that it provides for proportionate treatment to the LMO based on the proposed use of the product. For the deliberate release of LMOs into the environment B an activity that poses, on a relative scale, greater potential risk to biological diversity B the Protocol establishes an informed consent process that requires a detailed risk assessment, risk management measures, and consent by the importing country. For the introduction of an LMO for food, feed, or processing B an activity where the risk of harm to biological diversity or the environment is significantly less B the Protocol does not require advanced informed consent but allows parties to make an import decision based on the safety decision from the exporting country or conduct its own risk assessment. For the contained use of an LMO in a laboratory or greenhouse B an activity with less potential risk than a deliberate release B the Protocol does not require any specific procedures. Thus, depending on how an

LMO will be used, the Protocol puts in place different procedures that correspond to the relative risk of that activity on biological diversity or the environment.

The Biosafety Protocol also provides for differential treatment of LMOs based on their particular risk characteristics. Article 13 sets up a simplified procedure that allows certain LMOs that would normally qualify for the advanced informed agreement (AIA) procedures to have a different streamlined process or be exempted completely from notification and consent because those LMOs can be released in a safe manner. Similarly, Article 7 allows the Parties to meet and collectively exempt certain LMOs from the AIA procedures if those LMOs are not likely to have adverse effects. Therefore, the Protocol acknowledges that different LMOs deserve different treatment based on either the use of the LMO or the particular risk characteristics of the LMO.

Issues Unresolved by the Protocol

1. A Legal Standard for Safety

For the first introduction of an LMO in the environment, the Protocol requires the AIA of the importing country. The Protocol discusses in great detail what information is needed in the notification (Annex I) and what issues the risk assessment should consider (Annex III). Thus, the Protocol sets forth in detail the procedural requirements for approving the transboundary movement of LMOs.

There is no discussion in the Protocol, however, about what level of safety must be satisfied before an LMO is approved or what level of risk is acceptable before a country provides their consent to the LMOs' movement. There is no discussion about what happens after a risk assessment is conducted and some potential risks are identified that cannot be eliminated by a restricted or conditional approval (as will invariably happen since most human activity has some potential risk). Each country must decide what level of safety is sufficient and whether that safety determination should only look at the risks of the product or balance the benefits and risks of a particular application. Thus, while the Protocol puts forth a detailed administrative process to ensure the safety of LMOs, it is silent on the most critical aspect of the decision making process it establishes: the standard for approval. Each individual country must establish its own standard.

2. Role of Socio-economic Considerations in Approval Process

Article 26 of the Protocol states that parties "may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities." That provision, however, raises more questions than it answers, leaving each individual country to decide whether to factor socio-economic considerations into its decision making process, and if so, what to consider and how to do it.

The first question that arises is what socio-economic considerations can or should be considered in the decision making process. A narrow reading of Article 26 would not allow all socio-economic considerations to be considered but only those that arise from the impact of LMOs on biological diversity. A broader reading of the term "socio-economic considerations," however, could include concerns such as "impacts on farmers' incomes and welfare, cultural practices, community well-being, traditional crops and varieties, domestic science and technology, rural employment, trade and competition, the role of transnational corporations, indigenous peoples, food security, ethics and religion, consumer benefits, and ideas about agriculture, technology, and society." (La Vina, p. 3). Thus, the Protocol leaves it up to individual countries to define what they consider socio-economic considerations that will be considered in the regulatory process.

The other issue raised by Article 26 is how to factor socio-economic considerations into the biosafety decision making process. Countries that wish to include an analysis of socio-economic considerations must decide whether that will occur within the risk assessment process provided by Article 15 and Annex III or in a separate process after the risk assessment is completed but before an approval is granted. They also must clearly spell out what socio-economic considerations should be analyzed, what information should be used for the analysis, how that analysis should be performed, and by whom. Annex III of the Protocol, which sets forth the general methodology of the risk assessment process and information needed for that process, does not mention any methods or principles that relate to socio-economic considerations nor does it require any information about potential socio-economic issues. Thus, if a country wishes to include consideration of socio-economic issues, it must start from scratch and provide sufficient detail to make its biosafety system fair, predictable, and transparent.

When looking at different biosafety regulatory systems around the world, different countries have addressed socio-economic considerations in different manners. The United States does not factor non-scientific issues in its approval processes, but leaves those issues to be addressed by government agencies after a product is approved or to the marketplace. In contrast, Argentina requires a market analysis as a third part of its formal approval process (parts one and two involve environmental and food safety risk assessments) and can deny approval of a safe LMO if it will have adverse economic consequences for the country. (Burachik & Traynor, 2002). In South Africa, there is a provision which states that when deciding to approval a release, the Council may consider "socio-economic impacts" of the release on "a community living in the vicinity of such introduction." There is little discussion in the regulations, however, about what socio-economic impacts can be considered and when an impact should affect a release decision.

3. Addressing Food Safety Concerns

The Protocol primarily address environmental issues, with particular emphasis on impacts to biological diversity. For the public, however, the most important issue surrounding LMOs is whether the LMOs or products made from the LMOs are safe to eat. While the Protocol provides detailed legal and scientific procedures and processes to ensure that LMOs do not adversely affect biological diversity, it does not substantively address food-safety concerns.

A strong and protective biosafety regulatory system should address not only environmental issues but also food-safety concerns. Article 4 states that "This protocol shall apply to ... [LMOs] that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health." The placing of the phrase "taking into account risks to human health," however, leads to two possible interpretations: (1) "that human health concerns are addressed only if they result from the potential adverse effects of the same LMO on biological diversity;" (IUCN p. 12) or (2) that they can be addressed independent or separate from effects on biological diversity. It is unclear which interpretation is correct. Other parts of the Protocol do not discuss food-safety or the need for advanced informed consent before a GE food is marketed to consumers for consumption. In fact, the data required in Annex I and II makes no mention of food-safety information.

Whether or not the Protocol=s legal processes and procedures allow for a food-safety evaluation before marketing a GE food product, there is no substantive discussion about food-safety risks and what type of procedures should be set up to evaluate them. Thus, the absence of this issue will require countries to establish their own procedures to address this important issue if they seek to achieve a comprehensive regulatory regime.

4. Public Participation

Public participation in the regulatory process is essential for consumer trust in that process. It is important that the public has the opportunity to participate in the regulatory process and provide information that will inform the decision maker. The Protocol acknowledges the importance of public participation when Article 23 states that, "The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding Living modified organisms"

The Protocol, however, provides little guidance on how to conduct that consultation or how to factor the results of that consultation into the decision-making process. Public participation can take several different forms, including the opportunity to provide information and comments on regulations, guidance, and product applications, as well as the opportunity to provide oral and/or written testimony at public hearings. In some countries, such as the United States, the public is informed by a government publication that a policy or product application is available for review and a specific amount of time is provided to send the decision-maker comments relevant to the issue. A similar process occurs in the EU where all applications are made publicly available and the public has thirty days to comment. These processes work only if the public is provided with both enough information about the application or policy to comprehend the issues and enough time to provide thoughtful and useful information to the agency. Thus, public participation will only work if the system is transparent and information relevant to the government decision is made available before the decision is made.

After the comment period, the decision-making agency is required to review the comments and consider relevant ones in its decision. The Agency, however, must make its decision based on the evidence and facts in the decision record (which includes relevant comments), not on opinions received from the public about what they want to happen.

The Protocol expects that countries will include the public in their biosafety regulatory systems. How that will be accomplished is left to be decided by each country.

Some Thoughts on a Path Forward

Countries cannot and should not establish a biosafety regulatory system overnight. It will take time to establish a good system that balances the many competing issues and attempts to address each of the components discussed above. While that process is going on, here are some thoughts and points to keep in mind.

Interim Measures

Developed countries took years to establish their current biosafety regulatory systems. Those systems have changed over time and will continue to change as: (1) the technology changes; (2) the regulatory system becomes more familiar with the technology; and (3) new information arises about specific benefits and risks of applications of the technology. Some of them started by using existing laws and have since passed new laws specific to biosafety.

As an interim measure, countries should consider using existing laws, at least temporarily, to address the potential issues surrounding GE organisms. That could allow some regulation of GE organisms used in laboratories, confined field trials, and even commercial products. Moratoria should be avoided as they may prevent a country from benefitting from safe applications and will discourage public and private institutions from investing in biotechnology.

Do Not Reinvent the Wheel

As mentioned above, biosafety regulation has been going on in some countries for over a decade. There are many good lessons to learn from those countries about what to do and what not to do. A country close to East Africa with a working biosafety regulatory system is

South Africa. Portions of that system as well as other systems from around the world can be adapted to local laws and regulations. There is no need to start from scratch and reinvent the wheel; instead take some of the good aspects of other systems and adapt them to your country's situation.

In addition to using parts of existing regulatory systems, countries should explore whether portions of the risk assessments that were done for existing products in other countries can be used for the same or similar applications that they face. For example, some safety data may be portable, such as whether an engineered protein is a potential allergen. The data generated from tests in one country may be sufficient for conducting a risk assessment in another country.

Make the System Efficient

It is extremely important that the biosafety regulatory system be as efficient as possible. Possible ways to accomplish an efficient system would include setting up a system where the potential risk matches the regulatory process. In such a proportionate risk-based system, confined field trials would not receive the same treatment as the commercial release of a product. Such a system also might apply different safety standards depending on the issue. There might be one safety standard tailored to food safety risks while environmental issues might require a different standard that balances benefits and risks.

Countries should also consider pooling resources to address issues that are not defined by national boundaries. Environmental assessment might be conducted for a particular geographic region, which might encompass more than one nation.

Finally, countries should set up only regulatory steps that add value to the goals of the system. National Biosafety Committees or Institutional Biosafety Committees (IBC) should be established only if they contribute to one or more of the goals or components of the biosafety regulatory system. Many countries are following models that require the establishment of IBCs but it is unclear whether they add value to the regulatory process, especially for private institutions.

Box 1: EAC's POSITION ON BIOSAFETY REGULATORY SYSTEMS

The EAC recognises the need for an efficient biosafety system to guide the development in this area. In that regard the EAC's Council of Ministers has decided to establish a Technical Committee of Experts to address bio-safety issues and come up with an EAC regional policy on Genetically Modified Organisms. Concerned experts have already been identified and an initial meeting on this issue is scheduled to take place in Arusha from 14 – 15 June 2005.

The Community has also already taken concrete steps on institutional and policy issues as already mentioned including.

1. Conclusion of Common Agriculture and Rural Development Policy and Agriculture and Rural Development Strategy. These key instruments will be considered and cleared by The Attorney General of the three countries in their capacity as a Sectoral Committee on Judicial and Legal Affairs. The formal approval of the two instruments will be made at the next EAC Committee of Ministers Meeting in May 2005.
2. These two documents are the custodian of the overall regional development approach in Agriculture and Food Security.
3. Appropriate laws will be enacted when we start implementing the policy and strategy.

In addition, the EAC has prepared other key documentation and agreed on common or harmonized policies:- including:

- i. Sanitary and Phytosanitary measures (SPS);
- ii. Farm Input standards, measures and procedures: (These will Also be approved together with the other two instruments I mentioned earlier on).
- iii. Regional Seed Policy Harmonization as presented by Dr. Isaac Minde in this workshop
- iv. A project on Control of Trans-boundary Animal Diseases has been prepared and is in the process of implementation.

Preparation of Protocol in Environment and Natural Resources Management. The final document is ready and is now under scrutiny by the relevant technical evaluation before submission to policy organs for consideration and adoption. The Protocol contains provisions related to biotechnology issues that will guide investments, trade and operations in biosafety frameworks. The establishment/creation of an East African Science and Technology Council. The protocol will come into effect soon.

Conclusion

In setting up the Technical Committee of Experts at Regional level, consideration will be made in the composition which will focus on mainly key areas including Agriculture and Food Security, Health, Science and Technology and possibly private institutions.

NATIONAL APPROACHES AND INTERNATIONAL AGREEMENTS

Biosafety Regulatory System in Kenya (H. Macharia, Kenya National Council for Science and Technology)

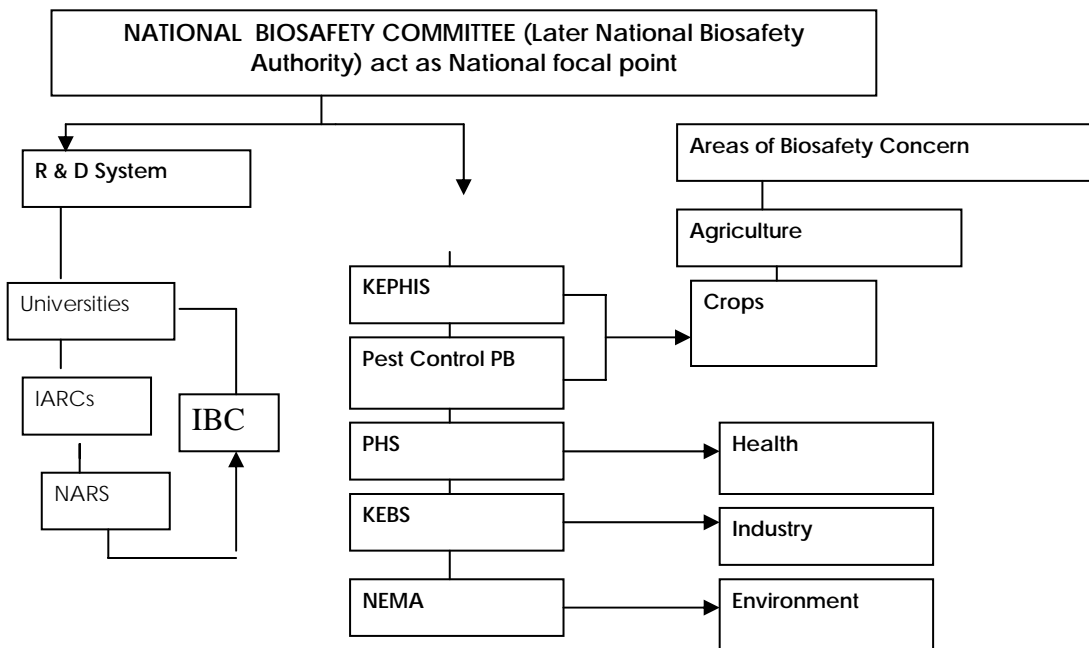
1. The Millennium Development Goals
2. These international agreements (Cartagena protocol on Biosafety, CBD, IPPC, WTO agreements, Codex Alimentarius).
3. National development strategies taken on board.

NBC through NCST:

- Advises government on all issues dealing with Biosafety issues on biotechnology through S&T Act.
- NCST is the Secretariat of the National Biosafety Committee.
- Coordinated drafting of biotechnology policy and Biosafety bill
- Has overseen development and implementation of National Biosafety framework.
- Coordinates on all biotechnology activities in Kenya

NBC Membership: comprises agricultural Research Institutes, 5 relevant Ministries, NGOs, Office of the President, 5 Regulatory agencies, Attorney –General, 3 National Universities, IBCs representative, NCST, Consumer Information Network and National union of Farmers

Framework for Effective Institutional Linkages



Implementation of Biosafety Regulations

1. Kenya has already approved five trials on confined facilities (Bt. Cotton, Bt. Maize, recombinant rinderpest vaccine, transgenic cassava, transgenic potatoes)
2. The trials are discussed by IBC before being presented to the NBC.
3. The NBC discusses the dossiers and give an approval and requests the regulatory agency to issue a permit.
4. Decision Point: Transparent because some members of NBC represent the Public.

Achievements

1. The NBC always works together with relevant stakeholders to develop strategies for increasing the competence and confidence of biosafety reviewers.
2. The Kenya policy for biotechnology and biosafety is compatible with other policy objectives related to food, agriculture, the environment, and sustainable development.
3. The NBC has been encouraging the following:
 - i. Regional and sub regional approaches to biosafety.
 - ii. Dissemination of information.
 - iii. Networking of Biosafety activities.
 - iv. Coordination of training on Biosafety issues.
4. If the system is to be seen as a legitimate part of the government's remit, the NBC Secretariat has been institutionalized as a permanent office.

PBS has provided support towards;

- Establishing a National Biosafety Committee Secretariat.
- Harmonization of Biosafety roles in Kenya
- Food and feed safety training
- Policy round table meeting
- Enhance legal expertise
- Publication information and participation

UNEP GEF provided support towards:

- Development of the biotechnology policy.
- Development of the biosafety bill.
- Handling requests issues.
- Follow up issues such as monitoring, inspections and awareness trainings.
- Public awareness and information

National Biosafety Framework Regulatory Regime on Genetically Modified Organisms (S. Mwinjaka & D. N. Kisyombe, Vice President's Office, Tanzania)

1. BACKGROUND AND CONTEXT OF NATIONAL BIOSAFETY FRAMEWORK (NBF)

Modern biotechnology is an emerging novel tool with potentials in improving human and animal health, agriculture, industrial and agricultural production as well as environmental protection. However, the development and applications of modern biotechnology have been associated with both opportunities and concerns over the risks of GMOs to human and animal health, biodiversity and the environment. Concerns raised against modern biotechnology may be grouped into environmental; human health; biodiversity; and socio-economic and ethical concerns.

These and other concerns have raised the necessity of putting in place National Biosafety Frameworks. The necessity emerged as one of the priorities following adoption of the Cartagena Protocol on Biosafety in 2000. Tanzania acceded to this Protocol on 16 March 2003.

The National Biosafety Framework is an output of the "National Biosafety Framework Project", an 18-month project which commenced in September 2002. This project was funded by the UNEP-GEF and implemented by the Vice President's Office.

Objectives

The NBF has the following objectives:

- Establish science-based, holistic and integrated, efficient, transparent and participatory administrative and decision making system so that Tanzania can benefit from modern biotechnology while avoiding or minimizing the inherent environmental, health and socio-economic risks; and
- Ensure that the research, development, handling, transboundary movement, transit, use, release and management of GMOs are undertaken in a manner that prevents or reduces risks to human and animal health, biological diversity and the environment.

Scope

NBF applies to the research, development, handling, transit, contained use, transboundary movement, release or placing on the market of any GMO whether intended for release into the environment, for use as food, feed or processing, or a product of a GMO / product thereof that may have adverse environmental, human and animal health and socio-economic as well as ethical and cultural effects on the inhabitants of Tanzania.

Key Elements

A National Biosafety Framework is a policy, legal, technical and administrative instruments set in place to address safety for the environment and shall include the safety of humans and animals in the field of modern biotechnology. The National Biosafety Framework (NBF) consists of the following key elements:

- a) National policies related to biosafety;
- b) Regulatory regime;
- c) Administrative and decision mechanisms;
- d) Monitoring mechanisms; and
- e) Mechanisms for public awareness, Education and participation.

The NBF serves as a basic guide to the implementation of the biosafety system in Tanzania. The NBF shall apply in tandem with two important documents, the National Biosafety Guidelines and the Biosafety Regulations.

2.0 BIOSAFETY REGULATORY REGIME

2.1 Environmental Management Act, 2004

The President of the United of republic of Tanzania signed the Environmental Management Act, 2004 in February 2005. Environmental Management Act, 2004 provides for the legal and institutional framework for sustainable management of the environment. The Environmental Management Act, 2004 provides for the regulation of development, handling and use of GMOs and products thereof. It proposes to empower the Minister responsible for Environment in consultation with sector Ministries to make regulations, issue guidelines and prescribe measures for the regulation of the development, handling, and use as well as the importation and exportation of GMOs and their products. The regulations and guidelines will among other things specify the following:

- Measures to protect environment and human and animal health including socio-economic, cultural and ethical concern;
- Measures necessary to regulate the handling, transport, packaging and identification of GMOs and products thereof;
- Measure to regulate, manage and control risks associated with import or export of GMOs and products thereof; and
- Measures to promote and facilitate public awareness, education and participation concerning the research, development, handling, transit, contained use, transboundary movement, release or placing on the market of any GMO whether intended for release into the environment, for use as food, feed or processing, or a product of a GMO / product thereof.

It is on the basis of the Environmental Management Act 2004, the proposed draft *Environmental Management (Biosafety) Regulations* will be established and made operational by the Minister responsible for Environmental.

2.2 The Draft Environmental Management (Biosafety) Regulations

The draft Biosafety Regulations provide for tools to facilitate decision making in terms of risk assessment and risk management. It also provides for liability and redress and places strict liability on the one who carries out activity in relation to GMOs.

The draft *Environmental Management (Biosafety) Regulations* are arranged in ten parts as follows:

- a) Part one deals with interpretation of various terms used in the regulations. Biosafety being a new area necessitates definition of some of the terms.
- b) Part two dwells on general principles which give a general direction in implementation. Such principles include precautionary principle, the principle of prevention and strict liability.
- c) Part three on institutional arrangement provides for the establishment of the National Biosafety Focal Point. It also proposes the establishment of the NBC and IBC.
- d) Part four is on approval of an activity. This part prohibits any dealings in GMOs and their products without the prior written approval of the NBFP. It provides for an elaborate procedure of notification and approval, which includes public participation and a duty to disclose certain information to the public.
- e) Part five is on risk assessment and decision making. It is this part which elaborates on the powers of the national focal point in decision making.
- f) Part six deals with risk management and this includes measures that may be imposed by the NBFP that are necessary to prevent effects of GMOs or their products on human and animal health, biological diversity or the environment.
- g) Part seven covers aspects of liability and redress. This part puts in operation the principle of strict liability. Strict liability is imposed on the person carrying

- out activity in relation to GMOs or their products when they directly or indirectly cause harm, injury or loss.
- h) Part eight is on offences and penalties. It lists a number of things if committed or omitted constitute offences under the regulations. It also provides for sanctions.
 - i) Part nine is on schedules. The schedules and any regulations made under or pursuant to this legislation is proposed to be an integral part of this legislation.
 - j) Part ten is on entry into force. The proposed regulations shall enter into force on the date of its publication in the official gazette.

2.3 Biosafety Guidelines

2.3.1 Risk Assessment and Management

Before any release is carried out, an evaluation of the impacts and risks posed to human and animal health and the environment by the release should be undertaken. Tanzania shall base its decision on a risk assessment carried out in a scientifically sound manner taking into account socio-economic as well as ethical and cultural considerations.

- a) The applicant shall carry out or cause to be carried out an assessment of any risks associated with GMOs or products thereof in respect of GMOs in question;
- b) No decision on any applicant to import, transit, make contained use of, release or place on the market a GMO or a product thereof may be made by NBFP without the assessment of risks to human and animal health, biological diversity and the environment, including the socio-economic conditions and cultural norms;
- c) The risk assessment of a GMO or a product thereof shall be carried out by the applicant or the Competent Authority as appropriate on a case by case basis and shall be done in accordance with risk assessment procedures as provided in the National Biosafety Guidelines for Tanzania Section 3.0 and Annex VI;
- d) The NBFP may require the applicant to bear all the costs for evaluating the risk assessment report or carrying out the risk assessment as the case may be;
- e) No person shall be involved in the evaluation of risk assessment in respect of a subject matter in which she/he has any direct or indirect interest of any kind, or if, for any reason, there is , or there is likely to be, a conflict of interest as a result of her/his participation in the evaluation process. A person with a conflict of interest shall declare the fact and withdraw from the evaluation process;
- f) If an independent risk assessment can not be undertaken, or if there is no possibility of verifying the independence of the risk assessment, the NBFP may reject the application; and
- g) The Competent Authority shall develop, maintain and use, as the need arises, a risk management strategy for protecting human and animal health, biological diversity and the environment, from the accidents of genetic engineering, the use of GMOs and their products. The risk management should be undertaken in accordance with risk management procedures provided in the National Biosafety Guidelines in Section 4.0 and Annex VII;

2.3.2 Inspection and Enforcement

In accordance to section of the draft Environmental Management Act, 2004 and Biosafety Regulations, the Inspectorate of Competent Authorities shall perform inspection and supervision. Authorized party shall pay inspection fees that will be established by the competent authorities. Inspectors have the authority to inspect sites containing GMOs like field trial sites etc for compliance with terms and conditions of authorization. Inspectors also have the authority to inspect contained facilities that may be used for research or storage of GMOs. The proposed system has flexibility to appoint different competent inspectorates on the case-by-case basis.

3.0 ADMINISTRATIVE AND DECISION MAKING MECHANISMS

3.1 Institutional Structure and Administrative Mechanisms

The draft Biosafety Regulations proposes the following four institutions for the regulation of GMOs:

- National Biosafety Focal Point (NBFP)
- Competent Authorities
Ministries responsible for Environment; Agriculture; Livestock; Health; Wildlife; Fisheries; Forestry, Transport and Communication, Industry and Trade, Science and Technology;
- National Biosafety Committee (NBC); and
- Institutional Biosafety Committees (IBCs).

The NBFP, Competent Authorities and other concerned agencies should address issues regarding the use of modern biotechnology particularly on biosafety issues, such as health, environmental and socio-cultural and ethical impacts. These Authorities and agencies should make consultations, formulate departmental directives and regulations on the access and use of the products of modern biotechnology, coordinate activities and programs on research and development and their applications, and allocate appropriate resources for the upgrading of capacities and capabilities to effectively regulate the GM technology and its products.

The Biosafety institutional structure is summarized in Figure 1 (see annex I). On the onset, it is important to note that the proposed structure recognize mandates of Competent Authorities in their respective disciplines.

3.1.1 *National Biosafety Focal Point (NBFP)*

The NBFP should be the Ministry responsible for environment. The roles and responsibilities among others are including:

- ❑ To review and approve biosafety applications for research, confined release, pre-commercial release or placing on the market; including to receive and forward applications to the Competent Authorities;
- ❑ To establish contacts and linkages with national, regional and international agencies/institutions;
- ❑ To establish a database for the purpose of facilitating collection, storage, retrieval and dissemination of information relevant to biosafety;
- ❑ To decide whether to accept or reject an application based on the advice by the Competent Authority and NBC; and to notify the Applicant about the results of the review;
- ❑ To declare through the Biosafety Clearing-House that a GMO or product thereof intended as food or feed or for processing (FFP) may be subjected to a full risk assessment;
- ❑ To maintain and make available to the public on request, a database on GMO or product thereof intended for direct use as food or feed, or for processing;
- ❑ To designate inspectors and undertake inspection as well as other control measures to ensure compliance with the Biosafety Regulations; and
- ❑ To establish a list of GMOs and products thereof to be regulated in Tanzania. The list will be reviewed periodically.

The NBFP should designate the National Biosafety Scientific Advisory Sub-Committee comprising of multidisciplinary team of experts in the field of biotechnology and biosafety. The National Biosafety Scientific Advisory Sub-Committee should be answerable to the NBC. It shall advise the NBC on scientific biosafety concerns. Such functions should include the review and ascertaining of the suitability of both physical and biological containment, confinement and control procedures appropriate at the level of assessed risk involved in relevant research, development and application activities.

3.1.2 National Biosafety Committee (NBC)

A NBC should comprise of representatives from governmental and non-governmental organizations and the private sector that are relevant to the issues of biotechnology and biosafety.

The NBC should have the following functions:

- ❑ Review relevant applications;
- ❑ Advise on policies, legislation and other policy instruments;
- ❑ Undertake study and evaluation of biotechnology research and control and minimize the concomitant risks and hazards associated with the deliberate release of GMOs in the environment; and to advise the NBFP and Competent Authorities;
- ❑ To ensure that adequate testing of GMOs developed elsewhere has been performed in the country of origin before it is introduced in a local trial programme;
- ❑ To review biosafety regulations and guidelines from time to time as necessary
- ❑ To facilitate the undertaking of socio-economic impact assessment and to initiate scientific and technical review of biosafety applications.

3.1.3 Relevant Ministries/ Competent Authorities

The NBFP shall designate Competent Authorities, which will be responsible for following up; supervising and controlling the implementation of the bio safety regulations i.e. perform the following roles and responsibilities;

- ❑ To review relevant applications or proposals for development, introduction, import, export, transit, contained use, release or placing on the market;
- ❑ To review, make or have made risk assessments of GMOs or products thereof. When the GMO or products thereof is to be imported, the cost will be borne by the exporter;
- ❑ To advise the NBFP;
- ❑ Designate inspectors and undertake inspection as well as other control measures to ensure compliance with the Biosafety Regulations; and
- ❑ To undertake assessment of socio-economic impacts as well as ethical and cultural impacts.

3.1.4 Institutional Biosafety Committee (IBC)

Institutions that are involved in the import, export, handling, contained use, release or placing on the market of GMOs or products of GMOs should establish IBCs to institute and control safety mechanism and approval procedures at the institutional level. These committees should have multidisciplinary teams whose roles and responsibilities shall include:

- ❑ To review the containment and confinement levels required by the Guidelines for the proposed research;
- ❑ To hold discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the purpose/objectives of the proposed GMO and other services;
- ❑ *To report immediately to the relevant Ministries/Competent Authorities and appropriate official in the concerned organization, any significant GMO activities, problems with or violations of the regulations and any significant research related accidents and illness;*

4.0 GENETICALLY MODIFIED (ENGINEERED) CROPS

Currently, there is no GMO products or GMO crops grown in the country either for research or commercial purposes. However, it was indicated that TPRI in collaboration with ICIPE are planning to introduce *Bt*-cotton in the Southern Regions of Tanzania for research purposes. Other institutions such as MARI, ADRI, SUA are also ready to undertake research on GMOs if they are required to collaborate with any other institutions at regional or international level. However, it is very important to all applicants who wish to import or export GMOs for research or commercial

purposes to follow procedures as stated in the Environmental Management Act 2004 that operationalise Biosafety Guidelines, Biosafety Regulations and Biosafety Framework.

4.1 Import of GMOs

4.1.1 Application Procedure

Any person who wishes to carry out an import, or transit, or deliberate release, or contained use of, or placing on the market, a GMO or product thereof or intended for direct use as food or feed, or for processing shall submit an application in writing to NBFP. The Applicant must have a collaborating partner. Recognized institution by NBFP and Competent Authorities. The application form must be completed and submitted by regular mail or courier delivery to the NBFP through the following address:

Permanent Secretary
 Vice President's Office
 P.O. Box 5380
 Dar es Salaam, TANZANIA
 E-mail: info@vpdoe.go.tz; biosafetytz@vpdoe.go.tz
 Fax: +255 22 2125297
 Tel: +255 22 2113983/2118416;

- a) No person shall import, transit, carry out the contained use of, or release of, or place on the market, a GMO or a product thereof without an advance informed agreement (AIA) or the explicit written approval of the NBFP;
- b) The application shall include:
 - i) The information specified in Annex III of the National Biosafety Guidelines for Tanzania and any other information as may be prescribed by Competent Authority ;
 - ii) Assessment report on risks that may be posed by the GMO or product thereof on human and animal health, biological diversity and the environment, including the consequences of unintentional release;
 - iii) Information from previous or current release of the GMO or product thereof in the country or in any other country;
 - iv) Information on previous approvals or rejections of the GMO or product thereof by any other country;
 - v) If the request for approval is for the purposes of research and development, the recommendations of the IBC;
 - vi) A clear and sequential description of the steps to be taken in the implementation of the project, and the monitoring and evaluation that will be made at the end of each step, and the method of disposing of any waste;
 - vii) The place where and the purpose for which the GMO or product thereof is planned to be developed, used, kept, released or marketed, including detailed instructions for use and a proposed labeling and packaging scheme;
 - viii) The applicant shall submit a declaration confirming that the information provided is correct including, where appropriate, an undertaking from the originator of such information affirming its accuracy and completeness
- c) Application should respond to all items listed in the course of action for transboundary movement of GMOs. Application(s) should be submitted four (4) months before importation.
- d) If portions of the application contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked "Commercial-in-Confidence" or "CIC Copy" by the notifier.

4.2: Inspection and Enforcement

In accordance to section of the Environmental Management Act, 2004 and draft Biosafety Regulations, inspection and supervision shall be performed by the Inspectorate of Competent Authorities. Authorised party shall pay inspection fees that will be established by the competent authorities. Inspectors have the authority to inspect sites containing GMOs like field trial sites etc for compliance with terms and conditions of authorization. Inspectors also have the authority to inspect contained facilities that may be used for research or storage of GMOs. Competences for the inspection supervision will be specified in permits or approvals.

The proposed system has flexibility to appoint different competent inspectorates on the case by case basis. On the other hand, the competent bodies already have other mandates; therefore, separation of the competences will have to be formalized for GMO regulation.

If an inspector during the performance of work or on the basis of a notification establishes that because of unfulfilled required conditions and requirements, the environment, human and animal health or socio-economic and ethical issues are at risk shall order the following measures:

- (a) prohibit contained use, deliberate release of a GMO into the environment or placing a product on the market,
- (b) order the temporary suspension of contained use, the deliberate release of GMOs into the environment or placing a product on the market,
- (c) order the rectifying of established irregularities within a time limit that the inspector specifies, and
- (d) Order remediation and other measures for rectifying or reducing the consequences of adverse effect that have occurred because of GMO management.

In order for the inspectors to discharge their duties effectively, it is necessary to:-

- a) Carry out a capacity needs assessment;
- b) Develop and implement capacity building programme including training, infrastructure, equipment and tools.

5.0 MONITORING MECHANISMS

The purpose of monitoring and evaluation is to gather data concerning the GMOs in order to assess the extent, to which transgenic have impacted on the biological diversity, environment and human and animal health. When referring to the environment, the main focus is on confined field trials and commercial release of GMOs. Thus, monitoring would determine effects, which could be categorized as severe, moderate, low, negligible or no harm. In the case of plants, monitoring should be undertaken to determine the level of horizontal gene transfer and to develop a monitoring and evaluation prospectus. Monitoring of the GMOs should be undertaken at different levels. The objective of monitoring plan is to:

- a) confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and
- b) identify the occurrence of adverse effects of the GMO or its use on human and animal health or the environment which were not anticipated in the environmental risk assessment.

5.1 Types of Monitoring

For the purpose of this NBF, monitoring is used to gather additional scientific data to assist the assessment of risk and decision-making. Monitoring is carried out for specific reasons and at specific times in the development of GMOs. The various types of monitoring that may be used by monitoring agencies are:

1. Case-specific monitoring

2. General surveillance monitoring; see earlier comment
3. Voluntary monitoring
4. Monitoring by applicants
5. Experimentation
6. Tracking
7. Surveillance

The competent Authorities should implement monitoring of post emergence following post emergency time periods established. Post release/harvesting monitoring is necessary where the risk assessment determines that the continuous presence of the released GMO presents risk of harm. Post-release monitoring will need to concentrate on confirming the removal of the released GMOs. Where appropriate, monitoring should concentrate on detecting and controlling any volunteer GMOs arising from the release. In some cases there may be uncertainty regarding the risk of harm from continued presence of an organism, especially over the long term. Post-release monitoring should then be designed to provide data to enable the uncertainty to be resolved. In case of plants, factors to be taken into account include:

- i) Seasonal effects, such as flowering and likely germination times;
- ii) Post-trial treatment of the release site; and
- iii) Longevity of seed or tubers in soil.

5.2 Reporting Requirements

The authorized party should comply to the reporting format set in the terms and conditions of authorization. However, for every GMO, there is a need to determine when to undertake monitoring and when to evaluate the work. The same process would explicitly identify who would undertake the monitoring and evaluation, and who would receive the reports.

6.0 MECHANISMS FOR PUBLIC AWARENESS, EDUCATION AND PARTICIPATION

Tanzania has experienced lively public debates on a wide range of issues related to science and technology but not on GMOs. However, the debates on GMOs coincided with growing public awareness on societal issues such as environment and sustainable development. This reflects the fact that involvement of the general public is crucial in the formulation and implementation of national policies.

The level of public awareness on biotechnology and biosafety in the country is extremely low, even amongst the scientific community. Possible explanations for low awareness include:

- a) *Recent nature of GMO technology;*
- b) *Limited knowledge on GMO technology at all levels;*
- c) *Limited access to relevant publications, the internet and other information sources; and*
- d) *Low level of awareness by the general public on benefits and risks associated with GMOs.*

6.1 Why Public Awareness, Education and Participation

As biotechnology develops rapidly, more and more GMOs and their products will be released into the environment and may thus pose potential risks to the environment and human and animal health. A proper mechanism should be established to create awareness and enable the public to participate in implementation of the biosafety measures. Awareness and participation are important:

- a) For consensus-building on issues that affect people directly or indirectly;
- b) To build a sense of ownership and collective responsibility;
- c) To promote sustainable development;
- d) To promote smooth implementation of the decisions;
- e) To build transparency and accountability;
- f) To provide balanced information in terms of pros and cons; and

- g) To harmonize institutions that provides awareness activities.

The Competent Authorities and other agencies, in making biosafety decisions, should promote and facilitate public awareness, education, and participation concerning the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs. They should incorporate into their respective administrative issuances and processes best practices and mechanisms on public awareness and participation.

6.2 Right of access to information

The right of the public and the relevant stakeholders to information about applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs shall be respected. Concerned government departments and agencies should, subject to reasonable limitations, protect confidential information as provided in the Proposed Regulations, and should disclose all information on such applications in a prompt and timely manner.

Confidential Business Information (CBI): All ministries agencies and institutions handling GMO applications shall ensure that they have procedures to protect confidential business information. In no case shall the following information be considered confidential:

- The name and address of the applicant.
- A general description of the GMOs.
- A summary of the scientific risk assessment conducted by the applicant.
- Where applicable, any methods and plans for emergency response; and

For information claimed as CBI, applicant must provide written justification.

Information on Biosafety Decisions: The public and relevant stakeholders should have access to all biosafety decisions approving or denying applications for the research, development, handling, transboundary movement, transport, use, transfer, release and management of GMOs. Such decisions need to summarize the application; the results of the scientific risk assessment and the evaluation of socio-economic risks; the public participation process followed; and the basis for approval or denial of the application.

6.3 Enabling environment

Enabling environment for public awareness, education and participation is a requirement to ensure smooth implementation of National Biosafety Framework. There is a need for:-

- a) Capacity building;
- b) Establishment and implementation of appropriate programmes and policy guidelines on participatory approaches;
- c) Networking among stakeholders;
- d) Regional/sub-regional and global cooperation; and
- e) Effective participation at all levels, public, government and private.

7.0 CHALLENGES AND WAY FORWARD

Arguably, in order to conduct work of a highly technical nature, such as modern biotechnology, in a manner that is safe and which contribute to sustainable economic development; caution has to be exercised not to perpetuate economic dependency without the necessary local capacity to deal with it.

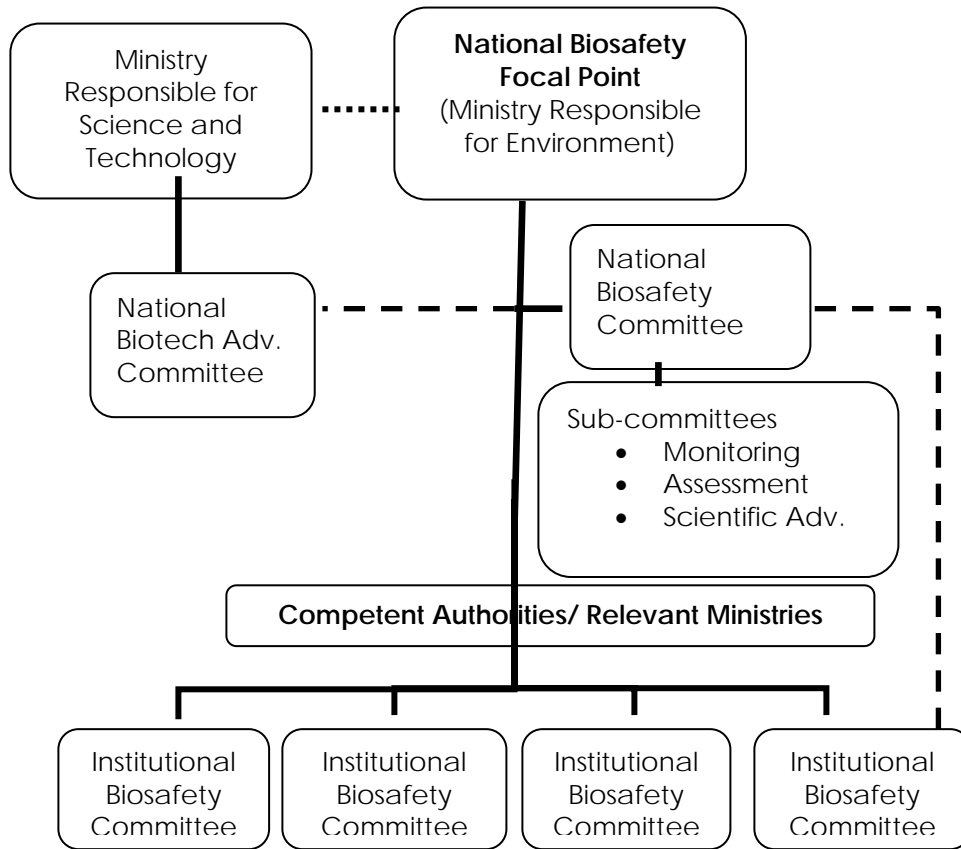
In that respect, perhaps the key question is, **are we ready?** Certainly, this survey has confirmed the findings from previous studies that like many developing countries, Tanzania is still under equipped in terms of technical capacity to conduct biotechnology and biosafety R&D while safeguarding biodiversity, human health and the environment taking into account socio-economic, cultural and ethical concerns. Currently, the available resources and capacity are severely limited and donor-dependent.

The issue of market for GMO is very crucial in connection to traditional export. Currently, most of the exported crops are non-genetically modified crops and marketed in the EU and in other countries. Potential market of GMOs is a key prerequisite for Tanzania before commercialization.

Certainly, modern biotechnology brings new challenges for policy and regulatory framework for the years ahead. Close cooperation on biotechnology, biosafety issues and trade at national, regional and international levels is very crucial and should be promoted.

Annex 1

BIOSAFETY INSTITUTIONAL STRUCTURE

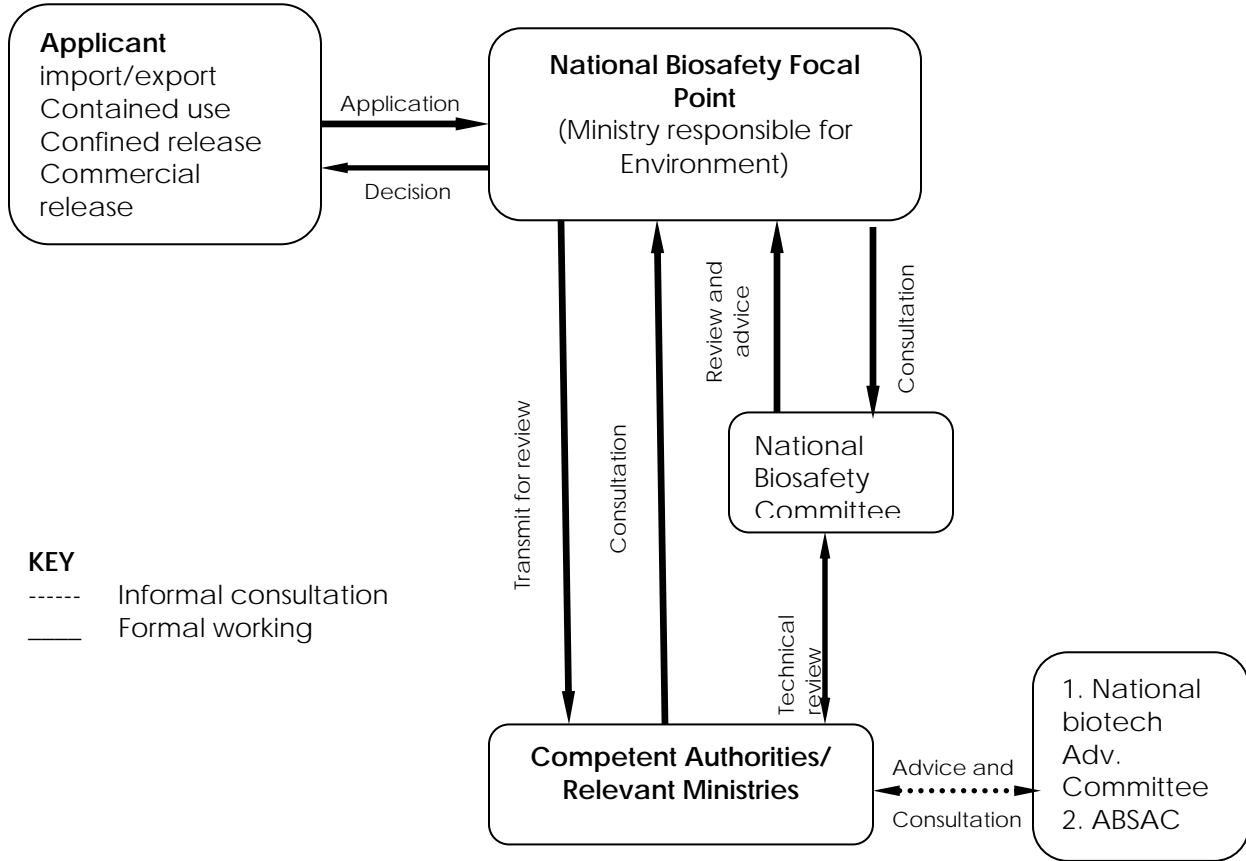


KEY

- - - - - Informal consultation
- _____ Formal working relationship

Annex II

DECISION MAKING STRUCTURE



Biosafety Regulatory system in Uganda (P. Nampala, C. Mugoya & T. Sengooba)

Why develop regulatory systems:

1. Science is a creative enterprise
2. Combines the exploration of the natural world with the generation of knowledge and its use of human endeavors
3. This combination of creativity with purpose is exemplified in the field of biotechnology
4. But the power of the new discoveries in genetics raises concerns in many societies with regard to the ethics and safety of their use, and the risks they may pose to human health, biodiversity and the environment
5. Thus the need to protect the human health and the environment from possible adverse effects of the products of modern biotechnology (BIOSAFETY)

CBD Requirement

The Convention on Biological Diversity agreed in 1992 required parties to establish national frameworks to ensure safe use of biotechnology (See : Article 8(g); Uganda Biosafety Framework). UNCST with support from UNEP GEF undertook a country study with purpose of develop a national biosafety framework for Uganda.

Implementation of NBF

1. Uganda signed and ratified CP (24 May 2000)
2. Obligation to comply with CP provisions
3. September 2002 – December 2005

Activities: Implementation of NBF

1. Components of a NBF
 - a. A Government policy on biosafety
 - b. A regulatory regime
 - c. A system to handle requests for authorizations (including risk assessment and decision making) and administrative functions
 - d. A system for follow up (enforcement and monitoring for environmental effects)
 - e. A system for public awareness and participation
2. National Biotechnology & **BIOSAFETY** Policy
 - The vision of this policy is "To make Uganda a country fully and safely utilising biotechnology in national development".
 - The goal of this policy is to contribute to the national goals of the PEAP focusing on poverty eradication, improved healthcare, food security and the protection of the environment through the application of biotechnology

Policy Objectives

- Build and strengthen national capacity in biotechnology through R & D
- Promote the utilisation of biotech living products and processes as tools for national development.
- Provide a regulatory and institutional framework for biotechnology development and applications.
- Ensure public and environmental safety in biotechnology development and application
- Establish measures for biosafety monitoring, risk assessment and management for all biotechnological applications.
- Regulation

Scope: "shall apply to the generation, import, export, contained use, release or placing on the market or of any genetically modified organism or their living products"

1. Institutional arrangements
2. Application and approval process
3. Public awareness and participation
4. Decision making procedures
5. Review of Decision
6. Risk assessment
7. Risk management
8. Unintentional release & emergence measures
9. Identification and labelling
10. Confidential business information
11. Export and import of GMOs
12. Liability & redress
13. Offences & penalties
14. Appeal

System Operationalisations (Manuals, guidelines forms, & factsheets)

1. Procedures for notifications and requests for permission for the contained use, (differentiated for plants, animals and micro-organisms)
2. Procedures for notifications and requests for permission for deliberate release (differentiated for plants, animals and micro-organisms).
3. Procedures for notifications and requests for permission for the placing on the market and import of GMOs (differentiated for plants, animals and micro-organisms).
4. A system to track dossiers
5. A system for the protection of confidential information
6. Internal rules of procedure for the National Biosafety Committee (NBC)
7. Manual for risk assessment to be used by the NBC on GMOs
8. Manual on procedures for the transboundary movement of GMOs

National Biosafety Guidelines

Interim

1. NBC established in 1995
2. Functional National Biosafety Guidelines
3. IBCs established- 2 applications
 - a. Bt cotton field trials (Did not takeoff)
 - b. HIV testing

Opportunities for multi-country collaboration

1. Obligations to the protocol (Cooperation) Examples:
 - a. Article 22 (Capacity building) "The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology....."
2. Cooperation
 - Article 6 (Transit and contained use)
 - Article 7 (Application of the advance informed agreement procedure)
 - Article 12 (Review of decisions)
 - Article 13 (Intentional transboundary mov't)

- Article 14 (Bilateral, regional and multilateral arrangements)
- Articles 15 & 16 (RA & RM)
- Article 20 (Information sharing and the BCH)

Implications.....

1. Policy advocacy to accelerate the establishment of NBF
2. Review existing relevant policies to provide for biotechnology applications
3. Minimize fragmentation of efforts and work towards establishing centers of excellence
Develop collaborative projects (R4D)
4. Harmonization of domestic regulations and institutional establishments for biosafety

Public Research, Regulation, and Development – Results of a Study (Joel I. Cohen, PBS)

Does regulation imply a cost to society? If so, how is the cost of compliance measured; what is the cost of repetition and redundancy? what is the cost of doing nothing; what is the cost of withholding technologies; can national regulatory systems afford these costs?

Early Assumptions About GM Crops

1. GM crops only from multinationals
2. Companies depend on transboundary movement and export for their GM seeds
3. GM crops = proprietary varieties alone
4. GM crop research not accessible to public research scientists in developing countries
5. GM crops do not take into account livelihood, food security and environmental sustainability
6. GM means farmers can't save seed

Are these assumptions still true or have developments outdated them?

1. GM crops only from multinationals
2. Companies depend on transboundary movement and export for their GM seeds
3. GM crops mean proprietary varieties alone
4. GM crop research is not accessible to public research scientists in developing countries
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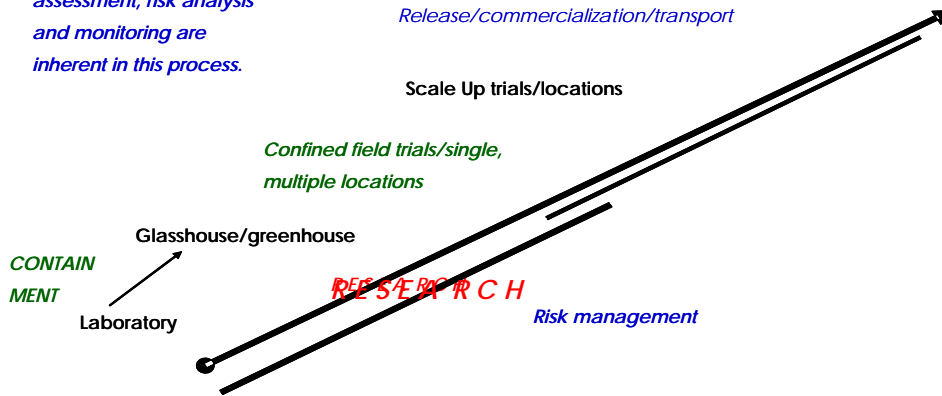
What about Livelihoods, food security and environmental sustainability? "The Biosafety bill must recognize that the introduction of GMOs will impact on livelihoods, food security and environmental sustainability. Issues relating to livelihoods, food security, equity and capacity building and environmental sustainability are not adequately reflected in the bill" *The Kenya GMO Concern Group*

Needs of the Poor Regarding GM Crops

"Crops created that fit not only the agroecology of the poorest regions, often characterized by marginal and heterogeneous environments, but must also fit social and economic systems." *Richard Chrispeels, 2000. If the poor deserve such crops, how will they receive them? Regulation is key to delivery.*

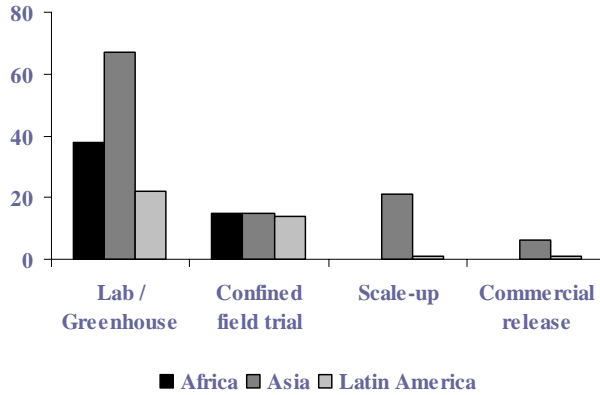
GM crops from public research in 16 developing and transition economies; including 4 African countries (Kenya, Egypt, South Africa, Zimbabwe)

Risk management, risk assessment, risk analysis and monitoring are inherent in this process.

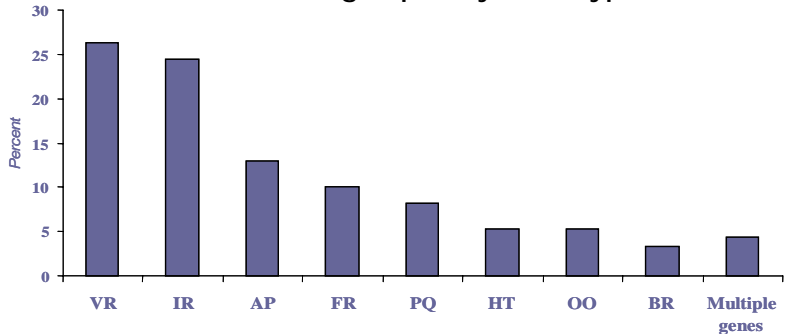


Contained use as defined by the Cartagena Protocol: *Contained use means any operation undertaken within a facility, installation, or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and impact on, the external environment.*

Number of Next Harvest events classified by biosafety and region



209 transformation events grouped by Phenotypic Trait



IR: Insect Resistance
VR: Virus Resistance
HT: Herbicide tolerant
AP: Agronomic Properties

PQ: Product quality
FR: Fungal resistance
OO: Other traits
BR: Bacterial Resistance

Food and environmental safety: so far, so good **“Thus far, in those countries where transgenic crops have been grown, there have been no verifiable reports of them causing any significant health or environmental harm.”** *State of Food and Agriculture. 2004. FAO*

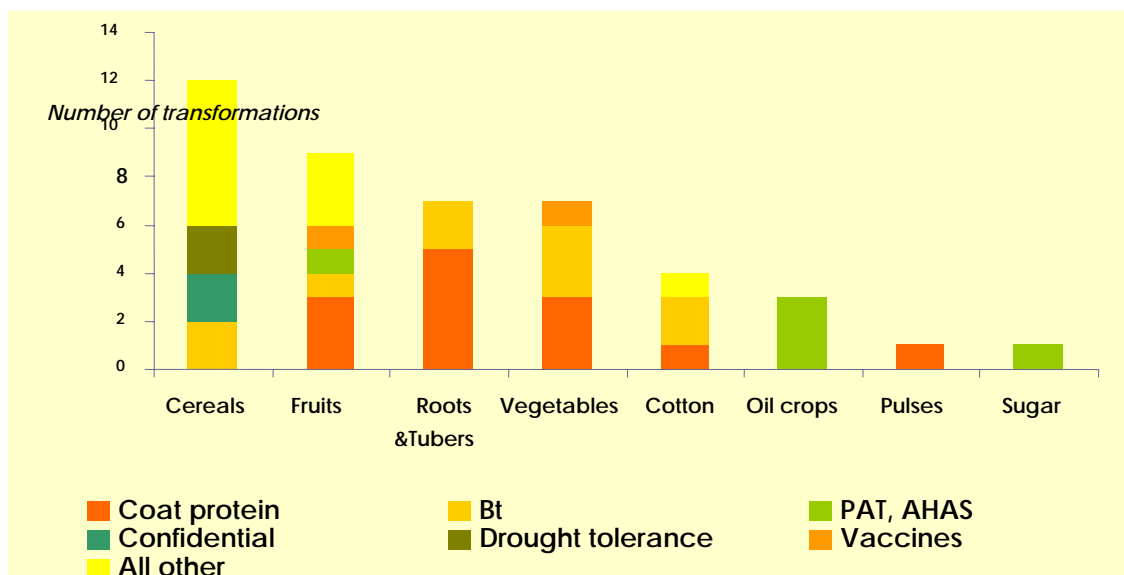
Indian Agricultural Biotechnology Task Force: Public Research Categories and Next Harvest data

India Report Numeral	Category 1 Prioritized target crop traits	Category 2	# of NH public transformation events
4.2.1	Insect pest resistance	Lepidopteron	35
4.2.2	Disease resistance	Bacteria	8
4.2.2	Disease resistance	Fungi	21
4.2.2	Disease resistance	Viruses	55
4.2.3	Abiotic stress tolerance	Drought	11
4.2.4	Quality improvement		9
4.2.5	Enhancing shelf life		6
4.2.7	Engineering male sterility		1

Confined Field Trials

1. Why are they important, and why are they different?
2. Difference between risk management and risk assessment.

44 Events in Confined Field Testing
Crop and Gene Group Combinations



Findings pertinent to our meeting

1. Similar crops, traits and environments, each being approved individually
2. Crops, traits address the poor
3. Confined testing lacks clear standards or regulatory requirements, done in isolation from same crops and traits elsewhere
4. Is it clear what is needed for PPQ offices to allow contained, or confined GM trials?
5. Confined trials of greatest significance to public research – will they be regulated as if for open release?

Conclusions

1. GM gradient: Contained, confined, commercial
2. Research: contained to confined
3. Public GM research reality; similar crops and traits across region
4. PPQ and NBCs – role for confined testing?
5. Will countries work alone or seek new models for the regulatory path ahead?
6. Will such collaboration lead to greater efficiencies, or greater bureaucracy?

PLANT PROTECTION AND QUARANTINE FOR NATIONAL BIOSAFETY SYSTEMS

The Role of Phytosanitary in GMO approval processes in Tanzania (R. Abdallah & G. Bamwenda, TPRI)

Introduction

Phytosanitary measure is defined as any officially prescribed standards for performing inspections, tests, surveys, or treatments of agricultural commodities in order to certify its health in connection with plant quarantine. The Phytosanitary standards are specified in the International Agreements and National laws. The International Plant protection Convention (IPPC) makes provision on trade in plants, seed and its products. Whilst the Sanitary and Phytosanitary (SPS) Agreement makes provision for Sanitary (food health) and Phytosanitary (plants health) protection. The common interest in both these international agreements is the application of international standards in the trading systems.

The IPPC is an international treaty for cooperation in plant protection, deposited with FAO and administered by FAO through the Secretariat for the IPPC. The IPPC provides the global standard setting mechanism for phytosanitary measures. Its purpose is common and effective action to prevent the introduction and spread of pests of plants and plant products, and the promotion of appropriate control measures. It covers both cultivated and wild plants; the direct and indirect effects of pests (as with many weeds); and the prevention of the introduction and spread of weeds, and their control. Therefore, the scope of the Convention is implicitly extended to the protection of natural flora from indirect pest damage. A broad interpretation has been universally supported and continuously reinforced through a history of interpretation and negotiation.

The IPPC also covers the movement of biological control agents, and other organisms of phytosanitary concern claimed to be beneficial. The role envisioned for the IPPC was to foster international harmonization in phytosanitary matters affecting trade and establish standards to help ensure that phytosanitary measures were not used as unjustified barriers to trade.

The role of the Convention with respect to trade has changed significantly as a result of the SPS Agreement. These cover the pest concerned and may also cover any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harboring or spreading pests that are deemed to require phytosanitary measures.

The IPPC calls for phytosanitary measures to be based on a pest risk analysis, which covers both economic and environmental factors including possible detrimental effects on agricultural and natural vegetation. The increased international trade in seed has resulted in a potential increase in the risks of introducing and spread quarantine pests globally. Hence, the need for the application of international phytosanitary standards to protect plants without creating trade barriers. The international Agreements must be incorporated in the National Plant Protection laws. It's main objective being to prevent introduction and spread of quarantine or regulated pests of an importing country.

A quarantine pest is a pest of economic importance (Viruses, bacteria, viroid, nematodes, weeds, insects etc.) which does not exist in the country or present but contained in a specific area. With the aim of preventing the introduction and spread of

quarantine pests into their territories, the importing country shall prescribe and adopt phytosanitary measures concerning the importation of plants and plant products such as detain and screen in a quarantine station, chemical treatment, place under open quarantine, destruction or prohibition on importation.

Countries shall institute restrictive measures only where such measures are made necessary by phytosanitary considerations, to prevent the introduction of quarantine pests. Phytosanitary measures shall be consistent with the pest risk involved, and shall represent the least restrictive measures available which result in the minimum impediment to the international movement of people, commodities and conveyances. This paper highlights on the role of Phytosanitary systems in the enforcement of biosafety.

Pest Risk Analysis

To determine which pests are quarantine pests and the strength of the measures to be taken against them, countries shall use pest risk analysis methods based on biological and economic evidence and, wherever possible, follow procedures developed within the framework of the IPPC.

Pest risk analysis (PRA) consists of three stages:

Initiating the process for analyzing risk:

Initiating the process involves identification of pests or pathways for which the PRA is needed.

Assessing pest risk:

Pest risk assessment determines whether each pest identified as such, or associated with a pathway, is a quarantine pest, characterized in terms of likelihood of entry, establishment, spread and economic importance.

Managing pest risk:

Pest risk management involves developing, evaluating, selecting and enforcing options for reducing the risk. Because some risk of the introduction of a quarantine pest always exists, countries shall agree to a policy of risk management when formulating phytosanitary measures.

Emergency action

Countries may, in the face of a new and/or unexpected phytosanitary situation, take immediate emergency measures on the basis of a preliminary pest risk analysis. Such emergency measures shall be temporary in their application, and their validity will be subjected to a detailed pest risk analysis as soon as possible.

The Biosafety Measures

The IPPC may be concerned with evaluating the potential "pest" characteristics (including weediness) of GMOs, that is, whether a GMO may be detrimental to plant life or health. The biosafety issues are addressed by the Convention on Biological Diversity (CBD) through its Cartagena Protocol on Biosafety. This concept refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care. This Protocol applies to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The Cartagena Protocol on Biosafety was adopted by the Conference of the Parties to the Convention on Biological Diversity as a supplementary agreement to the Convention on 29 January 2000. The Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology, and establishes an advanced informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory.

Risk assessment

Risk assessments undertaken pursuant to this Protocol is carried out in a scientifically sound manner recognizing risk assessment techniques. Such risk assessments are based, at a minimum, on information provided in accordance with available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Risk management

1. The Parties shall, establish and maintain appropriate mechanisms, measures and strategies to
2. regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
3. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
4. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.
5. Whether imported or locally developed, shall undergo an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.
6. Parties shall cooperate with a view to:
 - (a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
 - (b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Discussions

Any LMO that can be considered a pest of plants falls within the scope of the IPPC and will be subject to the provisions of the Convention. Four issues determine the area of overlap between IPPC and the Protocol:

- Standards for risk analysis (risk assessment) related to plant pests
- The interpretation given to the term "injurious" in the definition of the term pest;
- The interpretation of the word "economic" in the definition of quarantine pest and regulated non-quarantine pest (in the ISPM on pest risk analysis this is interpreted to include environmental effects); and
- The interpretation of the term "phytosanitary concern" in Article 7.1.d of the Convention.

A wide interpretation that would include effects on plant biodiversity under "injurious" or "phytosanitary concern", would allow for regulating certain LMOs under national phytosanitary legislation and providing quarantine services with the authority to take measures.

Biosafety as currently discussed in the CBD refers to environmental and human health safeguards concerning living modified organisms (LMO) produced by modern biotechnology. Biosafety protocols should eventually strive to protect resources for food and agriculture, while allowing for their sustainable use, development of international trade and their commercialization.

A mechanism must exist whereby both locally developed and imported GMO products can be evaluated in experimental trials for their potential usefulness and their biosafety impacts, before introduction into local agriculture. This can be done in confined field trial.

During the conduct of a confined field trial the risk mitigation measures are put in place to prevent the pollen- or seed-mediated dissemination of new genes into and within the environment; prevent the persistence in the environment of the Genetically Engineered plant or its progeny; and prevent the introduction of the Genetically Engineered plant or plant products into the human food or livestock feed pathways.

From the above information it is obvious that the GMOs or LMOs can easily be processed through a Phytosanitary system. The goals of Phytosanitary system is to protect agriculture and biodiversity and through SPS human health as well. Within the Phytosanitary, there is a well defined scientifically sound system for assessing and manage the risks. It is therefore inevitable to use the already existing well established Phytosanitary system to process approval of GMOs. This system is already under use by the developed countries such the United States of America and Canada. The system has proved to be efficient and effective. We should therefore adopt such systems. The important aspect however, is strengthening the capacity of the Regulators to enforce biosafety. This option is cost effective and efficient rather than creating a new system altogether. Moreover, biosafety inspections are not many at the moment; hence the Inspectors will be utilized in other Phytosanitary obligations.

The Current Situation in Tanzania

In Tanzania, a Plant Biosafety Office (PBO) has been established at the Post Entry Plant Quarantine Station which is based at the Tropical Pesticides Research Institute (TPRI). This is an office which receives all the applications of importation of plants and plant products. The application for GMOs is forwarded to the Agricultural Biosafety Scientific Advisory Committee (ABSAC) for review and scrutiny. ABSAC forwards its recommendations to the National Biotechnology Advisory Committee (NBAC) for approval. The NBAC finally sends its recommendations to the Minister for Agriculture and Food Security (MAFS) for his final approval. The whole process takes 90 days which is in accordance with the Confined Field Trial Directive (CFTD).

If approved, the confined field trial will be enforced by the Phytosanitary/Biosafety Inspectors using the CFTD, Standard Operating Procedures (SOPs) and the Inspectors Manual.

The Phytosanitary/Biosafety Inspectors and the Regulators have received initial training through Program for Biosafety Systems (PBS) and TPRI. The initial training will enable them process the applications and risk mitigation of confined field trials in Tanzania.

Implementing confined field trials in East Africa (Mark Halsey and Gratian Bamwenda)

Implementing Confined field trails in East Africa (Mark Halsey)

Kenya has made substantial progress in implementing CFTs, beginning with VR sweetpotato in 2000. Since that time, several screenhouse trials have been done under the leadership of Kenya Agricultural Research Institute (KARI). Recently, applications were approved for Bt maize (KARI/CIMMYT) and VR cassava trials (KARI/DDPSC). KARI is also preparing an application for field screening of second-generation VR sweetpotato lines. A second application for Bt maize (Monsanto) is also pending. A streamlined application format for CFTs was developed by a dedicated task force in 2004, and this application form has recently been officially approved by the Kenyan NBC.

In Uganda, banana is of primary interest, and collaborative research is underway between Kawanda Agricultural Research Institute, IITA and KUL for the development of lines resistant to banana diseases. PBS is assisting in the development of a glasshouse facility for early-stage contained testing of transformants for this project. An application for development of KARI/KUL lines is in preparation, and PBS assistance has been requested for its completion. UCST is working on the development of guidelines and supporting documentation to support CFT applications and implementation. Capacity building for regulators and others will be included as part of the development of the framework for CFT implementation in Uganda.

CFTs are an integral part of the development of new agricultural products. The key factors for consideration at this stage of development are the proposed confinement measures, including reproductive isolation and material confinement. With appropriate confinement measures CFTs can be implemented safely, thus enhancing decision-making for new agricultural products.

Building Capacity for Implementing Confined Field Trials in Tanzania (R.G. Bamwenda, TPRI)

Background

Currently, Tanzania has yet to embark on the research or application of Genetically Modified Organisms (GMOs) but it is in the process of developing national institutional structures, and legal and regulatory biosafety frameworks in the country. Interim structures such as the National Biotechnology Advisory Committee (NBAC), Sectoral Agricultural Biosafety Advisory Committee (ABSAC), and Plant Biosafety Office (PBO) have been established to serve as coordinative and advisory bodies as well as for enforcing Confined Field Trial Guidelines.

Simultaneously, Tanzania is also undertaking to develop technical and human resource capabilities to handle the GMOs in accordance with the requirements of national and international laws. Infrastructural capabilities as an integral component and enabler of technical and human resource, which essentially require major involvement with donors and central government are being worked out.

Confined field trials are essential to the scientific and economic as well as political and social success of the country and are prerequisite to the unconfined (general) environmental release of GMOs. During the conduct of confined field trials the risk mitigation measures are put in place to prevent the pollen- or seed-mediated dissemination of new genes into and within the environment; prevent the persistence in the environment of the Genetically Engineered plant or its progeny; and prevent the

introduction of the Genetically Engineered plant or plant products into the human food or livestock feed pathways.

The commercial success of plant biotechnology in the United States, Canada, Argentina and other countries would not have been possible without having in place systems that permit routine and safe conduct of confined experimental field trials. This capability to conduct preliminary trials is just as important in developing countries. A mechanism must exist whereby both locally developed and imported GMO products can be evaluated in experimental trials for their potential usefulness and their biosafety impacts, before introduction into local agriculture.

The safe conduct of confined field trials can only be accomplished through the combination of a robust regulatory framework, science-based risk mitigation measures, trained and vigilant inspection staff, and trained field personnel dedicated to abiding by the terms and conditions of trial authorization. As evidenced by some experiences in both developing and industrialized countries, weaknesses in any of these areas become quickly apparent, usually to the detriment of public trust.

Public opinion research, has demonstrated that public acceptance of new technologies, including biotechnology, is largely dependent on confidence in regulatory structures and processes. Even more generally, trust in the integrity and institutional governance of regulatory bodies is essential to securing market access both at home and abroad. Likewise, the poor performance of some groups conducting confined field trials calls into question not only their own reputation, but also tarnishes the image of the entire community development and the technology.

Development of Interim National Institutional Structures, and Legal and Regulatory Frameworks

1. A National Biotechnology Advisory Committee (NBAC) was developed in March 2002. This is a National Decision Making Body which is under the Ministry of Science, Technology and Higher Education (MSTHE) comprises of members from various Ministries in the country.
2. A Competent Authority of the Ministry of Agriculture and Food Security (MAFS) was established in 2004 and named as an Agricultural Biosafety Scientific Advisory Committee (ABSAC). ABSAC consists of members with various fields within the MAFS. ABSAC's mandate is to process application of Genetically Modified Plants and Plant Products (GMPs) in the country.
3. TPRI is the Secretariat ABSAC and the Plant Biosafety Office (PBO) for the MAFS.
4. Through PBS support and under AGBIOS supervision, Tanzania developed a Confined Field Trial Directive (CFTD) which will be attached to the Plant Protection Regulation 1999 of the PP Act 1997.
5. TPRI has (recently) developed Crop Biology Documents for Cotton and Maize, Standard Operating Procedures (SOPs) for Storage, Transport, Current Season (cotton and maize), Harvest and Disposition and Post Harvest Monitoring, Field Test Reports and Compliance Document Binder for field trials. The above activities were developed through an Internship program organized by AGBIOS Inc. and Rockefeller's support in Canada and USA (August – September 2004).

Human Resource Capacity Building

Several seminars on GMO have been conducted in Tanzania. TPRI in particular has conducted several seminars in 2003-2004 to various stakeholders in the Northern zone.

Seminars were also conducted to decision makers such as Members of Parliament and Officers in the MAFS.

Several trainings on Confined Field Trials have also been conducted in Tanzania. The trainings were conducted by TPRI in collaboration with Donald Danforth Plant Science Center (DDPSC) under the Program for Biosafety Systems (PBS) support. The trainings were conducted as follows:

1. Training of Regulatory Biosafety Inspectors on the Confined Field Trial Requirements February 7-11 2005, TPRI, Arusha, Tanzania. The course participants were from Kenya, Uganda and Tanzania. The course objectives were:
 - To familiarize Phytosanitary Inspectors with the principles and procedures of compliance and inspection required for the execution of safe confined field trials of GM crops.
 - To enhance participants understanding of the concepts and issues associated with modern agricultural biotechnology.

2. Training of ABSAC on Evaluation of Applications for Confined Field Trials February 14-16 2005, Bagamoyo, Tanzania. The training objectives were:
 - To enhance understanding of modern agricultural biotechnology among regulators.
 - To enhance the skill base, knowledge and experience of regulators for evaluation of applications for confined field trials of GM crops.

3. Training/Workshop of NBAC members February 18, 2005, Dar es Salaam Tanzania, on Confined Field Trial Systems in Tanzania; and Risk Assessment Concepts and Procedures. The workshop objectives were:
 - To familiarize members of the NBAC with the procedures and regulatory requirements for confined field testing of GM crops in Tanzania;
 - To brief them on training received by ABSAC and Field Inspectors in support of confined field trials;
 - To familiarize them with risk assessment concepts and procedures for general release of GM products.

Way Forward

- Training on CFT for Applicants such as the researchers, academicians, seed companies, farmers etc
- Public awareness creation/understanding on CFT and risk assessment issues in Tanzania

Conclusion

PBS has taken a correct and timely step in developing the Confined Field Trial requirements and strengthening the capabilities of the Regulators in Tanzania. These initiatives will enhance processing of GMO application for research in Tanzania. It is important to understand the performance and characteristics of the GM plants before its acceptance for commercial release. We hope that PBS will continue its collaboration with Tanzania so as to achieve its goals of safe introduction of plants and plant products in the country.

EXPERIENCES WITH REGIONAL AND COLLABORATIVE APPROACHES

Rationalization and Harmonization of Seed Policies, Laws, Regulations and Procedures in Eastern Africa: What Lessons Have We Learned? (Isaac J. Minde, ECAPAPA)

Introduction

The motive for the rationalization² and harmonization³ of seed policies, laws, regulations and procedures is based on the fact that the seed industry in the region is facing different standards and regulations in each country and that is costly to meet. These high costs, coupled with the relatively low level of effective demand, make it unprofitable for local or international seed companies to make the investment required to provide the quantity, quality and variety of seeds needed to support an expanding agricultural base in the eastern African region (ECA). Most of these costs take the form of non-tariff barriers which essentially refer to regulations, procedures and administrative and technical requirements other than tariffs imposed by the governments of these countries. The non-tariff barriers as they relate to standards, regulations and procedures can also become barriers to trade if they place unjustifiably discriminatory demands on importers, exporters or even domestic producers.

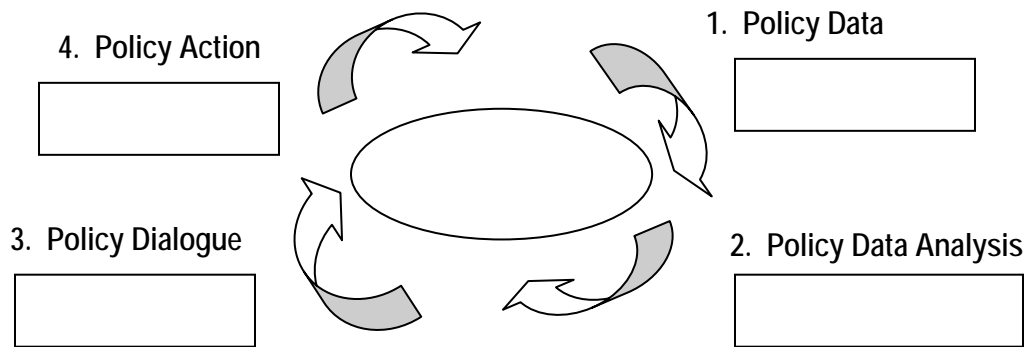
The rationalization and harmonization initiative was initiated in September 1999 in Kenya, Tanzania and Uganda, which served as pilot phase countries. In 2001, the project was subsequently expanded into a second tier of countries comprising of Burundi, Eritrea, Ethiopia, Rwanda and Sudan. The third and final group of countries, namely Democratic Republic of Congo and Madagascar were brought into the project in 2003. The ultimate aim is to have a unified understanding among the countries of the region that would allow seeds to move across national boundaries without a "visa".

The process in each of the countries began with seed industry subsector surveys and analyses conducted by national resource persons and supervised by a regional resource person to establish the state-of-the art of seed sector in the main areas of the seed. These included; variety evaluation, release and registration procedures, seed certification, phytosanitary issues, plant variety protection as well as import-export procedures. The purpose was to document and analyze the way things are and what improvements/changes are needed to make the sector more efficient nationally (rationalization) as well as making it more efficient regionally (harmonization). The results of the analytical process were then subjected to broad-based national consultative meetings comprising a wide-cross-section of stakeholders—public, private, civil society, Non-Governmental Organizations, community-based organizations, farmers' organizations, etc. These were followed by national decision-makers level types of consultative forums meant to facilitate dialogue leading into agreements at a national level on issues that needed to be rationalized and those that needed harmonization including the necessary steps that needed to be undertaken to ensure that the agreements are implemented. The process followed a policy-change cycle as depicted in Figure 1.

² This refers to making changes in the business system in order to increase efficiency or reduce waste.

³ The process of bringing together different approaches into a unified strategy

Figure 1: The Policy Change Cycle



The policy change cycle could be viewed as a model for multi-stakeholder, multi-disciplinary and cross-institutional approach for transforming research and analysis recommendations into policy actions. It thus acts as a loop (bridge) between agricultural policy research findings and practice. Seed policies and regulations were analyzed for their efficiency, harmonizable elements and implications for international treaties.

Four and half years ago today seed industry participants-- private and public, met at a regional forum with a view to bring together the deliberations that had taken place at national levels and to reach agreements at a regional forum on various issues in the seed sector. These agreements have been implemented at varying degrees for the last four years both at national as well as at regional level.

Objectives of This Paper

This paper is meant to respond to some of the objectives of this Policy Round Table. More specifically, the paper addresses in the context of regional collaboration, experiences and insights of the initiative on rationalization and harmonization of seed policies, laws, rules and procedures in eastern Africa. In this paper we reflect on the processes followed, the strengths and achievements of the initiative as well as reviewing the opportunities that made it possible. The paper then identifies some weaknesses focusing on the conditions and situations that are limiting or restricting faster implementation of agreed on policies. Last but not least the paper attempts to itemize some lessons learned which could be heeded by similar regional collaborative approaches in the region.

Achievements in the Rationalization and Harmonization Process

Each of the three African sub-regions has pursued harmonization of seed laws and regulations and agreements have been relatively easy to reach in all. It has also been observed that amongst the sub regions of Africa eastern African has made the greatest progress in implementing these agreements (Rohrbach et al 2003).

Achievements made in this process can perhaps best be classified into two groups-- indirect and direct benefits. Indirect benefits are those that were not necessarily intended at project inception but whose value in support of the seed industry as well as other related sub-sectors in the agricultural sector can easily be recognized. This includes among others; facilitation of the public and private forums to meet and view themselves as partners in development. Hitherto, there had been some impression that the public sector is the sole decision maker and the leader with the private sector being the

“follower”. The project has greatly diffused this distinction. As a result the private sector now participates in a number of functions in the seed sector such as certification of seed varieties, which were hitherto performed only by the public sector. For this reason, a lot of emphasis has been placed on facilitation of the establishment and strengthening of national seed trade associations. To date these include; Kenya Seed Trade Association of Kenya—STAK (although the initiative found it well established, significant support in terms of strengthening it has taken place in the recent past), Uganda Seed Trade Association – USTA, Tanzania Seed Trade Association—TASTA and Malagasy Seed Trade Association--AMPROSEM. This year, the initiative will facilitate the establishment of three additional national seed trade associations in Rwanda, Ethiopia and Congo Democratic Republic.

The initiative has also provided an opportunity for public and private officials working in the project countries to meet, know each other, share and exchange experiences. This has helped to build trust amongst them and has become a resource for subsequent regional initiatives. An additional point in this category is the fact that the project has set a good beginning in the region whereby skills and the necessity of using scientific-based evidence to argue for policy change without ignoring the political reality embedded within the policy making process is in place. Through this process of harmonization we have experienced how a regional approach can put peer pressure on “laggards”. Remarks such as “country X has moved ahead and it is only us in country Y who are still indecisive. We might be left behind if we are not careful” were quite common in the process. These benefits are indirect partly because such gains go beyond the seed sub-sector and partly because they were not necessarily intended at the beginning of the project.

Direct benefits are those gains associated with the objectives that were set at the beginning of the project. Examples are changes in the system that have caused increased transparency leading to increased efficiency gains and effectiveness in the sector. The streamlining of the variety evaluation and release procedures and streamlining of the variety evaluation committees has partly contributed to the increased number of seed companies presenting varieties for release. In 2004 for example the varieties released in Kenya by private companies increased by more than three times the number in 1999. Previously, variety releases by entrants from other countries were sporadic and rare. In December 2003, two companies released three maize varieties to the National Variety Release Committee of Tanzania as follows: Kenya Seed Company released maize hybrid H 515 and FICA Ltd of Uganda released Longe 4 and Longe 2H.

It is also important to reckon that this initiative has become a catalyst in facilitating information and knowledge sharing in the seed sector across Africa and beyond. The initiative is now a link of the regional seed sub-sector with global seed systems. Tuning to, as well as tuning the global seed system is gradually beginning.

What are the More Direct Achievements?

If reference is made to the project objectives, and given that it is now four and half years since the agreements were reached by the pilot countries (Kenya, Tanzania and Uganda) one is likely to ask the following questions about performance:

- Do farmers now have more seed choices?
- Has the price of seed come down because of more seed being available for the farmer to choose from?
- Is there a real increase in seed flow across national boundaries (increased trade)?
- Are farmers using more improved seed than they did before the project?

- Is farm level productivity increasing because of more use of improved seed?
- Is food security increasing?
- And are farmers feeling better off as a result of this project?

These are legitimate questions but perhaps one could argue that for a project of this magnitude, form and content, it might be premature to expect these types of impacts. However, it is important to provide evidence to show whether there is any promise of moving towards the stated impacts. We note below some of these pieces of evidence:

1. The pilot phase countries (Kenya, Tanzania and Uganda) moved on to implement real changes in shortening the time for release of new varieties. This was shortened from three years to one season.
2. In phytosanitary issues, the quarantine pests for seed material moving across the pilot phase countries were reduced from 33 to 3 pests.
3. Four other countries (Burundi, Ethiopia, Rwanda and Madagascar), beyond the pilot phase countries in eastern Africa have to a large extent embraced agreements of the pilot phase countries. The rest have not rejected but the process is still on. This provides promise that harmonization for the region will soon be a reality. There has been no objection by countries from second and third tier on the initial agreements.
4. Significant progress has been achieved in harmonizing and effecting real changes in procedures with respect to import and export regulations. Documentation and accompanying forms have been changed to promote efficiency.
5. Draft national and regional variety lists are now available and are in the process of being printed and circulated. These will go a long way in providing information to seed traders and farmers on what is available on the market.
6. Field and laboratory standards have been jointly prepared by member states—Kenya, Tanzania and Uganda with the expectations that other countries will also find them useful.
7. Implementation of the agreement on harmonizing seed classes is progressing and prototypes are in the process of being produced.
8. A 12-member Seed Regional Working Group (S-RWG) —from the private and public sector, meant to oversee the implementation of the agreements as well as being responsible for advising and handling of emerging issues in the seed sub-sector was as from February 2003 accepted as a member of the Committee on Agriculture and Food Security of the East African Community. This was a significant milestone because the members of the Committee on Agriculture and Food Security are key in the successful implementation of the agreements in the member countries. In a bid to further consolidate the ownership of the process this S-RWG was expanded in 2004. Through extensive consultations amongst subsector participants it was agreed to transform the S-RWG to a broad-based Eastern Africa Seed Committee which in principle comprises 40 members covering the entire 10 ASARECA countries. The members come from both the private and public sector. Its formation is also a strategy for ECAPAPA Coordinating Unit (CU) to let subsector participants be more and more in control of the affairs of the subsector. The strategy also enables ECAPAPA CU to gradually exit so as to be able to embark on new regional agenda.

Progress in the legislation: In the process of developing the agreements, two classes of agreements emerged—procedural/administrative (where the changes agreed on can be implemented immediately because of not being covered by any law) and legislative. Whereas members have endured to implement both, by their nature, “legislative” usually

take more time to implement because of the numerous steps involved and the involvement of many high level institutions—Parliamentary Committees, Cabinet Committees, ministerial consultations, etc. Despite these complex processes, quite a lot has been achieved across countries. For example in Kenya there have been several high-level consultations with attempts to discuss a bill that is attempting to rationalize three existing acts into one. In Uganda, the Plant Variety Protection Bill received quite some attention beginning December 2002 and it is still under discussion with a Parliamentary Select Committee. The Seed Statute has gone through debate by the Parliamentary Committee and it is now awaiting a Parliamentary debate. In Tanzania two acts have been enacted since 2002 with significant inputs and direction from national stakeholders in this project. These acts are the Plant Breeders Act—October 2002 and the new Seed Act of 2004 which replaced the one for 1978. In Rwanda the seed bill was enacted in 2003 and it incorporated many of the elements of the agreements emanating from the pilot phase countries. Regional experts under the support of this project helped Rwanda to operationalize the Seed Act by developing workable and private-sector friendly rules and regulations.

Some Constraints in the Implementation of the Agreements

What seems to be immediately apparent though is that in general, reaching agreements is the easy part but implementation is not easy.

Although quite some effort was spent in attempting to make the forums as representative as possible, not many grass-root operators in the seed industry know about the agreements. The question is: to what extent have the policy makers at various levels, breeders, agronomists, etc, in the national systems tuned to these agreements.

The speed of implementation of the agreements is also below what the CU would have expected. The reasons are among others; that there is no special group of persons in the national systems that are solely responsible for implementation of the seed trade agreements. Subsector participants have to allocate time for this from their day to day assignments.

Backsliding on agreements is sometimes a problem. This is a term the initiative uses to describe the tendency of some regulators to dishonor what was already agreed on. In one instance, when a member was asked “Why are we going back while we already agreed”? The member replied “You see members have the right to change their minds. Moreover, let me tell you that when we went for a broad national stakeholders’ consultation on the issues we had agreed on at the regional level, members came up with different views and we have to respect them”.

There is also a problem that seed trade harmonization does not necessarily lead to increased trade. There can still be other tariff and non-tariff barriers that may hinder the smooth flow of seed across national boundaries.

How Do We Make Use of Existing Opportunities?

Several frameworks are in place in the eastern African region as well as neighbouring regions that are supportive of the rationalization and harmonization of seed policies and regulations initiative. The Common Market for Eastern and Southern Africa (COMESA), the Southern African Development Community (SADC), the Intergovernmental Authority on Development (IGAD) and the East African Community (EAC) have all embraced the need to harmonize trade regulations and standards and in all cases, seed is no exception. The political goodwill and a politically enabling environment is thus in place.

Any effort toward implementation of agreements is not therefore likely to go to waste because necessary political support is in place. The National Agricultural Research Systems (NARS), are also in support. In fact, it is their scientists who expressed a need for this initiative because of their failure to move germplasm across national borders. The recently concluded East African Customs Union is also a lubricant into the on-going efforts of harmonization in the sense that whereas rationalization and harmonization are necessary, they are not sufficient conditions in ensuring smooth trade. Trade policies *per se* need to be in tune with the harmonization efforts. One can have all the harmonization agreed and done but then nothing moves because the actual trade policies remain prohibitive.

Challenges Facing Further Implementation of the Agreements

Several challenges remain critical if we are to fully realize the long term sustained benefits in our efforts of rationalization and harmonization of seed policies and regulations. We therefore need to ask ourselves some difficult questions if we are to realize some long term sustained benefits from this initiative. The following are some of the teething challenges:

- i. How do we handle the informal seed sector participants especially farmers who are indeed the majority in the industry—about 90 percent? Who is real concerned about them?
- ii. What is the possible impact of harmonization on the breadth of seed system development? Will the existence of economies of scale obtainable from regionalized seed market encourage greater commercial interest in the multiplication and sale of seed for many open- and self-pollinated varieties?
- iii. There are likely to be lingering questions about market development for open- and self pollinated seed crops of lesser interest to the commercial sector. In recent years, the market for seed of open- and self-pollinated varieties has been strongest in relief programmes. The consistency of these relief programmes in the region has encouraged a few larger companies to sell open-pollinated varieties of crops common to relief programmes such as sorghum, pearl millet groundnut and cowpeas. What are the implications on these developments on the harmonization efforts?
- iv. Genetically Modified Organisms (GMOs): Regional discussions of regulatory seed policies harmonization have to date not debated GMOs. There is no escape. There will be need to factor this debate into future discussions and define clear position on GMOs in the harmonization process.
- v. Need to go beyond East Africa in dealing with harmonization in phytosanitary issues: Whereas all is well in terms of harmonizing the handling of quarantine pests within east Africa, we have not dealt with issues on how to handle quarantine pests that are coming from outside the region. This is currently in the 2005 work plan.
- vi. Who will pay for the implementation of the agreements? To what extent and how can we attract the seed private sector to pay for this?
- vii. How can we best organize ourselves to meaningfully measure and document the results of this initiative?

In addressing the power of measuring results, Zozo (2004) says,
If you -----

- do not measure results, you cannot tell success from failure*
- cannot see success, you cannot reward it*
- cannot reward success, you are probably rewarding failure*
- cannot see success, you cannot learn from it*

-cannot recognize failure, you cannot correct it
-can demonstrate results, you can win public support

What Then Have We Learned?

Throughout this process, the CU has been making observations on some key striking issues that could be lessons for us for similar future regional initiatives. The following are some of them:

- i. There are more chances to succeed when the problem under investigation is real and common-felt. The problem of harmonization of seed policies and regulations was sounded by the sub-sector participants themselves.
- ii. Phasing of regional initiatives can be useful. We started with pilot phase countries and as we moved further afield we carried with us the lessons we had learned.
- iii. The process of rationalization and harmonization is technical (dealing with scientific facts), political (the process of making stakeholders of various types agree) and legislative (confirming and guarding the consensus reached) one. All these three stages are equally important. They all feature in the policy-change cycle- which we find to be science-based (analysis) as well as politically accommodating (dialogue).
- iv. Public and privates sector have to work hand in hand in all stages as each has a unique role to play.
- v. It helps for the sub-sector participants to own the process. They have to be the drivers in the implementation of the agreements. This means that participation needs to be broad-based and we have to strive for high levels of inclusiveness of partners
- vi. In conducting consultative meetings, we have learned that there is need to:
 - thoroughly analyze issues and have clear options ready before meetings
 - make the meetings as participatory as possible
 - practice transparency
 - respect diversity of views
 - have a core group of people dedicated to the initiative to discuss the issues before the actual meeting and
 - aim at reaching consensus not debate
- vii. It is human nature for people to fear change and its consequences. In the seed trade policies harmonization, we found that the fear was attributed to:
 - country losing business (this was the case between Uganda and Kenya)
 - country being dependent on another in the supply of technology
 - individuals losing power and authority
 - weaknesses and incompetence being exposed
- viii. Strategic partnerships based on mutual respect and mutual benefit with international agricultural research institutions are good catalysts in project implementation. In this seed trade harmonization initiative we are partnering with a wide range of institutions and persons—NARIs, universities, advanced research institutions, regional economic and political organizations, regional and sub-regional seed associations, international seed agencies, etc.

Conclusions

The eastern African region is furthest ahead in agreements on rationalization and harmonization of seed policies and regulations compared with the other African sub-regions. However, translating these agreements into practice takes time particularly when the changes required are of the “legislative” type. How to organize the broad array of participants in the industry to understand and implement the harmonization at a

reasonable speed remains a major task. It is also becoming very clear as we continue with these efforts that only a small fraction of the seed system is touched by these efforts—the relevance as of now is mainly directed to the formal/commercial seed sector. But the fact on the ground is that this represents only about 10% of the seed market.

Linking these efforts with the international seed system as well as responding to questions on how to cope with and internalize emerging issues in the seed system remains a big challenge. For example, there is need to come to grips with issues on GMOs.

Implementation of the agreements, however, is being pursued within a very conducive and enabling political environment. The EAC endorsed the need for harmonization at an early stage of these discussions. Other neighbouring regional integration bodies are equally supportive. There is need to take advantage of these developments and move faster to implement what has been agreed on. We, with interest in the promotion of the seed industry have to date been able to form a very friendly “network”. There is need to improve and intensify this relationship. One way is to establish a sub-regional seed association to complement the African Seed Trade Association.

COMESA rationale for Biosafety and regional work (Chikakula Miti, COMESA)

Background to GMOs

The first generation of GMO agricultural crops, produced by private companies, included insect-resistant maize and cotton engineered to contain Bt proteins from a naturally occurring soil bacterium, that many kinds of insects cannot digest, and herbicide-tolerant soybeans and canola. These first GM varieties were attractive to farmers because they allowed pests and weeds to be controlled while using fewer and less toxic chemical sprays, thus saving money and labour time while reducing field exposure to hazardous chemicals. Before commercial release, these new GM crops were tested for both food safety in human consumption and for biosafety (safety to other plant and animal species). When these tests found no increased risk compared to conventional crops, official regulators in the U.S., the EU, Japan, Canada, and in a number of other countries began approving these GMO crops for commercial use in 1995-96.

The total area worldwide planted to GM crops has increased since 1995-96 to reach a total of 67.7 million hectares (167 million acres) by 2003. Significant plantings of GM crops (greater than 50,000 hectares) can now be found in ten different countries. In 2003, 55 percent of all soybean hectares globally were planted to GM varieties, and 21 percent of all cotton hectares globally were GM.⁴

Despite this rapid uptake of this new technology in some countries, in many regions of the world today GMO crops have not yet been approved for commercial planting. This is particularly true in developing countries, where in many cases the regulatory systems that would be needed to test GMO crops for food safety and biosafety are not yet in existence. One GMO industrial crop, Bt cotton, has now been approved and is being planted widely in a number of important developing world countries (e.g., in China, India, Indonesia, South Africa) but GMO food and feed crops mostly are not. So as of 2003, 99 percent of all the world's GM food and feed crop acreage could still be found in just four Western Hemisphere countries: the United States, Argentina, Canada, and Brazil.

In most developing countries the planting of GMO food and feed crops has not yet been formally approved. In all of the developing countries of Asia (including East, Southeast, and South) only one country so far – the Philippines – has approved the planting of GMO maize. The planting of GMO rice, soybeans, or potatoes has not been approved yet by any country in developing Asia. In all of sub-Saharan Africa, only one country (South Africa) has yet approved the planting of any GMO crops (cotton, maize, and soybeans). Farming systems in all the other countries of Africa (including all the countries of the COMESA region) are still officially "GMO free." In all of the Middle East, not a single country has yet approved the planting of any GM crops, not even cotton.

Rationale for Biosafety work

Most COMESA countries have no formal positions on the question of biotechnology and biosafety. Neither do they have the capacity to determine the impact of biotechnology such as GMO maize on human health and on the environment and biosafety. Unfortunately, this is not a subject that the region can ignore for very long because in the face of serious food shortages, countries often have to make the choice for either

⁴ Clive James, "Preview: Global Status of Commercialized Transgenic Crops: 2003", ISAAA Briefs, No. 27-2002.

accepting or rejecting food aid with GMO such as happened a couple of years back. It is clear therefore that the region needs an informed position on the whole question of biotechnology and biosafety.

Farmers in the COMESA region might miss out on significant income gains. So far, wherever farmers have been permitted by regulators to switch from conventional to GMO crops, farmers have registered significant income gains from a combination of reduced pest damage, reduced labour costs, and reduced chemical purchases;

It might be more difficult for them to gain access in an emergency to sufficient quantities of whole maize kernels as food aid from the WFP. This is because more than half of all the maize distributed by the WFP comes from the United States, where GM and non-GM maize kernels are not segregated either domestically or in bulk shipments for export.

The income of farmers depends on the productivity of farm labour, which in turn depends heavily on the development and extension of affordable and productive technologies to farmers (e.g., improved seeds and animal breeds, water access, soil nutrients, and weed and insect management technologies). Many farmers in the COMESA region experience low incomes because such technologies are still not available to them. When food production does increase in the COMESA countries, it is usually a reflection of the region's growth in population (implying there will also be more people to feed), rather than a reflection of higher farm labour productivity. In sub-Saharan Africa as a whole between 1980 and 1997, average agricultural value-added per farm worker actually declined by 10 percent, according to the World Bank.⁵ As farm worker productivity has declined in Africa, rural incomes have stagnated, and as population has continued to grow the numbers of poor and poorly nourished people have increased. Between 1975 and 1995 the number of malnourished children in Africa increased from 18 million up to 31 million.⁶

Policy Options

The following regional Policy Options provide the potential way forward for COMESA in addressing the issue of biotechnology and biosafety. These policy options will be further explored in the in-depth study in consultation with both key public and private sector stakeholders with a view to coming up with informed policy options on this subject.

Country-by-Country Decision Making

In areas such as health and safety, regulatory power in the COMESA region has traditionally remained in the hands of the sovereign governments of the region. In the specific area of GMO policy, this traditional standard of national sovereign control has recently been reaffirmed in at least one African context.

In November 2002, the agricultural ministers of the COMESA countries, meeting in Kampala, agreed to create a regional policy on GMOs, including GMOs as food aid.⁷

In October 2004, the meeting of the COMESA ministers of Agriculture urged Member States to consult widely with industry leaders, civic leaders, and the general population as they seek to come up with their own national positions on GMOs and the whole

⁵World Bank, World Development Report 2000, Table 8, p. 288-89.

⁶Lisa Smith and Lawrence Haddad. 2000. "Overcoming Child Malnutrition in Developing Countries." Discussion Paper 30 (February). Washington, D.C.: IFPRI

⁷ "COMESA Agricultural Ministers Tackle Policy on GMOs, Food Security," COMESA Press Release, November 18, 2002.

question of biotechnology and biosafety, including effective dissemination of quality and balanced information.

Despite this imperative to seek a regional policy solution, most of the GMO biosafety policy models currently circulating within official circles in Africa retain the assumption of national sovereign control. For example, the 2000 Cartagena Protocol on Biosafety (which entered into force on September 11, 2003) encourages African governments to take a "precautionary approach" by giving each of them, as individual governments, a separate right to refuse imports of living GMOs (LMOs).

There is no regionally harmonized standard offered for the exercise of this right, and the "precautionary approach" endorsed by the Protocol does not require scientific evidence of risk to justify an import restriction (all that is needed is some scientific "uncertainty") so regional harmonization based on science is implicitly ruled out.

A Single Regional Policy

The COMESA countries might consider meeting the regional GMO policy challenge by agreeing at the council of ministers level to adopt a single import and commercial release policy for the region as a whole. It might not be easy to find a single policy agreeable to all the COMESA countries, of course.

In this regard, in October 2004, the COMESA Ministers of Agriculture urged Member States to support the work COMESA is undertaking with ASARECA by providing the necessary inputs and materials to ensure that the proposed regional policy being developed by COMESA takes into account the positions of individual countries.

On the issue of Biosafety approvals for the import and/or commercial planting of viable living GMOs (LMOs), no import or planting would be allowed in the COMESA region for any LMO food or feed crops. For non-food and non-feed crops such as cotton or flowers, COMESA countries would be allowed to approve plantings and imports country by country. The planting and import of LMO food and feed crops (e.g., maize, sweetpotato, banana) would not become legal until endorsed, case-by-case, by all the COMESA countries.

The advantages of announcing such a common policy for the COMESA region might include the following:

This common policy would reduce commercial risks. It would protect food and feed products both within and beyond the COMESA region from both official and consumer rejection, since all COMESA food and feed products would remain, for the time being, officially GMO-free.

This common policy would at least temporarily block the commercial release of living kernels of GMO maize in the COMESA region, but this would be for now a small loss to farmers, since locally adapted varieties of GM maize will not be emerging from development by the IRMA program until several years from now in any case.

This policy would also temporarily block the commercial release of GMO sweetpotato and banana, but high performing locally adapted GM varieties of these food crops are also some time away from being ready for commercial release in the region.

The disadvantage of this single regional policy approach might first be the practical difficulty of securing consensus approval from all 20 COMESA member governments to launch the new policy, and then securing consensus approval subsequently to make future changes in the policy if new information about GMO risks should appear, or when attractive new GMO food and feed crop technologies become available to farmers in the region. To provide some of the policy flexibility lacking in the single fixed regional policy approach, a third approach, modeled somewhat after the regional system of EU.

Variant of the Generalized System for COMESA

One possible variant of the EU approach that might work for COMESA countries would be as follows:

Within COMESA, as individual member governments develop their own working GMO crop biosafety approval systems at the national level, the COMESA Council will designate them as approved "application points." Initially, there may be only three or four such designated countries in the COMESA region, but the number would grow as biosafety capacity grows. Applications for the commercial release of GMO crops would first be made at the national level, to biosafety regulatory authorities in the designated countries.

If approved at the national level, an application would then be forwarded to COMESA headquarters, which would share the application with the national biosafety committees of all the other designated application point countries. If there were no objections raised, the original national approval would then be generalized to the entire COMESA region. If objections were heard, the issue would be taken up by the COMESA Council, and only if the Council then gave its approval would the national approval be generalized region-wide.

The three policy options summarized in this Background Paper represent only a highly preliminary first attempt to imagine the complete range of regional GMO policy choices that might be available to the COMESA countries. A more complete and extensive review of such choices will have to await close discussion with a wider range of officials and stakeholders in the region.

STRATEGIC APPROACHES TO REGIONAL COMMUNICATION FOR BIOTECHNOLOGY AND BIOSAFETY

Experiences from African Biotechnology Stakeholders Forum (ABSF) and Kenya Biotechnology Information Center (Margaret Karembu, ISAAA)

Overview

The African Biotechnology Stakeholders Forum (ABSF) was established in 2000 by a group of stakeholders who were concerned about increased negative publicity on biotechnology in Africa from foreign sources. The Forum was established to focus specifically on public education and awareness creation in biotechnology and related issues. This was as a result of acknowledged dearth in knowledge among the public and policy-makers coupled with a weak dissemination mechanism of balanced information to guide the decision-making process. The scenario left the public and decision-makers amenable to manipulation by anti-biotechnology groups who preyed on ignorance of African citizenry to propagate unfounded propaganda, aimed at creating fear and anxiety about the technology. This did not only impede policy formulation and technology development, but discredited the role of science and technology (S&T) in addressing livelihood challenges in Africa where technology needs are overwhelming. In carrying forward her agenda,

ABSF has a formal collaboration with the Kenya Biotechnology Information Centre (KBIC), one of ISAAA's network nodes of Biotechnology Information Centers (BICs) affiliated to the Global Knowledge Center on Crop Biotechnology (KC) based at the ISAAA SEAsia Center in the Philippines. This (KC) is a science-based information network with a global mandate that promotes public understanding of advancements in science and technology especially in the area of biosciences. The BICs, which are strategically located in developing countries, respond to specific national information needs and promote networking and partnership-building in producing, repackaging and disseminating science-based information between and among major stakeholders in agriculture and related fields. In Africa, ISAAA facilitates three other BIC's, one in Egypt (E-BIC) for the Arab-speaking Africa, one in Mali (M-BIC) for Francophone Africa and a joint venture in South Africa with AfricaBio. In carrying out the outreach program, ABSF and KBIC liaise with other existing programs and organs in the region to avoid duplication of effort. Individual and organizational membership spreads across boundaries and regions and goes as far as the US, East, West and South Africa. The Forum has established legal recognition in Kenya with sub-regional nodes in Ethiopia, Tanzania, Uganda, Malawi and Zambia.

Achievements

Since KBIC and ABSF's collaborative initiative started, both have worked hard towards addressing public and stakeholders' knowledge and concerns on advancements in biotechnology in Kenya and across Eastern Africa. Approaches and methodologies used include: stakeholders' sensitization workshops; scientific shows; traveling workshops; agricultural exhibitions; outreach to parliamentary working groups; and repackaging scientific materials by simplifying and translating into local languages to suit diverse audiences. Both electronic (radio, TV, internet) and print media (newspapers, newsletters, flyers, targeted mail) have also been used with great success. Notable achievements include: facilitating drafting of the Kenya Biotechnology Policy and Biosafety regimes; enhancing parliamentarians' understanding of biotech issues, hands-on training of several journalists with increased balanced media coverage and attention given to local issues from local sources (scientists, farmers, policy-makers); identification

of information gaps and education needs through national surveys thus guiding implementation of need-based and targeted outreach activities; demystifying biotechnology through scientific live-show demonstrations and exhibitions; and, facilitating experience-sharing through traveling workshops for farmers, journalists, policy-makers and researchers.

Linkages with global, regional and national networks both in the South and North, and, between public and private institutions have been created. These (linkages) have filled a vacuum that was hampering the exchange of experiences in biotechnology as well as enhancing knowledge of scientific and human capacities' availability. An important lesson learnt is that a well-coordinated, science based information network can activate informed debate, enhance public confidence in science and facilitate policy development thus creating an enabling environment for integrating biotechnology into the development agenda. The ABSF and KBIC outreach activities in East Africa have clearly demonstrated that expanding the knowledge-base and facilitating a dual experience-sharing initiative among key stakeholders can stimulate informed decision-making and harmonization of policies necessary in speeding up the adoption process. Arising out of the realized positive impacts of ABSF and Kenya Biotechnology Information Center, efforts are now being directed at up-scaling the Kenyan outreach experiences to the rest of the sub-region. This is in line with renewed commitment to revive the East African Community and particularly important now that Kenya recently launched a state-of-art Level-2 Greenhouse, a facility expected to stimulate growth and deployment of biotechnology in the region. A well- balanced communication strategy that facilitates information exchange on experiences from comparable and like-minded regions such as Southern Africa and South East Asia where small-scale farmers are leaping real benefits from adoption of GM crops forms part of an effective mechanism towards this endeavor.

Strategic Approaches to Communication for Biotechnology and Biosafety (J. Webster, AfricaBio)

AfricaBio Mission

- To promote the safe, responsible and ethical use of biotechnology and its products.
- Non-profit, non political, stakeholder biotechnology association supported across the food chain from technology developers to end-users

AfricaBio's role

1. Make available accurate information.
2. Encourage **informed** debate.
3. Promote safe, ethical and responsible use of biotechnology.
4. Interact with government and civil society.
5. Interact with international bodies.
6. Provide education and training.
7. Stimulate new biotechnology development

Approach taken by AfricaBio

- AfricaBio has public mandate to provide information on biotechnology (>40% respondents in independent survey wanted to receive information from a biotechnology association)
- Hands-on participatory methodology used for explaining biotechnology in communities

Key Activities

1. Stakeholder outreach
2. Training communicators
3. Developing communication materials
4. Situation analyses of South Africa and the region
5. Regional communication campaign
6. Demonstration projects that consumers, farmers, health care workers and decision-makers (political and industrial) can relate to (using GM maize, Soya and cotton). Will also be showcased to key decision makers in Africa.
7. Regional newsletter/website

Biotech acceptance

1. General issues
2. Biotechnology communication models
3. South African acceptance of biotech
4. What have we learnt?
5. Way forward

Why develop a biotech communication model?

1. Issues of biotechnology and biosafety have become central in policy development
2. Massive biotechnology misinformation campaign
3. Need for proper biotechnology communication campaign at the various stages of policy development in the African context

Case Study: Regional Public Awareness and Dialogue programme

1. Southern African project involving, Zambia, Malawi, Namibia, Mocambique, Zimbabwe, South Africa

2. Used external and internal communication tools

Role of Communication

External communication is concerned with the flow of information from the project to those who will benefit from its results.

Internal Communication

Internal communication involves the flow of information between the project team. Just as important as external communication-spokespeople need to be informed-each project member is a potential spokesperson.

Communication Strategies

1. Visually demonstrating the effectiveness of the technology
2. Strategic use of the media
3. Appropriate framing of messages for different target audiences
4. Continuously monitoring public perception
5. Established in 2001 to:
 - To provide accurate information on biotechnology.
 - To build capacity to communicate on biotechnology.
 - To link to and strengthen existing institutions, organizations, programmes.
 - To share what we learn in Africa.

Lessons Learnt

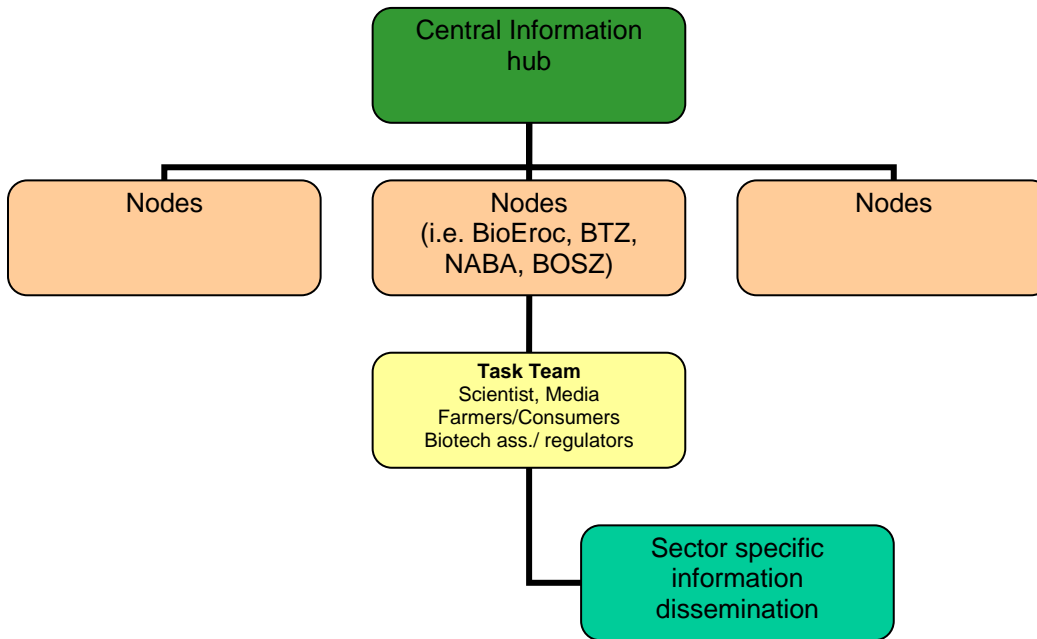
- Awareness raising is a continuous process
- Public understanding is a prerequisite for public acceptance
- Credible factual reference points are required (have you got a mandate)
- Issues need to be separated and addressed individually

Model Developed

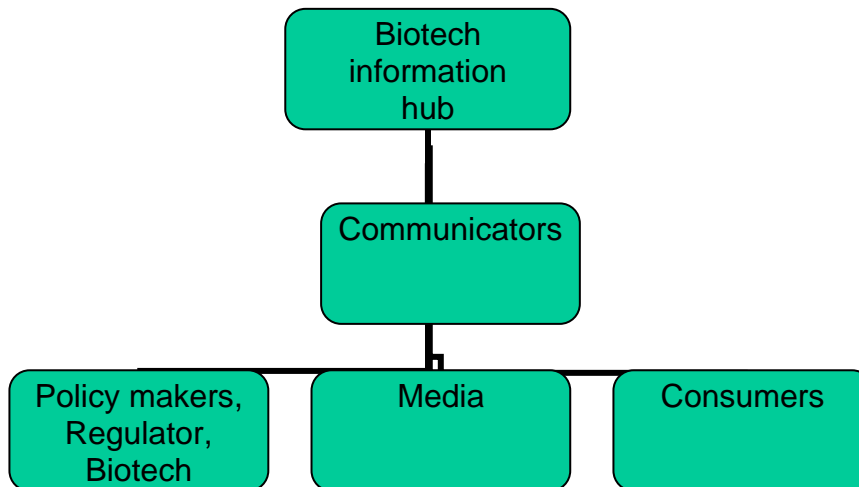
- Multi stakeholder approach – scientists, regulators, farmers, consumers, media, biotech ass.
- Tailor made materials for each target audience
- Multi-pronged approach to material development
- Promoting dialogue as opposed to debate

Highlights

- Development of a regional biotechnology message
- Establishment of networks across the region – BioEroc, BOSZ, NABA, BTZ
- Biotechnology Communicators Manual
- Decision makers booklet



Model for Information flow

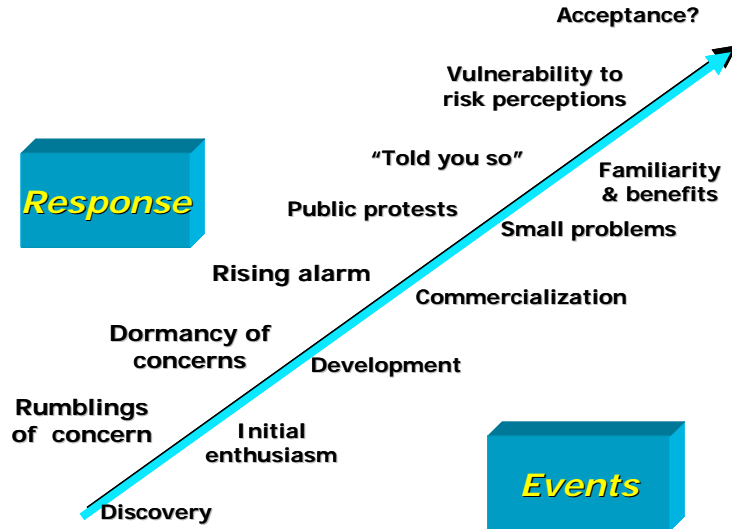


South African Experience

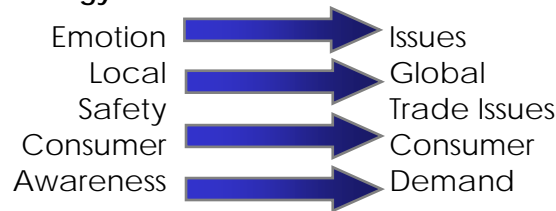
1. Public input is required throughout the policy development process
2. Start with the decision makers and opinion leaders
3. Credible, comprehensive information
4. Both generic and targeted information for variety of audiences
5. Carefully monitoring target audience and public reaction and media coverage.
6. any communication efforts centered solely on the scientific perspective are likely to experience little impact or possibly even detrimental results

7. the scientific response does not address the public's concerns, and reduces GM agriculture to a question of science, while ignoring other social, political, or ethical perspectives.
8. reliable and timely indicators of the changing opinion and media environment

The Road to Acceptance



Evolution of Biotechnology



What should stakeholders be doing?

1. Promote Acceptance:
 - a. Consumer / Social benefit
 - b. Information /Education
 - c. Transparency and choice
 - d. Confidence in regulations
2. Prevent Rejection
 - a. No incidents
 - b. Rapid and effective response to problems

Factors Affecting Consumer Attitudes Toward Biotechnology

1. Awareness
2. Information Sources
3. Education
4. Trust
5. Perceptions on Food Safety
6. Terminology
 1. "Biotechnology" - not "GMO"

Communication Strategies for Biosafety Policy Advancement (Adrienne Massey, PBS, Capacity building)

Fundamental Principle for Effective Communication

Whether the information being shared is complex or simple, a remarkably simple guiding principle governs effective communication:

To achieve the desired objective, the communicator must deliver the right information to the right audience.

In spite of its simplicity and commonsensical quality, this overarching strategic approach to communication is rarely used - except by companies attempting to sell a product - and becomes more essential as the flood of available information makes it increasingly difficult to capture the attention of your target audience.

Therefore, to be effective, communicators need to adopt a marketing mindset, even if they are not interested in selling an idea, agenda, policy or position. The communicators' objectives can be as neutral as sharing information for the sake of sharing information, notifying the public, or helping nonscientists understand a technical topic, but if they shy away from using the marketing approach as their fundamental approach to communication, information transmission will be inefficient and ineffective. The marketing mindset focuses primarily on the information needs and wants of the information consumer, not the information "seller."

A number of operational steps follow logically and sequentially from the fundamental principle of effective communication. The first step is to define the objective(s) as precisely as possible. The nature and details of the objective determine the audience (s). The interests and character of the audience define the information content and guide the shaping of the information, its packaging, and identification of the most effective conduit for getting this precisely tailored message to the targeted audience.

Effective Biotechnology/Biosafety Communication

Given the guiding principle described above, it is obvious that each country must develop its own biotechnology/biosafety (BT/BS) communication plan. One size definitely will not fit all, because the decisions that are made at each step in the process - defining primary and secondary objectives, deciding on the target audiences, shaping content, etc. - vary according to the country's position along the continuum of BT/BS development.

Even so, some general rules do apply. First of all, the process that is used in developing a strategic communication plan can be identical across countries. In addition, all countries will share certain tenets that guide effective biotechnology/biosafety communication, and certain key messages are applicable for all audiences.

A Few BT/BS Communication Tenets

- When it comes to effective communication, there is no such thing as the "general public." The general public is composed of many subpopulations whose information needs/wants vary from one subpopulation to the next and over time.
- Content choices should be driven by what the audience needs/wants to know, not what you think they "should" know.

- Attitude/style/intention trumps content quality. Content truth is secondary to a trusted voice. However, you can't fool the public for very long, so always tell the truth. Once you lose their trust, it doesn't matter what you say.
- Respect irrationality but do not assume that scientific and historical facts do not matter to someone who seems irrational. Empathize with them, but also respect them enough to give them useful information...and continue to respect them if they opt NOT to use it.
- Always place biotechnology/biosafety in a relevant context. It makes no sense to talk about biosafety without placing it in the context of biotechnology development. It makes no sense to talk about biotechnology without describing the evolution of biologically-based technologies that have now culminated in modern biotechnology. Paralleling the evolution of biotechnology has been an evolution of biosafety regulations.
- Recognize that you are not starting at ground zero. There is pervasive misunderstanding of modern biotechnology that is rooted not only in misinformation that is spread, knowingly and unknowingly, and a lack of familiarity with agriculture, especially its historical development. However, this content-based misunderstanding is exacerbated by emotions that may or may not have a factual basis.
- The misunderstanding is more widespread than you expect. For example, some plant breeders are anti-biotechnology because they fear biotechnology will replace plant breeding. Plant breeders function very well without biotechnologists; biotechnologists depend on plant breeders if they expect their research to be turned into useful products.
- Misunderstandings and misperceptions must be addressed first. If they are not dealt with, any additional information that is shared will be placed in a faulty mental framework.
- The "public" deserves more respect than it is given. Helping them learn *how* to think about BT/BS – which is essentially teaching them how to think like a scientist – rather than *what* to think is a gift whose benefits extend well beyond biotechnology/biosafety.
- Do not confuse the media or activism with the public. Consumer activism does not necessarily reflect consumer attitudes. All consumer groups or environmental groups are not the same. Just as the public is a composite of many different publics, the activist community is diverse.
- In every audience there is always someone who is open to new information.

Some Key Messages about BT/BS

- Modern biotechnology is the next step in a continuum of technological change, which is characterized by greater understanding of biology and increased "unnaturalness."
- The same holds true for genetic modification. We have genetically modified virtually all plants, animals and microbes that we use. At first we did not know genetic change was occurring and our modifications were not directed. Over time, our actions became purposeful, but were still devoid of any understanding of the mechanics underlying our manipulations. As such the manipulations were less precise and the results less predictable.
- There is no such thing as zero risk, and scientists can never prove something is 100% safe.
- The risks or costs of developing and using a technology must be compared to those of not developing or using it. There are always costs in using a certain technology, many of which can never be predicted *a priori*. However, the hidden costs of not developing and using a technology are often more deeply hidden. The risks of a

technology will always seem greater to someone who has never experienced the costs of not having that technology.

- Modern biotechnology does not equal genetic engineering. Modern biotechnology is a set of technologies, all of which are based on the use of cells and biological molecules.
 - Biotechnology is a set of tools, not a set of products or an industry.
 - The inherent nature of modern biotechnology makes it a very flexible set of tools and does not automatically restrict its application to rich countries and large farmers.
-

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About the Program for Biosafety Systems

The program for Biosafety System (PBS) is implemented by the International Food Policy Research Institute (IFPRI) based in Washington DC. The program operates in a number of regions in Africa and Asia. East Africa is one of the beneficiaries where the focal countries are Kenya, Uganda and Tanzania.

The purpose of the program is to facilitate select countries strengthen capacity to operate their biosafety systems efficiently and in accordance with national, regional or international policies and legal frameworks. The thrust of PBS is to foster Biosafety decisions making based on scientific facts and sustainable development strategies so as to support responsible development and safe use of agricultural biotechnology.

PBS is demand-driven and extends its support through four components: biosafety policy development and analysis of alternative models; Environmental Risk Assessment and Risk Management Research; Assistance with Regulatory Packages and Communication, Outreach and Capacity Building. IFPRI coordinates a dynamic consortium of international expertise from different institutions to take charge of these components.

PBS works with regional and national partners. Within the individual countries the program is links with a range of government and private organizations including councils of science and technology, agricultural research systems, crop inspection departments, ministry of health, national bureau of standards, universities and other bodies that may have a biosafety related responsibility. The program is guided by Country/Regional Advisory Groups that include mostly members of national biotechnology/biosafety advisory committees.



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