



Program for Biosafety Systems (PBS) in East Africa
Annual Report October 1, 2004 – September 31, 2005



Workshop for “Evaluation of Biosafety Applications” Jinja, Uganda

**TECHNICAL REPORT COMPILED BY
PBS REGIONAL OFFICE**

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1. Abstract – Scope of work

A series of activities have been carried out regionally and nationally in accordance with the East Africa regional work plan for 2005 (Appendix 1). The thrust here is to assist participating countries and the East African region as a whole to progress towards attaining efficient and functional biosafety systems. The current strategy is to assist countries have both regulatory and technical capacity to conduct confined field trials of transgenic crops. This effort is augmented by support towards risk assessment, risk management and risk communication. Activities on policy development also picked up while specific policy related studies on economic implications of GMOs to the region and on legal comparisons continued. Trainings in food and biosafety assessment were also carried out. A Regional Strategic Plan was developed. The region participated in the BBI competitive grants and two proposals were selected for funding. Work plans for 2006 were developed.

2. Description of Activities

a) *Policy Development and Implementation*

Regional Policy Round Table

An East Africa PBS Biosafety Policy Roundtable took place on 18th to 20th April 2005 in Entebbe, Uganda and was organized by PBS in collaboration with UNCST and NARO. The meeting provided an opportunity for countries of EA to exchange information on their biosafety policies and regulatory systems, reflect on regional and global regulatory parameters and discuss mechanisms to enhance efficiency through regional cooperation. There were about 50 participants. The topics presented in this first PBS roundtable featured discussions from Kenya, Uganda and Tanzania and these 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 biocology and biosafety
- Stakeholder perspectives and recommendations.

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.



Participants in the East Africa Policy Roundtable, 18th-20th April 2005, Entebbe, Uganda

Recommendations from the roundtable

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 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, or 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, it was apparent 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

- 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
- consensus needed on entry points for regional cooperation; after pointing out that countries are at various levels/understanding
- efforts are needed to ensure that research is linked to policy and decision making regimes
- it is important to 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 would save each country from trying to re-invent the wheel
- recognize broader need than country focus as seen that knowledge of science, technologies, and regulations will be shared across countries.
- recognize that East African borders are porous, hence possibilities of material moving from one country to another. There is therefore need to harmonize policies, inspection and administrative procedures and manuals
- workshop noted that one group understating such work is the EAC

Capacity building

- 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 required
- 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
- From the ASARECA-ECAPAPA experience with seed 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

Confined field testing

- 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

Communication

- 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.

From the meeting, and recommendations, some actions were identified and these included:

- Setting schedule and agendas for periodic meetings of the NBCs and their chairperson, with focus on particular documents, evaluations.
- 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.

Cost of Biosafety Regulations Study

This work was initiated for Uganda and Kenya. In Uganda, the work is being carried out in collaboration with NARO, and in Kenya with NCST. In both cases, local partners have been identified and collection of data started.

RABESA Initiative

This is a COMESA requested study lead by ECAPAPA, the policy arm of ASARECA. Other partners include PBS and ACTS. The study is designed to assess biosafety regulation in the context of macroeconomic, agricultural and trade policy. The participating countries include Egypt, Ethiopia, Kenya, Tanzania, Uganda and Zambia. The broad agenda of the RABESA initiative is to generate credible technical information that policy makers in the COMESA/ASARECA region need to make informed decisions and policy choices on biosafety and biotechnology. A regional workshop was held 11-13 July 2005, in Nairobi. The objectives of the workshop were to receive and discuss country food security, food aid, maize and cotton data in relation to GMOs; to receive and discuss commercial export risk related to growing GMO crops; to receive and discuss country presentations on stakeholder analysis in relation to biotechnology; to receive and discuss frequently asked questions and answers on GMOs and to discuss the structure, content and process of the national consultative meetings. The workshop developed the objectives of the planned national meetings, type of invitees and a generic agenda. It was agreed that the objectives of the workshops would be reviewed by COMESA if necessary and those proposed were:

1. To discuss the impact of biotechnology (GMOs) and biosafety on agricultural productivity, trade, and food security in the COMESA/ASARECA region.
2. To discuss the implications of national policy options on biotechnology and biosafety for agricultural trade promotion and food security.
3. To consider options for regional policy co-operation in biotechnology and biosafety in the COMESA/ASARECA region

The participants also provided input into the country report and consensus was reached on dates and on how to proceed with the national workshops that were regarded as critical for the overall success of the project.

Comparative Analysis of the National Biosafety Systems in East Africa

This study was initiated in 2004 and has continued during this year as a desk study. The study provided one of the key papers presented during the policy roundtable and starts by discussing components and characteristics of a good biosafety system and the international obligations relevant to biosafety. It provided insight on the key aspects of regulatory system in Kenya, Uganda and Tanzania and compares them across comprehensiveness, adequate law authority, the safety standards, socio economic considerations, proportionate risk-based review, public participation, transparency, scope of the biosafety regulatory systems and the interim regulatory systems. The paper also makes some comments on the African Model Law and makes suggestions on a path towards harmonization of biosafety regulatory systems in East Africa.

b) BBI Competitive Grants

East Africa participated actively and effectively in this year's call for pre-proposals. Eight pre-proposals from East Africa (Appendix 2) were selected for development into full proposals. Three proposals were on cotton while the other five addressed maize, sweet potato, rice, cowpeas and a vaccine for rift valley fever. The three cotton proposals were pulled together and eventually five full proposals were submitted for final consideration under the BBI Competitive Grants.

On final submission, two proposals were selected for funding and these were:

- Gene flow from cultivated rice (*Oryza sativa*) to its AA genome wild relatives in the East African region: key research for transgenic risk assessment. The proposal was submitted by three scientists including Samuel Kiboi, Margaret Nkya and Teklemaimanot Haileselassei from Kenya, Tanzania and Ethiopia respectively with a USA based collaborator Allison A. Snow from Ohio State

University. The three regional scientists were finalizing PhD courses at Department of Ecology and Systematics, Lund University Sweden with support from BIOEARN. The aim of the project is to enhance the safe introduction of promising GM rice varieties in Africa when possible ecological and evolutionary consequences of gene flow from cultivated rice to its wild relatives are better understood.

- Can *Bt*-cowpea be deployed in Africa without incidences on wild cowpea biodiversity and demography? The proposal was submitted by ICIPE, Nairobi, Kenya where the lead scientist is Remy S. Pasquet. Other collaborators include, Jeremy T. Ouedraogo, Sebsebe Demissew and Paul Gepts from Borkina Faso and Ethiopia, USA University of California Davis respectively. The overall aim is to facilitate the future deployment of genetically-engineered cowpea in Africa and to build capacity to carry out research related to biosafety of genetically-engineered crops.

An enormous amount of effort went into preparing the proposals. It appears one of the criteria for this CGS is “effect of biodiversity” and this is extremely difficult to fulfil unless the crop addressed originates from the area where the research is to be carried out.

C) Regulatory Approval Strategies and Consultative Guidance

Phytosanitary Inspectors Course

In the effort to strengthen capabilities of Phytosanitary Inspectors to enforce biosafety regulations, a course was conducted in Arusha, Tanzania from 7th – 11th February 2005. The training was organized by TPRI in collaboration with Donald Danforth Plant Science Centre (DDPSC). 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 and to enhance participants understanding of the concepts and issues associated with modern agricultural biotechnology. This course was a regional event, attended by 14 Tanzanians, 5 Ugandans and 4 Kenyans. A highlight of the course was a field exercise, in which the attendees evaluated the suitability of two sites for conducting CFTs of either maize or cotton. Including regional participants in this course at least partially met the requirements of training inspectors in the other two countries.

Tanzania: CFT workshops

In order strengthen capacity for technical teams expected to regulators CFTs, a three-day workshop was organized for Agricultural Biotechnology Scientific Advisory Committee (ABSAC) on 14th – 16th February at Bagamoyo, by TPRI in collaboration with DDPSC. Emphasis was on review and approval process for confined field trial applications; segments were also given to familiarize the participants with the guidelines and SOPs in place for conduct of CFTs in Tanzania. The participants obtained hands-on experience on the process of review and approval, and were able to identify areas for improvement in the application form for subsequent revision.

As a follow up to the ABSAC training, a one day briefing for members of the National Biotechnology Advisory Committee was organized by TPRI and DDPSC and held in Dar es Salaam on 18th February. Participants were briefed on the purpose and execution of CFTs, and on the training received by the inspectors and ABSAC that underpins the CFTs system in Tanzania. Several articles in the local press publicized the different workshops and addressed issues related to the development of GM crops in Tanzania.

The three consecutive training/awareness activities above (Appendix 3) highly improved the capacity for Tanzania to handle applications for introducing transgenic crops for testing under confined conditions. It is important to note that these trainings were preceded by preparation of documents necessary for regulating CFTs such as regulations in form of schedule 18 that was appended on the Crop protection Act, SOPs and

inspectors manual. Hence all these activities add up to Tanzania being ready to process applications for conducting CFTs .

Kenya: Training on Cassava CFT handling

In an effort to continue building skills for conducting confined field trials, a training of trial managers, technicians and inspectors on handling cassava field trials was held in Kenya in April 2005 at the site where GM cassava is presently being grown in a containment facility. This activity was organized in collaboration with DDPSC.

Uganda: Guidelines for Confined Field Trials

Internal meetings were held between NARO, UNCST and the Phytosanitary officials to synthesize requirements for Uganda before it can undertake CFTs. In this regard PBS was requested to assist with production of vital CFT documents including guidelines, inspectors' manual and biology documents pertaining to Uganda specific needs.

In June 2005, a team of Ugandans working under consultative guidance from DDPSC developed draft guidelines, standard operating procedures (SOPs) and a banana biology document required for conducting confined field trials. These documents were presented, discussed and reviewed by a technical team in a workshop held in Entebbe in July. The technical workshop was followed by one-day meeting with NBC members and other senior managers to brief them about the developed documents and capture their contributions.

These documents are now ready for presentation to the NBC for approval and thereafter they will be appended to the National Biosafety Guidelines. Plans are also underway to finalize the priority crops' biology documents and inspectors' manuals.

Uganda: Containment facility consultancy

On request from NARO Uganda, Hector Quemada, leader for the BBI component, worked with the NARO Engineer and in consultation with NARO scientists, ABSP II and USAID Uganda to design a cost effective and desirable biosafety containment facility for Uganda. The report with the recommended structural design and bills of quantities has been submitted to NARO and to USAID Uganda Mission. The construction will be funded by ABSP II and the structure will be located at NARO's Biotechnology Centre in Kawanda Agricultural Research Institute. This structure will be a significant contribution to NARO capacity and will enable research on GM plants that may be imported into the country or produced locally.

Uganda: Application for introducing banana plantlets resistant to black sigatoka

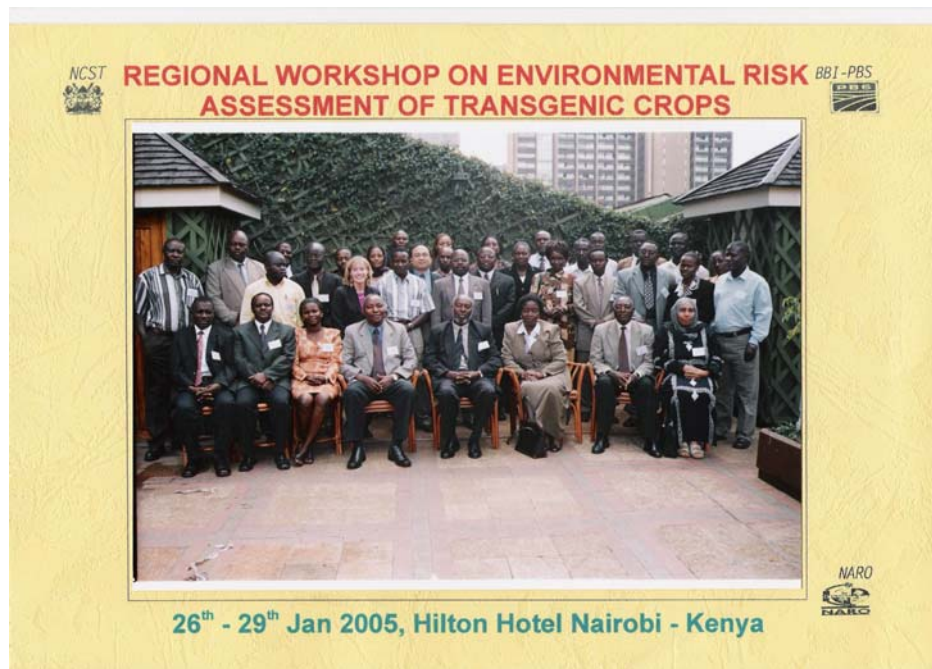
Two Ugandan scientists participated (this is also partly training) in filling an application form for introduction of GM banana plantlets resistant to black sigatoka in Uganda. This activity was carried out in September 2005 in Belgium and involved two consultants provided by DDPSC, two Ugandan scientists and the scientists from Luverne Belgium. ABSP II was involved in identifying these consultants and developing their terms of reference. The application was forwarded to NARO who in turn submitted it to the NBC. Preparing the application form was an important step for initiating testing of GM materials in Uganda.

d) Technical Training on Biosafety and Food Safety

Environmental Risk Assessment for Genetically Modified Plants

A regional workshop was held on January 27 and 28 in Nairobi, Kenya (Appendix 4). This workshop was designed to strengthen the base of expertise of key personnel in the region in the area of risk assessment, risk management, and risk communication with a focus on priority research areas and products for the region. Case studies of environmental risk assessment of GM crops likely to be used in Eastern Africa were discussed and participants took time to review priority research areas and other activities pertaining to risk

assessment and risk management. 38 participants from Kenya, Uganda, and Tanzania were in attendance. These participants were researchers and other personnel expected to conduct the actual risk assessment and advise regulatory agencies on risk management. This meeting was organized in collaboration with the Kenya NCST. Technical input was mainly by Hector Quemada and Karen Hokanson (BBI component managers) of PBS while ISAAA-Kenya contributed on risk communication.



The training contributed to improved knowledge on the concepts of biosafety research in the region and this was reflected in the quality of research proposals later submitted for competing for the Biotechnology – Biodiversity Interface grants

Safety and Risk Assessment of Foods and Feeds Derived from GM Plants

These workshops took place on 2 – 3 and 5 -6 May 2005 in Uganda and Kenya, respectively. These events were organized in collaboration with International Life Science Institute (ILSI). The objectives were to provide participants with a better understanding of how to assess GM food safety and contribute to building a core of expertise among regulatory scientists, administrators, and decision makers in GM food and feed safety assessment. About 20 participants from each of the three countries attended. Participants commended the course but pointed out the need for more training; short-term for regulators and long-term practical training for the scientists involved. The need for frameworks to deal with GM food and feed products was also raised.

Uganda: Master of Science training in biosafety and food safety

Three Ugandan students were awarded scholarships for Master of Science training in Molecular Biology, Environmental Safety and Food Safety under Makerere University of Kampala. The scholarships are sponsored by USAID under the Uganda Associate Award. Course work started in September 2005 and the thesis research to be concentrated on in the second year of the course.

MSU Food Safety and Biosafety Courses (July-August 2005)

One scientist from Kenya Bureau of Standards participated in the MSU courses on food safety and biosafety.

Biosafety Internship at MSU (Sept 2005)

Dr. Stephen Mugassa of University of Dar es Salaam attended a one-month internship at MSU, USA from August to September 2005 (Appendix 5). During his internship he developed a curriculum to aid teaching “Biosafety, Bioethics and Biopolicy Course” at the University. He also developed special modules to offer continuing education programs for the regulators, decision makers and other stakeholders. In the coming year, a seminar to discuss the developed biosafety curriculum will be organized for university academicians from the three EA countries.

e) Communication Strategies and Outreach

The PBS component leader for communication and capacity building (Adrienne Massey) visited the region from 11th to 22nd March 2005. The purposes of this visit were to familiarize herself with the biotechnology/biosafety communication status in Uganda, Kenya and Tanzania and discuss how she could contribute to the development of the communication strategy proposed in the work plan. During her ten days stay Adrienne held productive discussions with government officials, NGOs dealing with communication on biotechnology and also visited USAID country missions. Adrienne gave seminars on communication by scientists, the challenges faced and how these can be tackled. Follow-on activities identified after this initial visit include joint communication training activities and development of communication strategic plans for each country. Local partners for the PBS communication activities for the three countries were identified.

f) Eastern Africa Regional Strategic Plan

A retreat was organized on 9 –12th June 2005 in Kampala to develop a draft PBS East Africa Strategic Plan. Participants included regulators from partner institutions from each of the three countries. Following this retreat, three consultative meetings were held on 5th September for Uganda and 6th for Kenya and Tanzania to review the draft document. Participants in these meetings included NBC members, representatives from research institutions, university academicians, consumer representatives and inspectors from Phytosanitary Departments. During the meetings, strategic partnership was stressed as a cornerstone for the success of PBS. Also, increased emphasis on information packaging and dissemination was highlighted and in response the program has proposed to develop an information hub in the 2006 work plan. The final draft of the strategic plan is provided in Appendix 6

g) PBS Management: Regional Advisory Group

The regional advisory group was kept informed about program activities. Uganda advisory group, a ten-person team, was appointed and entrusted with guiding the implementation of the country project.

A quarterly circular entitled “PBS East Africa Activity Highlights” was initiated and this provides on-line communication on accomplished activities, up-coming events and news items. The newssheet was initiated because of the interests, questions and concerns about program work.

In the forth quarter, a planning meeting to develop the program work plan 2006 for the Uganda AA was held with participation of ABSPII and APEP. Special attention was paid to synergy between these three USAID funded biotechnology programs.

Kenya: Establishment of NBC Secretariat and functional equipped office

Purchase of office equipments including 10 computers was accomplished and these were distributed to the regulatory agencies. Development of a website and database for biotechnology and biosafety in Kenya was initiated.

3. Networking and linkages with stakeholders

Dr. Joel Cohen, PBS program director, visited the region from 11th –23rd March 2005. During his stay he held productive meetings with many PBS partners, country missions and was able to exchange views with key participants of the upcoming policy round table. The Regional Coordinator joined Joel Cohen and Adrienne Massey during visits to Kenya and Tanzania, from 17th to 23rd March 2005. Objectives were to: Touch base with the country advisory groups and other partners to track progress on project activities; to participate in discussions on the prospects and plans for the communications activities to be initiated; and, take advantage to participate in the visits to the USAID Missions in the two countries to be more familiar with the donors at the country level and their views on the progress and plans of PBS.

The regional coordinator attended the Preparatory Seminar for the 2nd Meeting of the Cartagena protocol on Biosafety held 3-4th March at DDPSC, Saint Louis. The main message here was the challenge to public sector scientists in the various countries to hold discussions with officials who attend these COP meetings. It is important that the negotiators are fully informed about the opinions and needs of public sector scientists pertaining to the Cartagena Protocol.

4. Assessment of progress made during the reporting period

This year, progress on implementing the proposed activities was satisfactory. All regional planned activities and most of the Uganda work was on course. Besides participating in the regional activities, substantial effort in Kenya was on preparing a new project to be supported by the Kenya Mission as an Associate Award. In the case of Tanzania resources are the main limiting factor as no additional funds are yet secured besides the limited support from the EGAD.

Special effort needs to be paid to Tanzania where very little progress is being made due to lack of resources and unworkable operational modalities. For example the country could not implement the approved in country consultative workshops and develop the communication strategy largely because the funds were not provided. It is urgent for Tanzania to develop an MOU/sub-agreement with IFPRI so that funds can be transferred for in-country expenses relating to the approved program activities.

Appendix 1

East Africa Work Plan 2005

\$454,915¹

1. Purpose and Objectives for EA Regional Plans

This work plan will enable the participating countries and the East African region as a whole to progress towards attaining efficient and functional biosafety systems.² During the first year of PBS implementation, country programs were developed for Kenya and Uganda. This work plan presents activities that are to be done regionally and nationally. Proposed activities have been identified through consultations with stakeholders and have been discussed and endorsed by regional and country advisory groups. Focal point persons have been involved in defining these activities. Whenever appropriate, APSP11 will be a partner in implementing the project activities.

2. Proposed Regional Activities for 2005

2.1. Eastern Africa Regional Strategic Plan: Gap analysis

Developing the Eastern Africa PBS strategic plan is an important activity for 2005 that also responds to a request from the AEB. This activity will provide for gap analysis for biosafety systems in the region giving due consideration to existing country and donor efforts in this area. Priority needs that can be covered within the PBS portfolio will be consolidated and further developed to spell out how they will be addressed to achieve the target outputs and outcomes. Strategic partnerships (including ABSP-II) will be identified/formed specifically articulating how PBS presence in the region will benefit other ASARECA countries. The strategic plan will be a useful instrument for guiding the implantation as well as the monitoring and evaluating the impact of the program. The strategic plan will be the basis for the annual work plan for the subsequent years of the project.

The current country workplans will also be reviewed during this process. As different countries and regional strategies occur at different times, this provides an opportunity for further integration. Additional regional activities will come from the East Africa Regional Advisory Group during this analysis. These will then be implemented in-country, given restrictions on budgets, in a prioritized manner. This process will also include the RABESA initiative (see later), as well as the East African regional policy roundtables. In addition, Tanzania will come into the process, as their country plans are finalized. The regional advisory group is well represented from all countries, and SROs. However, new activities identified will have to look for new funding, as the regional activities are funded through EGAT. Below are listed identified activities, during which the countries will be brought together, and begin the opportunity of comparative analysis and sharing of national information. Finally, results from national program work will be brought to the regional advisory group, and further uptake, dissemination and use will be discussed.

2.2. Supporting Policy Development and Implementation

A number of policy studies — such as those on regulatory costing, legal frameworks, and trade implications of GM adoption — were initiated in 2004 and will continue in 2005. The regional policy round table proposed for last year will be held in April, 2005. From these activities it is expected that more

¹ This amount is from EGAT funding.

² To fulfill these obligations, as well as work for Kenya, Tanzania, and Uganda, an increase in Theresa's time is expected. Negotiations are underway with all parties, to see how this can be done. At this time, it is suggested this can be accomplished by agreement with NARO that Theresa become a NARO-seconded employee to PBS. Details to be completed first quarter.

beneficial policies and efficient regulatory modalities for multi-country use will be generated for further discussions and probable adoption. Specific activities include:

- Cost of biosafety regulations studies , focusing on GM products identified by national project partners;
- Policy round tables, identifying biosafety implementation challenges and options, and opportunities for regional collaboration and exchange;
- Develop methodologies and initiate implementation of a study that will assess biosafety regulation in the context of macroeconomic, agricultural and trade policy. Includes trade to sensitive areas and labeling issues.
- Legal analysis of the biosafety frameworks in East Africa

2.3. Regulatory Approval Strategies and Consultative Guidance

Countries of EA are already receiving or expecting applications for introducing GMOs and this is mainly for evaluation under contained or confined field conditions. It is important to help such countries make well-informed decisions that are science based and favor sustainable economic advancement. The requests put to PBS so far have been for building capacity for evaluating applications with emphasis on GM products that are likely to be handled in the region and this include products ABSP-II is planning to work with. Training courses on reviewing applications for confined testing of GM plants have been conducted in the countries by PBS. Follow on activities to progress towards implementation of the confined field trials are proposed in this work plan.

In addition to the country-specific activities, PBS will organize a workshop on confined field trial compliance and inspection as an East Africa regional event in 2005, for inspectors of the anticipated confined field trials from Kenya, Tanzania and Uganda.

2.4. Technical Training on Biosafety and Food Safety

The region lacks expertise for food safety assessment specifically for GM food. The regulatory system for GM food is absent or not adequately articulated in the different countries of the region. Country food safety training courses are proposed. The MSU food safety training opportunities could be used to train trainers who would also develop University curriculum for a post graduate food safety course back in the region. This activity will contribute knowledge on safety of GM food products.

Associated with the BBI program, a regional training course on risk assessment and risk management research is proposed to enhance expertise in this area. Products of interest to ABSP-II will be a direct relevance to this course. The other activities proposed are tailored to BBI and include a meeting for pre-selection of concept notes and supporting identified partners to meet and interact as they prepare the proposals.

2.5. Communication Strategies and Outreach

There have been various efforts to communicate biosafety in the region, but there continues to be a great need to disseminate factual, impartial information. During 2005, PBS plans to review the communication efforts that have so far been carried out in the region with due consideration to the different approaches used. The outcome of the review will help to design country communication strategies. PBS also proposes to conduct a short training course on communication for biosafety spokespersons in the ECA region. This effort will contribute to developing country-specific mechanisms to communicate effectively with the public and with the media.

2.6. PBS Management: Regional Advisory Group

The regional coordinator has responsibility to work with the advisory group before and after the annual meeting to ensure familiarity with all undertakings. The Regional Advisory group specifically recommended regular communication and providing of information to project members and other stakeholders and this activity will be undertaken during the year.

In addition to working at the sub-regional level, PBS has earmarked funding for in-country work in Kenya, Uganda and Tanzania. Based on the multi-year proposals approved for each country, specific activities are summarized in the following sections.

Kenya Work Plan

\$142,307³

1. Purpose and Objectives

Kenya's overall development goal is to build a functional national biosafety regulatory system by establishing a biosafety management system, strengthening capacity building to ensure safety of bioengineered products, including their import or export, handling, transport and use in country. The overall objective is to assist the Government of Kenya in building human and infrastructure capacity within the principal regulatory bodies: Public Health, KEBS, KEPHIS and DVS. This would help to efficiently and effectively carry out risk assessments and monitoring of biotechnology products, including (but not limited to) GMOs or LMOs. Specific objectives for development between NCST, national stakeholders and PBS are to:

- Enhance the human resource capacity within the regulatory agencies to carry out and oversee technical and support functions in biosafety operations and risk assessment;
- Facilitate and enhance acquisition (within regulatory agencies and the NBC) of technical information on GMOs to assist in risk analysis or assessment;
- Facilitate close and effective collaboration and linkages among the regulatory agencies (plant and animal health and food safety) as well as with more advanced research laboratories, donors, and other stakeholders, particularly in the area of biosafety;
- Develop protocols for the regulation of GMO products, and;
- Enhance policy decisions for and analysis of regulatory options for Kenya, and as related to its neighbouring countries.

2. Rationale and Gap Analysis

A study of the Kenyan biosafety system was undertaken in 2002-2003, applying the conceptual framework for biosafety systems. The report⁴ identified the following gaps, which were taken into account in developing the Kenya work plan for PBS:

- There is need for development of expertise within regulatory agencies and funding for the necessary training for field inspectors, monitors, and laboratory technicians.
- In general, the NBC takes a cautious, single-minded approach to risk assessment. The reviews focus on risk alone, and give no consideration to benefits use of the GMO could bring, or to the risk of disallowing GMOs and therefore continuing to use conventional varieties and agronomic practices.
- For efficiency in NBC members, its secretariat and IBC members, it was suggested the necessity for more effective performance of their duties, there should be introductory seminar/training for members on

³ These funds are above the EGAT funding level, as provided by USAID/Kenya. The total budget exceeds the available funds by \$52,888. This is covered through the new Associate Award, which the mission has requested.

⁴ Macharia, H. and P.L. Traynor. 2003. Analysis of the Biosafety System for Biotechnology in Kenya: Application of a Conceptual Framework. Country Report No. 65. The Hague: International Service for National Agricultural Research.

- concepts and issues, RA/RM principles and procedures to optimize capacity on biosafety reviews.
- It was found that a summary of NBC deliberations on applications is made; there is no records of what question or issues were examined, no summary of pertinent findings, no technical justification to support the committee's conclusions, or how the recommendation was reached. The same is true for IBC committees. The lack of documentation could put the committees' work on trial should there be some problem arising from an approved activity.
 - There is also need on training on information exchange on biosafety both internationally, regionally and nationally.

3. Activities Planned for 2005

This plan is based on remaining items not fully accomplished in 2004, which will carry over to 2005. By end of 2005, all the items below should be accomplished.

3.1. Establishment of NBC Secretariat and functional equipped office

Purchase of essential equipment and office furniture will be completed by second quarter. Website and database development will be accomplished in the third quarter of 2005. Administrative support is handled on an as need basis.

3.2. Supporting Policy Development and Implementation

Regulatory institutions in Kenya are varied and include NCST, KEPHIS, Ministry of Health, Kenya Pests and Products Board, Department of Veterinary Services, Kenya Bureau of Standards, National Environmental Management Authority (NEMA in the Ministry of Environment, Natural Resources and Wildlife), the Attorney General's Chambers, and perhaps others (Kenya Industrial Property Institute, KIPI). Much work was accomplished here in 2004. New events will be determined for Kenya and consortium members and this will related to implantation of the proposed roles.

3.3. Regulatory Approval Strategies and Consultative Guidance

This part of the Kenya work plan builds on a strong foundation laid in 2004, through collaboration between NCST, KEPHIS and DDPSC, and includes:

- Conduct follow-up regulatory support to NCST and KEPHIS to consolidate earlier work on a new and improved application form for confined field trials
- Provide consultative guidance for public sector developers, or for developers of products supported by ABSPII, delivering on-demand services for all phases of product development from conception through laboratory and confined trials, to commercial launch. For Kenya, this includes support for the application and implementation of field trials with the 'second generation' set of genetic constructs for control of sweetpotato virus disease.
- Train inspectors of confined field trials on compliance, monitoring and enforcement, provided as an East Africa regional workshop for Kenya, Tanzania and Uganda.

Tanzania Work Plan

\$100,000 (approximately)⁵

1. Purpose and Objectives

Tanzania has submitted a four year proposal to PBS for support. Priority activities as outlined below will be supported for 2005 while the country will continue to benefit from regional activities. The goal of the Tanzania proposal is to build enabling environment for a functional biosafety framework in Tanzania. Specific objectives include:

- To conduct consultative meetings to review national biosafety framework for its implementation
- To build capacity and set platform for conducting confined field trials
- To enhance public awareness on biotechnology policy, biosafety and food safety

2. Rationale and Gap Analysis

There is a need to establish a functional biosafety system for Tanzania because of the growing number of applications for introducing GMOs into the country. In addition, neighboring countries already decided to allow the release of GMOs hence, introduction into Tanzania through unnoticed transboundary movement of plant material is possible. More importantly there is a growing demand for introducing *Bt* cotton in the Southern Highlands where cultivation of cotton is banned because of red bollworm.

The need for a functional bio-safety system is made more urgent by the fact that modern biotechnology applications and products of genetic engineering are increasingly becoming available on the market, especially agricultural products. The use of genetically engineered/modified (GM) crops in agriculture is now a reality and we are now beginning to see them being grown commercially worldwide. For instance, global area of GM crops reached 67 million hectares in 2003. In East Africa, Kenya is already conducting confined field trials of genetically engineered crops such as the virus-resistant sweet potatoes, insect resistant *Bt* Cotton and insect resistant *Bt* maize.

To apply GM technology to solve such problems requires capacity building in the field of risk assessment and management as well as socio-economic and ethical aspects associated with adoption of the GM technology. It is therefore, important to strengthen the national capacity in all subjects related to safe application of biotechnology.

In view of the above, it is now momentous for Tanzania to take steps, in collaboration with development partners to build a functional National Biosafety Framework that would facilitate the safe application of modern biotechnology in the country.

3. Proposed Activities for 2005

Tanzania, through a joint effort between TPRI, COSTECH and the Vice-President's Office, has submitted a four year proposal to PBS for support. The proposal is still under development, and will be finalized based on an in-depth analysis of needs and gaps for PBS assistance. Initial priority activities as outlined below will be supported for 2005 while the country will continue to benefit from regional activities.

⁵ EGAT funding, to be agreed upon.

3.1. Supporting Policy Development and Implementation: Stakeholder consultative workshops

Tanzania has finalized a draft National Biosafety Framework (NBF) under the support of UNEP-GEF in July 2004. However, this draft needs further consultations with stakeholders in order to discuss any concerns, incorporate good suggestions and eventually get this framework endorsed. Two regional consultative workshops are planned in response to this need.

3.2. Technical Training on Biosafety and Food Safety

In the area of food and feed safety a workshop targeting policy makers, scientists and officials responsible for biotechnology and biosafety is proposed. This activity is needed to contribute to developing consensus on GM good safety and the general principles of assessing for food and feed safety.

3.3. Regulatory Approval Strategies and Consultative Guidance

The focus will be on building capacity with newly established bodies in charge of the regulatory process and inspectors presently placed with the agricultural competent authority. This activity is expected to provide capacity required to design, implement and ensure compliance in confined field trials, and will include:

- Training Tanzanian regulators (ABSAC, NBAC) and applicants (TPRI), thus building capacity to write, review, and approve applications for confined field trials, and to design and implement these trials.
- Providing linkages and support to engage developers of key technologies (i.e., Bt. cotton) in dialogue with Tanzanian scientists and regulators, resulting in evaluation of those technologies in the country.
- Providing consultative guidance for public-sector developers or for developers of products supported by ABSPII, delivering on-demand services for all phases of product development from conception through laboratory and confined trials, to commercial launch.
- Training inspectors of confined field trials on compliance, monitoring and enforcement, provided as an East Africa regional workshop for Kenya, Tanzania and Uganda.

Uganda⁶ Work Plan

\$158,264

1. Purpose and Objectives

The proposed work plan for 2005 comes from the proposed activities of the country proposal, further discussed with PBS management during formulation of the Uganda Associate award. During October 2004, a planning meeting was convened by UNCST and the PBS Regional Coordinator to fine tune the project work plan in accordance with the available budget and come up with the first year work plan. The Program Director, two consortium members, USAID officials and the APEP biotechnology advisor and ABSP-II coordinator attended this meeting.

The goal of the Uganda Associate Award is to contribute to establish favorable environment for proper regulation for approval and use of products of modern biotechnology for research purposes, food or feed. The specific objectives include:

- To assist with advocacy for biotechnology and biosafety policy
- To strengthen the regulatory framework to facilitate implementation of confined field trials.
- To develop capacity for environment and food safety assessment through short-term trainings and MSc. courses.
- To improve awareness and improve communication skills on biosafety and food safety.

⁶ Funds made available from the Ugandan Associate Award.

2. Rationale and Gap Analysis

Uganda places high priority on the effective implementation of a national biosafety system, both to encourage the growth of domestic biotechnologies and to ensure safe access to new products and technologies developed elsewhere. The current absence of a strong regulatory framework hinders public and private sector investment in biotechnology and makes products of biotechnology unavailable in the country, and reduces the ability of development agencies to support investments in research.

USAID/Uganda, UNCST and PBS jointly defined important gaps and priority activities to strengthen the national biosafety system, which will include biosafety policy review and development, technical training in key skill areas of biosafety application and risk assessment, coordination of national institutional roles, and assistance in reviewing regulatory applications of genetically engineered crops. They will also include development and implementation of a strategy for communication and outreach activities on biosafety issues. PBS will assist technology development projects, such as the ABSP-II East African Highland banana project, and other biotechnology projects in development of regulatory packages for product deployment in Uganda. PBS/Uganda will coordinate with other biosafety capacity building projects, namely the ongoing UNEP/GEF implementation project and the regional BIOEARN program, in order to avoid duplication of efforts.

3. Proposed Activities for 2005

3.1. Supporting Policy Development and Implementation

The Uganda biotechnology and biosafety policy has been prepared. The draft biosafety regulations were prepared in 2000, reviewed and updated in 2003 and further advancement is waiting for government approval. Advocacy of the biotechnology and biosafety policy is critical to make sure that policy makers, implementers and the wider stakeholders appreciate and support its approval and implementation. In this regard PBS is proposing to engage in policy dialogues with members of relevant sectoral committees and top management officials in line ministries at national and regional levels.

3.2. Regulatory Approval Strategies and Consultative Guidance

The scientific community needs a favorable environment and guiding procedures to facilitate evaluation of GM materials that may be produced locally or introduced. The PBS program for Uganda is focusing on training regulators on procedures and requirements for confined field trials. The regulatory system itself needs review to specifically cater for field trials and PBS will work with UNCST to address this need. Specific activities will include:

- Provide consultative guidance for design, assessment and launch of contained testing facilities, and for drafting of confined field testing directive.
- Provide consultative guidance for public-sector developers or for developers of products supported by ABSP-II, delivering on-demand services for all phases of product development from conception through laboratory and confined trials, to commercial launch.
- Respond to request for consultative guidance from NARO, developers of transgenic banana in Uganda, building in regulatory considerations during product conception, planning and development.
- Train inspectors of confined field trials on compliance, monitoring and enforcement, provided as an East Africa regional workshop for Kenya, Tanzania and Uganda.

3.3. Technical Training on Biosafety and Food Safety

Some scientists have benefited from short-term courses on risk assessment and risk management but the overall expertise in this area are very minimal. There is need to build expertise and confidence among Ugandan scientists that there are able to analyze and advise on both environment and food safety of GMOs and derived products. The recent Uganda planning meeting strongly proposed formal training (MSc) to be undertaken for purposes of building capacity in biosafety risk assessment and risk management. The training will be based at Makerere University and assistance from MSU for this activity is being sought. For the effective implementation of biosafety and food safety regulations, capacity building of the government regulatory agencies is needed. In 2005, this priority will be addressed through related training activities, as follows:

- In-country food safety workshops in collaboration with MSU and ILSI
- Participation in the MSU biosafety and food safety courses

3.4. Communication Strategies and Outreach

There has been substantial effort to communicate biotechnology and biosafety to parliamentarians, government leaders and a cross section of stakeholders. This has encompassed discussions on policy, benefits and risks, international protocols, safety issue etc. The players have been many including concerned government departments, NGOs and academicians etc. However there is still a lot of misinformation on biotechnology in general and GMOs in particular. PBS is proposing to review the approaches that have been used and work with relevant players to come up with a revised communication strategy. PBS also plans to support public hearings and to produce communication materials on biosafety during 2005. PBS will work with ABSP-II in this activity. Study tours, particularly to developing countries where there are success stories are also proposed as well as producing and disseminating information materials.

Regional Policy Support: The RABESA Initiative

\$20,000 plus \$200,000⁷

1. Introduction

Developing countries in general and in particular the COMESA and ASARECA countries are at a cross-roads as to whether or not to embrace the rapidly evolving biotechnology and related products such as Genetically Modified Organisms (GMOs). This is a time when the African continent is faced with many challenges including declining agricultural productivity as well as increasing food insecurity. It has been argued that GMOs might have the potential to increase productivity, reduce costs of pesticides and labor, lower pollution of environment, reduced human exposure to chemicals and increase farm level incomes. Conversely, concerns have been raised about the potential ethical, environmental and food safety threats that GMOs may pose.

The pace at which ASARECA/COMESA countries are engaging in biotechnology is a cautious and precautionary one. This is being informed by the lag in their own internal policy and regulatory capacities for GMOs and fear of encountering difficulties in selling those crops in some of the international markets. On the other hand, the cost of not adopting GMOs might be too high for the COMESA countries. There is a likelihood of losing significant income gains and danger of not gaining access to emergency food aid from organizations such as the World Food Programme (WFP). Failure by the ASARECA/COMESA countries to engage in agricultural biotechnology is likely to increase biotechnology divide in the region. Also, the cost of establishing and implementing precautionary policies and biosafety infrastructure to assess risks that

⁷ The first figure comes from EGAT funds provided for Dr. Robert Paarlberg while the second figure comes from support for this initiative provided by REDSO.

might be posed by GMO crops and trafficking of GMO materials across international borders are other major challenges for COMESA countries.

While each country strives to establish the policy and regulatory frameworks on biosafety and biotechnology, few have the capacity to fully enforce them. This makes the need for a common regulatory approach and policy position in the COMESA region plausible through setting acceptable standards that could be automatically approved everywhere, even without any testing.

COMESA, ASARECA's Eastern and Central Africa Programme for Agricultural Policy Analysis (ECAPAPA), the African Centre for Technology Studies (ACTS) and the Programme for Biosafety Systems (PBS) have entered into a joint research agenda. The goal of the agenda is to support COMESA in exploring possibilities for putting in place a regional approach to biotechnology and biosafety policy in the region. In 1997, ASARECA created the Eastern and Central Africa Programme for Agricultural Policy Analysis (ECAPAPA) to increase the ability of individuals and institutions to influence and to apply agriculture policies; develop policy recommendations to inform the policy making process through data collection, analysis, dialogue and action; and provide policy information to a wide cross section of stakeholders. The Program for Biosafety (PBS) is a global programme that intends to effectively, address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade and environmental objectives. The African Centre for Technology Studies (ACTS) is an international intergovernmental policy analysis, research and training organization located in Nairobi, Kenya. ACTS seeks to harness science and technology for Africa's sustainable development. Since the mid 1990s, ACTS has been active in the arena of biosafety and biotechnology.

2. Project Objectives

The overall project objective is to document a balanced review of the technical information needed to inform COMESA's regional biosafety, policy choices responsibly.

Specific objectives include:

- a. Undertaking stakeholder analysis in the ASARECA/COMESA countries highlighting opportunities, challenges, views and positions related to their engagements in trade, GMOs and food security;
- b. Analyzing commercial risks that ASARECA/COMESA countries are likely to face in the destination export markets both regionally and internationally if permission to plant GMO crops was granted.
- c. Estimating impacts of GMO crops on farm income in the ASARECA /COMESA region;
- d. Estimating impact of precautionary GMO principles on access to emergence food aid and food security in the ASARECA/COMESA region; and
- e. Identifying a range of regional biosafety policy options for decision-making on issues of GMOs and trade in ASARECA/ COMESA countries.

3. Expected Impacts

The overall impact is to ensure improved food security and incomes in the agricultural systems in the ASARECA and COMESA countries through adoption of productivity enhancing technologies. The project will help to ensure that the ASARECA/COMESA countries have a balanced view of the costs and benefits of biotechnology/GMOs for better decision-making.

Specific outputs include:

- a. A body of knowledge on the implications of biotechnology on trade and food security will be generated;
- b. Analysis of the potential costs and benefits of adoption of GMO crops at farm level;

- c. Informed decisions on trade in GMO products and emergency food aid; and
- d. A range of feasible policy options and choices for biotechnology/biosafety in the ASARECA/COMESA region will be generated.

4. Activities

Specific project activities will include:

- a. **Agenda setting and constituency building:** The main objective of this activity will be to identify key stakeholders including individuals; institutions and organizations in the focal countries involved directly or indirectly in trade, biotechnology and food security related issues.⁸
- b. **Desk research and analysis:** Data for each of the six countries on volume, value and destination of food and feed exports will be assembled for estimation of commercial risks/export losses that the six countries may face if GM crops are allowed to be grown by their farmers. Literature review will broadly revolve around the implications of GM crop commodities on trade, farm income and food security at global, regional (African context), sub-regional and national levels. Market access barriers and consumer preferences associated with GMOs in the destination export markets will be captured. The non-GMO factors that are expected to impact on trade in the foreseeable future will also be reviewed.
- c. **Empirical data collection:** Data will be collected on national food imports including emergency food aid and food aid policies. This activity will aim at establishing the possible food security benefits that ASARECA/COMESA countries may gain from placing fewer restrictions on GM commodity imports in the form of emergency GM food aid. Information will also be collected on cotton and maize production. The data will be used to estimate farm income benefits that might trickle down to farmers if the relevant authorities in the ASARECA/COMESA region permitted planting of Bt maize and Bt cotton.
- d. **National workshops:** Workshops will be integrated with the PBS policy roundtables including each of the focal countries. The workshops will seek to disseminate and share research findings on the implications of modern biotechnology on trade and food security in the focal countries. The workshops will also seek to capture the thoughts of these countries on the need for a regional common policy on GMOs.
- e. **Regional workshop:** A regional workshop bringing together key stakeholders from the ASARECA/COMESA countries and representatives from the COMESA secretariat will be held to reflect on the consolidated findings emerging from national workshops and the justification for regional policy choices. The range of regional policy options acceptable to the ASARECA/COMESA countries will be explored.
- f. **Information dissemination:** ASARECA/ECAPAPA and ACTS will create a project web page; publish newsletters, policy briefs and a monograph on issues emerging from the project. National and regional workshop reports and the final project document on regional policy options will be submitted to the COMESA secretariat for onward dispatch to all the COMESA focal points.

⁸ The focal countries are Egypt, Ethiopia, Kenya, Tanzania, Uganda and Zambia.

Appendix 2

List of East Africa Pre-proposal selected under the BBI Competitive Grant

- 1B01-05** *Binepal* Assessment of the impact of capriovox-Rift Valley Fever recombinant vaccine in wildlife populations
- 1K01-05** *Kiboi* Gene flow and fitness studies of hybrids between cultivated rice (*Oryza sativa*) and its wild/weedy relatives
- 1V01-05** *Valentine* Gene flow and its consequences: a case study of *sweet potato feathery mottle virus* coat protein mediated
- 1W01-05** *Watura* Non-target studies in Bt cotton and neighboring wild ecosystems in East Africa region
- 1H01-05** *Hamisy* Assessment of the impact of introducing genetically modified cotton on biodiversity in East Africa
- 1A01-05** *Abdullah* Pollen dispersal studies in cotton in East Africa and that of Bt cotton
- 1P01-05** *Pasquet* Can Bt-cowpea be deployed in Africa without a demographic explosion of the wild cowpea populations?
- 3O02-05** *Osir* Assessment of the impacts of genetically engineered maize on non target beneficial arthropods and soil biota

Appendix 3

Report on PBS Biosafety Training Program on Confined Field Trials in Tanzania, 7th – 18th February 2005

By Roshan Abdallah, R. G. Bamwenda and Mark Hasley
Tropical Pesticides Research Institute (TPRI)

In the effort to strengthen capabilities of Phytosanitary Inspectors to enforce biosafety regulations in Tanzania, TPRI submitted a concept paper to USAID. USAID responded by sending to TPRI its consultant on Program for Biosafety Systems, AGBIOS, Canada. TPRI and AGBIOS identified the following areas of cooperation/partnership in the enforcement of biosafety systems.

1. Development of confined field requirements for Tanzania.
2. Formulation of application processes for confined field testing in the country.
3. Development of standard operating procedures (sop) for field testing of genetically modified (gm) crops.
4. Development of Compliance Management Program (CMP) field tests.
5. Strengthening capabilities of phytosanitary inspectors through short term targeted training in the country and abroad.
6. Undertake orientation or on job training in countries which perform field inspections.
7. Development of information/communication systems.

As an outcome of the collaboration, the following activities were undertaken:

1. A confined field trial directive (CFTD) was developed and it is in a process of being appended to the regulations of the plant protection act 1997. We hope this activity will be finalized soon;
2. AGBIOS organized a six weeks internship for TPRI and KEPHIS Inspectors in the USA and Canada to support capacity building. The regulatory internship exposed the inspectors to various important aspects needed in the implementation of confined field trial directive. The output of the internship was development of crop biology documents, standard operating procedures (sop) for carrying out of confined field trials as well as a inspectors manual on related inspection and audit activities.

Furthermore, TPRI initiated collaboration with Donald Danforth Plant Science Center (DDPSC), USA. TPRI and Donald Danforth Plant Science Center identified the following areas of cooperation/partnership under the PBS program.

1. Training of regulatory inspectors on understanding of the confined field trial directive (CFTD), the biology documents, SOPs and the inspector's manual.
2. Training of Agricultural Biosafety Scientific Advisory Committee (ABSAC) on the biology documents, SOPs and the inspectors manual (audit) and processing of applications of GMOs for research purposes according to the CFTD.
3. Training of National Biotechnology Advisory Committee (NBAC) on approval processes of application of GMOs for cft.
4. To conduct research on bt cotton in the southern regions of Tanzania where quarantine for growing cotton is in place due to the problem of red bollworm *Diparopsis castanea*).
5. Potential for research on gm cassava. Both researches may be carried out by Tanzania scientists based at TPRI, Universities, Ari-Mikocheni, Ilonga and Ukiriguru research stations in collaboration with other international organizations. The TPRI plant biosafety office (PBO) will carry-out the safe handling, inspections and monitoring accordingly.
6. Development of good laboratory practice (GLP) for contained environment.
7. To hold workshops for applicants (researchers, academicians & private companies) on understanding of biosafety issues.

The Donald Danforth Plant Science Center (DDPSC), USA, resource persons together with TPRI resource persons conducted 3 training programs in Tanzania. The three workshops were delivered in February 2005 in direct response to TPRI's letter of request. Each workshop had separate emphasis and objectives:

- 1) Inspector's workshop, 5 days, Arusha. Train Phytosanitary inspectors in details of biosafety and biosafety inspection, with emphasis on confined field trials (CFTs).
- 2) ABSAC workshop, 3 days, Bagamoyo. Familiarize the agricultural sector biosafety committee (Agricultural Biosafety Scientific Advisory Committee -- ABSAC) with CFT goals and methods, and with the review process for cft applications.
- 3) NBAC briefing, 1 day, Dar es salaam. Familiarize the national biotechnology policy body (national biotechnology advisory committee – NBAC) with the role of CFT in development of agricultural biotechnology, and brief them on the training provided to the inspectors and ABSAC.

Agendas included the specific objectives of each workshop. The workshops were developed and coordinated by Dr Abdallah of TPRI and Mark Halsey (RSA/DDPSC). Resource persons attending all three workshops were Dr Bamwenda, Dr Abdallah, Dr Sivramiah shantharam (Biologistics International), and Dr Mark Halsey. Lawrence Kent (RAS/DDPSC) and Dr Nick Linacre (IFPRI) joined the ABSAC and NBAC workshops as resource persons. A summary of the evaluations of each workshop is attached; copies of the evaluation forms are available on request.

Inspectors workshop, Arusha

The inspector's training course was held 7th – 11th February, at TPRI in Arusha. The venue provided not only an excellent facility, but also outstanding secretarial support, technical services, and internet access (although there was not much time to take advantage of this). The course was a regional event, attended by 14 Tanzanians, 5 Ugandans and 4 Kenyans. The international visitors were coordinated by Dr Theresa Sengooba, PBS regional coordinator for east Africa. Most of the participants were phytosanitary inspectors, but several had other regulatory roles. A highlight of the course was a field exercise, in which the attendees evaluated the suitability of two sites for conducting CFTs of either maize or cotton.

Participants were fully engaged and interested throughout all five days of the training – an impressive and gratifying situation. Based on the evaluations and on informal feedback, this course was an outstanding success. Thirteen of 21 responses rated the course as 'excellent', and all respondents indicated that the objectives were met (summarized evaluations for each workshop are attached to this report). This introductory course will be of interest elsewhere, and is planned for west Africa in 3rd q and southern Africa in 4th q.

The next steps will be to develop training for authorized parties (under whose auspices CFTs are done) and trial managers. This training ideally will include the inspectors as well, working toward a 'partnership for compliance' between these two parties. At the same time there is an opportunity to functionalize many processes by instituting routine systems – establishment of personnel training files, routine facility and records inspections, systematization of site and trial codes, development of ancillary forms and documents facilitating communication from the regulatory authority and compliance on the part of the ap and trial manager.

The workshop was closed by Dr Hussein Mongi, chairman of the Tanzania coffee board and president of alpha seed company in Moshi. He expressed interest in PBS support for development of tissue culture techniques and facilities for the production of coffee seedlings, which he indicated were in short supply in east Africa. I encouraged him to send details of the sort of assistance envisioned, so that an assessment could be made regarding PBS involvement.

ABSAC workshop, Bagamoyo

A three day workshop was held for ABSAC on 14th – 16th February at Bagamoyo. Nine members of ABSAC attended, including Dr Abdallah and Dr Bamwenda. The group was small, cohesive and was able to be quite focused. Emphasis was on review and approval process for cft applications; segments were also given to familiarize the participants with the guidelines and SOPs in place for conduct of CFTs in Tanzania. On the final day of the workshop, mock cft applications were evaluated for Bt cotton and for cassava, the latter prepared by DDPSC. The review process of these applications was a highlight of the course – the participants obtained hands-on experience on the process of review and approval, and were able to identify areas for improvement in the application form for subsequent revision. The exercise was also a valuable introduction to the DDPSC for cassava project, which has the potential to move forward and become a real case in the near future. One area of concern that surfaced was public perception and the need for public education and outreach. Fear of 'public' (or NGO?) Reaction to confined

testing lead to some sentiment for contained (i.e., glasshouse) testing only, an issue that needs to be confronted directly in the future.

NBAC workshop, Dar es salaam

A one day briefing for members of the NBAC was held in Dar es salaam on 18th February. Participants were briefed on the purpose and execution of CFTs, and on the training received by the inspectors and ABSAC that underpins the cft system in Tanzania. There was keen interest in the short program, and it seems that much more training and background would be well-received by the committee. This briefing is the topic of a segment in Agbioview (02/23/05, GMO's: Africa's possible solution to perpetual food crises). Several articles in the local press publicized the different workshops and addressed issues related to the development of gm crops in Tanzania; copies of these articles are available on request.

Appendix 4

Report On Workshop On Environmental Risk Assessment For GMO's

by Karen Hokanson, Hector Quemada, Theresa Sengooba
cc: 25th to 29th January 2005

Background

A workshop/training course on environmental risk assessment for GMO's was organized at the request of the PBS East Africa Regional Program. This workshop was designed to strengthen the base of expertise of key personnel in the region in the area of risk assessment, risk management, and risk communication with a focus on priority research areas and products for the region. The participants in the workshop were researchers and other personnel who conduct the actual risk assessment and advise regulatory agencies in procedures for risk management. These personnel have some experience in risk assessment, but were interested in strengthening their knowledge and capabilities through a better understanding of the fundamental concepts and techniques being employed worldwide, and in identifying the most immediate applications of these risk assessment and management concepts and techniques in their region.

The workshop objectives were to:

1. Enhance the capabilities of key personnel in the eastern Africa region by exposing them to the latest concepts and techniques in Environmental Risk Assessment regarding GM crops
2. Present case studies of environmental risk assessment of GM crops likely to be used in eastern Africa
3. Through a workshop, facilitate the participants in reviewing priority research areas and other activities pertaining to risk assessment and risk management.

The workshop was held on January 27 and 28 at the Hilton Hotel in Nairobi. The workshop was primarily organized by Dr. Theresa Sengooba and Dr. Harrison Macharia. The main resource persons were Dr. Hector Quemada and Dr. Karen Hokanson. Dr. Sam Wakhusama from ISAAA/Kenya gave a presentation on Risk Communication. There were 38 participants at the workshop, and they came from Kenya, Uganda, and Tanzania. They were mainly scientists and represented diverse fields of expertise, including molecular biology, ecology, entomology, and plant pathology. The Workshop Agenda is included below.

Activities

1. Delivery of 2 day training workshop.
2. Participants were furnished with a CD of all presentations for reference.
3. A course evaluation was submitted by participants to refine similar training in the future and to identify future training needs.

Report

1. The first part of the workshop included formal opening statements from Kenyan officials. Hector Quemada gave an introduction and overview of PBS. John Komen was also present for a brief period during the first morning and gave some informal welcoming remarks in behalf of PBS. Theresa Sengooba introduced the workshop.
2. The first presentation was by Sam Wakhusama, ISAAA, on risk communication. The presentation was well received and generated some interesting discussion. It was especially effective to have Sam speak, as he represented the only local resource person in the workshop.
3. The next four presentations were designed to build one upon the other, and did so effectively with ample opportunity for questions and discussion between them. Hector presented a brief introduction to plant transformation first. This presentation may not have been informative for many of the participants who already had a good understanding of the technology, but it was necessary for the few who did not, and it led effectively into the rest of the workshop. Karen Hokanson gave the next presentation, which was an introduction to environmental risk assessment, and included general information on the characteristics and process of risk assessment, risk management, and monitoring, and clearly distinguished these practices for field trials from those for commercialization. Hector followed with a presentation in more detail on the scientific issues considered in a risk assessment for commercialization, including consequences of gene flow and nontarget effects. Karen then presented case studies of risk assessment for HT rice and IR cotton, again clearly distinguishing the considerations for field trials from those for commercialization.
4. These first presentations set the stage for the next portion of the workshop, which was an exercise that gave an opportunity for those attending to participate more actively in the workshop. At the end of the first day Hector introduced this next session by taking the participants through a systematic approach to risk assessment using Bt Corn as a model. On the morning of the second day, the participants broke into three groups according to crop (cassava, banana, and sweet potato) and applied the information learned the previous day to begin to systematically approach a risk assessment for commercialization of these crops. The groups identified traits being engineered into the crop, and discussed the potential risks for each in terms of hazard level and exposure. The workshop reconvened and a reporter from each group shared the conclusions.
5. Following this exercise, Theresa gave a presentation on biosafety in East Africa and the research priorities identified by ASARECA. Hector and Karen then presented the BBI program as a potential means of addressing risk assessment research priorities.
6. The last exercise of the workshop was a brainstorming session of all participants to identify crops and traits with the most immediate risk assessment needs in the region. This information was captured and will be incorporated into the country/crop/trait matrix to help form BBI and other PBS priorities.
7. At the end of the workshop, all of the participants traveled by bus to KARI to tour the biotechnology center and containment facilities. This tour was of great interest to the participants, and was also a nice change of venue. Upon returning to the Hilton,

Kenyan officials gave closing remarks, and the workshop was officially closed.

8. 18 of the 38 participants returned evaluation forms. These are summarized below:

Out of the 18 evaluations completed, 8 rated the workshop as Excellent, 9 as Good, and 1 as Average. None were rated Fair or Poor.

When asked, on balance, whether the workshop objectives were achieved, 14 evaluations were marked Yes, 2 were marked Partially, and 2 did not respond.

Participants were also asked to rate whether each of the three objectives individually (listed above) was met, with a score of 1 meaning the objective was not achieved and 5 meaning it was achieved. The first objective received an average score of 4.1, the second of 3.9, and the third of 4.1.

When asked to list the most useful sessions of the workshop, several participants (6) simply noted that all sessions were useful. The sessions cited most often as useful were the Introduction to Risk Assessment of Genetically Engineered Plants, and Scientific Issues for Environmental Risk Assessment. Other sessions mentioned as useful by several participants were Systematic Approach to Environmental Risk Assessment-Introduction and Application Exercise, Risk Assessment and Management for Bananas, Sweet Potato, and Cassava: Application of Principles Learned, and Risk Communication. Several participants also noted that the visit to the biosafety complex in NARL/KARI was useful.

When asked to list the least useful sessions of the workshop, most participants (13) wrote None or left the question blank. No session was mentioned with frequency as being not useful.

Some strengths of the workshop that were mentioned included that it was informative and enhanced the capabilities of the participants, the presentations were good, and the resource persons were knowledgeable. Many comments on the strengths of the workshop reflected an appreciation of the participatory approach, and the detailed responses and open discussions following the presentations and during the sessions. Participants also considered the opportunity to interact with other participants from multidisciplinary fields to be a strength of the workshop.

The main weakness noted on the evaluations was that there was not enough time to cover more information, and that either another day or better time management would have helped with this problem.

11 participants answered Yes to the evaluation question “Were regional and country speakers adequately represented at the workshop?” Some of these included comments that there was adequate opportunity for regional and country representation through participation in activities and discussions. 7 evaluators marked No for this question, and these mainly commented that the resource persons and presenters were from the US, and more local representation would have been better.

Several evaluators suggested that presentations by regional speakers on the status of research and/or the regulatory status in the region would have been informative and would have been an opportunity for more local participation. Other additional topics that were suggested included more basic information on the transformation process, more on the types of traits being worked-on currently and the mechanism or mode-of-action controlling these, more on consumer perceptions and acceptance, more on risk management including

one request for a visit to a confined field trial, and more on parallel experiences in Asia, South Africa, or South America. Other topics mentioned included views of economic experts, human vaccines, and the Cartagena Protocol in the EU and US context.

The final question on the evaluation concerned follow-on activities. No follow-on activities emerged most frequently, except for follow up training that was more in depth or that included the “latest” information. Some other follow-on activities that were suggested were a continued role of participants in the implementation of biosafety, continued discussions among participants within and between the countries, increased networking between the countries, travel among countries within the regions and/or outside of the region for hands-on training in biosafety, capacity building at a high level, pursuing research on environmental risk assessment, developing guidelines and regulations, inspector training, monitoring training, and posting useful information on related topics at the PBS website.

Future Actions and Decisions to be Taken (person responsible)

Program
**Capability Enhancement Training on
Environmental Risk Assessment of Transgenic Crops**

**Dates: January 27 – 28, 2005
Venue: Hilton Hotel in Nairobi**

Course Outline

DAY 1: January 27, 2005

TIME	SESSION
8:00 AM - 8:30 AM	REGISTRATION
8:30 AM - 9:00 AM	Welcome Remarks & Overview of PBS - Dr. Hector Quemada, PBS/BBI Manager Overview of the Workshop -Dr. Theresa Sengooba, PBS EA Opening Address by Prof. G.K. King'oriah, Exec Secretary NCST Prof. F. Gichaga, Chairman NCST
9:00 AM -10:00 AM	Risk Communication Samuel Wakhusama, ISAAA
10:00 AM -10:30 AM	BREAK
10:30 – 11:00 AM	Review of Plant Transformation Techniques Dr. Hector Quemada, PBS-BBI
11:00 AM -12:00 PM	Introduction to Risk Assessment of Genetically Engineered Plants <ul style="list-style-type: none"> • Baselines for Comparison/Familiarity • Risk Assessment/Risk Management—Field Trials vs. Commercialization • Monitoring Dr. Karen Hokanson, PBS-BBI
12:00 PM -1:00 PM	LUNCH BREAK

DAY 1: January 27, 2005

TIME	SESSION
1:00 PM – 2:00 PM	Scientific Issues for Environmental Risk Assessment <ul style="list-style-type: none"> • Consequences of Gene Flow, fitness and ecological components • Non-target effects • Specific topics <ul style="list-style-type: none"> - Evolution of resistance - Viral recombination - Horizontal gene transfer Dr. Hector Quemada, PBS-BBI
2:00 PM – 3:00 PM	Case Studies in Environmental Risk Assessment and Management Dr. Karen Hokanson, PBS-BBI
3:00 PM – 3:30 PM	BREAK

3:30 PM – 5:00 PM	Systematic Approach to Environmental Risk Assessment— Introduction and Application Exercise Dr. Hector Quemada, PBS-BBI
5:00 PM – 6:30 PM	BREAK

DAY 2: January 28, 2005

TIME	SESSION
8:00 AM – 10:00 AM	Risk assessment and management for bananas, sweet potato and cassava: application of principles learned Dr. Hector Quemada – PBS-BBI Dr. Karen Hokanson – PBS-BBI
10:00 AM – 11:00 AM	Overview of biosafety in E. Africa including priority research areas identified by ASARECA Theresa Sengooba, PBS
11:00 AM – 11:30 AM	BREAK
11:30 AM – 1:00 PM	Workshop: Priority Research Areas, Overview of PBS's BBI component. <ul style="list-style-type: none"> • Overview of BBI: Dr. Hector Quemada—PBS-BBI 15 minutes • Description of funded projects: Dr. Karen Hokanson—PBS-BBI 30 minutes • Definition of East Africa research priorities with respect to BBI component: Dr. Theresa Sengooba—PBS EA
1:00 PM – 2:00 PM	LUNCH BREAK
2:00 PM – 3:00 PM	Visit to Biosafety Complex in NARL/KARI
3:00 PM – 4:00 PM	CLOSING PROGRAM Messages Closing Address by Prof. Richard W. Mwangi UON
4:00 PM – 5:00 PM	DEPARTURE

Organizers: PBS BBI component, PBS EA Regional Office, PBS Kenya

Appendix 5

END OF INTERNSHIP AT MICHIGAN STATE UNIVERSITY: REPORT TO REGIONAL COORDINATOR USAID- PROGRAME ON BIOSAFETY SYSTEMS (PBS)

BY

DR MUGASSA S.T. RUBINDAMAYUGI (PhD)
DEPARTMENT OF MOLECULAR BIOLOGY AND BIOTECHNOLOGY,
FACULTY OF SCIENCE,
UNIVERSITY OF DAR ES SALAAM

Address

P.O.BOX 35179

DAR ES SALAAM

TEL Office : 255 22 2410223

TEL Mobile: 255 744 270791

FAX: 255 22 2410078

E-mail: mugassa@amu.udsm.ac.tz; mugassa@yahoo.com

A. ACTIVITIES DURING INTERNSHIP AT MICHIGAN STATE UNIVERSITY

This internship that I had at the Institute of International Agriculture (IIA), Michigan State University (MSU) was arranged by the regional PBS office through Tanzania Commission for Science and Technology (COSTECH). The selection of MSU was based on the institutional strength in the subject and its long experience in capacity building through conducting biosafety courses to institutions and experts from developing countries. The main objective of undertaking the internship was to develop teaching material for an undergraduate course “Biosafety, Bioethics and Biotechnology Policy – BN 305”. This course will be offered to undergraduate student for the first time during the second semester of Academic year 2006/2006.

B. COURSE MATERIAL DEVELOPED DURING THE INTERNSHIP

During my stay at MSU I was able to develop a comprehensive course outline for the “Biosafety, Bioethics and Biotechnology Policy – BN 305” course. This course is for the student in “Molecular Biology and Biotechnology” degree program at the UDSM. The course content is in line with the course description provided in the UDSM prospectus. It assumes the student understands the current known application of biotechnology tools. Consideration is also given to the non-biotechnology student with background in biology to be able to take the course. In this case, the course contents described in brief the applications, benefits and concern raised worldwide.

More focus is given on risk assessment, management and communication principles and procedures which are corner stone of biosafety. The role of ethical and social economic consideration in formulation of national and international biotechnology and biosafety policies, and regulatory systems is to be introduced and explained. The course material also touches on issues of “Intellectual Property Rights” as related to biotechnology innovation and commercialization. The course outline is shown in this report.

C. RESOURCES MATERIAL UTILIZED

My stay at MSU enabled me to access teaching material used in previous courses taught at MSU with similar contents. These courses included the regular undergraduate courses and other tailor made courses for various training workshops. I was also able to access a number of books, paper and websites used in teaching of these courses by MUS faculty members. The contact with the office of the MSU Intellectual Property’s Licensing Officer who explained the process and procedures of licensing university invention was a good chance for me to understand the links between biotechnology teaching and research innovations at university level and patenting. Websites of international regimes responsible for management and governance of biotechnology also provided good resources. These resources material will be recommended as reading material for students for the “Biosafety, Bioethics and Biotechnology Policy – BN 305 course”. I can also use these resources material for other training initiatives.

It should also be noted that the same teaching material prepared will also be used in future to teach targeted groups like biosafety regulators, policy makers and other stake holder like the

media professional who are responsible for communicating to the public the impacts of biotechnology to human needs, adverse impacts and social – economic impact.

This course and its content is still new to many developing countries and especially now when the issue of biosafety issues related food safety and environment. This is indicated by a number of undertakings by United Nations organization like Food and Agriculture Organization (FAO), United Nations Environment and Development Program (UNEP), World Health Organization (WHO) and many more donor agencies trying to build capacity in biotechnology management and regulation. One of these initiatives is the USAID –PBS of conducting “Food Safety and Biosafety Courses”. The material developed will be used in the forthcoming course to be held in Pretoria, South Africa, 7-11 November 2005. This course is organized by MSU, The Vegetable and Ornament Plant Research Institute and PBS. I have been invited as guest lecturer to this training workshop. The course title is “Africa Region Food Safety and Biosafety Short Course”.

D. INTERACTION WITH FACULTY MEMBERS AND OTHER EXPERTS

On my arrival I had a meeting with faculty members who are involved in teaching biosafety and bioethics related courses. I briefed them on what I intended to achieve and they provided me the relevant teaching resources they use. I used this recourse to develop the course material according to the requirement of the prescribed course description. During my stay I had briefing meetings every week with these faculty members. In these meetings we discussed the quality and content of the teaching material which I was developing. The following is a list of faculty members interacted with:

Prof. Karim. M. Maredia

Prof James Hancock

Prof Rebecca Grumet

Dr Cathy Pisano Weir

Ms Cholani K. Weebadde PhD Candidate

Dr Thomas C. Herlache (Licensing Associate, Office of Intellectual Property, MSU)

E. SHARING THE COURSE WITH OTHER UNIVERSITIES IN THE REGION

Taking into consideration that PBS initiative is a regional one. The course material developed was meant to be shared with other universities in East Africa as desired by PBS programme. This consideration was also enhanced by the fact that, I am also involved in regional research and training initiatives for “Capacity Building for Biosafety and Ecological Impact Assessment of Transgenic Crops in East Africa”. Part of this initiative is to aim to conduct training to different experts involved in biosafety in East African countries. The course material prepared will also serve the purpose. This initiative involves three biggest Universities in the region, these include: University of Dar es Salaam –Tanzania; Makerere University – Uganda; Nairobi University Kenya. The fact that the program that funded the initiative is also a regional initiative, the course material prepared can also be used in starting similar teaching programmes in these universities. These courses can be run under continuing education program which exist in the different universities in the region now.

F. GUIDELINES FOR BIOSAFETY, BIOETHICS AND BIOPILICY COURSE: BN 305

1.0 COURSE DESCRIPTION

Risks, benefits and impacts of biotechnology to human health, society and the environment. Genetically modified organisms (GMOs), transgenic and the environment, transgenic and human health (toxins and allergens). Fundamental ethical concerns of biotechnology. Risk assessment of transgenic organisms. International protocols on biosafety and intellectual property rights.

2.0 COURSE GOALS

The students should become:

- Conversant with the current state of biotechnology concerns, biosafety, bioethics and biotechnology policy issues.
- Capable of discussing and debating, issues of principles underlying biosafety bioethics, and the conflicts between the applications of biotechnology.
- Informed on the various practices of risk analysis procedures as applied in biosafety.
- Informed on global regulatory regimes in biosafety such as World Trade Organization (WTO), Cartagena Protocol on Biosafety (CPB) of Convention on Biological Diversity (CBD), and Codex Alimentarius Commission (CAC).
- Informed of principles and procedures used to develop biotechnology and biosafety policies and regulation systems.

3.0 COURSE OBJECTIVES

- 3.1 Provide a comprehensive overview of all aspects of biosafety with emphasis on management of impact of modern biotechnology to humans and environment.
- 3.2 Acquaint the students with the basic principles and practices applied in risk assessment, management and communication on environmental safety
- 3.3 Acquaint the students with the principles and practices applied in risk assessment, management and communication on environmental safety.
- 3.4 Acquaint the student with different conceptions and misconceptions on application of modern biotechnology.
- 3.5 Make an overview of consequences of different conceptions and misconceptions on application of modern biotechnology.
- 3.6 Enable the student to understand the core principles of risk assessment and application of precautionary principle.
- 3.7 Introduce to the students the biosafety practice as related to global regimes or international treaties and agreements. (CPB, WTO, SPS, TBT).
- 3.8 Acquaint the students with the precautionary principle as employed in Codex Alimentarius, WTO/SPS/TBT agreements and Biosafety Protocol.

- 3.9 Inform the students the importance of raising public awareness on issues surrounding biotechnology application and biosafety regulatory systems.
- 3.10 Develop in students an understanding of ethical issues confronting application of modern biotechnology in agriculture, food, medicine, industry and environmental biotechnology.
- 3.11 Acquaint students with procedures of developing national biotechnology policies and biosafety frameworks.

4.0 COURSE OUTLINE AND TOPICS

1. Introduction to general concepts on biosafety, bioethics and biopolicy
2. Overview of wide applications of biotechnology and concerns worldwide: Controversies surrounding it.
3. Biosafety principles and procedures for research involving microbiological, biomedical and rDNA molecules: Overview of biosafety levels.
4. Conceptual issues in risk analysis: Risk assessment
5. Biosafety risk assessment of food and feed derived from transgenic organisms.
6. Environmental safety: The case of environmental risk assessment of transgenic plant crops
7. Precautionary principle in biosafety risk assessment and divergent interpretation
8. Risk management and communication
9. Perception and misconception of benefits and risks of biotechnology
10. Bioethics: Ethical and social issues arising from biotechnology innovation and commercialization.
11. International conventions, treaties and agreements on Biosafety
12. Biotechnology and Intellectual Property Rights: Ethical and Social Economic Issues.
13. Biotechnology policy (biopolicy) development: The case of developing countries.
14. Overview of governance of biotechnology: Implementing of National Biosafety Frameworks.

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- 6.13 Muller, W (2001). *Risk Management Strategies for Living Modified Organisms that Take Uncertainty into Account*. *OECD- Proceeding of an International Conference on LMOs and the Environment*. 27-30 November, 2001, Paris, France.
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- 6.16 Staub, J.E., F.C. Serquen and M. Gupta (1996). *Genetic Marker, Map Construction, and Their Application in Plant Breeding*. *HortScience* 31(5): 729-741.
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Appendix 6

**PROGRAM FOR BIOSAFETY SYSTEMS
(PBS)**

'Building Functional Biosafety Systems'

**Strategic Plan for PBS Eastern Africa
2006 - 2008**

Final DRAFT

REGIONAL COORDINATION OFFICE
PROGRAM FOR BIOSAFETY SYSTEMS EASTERN AFRICA
P.O. BOX 28565, KAMPALA, UGANDA
TEL:+256 41 234613, MOB: +256 77 365492, FAX: +256 41 234614, EMAIL:
t.sengooba@ifpri.bushnet.net

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Executive Summary

A facilitated three-step participatory approach involving a wide stakeholder base was used to develop a coherent framework for facilitating the development of effective and efficient biosafety systems for Eastern Africa based on the experiences of the global Programme for Biosafety Systems (PBS) which provided a common framework for analyzing the separate experiences with biosafety systems within the national and sub-regional context.

The PBS-EA Strategic Plan puts emphasis on regional information sharing, sharing regulatory procedures and documentation and dialogue and action on biosafety. This calls for harmonization of biosafety instruments and maximizing the use of scarce institutional, financial, technical and human resources within the region. The preparation of the Strategic Plan was driven by the need to better coordinate initiatives that focus on regional needs and priorities, and the relevance and ownership that comes from sovereignty.

Based on the above considerations, numerous challenges identified were synthesized into **4** major challenges that are cross cutting in all the three countries (Kenya, Uganda, and Tanzania). These were, (i) How to foster an efficient regulatory environment characterized by transparency and stability, (ii) How to provide an effective system that ensures accountability and stakeholder participation, thus building public confidence in decision making, (iii) How to develop acceptable criteria to weigh risks/benefits while considering agricultural productivity, environmental, and human health concerns, and (iv) How to improve capacity for implementation of biosafety frameworks and respond to the other needs for biosafety at national and regional levels.

The **vision** for PBS-EA has been defined as *“Functional biosafety systems within a sustainable regional development strategy”* with a **mission** *“To foster regional capacity for science-based decision-making, policy development and implementation of harmonised biosafety frameworks”*.

The strategic goals were formulated as (i) Biosafety regulatory environment responsive to stakeholder needs and national/ regional development goals, (ii) Regional and national capabilities for confident and competent science-based decision-making, (iii) Operational capacity and approaches for generating, accessing, disseminating and sharing information on biosafety, and (iv) A dynamic regional platform for policy advocacy, lobbying, coordination and resource mobilization for improved biosafety systems. Together they provide the strategic orientation and positioning of PBS Eastern Africa and demonstrate the

organizational commitment to achieve impacts in the 4 areas through a range of strategies.

PBS-EA acts complimentary to other regional initiatives and facilitate the addition of value to on-going national efforts. In the course of implementation, PBS-EA will be guided by important core values including (i) engagement with partners in an inclusive, transparent and trustworthy manner, (ii) fostering innovative regional approaches to biosafety regulatory decision making and management, through enhancing scientific-based decision making, and (iii) strengthening the national biosafety systems following the principle of subsidiarity.

ABBREVIATIONS AND ACRONYMS

AATF	African Agricultural Technology Facility
ABSF	African Biotechnology Stakeholders Forum
ABSP	African Biotechnology Support Program
ASARECA	Association for Strengthening Agricultural Research in eastern and Southern Africa
BBI	Biotechnology Biodiversity Interface
BIOEARN	East African Regional Program and Research Network for Biotechnology, Biosafety and Biotechnology Policy development
CAG	Country Advisory Group
COMESA	Common market for Eastern and Central Africa
COSTECH	Commission for Science and Technology (Tanzania)
DNA	Deoxyribose Nucleic Acid
DVS	Department of Veterinary services
EAC	East African Community
GDP	Gross Domestic Product
GMO(s)	Genetically Modified Organism(s)
IBC(s)	Institutional Biosafety Committee(s)
LMO(s)	Living Modified Organism(s)
MAAIF	Ministry of Agriculture, animal Industry and Fisheries
MDGs	Millennium Development Goals
MENREW	Ministry of Environment, Natural Resources and Water
MoARD	Ministry of Agriculture and Rural Development
MoH	Ministry of Health
MSTHE	Ministry of Science, Technology and Higher Education
MTTI	Ministry of Trade, Tourism and Industry
MWLE	Ministry of Water, Lands and environment
NARO	National Agricultural Research Organisation
NBA	National Biosafety Authority
NBC	National Biosafety Committee
NBFP	National Biosafety Focal Point
NBFU	National Biosafety Framework for Uganda
NCST	National Council for Science and Technology (Kenya)
NEMA	National Environment Management Authority
PBS	Program for Biosafety Systems
PBS-EA	Program for Biosafety Systems – Eastern Africa
PEAP	Poverty Eradication Action Plan
PMA	Plan for Modernisation of Agriculture
PPB	Pest and Product Board
PRSPs	Poverty Reduction Strategy Papers
RAG	Regional Advisory Group

TFDA	Tanzania Food and Drug Authority
TPRI	Tropical Pesticides Research Institute
UNCST	Uganda National Council for Science and Technology
UNEP/GEF Facility	United Nations Environment Program/ Global Environment
USAID	United States Agency for International Development
VPO	Vice Presidents Office

1.0 BACKGROUND

1.1 Biotechnology and Biosafety in Context

Modern biotechnology has great potential to positively impact: the agricultural industry, food security, environmental conservation as well as human and livestock health. Recombinant DNA techniques have provided scientists with the unprecedented ability to introduce new traits into plants and animals that could not have been accomplished through traditional methods. In the case of plants the new traits include enhanced resistance to pests and diseases; potential tolerance to abiotic stresses, and enhanced nutritional characteristics. Modern biotechnology contributes towards eradication of diseases in human and livestock through development and production of vaccines, novel diagnosis of various diseases, and provision of medication for many diseases. Modern biotechnology also contributes to alternative sources of industrial products and services.

Despite the benefits that can be derived from biotechnology, there are perceived concerns that such technology could pose risks to human and animal health and to the environment. Such fears relate to replicability and uncontrollable spread of genetically modified organisms (GMOs) when released into the environment; allergenicity, toxicity and food contamination; and increased antibiotic resistance to disease-causing organisms in both human and livestock.

The potential for adverse environmental and human health consequences arising from the introduction of GMOs, especially in agriculture, has led to development of regulatory regimes that are specifically applied to ensure safe and sustainable use of the technology. The development of an effective biosafety system is a national obligation under the Cartagena Protocol and is important to encourage investment in the technology. In addition to being efficient the regulatory regime has to be transparent so as to reassure stakeholders that modern biotechnology is based on scientific principles and is cognizant of community and national interests. Developing efficient and operational Biosafety Frameworks is a challenge to many developing countries as it involves developing specialized capacities and multi-institutional networking mechanisms.

1.2 Program for Biosafety Systems

The Program for Biosafety Systems (PBS)⁹ is implemented through a consortium of USA-based public and international organizations¹⁰ and funded by the U.S. Agency for International Development, Office of Agriculture and Food Security,

⁹ Details on the program can be found in the proposal submitted to the U.S. Agency for International development, Office of Agriculture and Food Security, Bureau for Economic Growth, Agriculture and Trade. Reference: Request for Applications (RFA) EGAT/AFS-02-001 "Program for Biosafety Systems" (PBS). See also the PBS website: <http://www.ifpri.org/themes/pbs/pbs.htm>

¹⁰ International Food Policy Research Institute (IFPRI)/ Donald Danforth Plant Science Center (DDPSC; Michigan State University (MSU); Western Michigan University (WMU) and other consultancy farms

Bureau for Economic Growth, Agriculture and Trade. The program is implemented over a 5-year period (2004 – 2008) and aims at strengthening biosafety policy development and decision-making through support to key regional and national institutions. The program activities are grouped into four components: policy development/new (alternative) models; risk assessment and the Biotechnology-Biodiversity Interface (BBI); facilitating regulatory approval; and development of skills/strategies for communication and public outreach. Capacity building is cross cutting through the different components.

PBS is based with IFPRI Washington and has programs in Asia and Africa. In Africa the regions covered include West, Southern and East Africa. The program in East Africa covers Kenya, Uganda and Tanzania. The EA regional coordinator is supervised by the Program Director and links up with the program consortium teams that provide technical backstopping for the different components of the program. Implementation follows a systems approach to biosafety, involving Country/Regional Advisory Groups and country focal point institutions and persons that provide the coordination function for the various activities. The program is partner-driven and the regional/country advisory group play a key role in deciding the priority activities. In case of country activities the lead institution has to specifically request for the activity.

1.3 Biosafety in Eastern Africa

In Eastern Africa, national processes for biosafety framework and legislative development have taken precedence over sub-regional approaches. National biosafety frameworks are key components of the UNEP/GEF program presently implemented in the three countries and supporting capacity building and compliance with the Cartagena Protocol on Biosafety. Within the region, however, countries are at different stages in developing their national biosafety systems.

Kenya: has a draft biosafety bill and a draft biotechnology policy developed through the Science and Technology Act Cap 250 Laws of Kenya which established the National Council for Science and Technology (NCST). The Biosafety bill and biotechnology policy address the development of biotechnology in agriculture, foods and feeds, health and environment. It outlines the rules and regulations for minimal risk acceptable to enable biotechnology research and development, importation and release of biotechnology products. Implementation of the biosafety legal framework and policies is undertaken through several government ministries and departments that carry out similar functions on conventional products.

In April 2003 a national stakeholders meeting on biotechnology issues, proposed that: the NCST through the National Biosafety Committee (NBC) becomes the coordinating office on issues related to biosafety in biotechnology before the proposed National Biosafety Authority (NBA) is established; the National Environmental Management Authority (NEMA) of the Ministry of Environment,

Natural Resources and Water (MENRW) oversees the regulatory role of biosafety issues relating to the Environment; the Department of Veterinary Services (DVS) regulates veterinary drugs and related services; the Pest and Product Board (PPB) of the Ministry of Agriculture and Rural Development (MoARD) regulates biopesticides. These regulatory roles are in the process of being crystallized and harmonized.

Meanwhile Kenya has already approved five GMO trials to be done under confined facilities (Bt. Cotton, Bt. Maize, recombinant rinderpest vaccine, transgenic cassava, transgenic potatoes). Such trials are discussed by IBC before being presented to the NBC.

The NBC discusses the dossiers gives an approval and requests the regulatory agency, in this case KEPHIS to issue a permit.

Tanzania: The Government of Tanzania has prepared a National Bio-safety Framework to be implemented through the Tanzania Commission for Science and Technology (COSTECH) of the Ministry of Science, Technology and Higher Education (MSTHE) in collaboration with the Vice President's Office (VPO) and other lead institutions that include the Tropical Pesticide Research Institute (TPRI) and the Tanzania Food and Drug Authority (TFDA). COSTECH has responsibility for coordinating and promoting science and technology development activities. The VPO is responsible for environment and is the National Biosafety Focal Point (NBFP) while TPRI is charged with the administration of the Plant Protection Act which provides authority to regulate the importation and environmental introduction of any articles that may be pests or injurious to plants, or plant products. The responsibility for all phytosanitary matters within Tanzania was delegated to TPRI. Tanzania has developed regulations (Schedule 18) under the Plant Protection Act to cater for handling and management of confined field/experimental trials of GMO plants. The TFDA on the other hand controls quality, safety and effectiveness of food, drugs, cosmetics, herbal drugs, medical devices and related product so as to protect the health of the consumers and general public against hazards related to such products. The EMA law provides for the legal and institutional framework for sustainable management of the environment, and the regulation of development, handling and use of GMOs and products thereof. This law empowers 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.

Uganda: In Uganda's Plan for Modernization of Agriculture (PMA), biotechnology is identified as a strategic research and development field basically to "ensure Uganda's capacity to cope with global scientific trends". It is thus recognized as a policy challenge that "a sound regulatory structure for new technologies such as genetic modification is essential". The National Science and Technology Policy was revised in 2001 to include, *inter alia*, specific provisions for biotechnology, viz: "to guide the judicious use of

biotechnology for sustainable development and to ensure effective control of transboundary movements of LMOs and products thereof resulting from biotechnology". This provided a broad national policy framework within which a sector-specific biotechnology and biosafety policy was developed. A draft National Biotechnology and Biosafety Policy was developed and submitted to cabinet in 2004. This draft policy relates to national development goals/priorities, relates to millennium development goals, emphasizes capacity building, regional collaboration, networking and information sharing, establishes biosafety structures/instructions and sets a stage for legal backup. The country is also in process of developing a national Biosafety Bill.

Meanwhile the national biosafety framework launched in 2002 is used to guide biotechnology related work in Uganda. It prescribes the policy and regulatory regimes, institutional and administrative measures, risk assessment and management measures and monitoring and enforcement mechanisms for biosafety.

The National Biosafety Committee (NBC) is a national administrative arm of the UNCST on matters concerning biosafety. The NBC is a multi-institutional and multi-disciplinary team that provides technical advice on biosafety to government and maintains links with biotechnology institutions through institutional biosafety committees (IBCs).

Uganda has developed guidelines to enable introduction and use of GMOs for research purposes under confined field trials.

Regional Programs: Several partners are currently involved in biosafety undertakings in the region the key ones include UNEP/GEF, PBS, BIOEARN, ABSF and the ASARECA programs for biotechnology and biosafety.

The EAC has also recognized the need for an efficient biosafety system to guide the development of biotechnology in its region. In that regard the EAC's Council of Ministers established a Technical Committee of Experts to address bio-safety issues and come up with an EAC regional policy on Genetically Modified Organisms. The Community has prepared a Protocol on Environment and Natural Resources Management that contains provisions related to regional biosafety frameworks.

1.4 Rationale for PBS-EA and the Strategic Plan

The need for a strategic plan is a result of several key concerns. First, there is a political will on the part of national biosafety policy makers to make biosafety regulation more responsive to stakeholder needs. Key policy issues relate to trade (including trans-boundary movements), enhancing agricultural productivity and food security and the overall need to use modern biotechnology in a safe and sustainable manner.

As member countries (Kenya, Uganda, Tanzania) further develop their frameworks, an opportunity is presented to emphasize regional information sharing, sharing regulatory procedures and documentation. The cumulative

experience, national capacity, and other regional bodies and agreements mean that a distinct opportunity exists to further sub-regional dialogue and action on biosafety. These activities help countries prepare now for future collaboration, exchange of information, inform one another of developments of value for the sub region, and start with basic points for agreement.

The East African countries are independently developing and strengthening their national instruments for environmental management and methods for implementation of National Biosafety Frameworks. They are at different levels of development. The porosity of national borders may require harmonizing regional and sub-regional legal instruments to simplify the process of applying and conforming to regulations and the safe introduction of GMOs into the environment.

Furthermore, commonalities among national regulations help create a more consistent regulatory environment in a region, which in turn makes it easier for regulators to review biotechnology applications, know how to meet regulatory requirements for importation, confined field trials and eventually, commercial use.

The principle of meeting and sharing information regionally, as well as preparing for cooperation and exchange of information, human capacity and recognition of application assessments has been called for by some authorities in East Africa. Setting up regional networks and systems with the necessary authority to oversee development of modern biotechnology within the region is a key strategy to realising this.

PBS provided a common framework for analyzing the separate experiences with biosafety systems within the national and sub-regional context during the policy round table workshop held in April 2005. Some commonly-shared challenges and opportunities where a sub-regional program could add value to the individual actions of the three countries were apparent. It was accepted that this might require PBS-EA, within the framework of the current project support, to consider broader issues, more pluralistic partnerships, and ways to facilitate cooperation among more decentralized institutional and individual actors within each country. Insights have been gained in some of these areas - one of the key insights being the need for a framework for sharing experiences and lessons learnt in implementing the national biosafety framework.

The current national biosafety frameworks are part of a process of evolution that is consolidating fragmented institutional efforts into nationally coordinated thrusts. The regional dimension represents a delicate balancing of two desirable things: the coordination of initiatives that focus on regional needs and priorities and the relevance and ownership that comes from sovereignty. The balancing of these two "goods" leads to the need for new network, mechanisms, incentives and management processes that create the special niche for regionally coordinated initiatives that add value to national undertakings.

The Strategic Plan provides a framework for facilitating the development of effective and efficient networking for biosafety in Eastern Africa.

2.0 THE PBS STRATEGIC PLANNING PROCESS

The development of a regional strategy entails mobilisation of the member constituency in terms of commitment, accountability and responsibility. This requires a process-type approach that is based on consultation, participation and ownership. In the context of PBS Eastern Africa, this would bring out national ideas, sentiments and perceptions. Members have to build a common shared vision and mission of the regional program that is addressing their demands and creating benefits for them.

PBS Eastern Africa decided to apply a facilitated process where national representatives rather than an expert consultant approach to strategic planning generated the ideas and products. Through the energy and ownership by the national stakeholders, PBS Eastern Africa would be based on strong pillars within its constituency.

A three-step participatory approach was used and a wide stakeholder base was involved in all stages of the strategic planning process, starting from the process design to the writing of the final strategy. The major steps were:

1. ***Strategic Planning Expert Meeting:*** A select team from the three countries met in Kampala, 9-11 June 2005 to brainstorm on some critical issues to be addressed by PBS Eastern Africa, elaborate on the trends, issues and challenges relating to biosafety and identify key areas, especially gaps, and functions to be addressed at institutional, national and regional levels.
2. ***Drafting the Synthesis Report:*** The facilitator to the Expert meeting synthesized and added value (based on other available documentation) to the outcomes of the meeting and consolidated the vision, mission, strategic goals and governance of PBS Eastern Africa.
3. ***National Consultations:*** The draft document was validated with representatives of country and other stakeholders from the demand and the supply side. The aim was to build the natural foundation of PBS Eastern Africa as a regional program.

The outcomes of the consultations at various levels were compiled into the final strategic plan by the facilitator and Regional Coordinator.

3.0 CHALLENGES FACED BY PBS EASTERN AFRICA

Numerous challenges were identified in the expert meeting and feedback from national consultations. They were synthesized into **4** major challenges which are cross cutting in all the three countries:

1. How to foster an efficient regulatory environment characterized by transparency and stability.

Currently no country has a comprehensive biotechnology and biosafety policy and regulatory regime. This creates uncertainties and for those wanting to invest in biotechnology.

Rationalizing biosafety regulations with other on going strategies and frameworks for food and feed safety, seed and phytosanitary regulation, importation, and other relevant legal instruments would greatly improve the regulatory environment. Furthermore, some elements in the various national regulations are incomparable.

2. How to provide an effective system that ensures accountability and stakeholder participation, thus building public confidence in decision-making.

The level of awareness on biotechnology and biosafety issues in Eastern Africa is extremely low, even among the scientific community leading to polarisation of debate.

Inadequate public understanding of biotechnology and biosafety is a constraint to stakeholder participation in policy and decision-making processes, while limited awareness amongst policy/decision makers constrains the expeditious enactment of the enabling policy/legal frameworks. Effective priority setting and policy decisions must be based on understanding on country's (region's) needs as well as understanding of the technology.

3. How to develop acceptable criteria to weigh risks/benefits while considering agricultural productivity, environmental, and human health concerns.

There is a paucity of information and data on biosafety which impedes science and socio-economic-based decision-making, on GMOs and related aspects. Countries need to establish safety standards that can guide decision making while also safeguarding environmental, ethical and human health concerns.

4. How to improve capacity for implementation of biosafety frameworks and respond to the other needs for biosafety at national and regional levels.

Inadequacy of skilled manpower, infrastructure and financial resources to support a biosafety system is a common problem in the region. Establishing partnerships at institution, country and regional levels provides an option to rationalize the inadequate infrastructure and human resources for maximum output, effectiveness and efficiency.

4.0 PBS EASTERN AFRICA VISION, MISSION, CORE VALUES AND NICHE

4.1 Vision

“Functional biosafety systems within a sustainable regional development strategy”.

PBS Eastern Africa vision is to support the biosafety process in the region to attain high level of technical competence for biosafety reviews and decision making. The policy makers and regulators would be reflective practitioners who apply scientific, economic and ethical principles to biosafety regulation. They would seek knowledge from various sources and facilitate joint learning about the risks and benefits of biotechnology products and promote the responsible application of biotechnology within a sustainable development agenda.

These impacts on the biosafety system require a strong mission of PBS Eastern Africa as a regional program including the regional coordinating secretariat, the regional advisory group, the national biosafety committees with their stakeholders to operate as a functional system.

4.2 Mission

“To foster regional capacity for science-based decision-making, policy development and implementation of harmonised biosafety frameworks”.

The PBS-EA mission commits the program to supporting regional information sharing, sharing regulatory procedures and documentation in the development and implementation of National Biosafety Frameworks. Critical to achieving the mission is the promotion of regional collaboration and exchange of experience on issues of relevance to the national biosafety frameworks, and harmonizing legal instruments to simplify the process of applying and conforming to the laws governing biosafety. It seeks to maximize the use of scarce institutional, financial, and technical and human resources within the region for effective and efficient operations of the biosafety systems.

As no country is isolated from its neighbours, the PBS-EA mission recognizes that there is a clear need to strengthen regional ties between countries by assisting in setting up regional networks and helping to set up systems with the necessary authority to oversee the development of modern biotechnology within the region. Decisions and policies that directly relate to the mission and work of PBS-EA would hinge on: strengthening human resources/relevant expertise pertinent to issues of biosafety at regional levels.

4.3 Core Values

PBS Eastern Africa as a partnership of individuals and institutions has the following values – **Partnership, Commitment and Excellence** - to guide its operations. All partners commit themselves to these shared values.

- PBS Eastern Africa builds most of its activities on partner-leadership as well as with external stakeholders and development partners. PBS Eastern Africa commits itself to engage with partners in an inclusive, transparent and trustworthy manner where credits are shared with integrity and accountability and obligations are shared in a reliable way while being fully committed to the impacts and strategic goals.
- The fundamental value of PBS Eastern Africa is its commitment to fostering innovative regional approaches to biosafety regulatory decision making and management, through enhancing scientific-based decision making for biosafety systems, facilitating the development and implementation of regional policies, supporting observation of similar/common practices across countries.
- PBS Eastern Africa is committed to strengthening the national biosafety systems following the principle of subsidiarity, where everything should be handled at the lowest possible level. The regional program will encompass only activities that are best executed regionally, while taking deliberate steps to expand and strengthen national competencies.
- PBS Eastern Africa believes in quality in all its actions. It will pursue quality in the way it designs its support interventions as well as in the quality of outputs / outcomes of the interventions.

These values will enhance active participation and commitment to the implementation of the set strategic goals, and foster the desired transformation in biosafety in the region.

Niche

PBS Eastern Africa is not the only program on biosafety in the region. PBS-EA specific niche within the broader support to biosafety is to focus on:

- Regional policy research and development by providing information and recommendations that help policy makers choose between regulatory options and tradeoffs. The Program will seek ways to enhance existing systems, while highlighting alternative models for regional consideration (**Strategic Goal 1**).
- Risk assessment and risk management studies to provide new knowledge upon which to conduct/complete a risk assessment or devise risk management options (**Strategic Goal 2**).

- Communication and outreach to create greater awareness on biosafety amongst policy makers and other stakeholders (**Strategic Goal 3**).
- Building, rationalizing and sharing regional capacities and resources in biotechnology and biosafety as a major value-added at regional level (**Strategic Goal 4**).

The principal partners in the PBS-Eastern Africa group include: Association for Strengthening Agricultural Research in East and Central Africa (ASARECA; Uganda); East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN; Uganda); National Agricultural Research Organizations (NAROs); Universities; Regulatory and Science & Technology Ministries/Bodies, and NGOs concerned with biosafety policy and communication. In all three countries the National Councils of Science and Technology provide focal point for the program.

5.0 PBS EASTERN AFRICA STRATEGIC GOALS

Four strategic goals were derived from the challenges, the vision of the impact which PBS Eastern Africa would like to achieve and the functions at different levels which were identified as necessary to produce the desired impact. Together they comprise PBS Eastern Africa response to the challenges and demands from the national stakeholders. They provide the strategic orientation and positioning of PBS Eastern Africa and demonstrate the organizational commitment to achieve impacts in the 4 areas through a range of strategies. These were formulated as and are described in detail below.

1. Biosafety regulatory environment responsive to stakeholder needs and national/ regional development goals
2. Regional and national capabilities for confident and competent science-based decision-making.
3. Operational capacity and approaches for generating, accessing, disseminating and sharing information on biosafety.
4. A dynamic regional platform for policy advocacy, lobbying, coordination and resource mobilization for improved biosafety systems.

5.1 Strategic Goal 1: Biosafety regulatory environment responsive to stakeholder needs and national/regional development goals.

What is involved in this strategic goal?

This strategic goal seeks to facilitate the development and implementation of relevant regional biosafety policies and regulations. Limited interaction within the region impairs the ability of biosafety regulators to benefit from knowledge and experience gained by other countries and regions, and it presents a risk of formulating inadequate or inoperable laws within the prevailing regional setting. Lack of harmony in policies and regulatory regimes may negatively affect trade and discourage technology transfer. This strategic goal seeks to prescribe modalities of how to harmonize policies, inspection and administrative procedures and manuals. Within the context of biosafety systems, the following need attention;

1. fostering an efficient regulatory (policy and legislative) environment characterized by transparency and stability,
2. providing an effective biosafety system that ensures accountability and stakeholder participation, thus building public confidence in decision making, and
3. rationalizing biosafety regulations with other on going strategies and frameworks for food safety, seed laws, phytosanitary regulation, and other relevant laws.

What we intend to achieve in this strategic goal?

This strategic goal seeks to achieve the following outputs and impacts:

- Existing biosafety systems evaluated to identify critical decision points that have a bearing on regional performance and identification of alternative policy options.
- Trade-offs between different regulatory system designs, their costs and the level of safety achieved their relation to other macro policies (such as agricultural development, poverty alleviation) and their impact on technology deployment and adoption understood.
- National regulations harmonised to create a more consistent regulatory environment in the region, making it easier for regulators to review biotechnology applications, know how to meet regulatory requirements for importation, confined field trials and eventually, commercial use.

What are the main challenges?

Developing and implementing responsive policies in the region faces a number of challenges. In this strategic goal, the challenges presented below have been derived from a logical analysis of problems and existing opportunities with respect to biosafety. The key opportunities include; Existing systems which can be improved; other stakeholders in the region with whom PBS Eastern Africa can collaborate to promote safe use of biotechnology and the active debate that is going on about the introduction and use of GMOs. The major problems include limited funding, limited skills necessary to objectively examine different trade-offs in the decision-making process, poor linkages and monitoring and evaluations systems. Accordingly the main challenges in this strategic goal include:

- How to achieve consensus on regional approaches to biosafety systems, regulations and policies.
- How to balance between the costs of biosafety regulation and the levels of risk partner countries are willing or able to tolerate and the urgency with which partners are able and willing to authorise the testing of promising new technologies that could contribute to agricultural development, poverty reduction and food security.

Main strategies to address the challenges

The main strategies to address these challenges include the following:

- Examining and analysing the existing biosafety systems, regulations and policies in the partner countries;
- Dialogue on alternative models and approaches to biosafety;
- Fostering the development of the skills necessary to examine the different trade-offs involved in the decision making process;

- Addressing information sets needed by policy makers and stakeholders.
- Proposing steps that allow countries to manage issues of immediacy while providing policymakers with experience that can be used to guide the development of a rational statutory process under either new or adapted legislation.
- Developing interactive and or participatory frameworks for regional harmonisation while considering alternative approaches to biosafety.
- Facilitating the formulation of an appropriate regional biosafety system, taking into account the national political and technical institutions and processes, the diversity of domestic interests, the strengths and capacity of the public and private sector interest groups.

5.2 Strategic Goal 2: Regional and national capabilities for confident and competent science-based decision-making.

What is involved in this strategic goal

Maintaining high levels of standard, efficiency and effectiveness in risk assessment; risk management; conducting field research against a backdrop of having limited human capacity, technical know how and financial resources to support a biosafety system, given numerous pressing national needs and priorities is a key challenge that the Eastern Africa countries face. This strategic goal seeks to address the issues that could be used to prescribe modalities to strengthen regional and national capacities for biosafety. The purpose of this strategic goal is to promote efficient utilization of limiting resources in Eastern Africa for strengthening and implementing biosafety systems. The key components of this strategic goal are:

1. Effective resource rationalisation to support training and enhance networking.
2. Sharing of resources to reduce transaction costs, increase cost-effectiveness and provide solidarity and promote efficiency in risk assessment and risk management.
3. Promote a regional mechanism for developing acceptable criteria and standards to weigh risks/benefits while considering agricultural productivity, environmental, and human health concerns.

What we intend to achieve in this strategic goal?

The outcomes and impacts of implementing this strategic goal will be:

- Available expertise in the region efficiently and effectively utilized.

- Centres of specialisation to support contained and confined field trials, risk analysis and management as well as those for food safety assessment strengthened.
- Training programmes on biosafety developed jointly and conducted regionally to permit efficient utilization of available facilities, expertise and funds.
- Improved confidence for document review and competence in decision-making

What are the main Challenges?

Rationalization and sharing of resources to promote efficiency, effectiveness and reduction in transaction costs for biosafety faces a number of challenges including.

- How to facilitate regional and national policies that would promote sharing of facilities, expertise and information resources for benefit of biosafety systems.
- How to develop a system to harmonise implementation of the biosafety systems in spite of variances in present institutional structures in charge of biosafety frameworks at national levels.
- How to strengthened attention to biosafety within region bodies like ASARECA, COMESA and the EAC.

Strategies to address the challenges

The main strategies to address the challenges of implementing this strategic goal include the following:

- Facilitating a fact-based negotiation process among the partner countries to reach consensus on common elements and on facilities and modalities for sharing
- Establishing a database of facilities, existing human resources, other information types for the region
- Supporting development of centres of specialization to promote resource sharing and utilization
- Formulating policies and mechanisms for joint capacity building and awareness programs
- Supporting the development of training materials and operational guidelines

5.3 Strategic Goal 3: Operational capacity for generating, accessing, disseminating and sharing information on biosafety

What is involved in this strategic goal?

This strategic goal addresses the issues related to how valuable information can be shared, and for the purpose of using, allowing additional data for informed regulatory decision making. The key elements of this strategic goal include:

1. Efficiency and effectiveness in generating, accessing and disseminating relevant information sets needed by policy makers and stakeholders.
2. Responsiveness and relevance data and information to national requirements
3. Management systems that promote efficiency, innovation and self learning in information generation, analysis and use
4. Contribution to policy reform and implementation within context of national development

What do we intend to achieve

In this strategic goal PBS Eastern Africa intends to achieve the following:

- Increased awareness of regional biotechnology issues
- Access to and sharing of information on biosafety within the region enhanced
- Mechanisms to disseminate and share biosafety information within the region institutionalized and or operationalized
- Communication facilities and skills for biosafety enhanced

What are the main challenges in this strategic goal?

Limited communication skills coupled with the apparent lack of human and capital resources has led to inadequate scientific and social economic information to support assertions on perceived risks. Mechanisms for biosafety communications at both regional and national levels are not institutionalized and are currently functioning in isolation and in an adhoc manner. The key challenges that this strategic goal aims to address include:

- How to improve availability of scientific/social economic information for risk assessment, analysis and mitigation strategies
- How to improve communication and networking amongst institutions involved in biotechnology and biosafety at national and regional level

Strategies to address the challenges

Strategies to address the challenges of this strategic goal include the following:

- Providing a regional link in identifying information needs of various stakeholders, sources and diversity of information.
- Facilitating the generation of information tailored on the needs of the region

- Strengthening capacity of scientists, regulators, policy makers and other stakeholders to efficiently use biosafety information and communication technology
- Improving communication between key regional stakeholders

5.4 Strategic Goal 4: A dynamic regional platform for policy advocacy, lobbying, coordination and resource mobilisation

What is involved in this strategic goal?

The key component of this strategic goal is to create an umbrella network as a voice and means to garner support for regional policies and frameworks on biosafety. PBS Eastern Africa will achieve this strategic goal by facilitating regional networking for advocacy and lobbying, mobilizing resources and promoting innovation.

What do we want to achieve?

As a regional network PBS-EA in this strategic goal will seek to achieve the following:

- Enhanced appreciation and greater ownership of regional collaborative action for biosafety regulation.
- Invigorated and innovative biosafety systems
- Increased investment in biotechnology and biosafety training, research and development

The overall impact of implementing this strategic goal will be the creation of a body of scientists, regulators policy analysts and makers who can respond collectively to regional biosafety issues. The strong advocacy and lobby function at regional level will enhance resource mobilization permitting, the region to source additional funds to promote economic growth and attainment of national development thrusts.

What are the challenges?

There are a number of key challenges of this strategic goal. The major issue is how to increase public awareness (education and participation) about biotechnology and biosafety. The level of awareness on biotechnology and biosafety issues in Eastern Africa is extremely low, even among the scientific community leading to polarisation of debate. Because of this inadequate public understanding of biotechnology and biosafety, objective stakeholder participation in policy and decision-making processes is constrained. In addition, limited awareness amongst policy/decision makers is a major constraint to the expeditious enactment of the enabling policy/legal framework.

The key challenges of this strategic goal include:

- How to promote convergence of opinions about biosafety amongst the different categories of stakeholders.
- How to advance integrated biosafety systems dealing with the statutory provisions and bureaucratic limitations in the partner countries.
- How to ensure commitment to, ownership of and investment into regional mechanisms
- How to develop a system of resource mobilization and utilization that promotes equitable and effective utilization of resources

Strategies to address the challenges

The main strategies to address the challenges of this goal include the following;

- Creating large constituency within the partner countries that engages actively and objectively in biosafety debate and decision-making.
- Assisting governments to develop effective harmonised biosafety systems
- Promoting information sharing on biosafety policies, priorities, successes and failures
- Facilitating the conduct of workshops, meetings and conferences to elaborate common regional biosafety issues and distribution of tasks to reduce duplications and build a regional critical mass
- Participating in regional and international fora to advocate and defend regional interests pertaining to safe application of biotechnologies
- Membership to high-level and influential committees/task forces/panels related to biosafety
- Lobbying to obtain more support for rational biosafety systems
- Arranging consultations, studies on regional biotechnology issues

6.0 PBS EASTERN AFRICA ROLE AND CORE FUNCTIONS

The strategic goals describe what PBS Eastern Africa can address within her niche and indicate that most of the actions require partnerships with regional and national organizations and actors. PBS will play a complementary role to existing programs and institutions through facilitating the implementation of regional actions. In particular, PBS-EA will strive to integrate its work in the activities of regional (e.g. ASARECA, EAC) and national strategic partners to ensure sustainability. A desired feature of the PBS-EA is functionality of efficient and effective mechanisms for receiving, prioritising and responding to regional biosafety issues. The Regional Secretariat will provide a coordinating mechanism for regional action. The core functions are:

1. Facilitating and organizing platforms for regional training and policy dialogue

1. Supporting development of specialized platforms or networks for knowledge exchange and training
2. Targeted support to respond to specific training needs

2. Promoting regional partnerships and networks for biosafety

Support efforts to rationalize resources (human and infrastructure) so as to promote efficiency and effectiveness in biosafety training and regulation. This can be done by;

- Supporting mechanisms for sharing experiences
- Linking institutions to other research and development networks in the region and internationally

3. Supporting information access, exchange and availability

- Promote information exchange and availability by inventorying existing and new knowledge generated in the region
- Facilitate acquisition of and access to information and data bases relevant to the region
- Develop a database of expertise in the region and promote access to expertise from outside of the region

4. Resource mobilization, lobbying and advocacy

- Advocacy and lobbying
- Sourcing funds to support grant schemes, strategic initiatives, networking, joint facilities, and other regional activities.

7.0 PBS EAST AFRICA GOVERNANCE AND MANAGEMENT

PBS Eastern Africa is designed to provide an efficient and innovative regional framework for promoting safe application of modern biotechnologies. It therefore aims to catalyse national responsiveness to biosafety requirements. It is also meant to provide a mechanism for collective action at regional level and reducing transaction cost for partner countries. The PBS Eastern Africa program is based on commitment and collective action by participating public and private institutions and their partners involved in biotechnology and biosafety advancement in the region.

There is a Regional Coordinator to oversee regional activities in consultation with the Advisory Groups and with the national focal point persons for day to day operations. The Regional Coordinator has a lean secretariat that operates as a facilitating unit and an internal service provider to the program. Its main management functions are:

- Convene, and ensure proper composition and functioning of Regional Advisory Group
- Facilitate identification and implementation of priority actions for PBS-- including BBI--at national and regional levels, and the development of annual work plans to address these
- Liaise with PBS Director and Assistant Director to facilitate implementation, funding and reporting of collaborative activities
- Initiate and support regular interaction with national and regional policy-making bodies to communicate program results and promote their integration into policy processes
- Support effective communication, sharing, and publication of PBS results in partner countries and regions
- Resource mobilization, lobbying and advocacy

This strategic plan was drawn half way the project life for a number of reasons including consolidating coherence of the project priority activities, strengthening partner contribution to the strategic direction and to the rational use of the program investment. The strategic plan has pointed main challenges and the strategic goals in overcoming them. The document provides strategies to address the different challenges and from these specific activities can be derived.