



EAST AFRICA PROGRAM FOR BIOSAFETY SYSTEMS (PBS, EA)

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PARTICIPANTS AT THE EAST AFRICAN COMMUNITY GMO POLICY WORKSHOP, 12-14TH SEPTEMBER, 2006

PREPARED BY: PBS REGIONAL COORDINATION OFFICE

OCTOBER 2006

1. Abstract – scope of work

The purpose of PBS is to help participating countries such as those of East Africa to develop functional Biosafety systems that will support application and use of modern biotechnology in a safe and sustainable manner. In the long term this support is expected to translate into judicious use of modern agricultural biotechnology in order to increase agricultural productivity, leading to higher rural incomes. PBS addresses this goal through facilitating biotechnology/biosafety policy development and approvals, assistance for strengthening the biosafety legal and regulatory systems, capacity development for risk assessment and risk management of GM plants that may be released into the environment as well as re-enforcing the system for public information and public participation. The East African region made progress during the year through both regional and country based activities. There was better understanding of regional policy implications and options for biosafety/food safety and Uganda made progress towards implementation of Confined Field Trials. The major partners involved in this work included the Country Councils of Science and Technology of the three countries, the Donald Danford plant Science Centre and Michigan State University. At the Uganda level, NARO, Makerere University and the Uganda National Bureau of Standard were also key partners.

This report covers PBS activities carried out in East Africa under the USAID EGAT Leader Award and also the Uganda Associate Award project during the 2005/06 fiscal year.

I. PBS MANAGEMENT

PBS Revised Strategy

The Regional Program Officer (RPO) attended the PBS Strategy Review meeting in Washington on 1 to 3rd March. The purpose of the meeting was to take a fresh look at PBS as whole and work through a refocused strategy for the remaining period of the first phase of the Program. During the meeting gap- analyses and log frames for Uganda, Tanzania and for the East African region were initiated and these were finalized back in Uganda and are presented in Appendix 1 and 2. The intermediate goals to drive the regional agenda were defined as; A common policy on GMO commodity trade to be incorporated by East African Community, Similar standards for risk assessment of specific commodities and Communication / Sharing information and experience on biosafety. The intermediate goals for Uganda project contribute to the Approval of Uganda Biotechnology and Biosafety (BB) Policy and the legislation, enhanced capacity for risk assessment and risk management, support to regulatory system for confined field trials of transgenic plants, initiating a functional system for review and approval of commodity imports as well as capacity for review of application for commercial release. These objectives have subsequently been used as reference points when discussing priorities and formulating program activities.

COP8-MOP3

The RPO attended the Conference of Parties meeting which took place in Curitiba – Brazil 13th to 17th March 2006 as a participant in the Public Research and Regulations Foundation. The main objective of the Foundation is to involve the public research sector in formulation of regulations and international agreements relevant to modern biotechnology. The group took off

two days prior the meeting to prepare for the cohesive participation and formulated submissions that were made during the different sessions of the negotiations. PBS impact during this MOP was through the contribution through PRRI, the side events and interactions with the regional groups such as the one for Africa. The highlight of this COP-MOP was reaching an agreement on one of the most contentious articles 18 2b of the Cartagena Protocol on ‘Handling, Transport, Packaging and Identification’ of GMOs made for food feed or processing.

Regional Advisory Group Meeting; Nairobi, 25th June 2006.

This meeting was organized in accordance with the responsibility for the RPO to seek guidance from the Regional Advisory Group on priorities and strategies to be followed in implementing the Program. The specific purpose was to review progress of PBS in East Africa; update and discuss the new evolving PBS strategy and to provide input into the planning process for the proposed “EAC Regional Workshop on the development of a Regional Biosafety Policy”. The meeting was timely and took advantage of the Advisory group interacting and sharing views with the then new PBS Program Director Willy De Greef.

New CTO at USAID Uganda Mission

Mr. Jim Dunn who was in charge of PBS at the Uganda Mission left the country on 17th March and was replaced by Mr. Loren Hostetter, as the Agriculture Advisor. A meeting was held in attendance of the ABSP II Coordinator, Dr. Tilahun Zeweldu to brief the incoming officer about PBS so as to ensure smooth transition of the project. Coherence between PBS and ABSP II work plans was stressed during this meeting.

II. ACTIVITIES UNDER THE PROGRAM OBJECTIVES

a) Policy Development and Implementation

Legal Issues Involved in Establishing National Biosafety Regulatory Systems

A two-day meeting was held at Stanley Hotel, Nairobi, Kenya on December 7-8, 2005. The primary participants were 17, and included mainly lawyers and key regulatory officials from Kenya, Tanzania and Uganda. The specific objectives of the workshop were:

1. To convene a meeting of legal and regulatory experts to discuss in greater detail legal issues surrounding the establishment of national biosafety regulatory systems that were identified at the East Africa – PBS Roundtable in Entebbe, Uganda, in April, 2005.
2. To explore legal and regulatory issues that might arise when establishing biosafety regulatory systems that are comprehensive, efficient, workable, transparent and participatory.
3. To discuss cooperation and coordination among the national biosafety regulatory systems in East Africa.
4. To enhance legal and institutional capacity on biosafety in Kenya, Tanzania, and Uganda. To build a network

Main accomplishment from this activity was the bringing together a critical mass of legal experts concerned with biosafety to share and discuss the legal comparison paper developed by Greg Jaffe. This provided participants with better insight of critical legal issues and how these may impact implementation of the regulatory regime for the individual country and the region as a whole. Recommendations on how to proceed with the harmonization process were generated and

are being pursued in collaboration with ASARECA and the EAC. Appendix 3 presents a report from this workshop.

RABESA initiative

A project on the Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa (RABESA) was implemented jointly with ECAPAPA, PBS and ACTS. The participating countries include Egypt, Ethiopia, Kenya, Tanzania, Uganda and Zambia. The broad agenda of the RABESA initiative was to generate and analyse technical information required to inform COMESA/ASARECA countries on regional biotechnology and biosafety policy choice options.

National surveys, followed by consultative workshops were conducted in the various countries. The objectives of the workshops were to receive the country report and:

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

The country workshops brought together a wide range of stakeholders-policy makers, scientists, and practitioners in the areas of trade, food security and biotechnology/biosafety. The outcomes of the meetings were synthesized and further discussed in a regional workshop reported below.

RABESA Regional Workshop—This took place from May 29 to 31st.at Hilton Hotel, Nairobi. The objective of the workshop was to generate an advisory paper for COMESA Ministers of agriculture and Ministers of trade on the most appropriate approaches to developing and managing agricultural trade involving GMO crops and products. The workshop was attended by 85 delegates coming from 17 African countries. Three principal recommendations were declared from the workshop and these were: (1) in case of GMO for commercial planting there should be centralized regional assessment to be followed with national decisions; (2) in case of trade COMESA should provide advice/information from a central regional clearing house to help national decision and (3) in case of food aid guidelines should be developed at regional level and decisions left to be taken at the country level. A Follow on (RABESA II) project for implementing the recommendation was sought under the leadership of the Nairobi USAID regional office.

East African Community Consultative Workshop

East African Community (EAC), PBS and ASARECA organized a three day workshop from 12th to 14th September 2006. The general objectives of this workshop was to review EAC national biosafety frameworks for GMOs and recommend the way forward for the development of an EAC regional policy, legal and regulatory framework on GMOs with a focus on a number of areas, including, food safety, trade, environmental and public health issues. The specific objectives of the meeting were to:

1. Enhance participants' awareness on biotechnology and biosafety legal and regulatory issues
2. Share information and experience on biotechnology and biosafety advances in the region

3. Identify and/or recommend priority areas of biosafety where common procedures and/or policy is needed
4. Map out a process for facilitating an EAC regional policy and a regional framework on biosafety

The workshop was attended by over 90 participants and these included 12 members of parliament and many very senior government officials and biosafety regulators from the region. Important recommendations were made during the workshop and these have been synthesized as follows:

1. EAC to establish a multi-sectorial Committee on Modern Biotechnology and Set up a desk at the secretariat for immediate co-ordination
2. Establish a policy on public awareness and participation at all stages of biotechnology application
3. Establish a policy to enhance information sharing and networking including a regional BCH
4. Establish EAC representation at international level treaties, conventions, protocols and agreements
5. Encourage EA countries to accelerate and finalise their biosafety frameworks
6. Establish food safety focal points in partner states
7. Harmonise Regional food safety systems to address analysis, inspection, monitoring etc to promote trade and establish guidelines to handle emergency food aid
8. EAC Resource mobilization and sharing including human and infrastructure (Centres of excellence)
9. Harmonization of Risk analysis and environmental safety assessment tools
10. Harmonize Curriculums on bio-safety

Several of these recommendations touch on PBS planned activities significantly contributing to the program goals. The challenge is to move the outcome of this gathering forward and make sure PBS implements some of the recommendations that are in line with the project objectives.

Advancing Uganda Biotechnology and Biosafety Policy

The Uganda biotechnology and biosafety policy has been drafted and further advancement is waiting for government approval. Advocacy of the biotechnology and biosafety policy is critical to make sure policy makers, implementers and the wider stakeholders' community appreciate and support its approval and implementation. In this regard PBS organized a one-day meeting to map out strategies that should assist to move the policy forward for approval. The meeting was facilitated by Adrienne Massey, leader PBS communication component. As a strategic intervention for pushing the policy forward, the meeting identified 10 officials, who will work closely with UNCST and other relevant stakeholders. This group was put in charge of spearheading the advocacy and lobbying the different actors so that the policy can be presented to cabinet, discussed and eventually approved. The group met periodically and has prepared a number of documents including a repackaged policy; a policy briefing paper and sector specific policy briefs that are designed to ease reading and understanding the draft policy for non-technical persons.

b) Enhancing capacity for risk assessment and risk management

BBI Competitive Grants

The program addresses this objective through supporting specific training courses and research projects through the BBI Competitive Grants. This year seven BBI pre-proposals from East Africa and four others that involved collaboration with East Africa were short-listed. The RPO participated in the review of these eleven pre-proposals as part of the BBI grant process. Of the three proposals eventually selected for funding this year, one was from East Africa and the research is on “Baseline biodiversity impact studies of transgenic Bt cotton on wild ecosystems in the East African region” and the collaborators are William Hamisy, TPRI, Tanzania; Charles Watura, KARI, Kenya; Simon Byabagambi, Makerere University, Uganda; Roshan Abdallah, TPRI, Tanzania; John Pleasants, Iowa State University USA; Jonathan Wendel, Iowa State University, USA; and Neal Stewart, University of Tennessee, USA.

Master of Science training in biosafety and food safety:

Three Ugandan students started course work for their Master of Science course in Molecular Biology, Environmental Safety and Food Safety under Makerere University of Kampala in September 2005. Monitoring of the progress made by the M. Sc. students in terms of identifying supervisors, discussing research topics, preparation of proposals and course units undertaken. It was agreed that the students focus their research work on bananas. The topic for the molecular biology student is ‘*Gene Expression Studies in Musa balbisiana Showing Tolerance to Xanthomonas campestris pv. Musacearum Infection*’. The topic for the environmental risk assessment student is ‘*Assessment of the potential of Horizontal Gene flow to Bacteria from transformed East African Highland Bananas (Musa)*’. The third student is working on food safety issues in terms of ‘*Safety assessment of the rice chitinase and cystatin genes used in the transformation of the East African Highland Bananas against Nematodes and Black Sigatoka*’. This student (food safety issues) had the opportunity to attend a three months’ hands-on training in an advanced molecular biology laboratory in Leeds UK where one of his supervisors Dr. Howard Atkinson is based. This particular lab is collaborating with the NARO Banana Project at Kawanda and is supported by ABSPII.

A 4th M. Sc. student was identified during the year in collaboration with UNCST and was offered a two year MSC course under Makerere University starting July 2006. The student is Kenneth Kirya a first class degree holder from the Department of Crop Science, Makerere University. His research topic focuses on possible environment questions (gene flow) for Uganda in relation to transgenic cotton.

These Masters degree training are designed to support introduction of transgenic crops in the country by addressing researchable questions that may be raised by the regulators while at the same time technical expertise in biosafety research and risk assessment are improved.

c) Support to regulatory system for confined field trials

This objective is addressed through training regulators, developing various documents necessary for implementing the trials and providing technical back up for decision making.

Regional Workshop for Field Trial Design and Completing Applications for Confined Field Trials; 21st to 23rd June Bagamayo Tanzania

The objective of the workshop was to share experiences and knowledge in the design and implementation of confined field trials intended for crops created utilizing the techniques of modern biotechnology. The participants were also provided with hands-on experience in completing applications suitable for submission to regulatory authorities. This capacity building workshop was attended by over 30 participants 13 of them from Uganda and the rest from Tanzania. The activity was lead by DDPSC, local organization was taken care of by COSTECH, Tanzania and resource persons comprised of both international and Regional Scientists.



With this training accomplished and similar ones conducted in the region within the last two years, the EA region has now reasonable general capacity to prepare and evaluate applications for introduction of GMO plants for experimental use.

Training Uganda Regulators

A two-day workshop for NBC and IBCs was held at Grand Imperial Hotel on 2-3rd November 2005 in Kampala. The purpose was to enhance the knowledge of regulators concerning the characteristics and purpose of CFTs, and to enhance the skill base of the National Biosafety Committee and the NARO Institutional Biosafety Committee in review, approval and oversight of confined trials of GM plants. The resource persons included two international consultants and two local persons. The Chair of the NBC and the Vice Chair who had made trips to the USA in the recent past and visited field trials of GM crops also made presentations about what they learnt during their visits. The workshop was quite interactive and the discussions held indicated that at least most of the key members of both these committees understood the cardinal principles of CFTs and are ready for the job. ‘We now know, let’s do it’ the NBC Vice-Chair called out.

Uganda Confined Field Trial Guiding Documents

A two day residential meeting was held on 27-28th March to finalize the documents for use in CFT implementations in Uganda. The documents worked on included the overall National Guidelines for CFTs, the Standard operating procedure (SOPs), the Trial manager's handbook and the Inspectors Manual. The Ministry of Agriculture requested for a further look at the inspectors' manual, otherwise the documents were finalized and forwarded for final editing and printing. Production of these documents was timely at that time when applications for introducing GMOs for research were also in processes.

Uganda Inspector's Manual for CFTs

A half-day meeting was also held on 4th November 2005 with representatives of the Plant Health Inspectorate (MAAIF), and other members of the task force group that worked on the CFT documents as well as a visiting consultant from DDPSC. The purpose of the meeting was to assess progress with drafting the Inspectors' Manual and decide how this job was to be completed in line with the Ministry's request. The consultants explained the basic concepts of how the manual is used. The task group and the Ministry (Crop Inspectors) would review the manual and improve on the draft to suit Uganda's need. The NBC chair and Dr. Charles Mugoya, the leader of the biotechnology and biosafety program in ASARECA, were identified to edit the draft and this was expected to enhance both ownership and possible spill over effects within eastern Africa.

Containment facility consultancy for Uganda

The report and the recommendations on the containment facility by the PBS consultant Hector Quemada were presented to and accepted by NARO, the recipient partner. The project document to commit the construction under ABSP II was signed. NARO called for the construction bids on the 23rd December 2005 and the closing date was 25th January 2006. The contractor was identified and the signing of the building contract was done in March. Construction of the facility was effected by ABSP II and was expected to last for eight months.

d) Initiating a functional system for review and approval of commodity imports

Initial effort was directed to building capacity for safety assessment and this was done in collaboration with MSU. One trainee, Jacqueline Kyokunda Kwesiga from the Microbiology Laboratory of Uganda Bureau of Standards attended a two-month internship course for food safety assessment including data interpretation at Michigan State University. She produced a good report that has been suggested for further development into a manual for food safety assessment guidelines to be a reference material for regulators.

Another trainee, Patricia Bageine Ejalu who is the Vice-Chair, NBC based at Microbiology Laboratory of Uganda Bureau of Standards benefited from an On-line course on 'International Food Laws and Regulations'. National Bureau of Standards has been targeted to strengthening as a focal point for GMO food product safety assessment.

d) Communication / Sharing information and experience on biosafety

Communication on biotechnology/biosafety is critical to ensure that decision makers and key stakeholders are adequately knowledgeable about modern biotechnology and are up to date in terms of regional and national needs and priorities. The program undertook several activities to address this objective:

Communication Strategy

A workshop was organized for purposes of developing a communication strategy for biotechnology and biosafety in Uganda. The meeting was one day and was facilitated by Adrienne Massey, leader PBS communication component. Participants included biosafety experts, journalists, regulators, scientists and NGOs. The workshop decided to peg the Communication Strategy to the country vision and mission on biotechnology as stipulated in the draft national policy on biotechnology and biosafety. Key audiences were identified as policy makers, media, scientists and extension agents. Key messages were identified as:

1. Definitions of biotechnology and biosafety,
2. Biotechnology as a tool,
3. Benefits of biotechnology and
4. Regulation of biotechnology in Uganda.

In January, 2006, discussions were held with the Uganda USAID Mission Biotechnology Advisor, ABSP II Coordinator and the UNCST biosafety officer, on how to finalize the communication strategy, building on what the PBS international consultant had done. A local consultant was hired in consultation with PBS management and appointed to do three main jobs:

- Produce communication strategy for BB
- Design a web page for Biosafety under the UNCST website.
- Assist PBS to organize media training workshop and to start a newsletter.

The communication consultant produced a draft Communication Strategy that was presented to the country advisory group and ABSPII communication experts for their input. An action plan in line with this strategy and the Uganda PBS objectives was developed and this covered both PBS and ABSPII interests. Outputs that form the basis for the action plan include:

1. Approved policy,
2. Informed public about biotechnology and biosafety system in the Uganda,
3. Appropriate technologies transferred and adopted, and
4. Biotechnology products developed and biosafety research conducted.

Media Workshop

This workshop took place 23-24 March and was organized with support of a local consultant. The major objective of the workshop was to improve the capacity of the media Journalists to cover agricultural biotechnology more accurately and in a credible manner. This will increase their potential to inform the audience about agricultural biotechnology so as to help biotech policy decision-making process move faster and in the right directions. Proper communication on Biotech and Biosafety is critical at this stage in Uganda when application for introducing GMO for research purposes are in process. There were over 30 participants from different Media houses. The highlight of the training was a visit to biotechnology labs that was followed by

formulating news and feature articles which were reported in different media. The main achievement here was that PBS/ABSPII established a relationship with an increasingly more knowledgeable media group.

BioVision Newsletter

In line with the communication strategy, two volumes of a quarterly newsletter BioVision were published. Feedback on these issues indicates that the newsletter is good but needs to adopt a regional focus for the benefit of both the local and regional clients.

BioVision Website

A project website was constructed in consultation with the UNCST, a website designer, a communication consultant and the ABSP II officer based with USAID. The product was posted on the internet as www.biovisioneastafrika.com and final adjustments continued before launching the site.

Posters

The project started producing posters talking about different aspects of biotechnology and biosafety. One poster “Uganda GMO Application Process” was published and circulated to relevant institutions and the second poster “Understanding Biotechnology” was initiated.

Documentary Film

A documentary on “Understanding Biotechnology/Biosafety and its current status in Uganda” was cast with the intention of demystifying this technology for our target groups. Shooting a documentary was done by a professional journalist. This documentary is designed to depict, traditional and conventional biotechnology, modern biotechnology initiatives in Uganda and the key persons involved.

e) OTHER DEVELOPMENTS:

Banana application in Uganda

The application to conduct ‘Confined Field Trials for Bananas for Resistance to Black Sigatoka’ was submitted to the NBC in November 2005, first considered in April 2006 was finally approved. This approval was communicated to the Director General NARO by the chairman of the NBC on the 4th September 2006 and the applicant was allowed to conduct the trial for 18 months starting from the time the plants will be sown.

Support to Bt cotton initiative

Several meetings were held with partners in relation to introduction of Bt cotton in Uganda. PBS took part as an interested partner. These meeting discussed both the seed testing agreement and the research agreement between NARO, DELTA Pine and Monsanto. The seed testing agreement was simple and was agreed upon but more discussions are still on-going with the research agreement.

f) Publications

Sengooba T., Mugoya C., Traynor and J. Komen. 2006 Analysis of the Biosafety System in Uganda: Regulatory Framework, policy and Procedures 23 pages. The document was published by BIOEARN.

A 52 page publication on “Comparative Analysis of the National Biosafety Regulatory System in East Africa” by Greg Jaffe came out of the press and circulation started.

The National Guidelines for Confined Field Trials, 21 pages.

Uganda Trial Managers’ Handbook for Confined Field Trials, 60 pages.

BioVision Newsletter, Vol.1 and 2.

Poster on “Uganda GMO Application Process”.

Proceedings for the East African Policy Roundtable, April 2005 were published and circulation started during the EAC workshop where over 100 copies were picked.

These publications are available on www.biovisioneastfrica.com.

III. ASSESSMENT OF PROGRESS

All planned regional activities were accomplished during this fiscal year. Under the Uganda AA most planned activities with the exception of two were accomplished. Sensitization of parliamentarians about the policy was pushed forward to the first quarter of next year because that was when the participants would be available after the general election. Training of trial managers in relation to the banana CFT was not effected as DDPSC decided to do this training when the GM banana trial was insight.

Appendix 1

Program for Biosafety Systems (PBS) Medium-Term Plan 2007-2009

Logframe matrix

PROJECT: [Combined activities for Kenya, Uganda and Tanzania PBS Project]

MANAGER: [Theresa Sengooba]

Hierarchy of Activities/Objectives	Indicators/Milestones for Achievement	Means of Verification	Important Assumption
<p>Goal: The overall goal of the program, is to more effectively address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade and environment objectives</p>	<p>Enhanced use of modern biotechnology and biosafety integrated within relevant institutions</p>	<p>GM commodities in use</p>	<p>GM commodities in use</p>
<p>Intermediate Goals</p> <ol style="list-style-type: none"> 1. A common policy on GMO commodity trade to be incorporated by East African Community 2. Similar standards for risk assessment of specific commodities 3. Sharing information and experience on biosafety 	<ol style="list-style-type: none"> 1. Policy recommendations of commodity trade incorporated 2. Common standards for risk assessment adopted 3. Biosafety regulators data base 	<ol style="list-style-type: none"> 1. Policy document 2. Published standards 3. Access to data base 	<p>Commitment by regional authorities</p>
<p>Purpose To promote common understanding and procedures in the regulation of biotechnology and reduce trade barriers for GMO products in East Africa</p>	<ol style="list-style-type: none"> 1. Regional policy recommendations presented to EAC 2. Common standards for risk assessment documents 	<ol style="list-style-type: none"> 1. Reports 2. Recommended Safety standard 	

Hierarchy of Activities/Objectives	Indicators/Milestones for Achievement	Means of Verification	Important Assumption
<p>Outputs</p> <p>1.1 Policy recommendations for GMO commodity trade</p> <p>1.2 Policy recommendations of GMO food safety</p> <p>2.1 Recommended safety standards to guide risk assessment</p> <p>3.1. Publications and reports</p>	<p>1.1.1 Policy on commodity trade published</p> <p>1.2.1. Policy on GMO food published</p> <p>2.1.1 Decision documents on safety standards</p> <p>3.1.1 Publications and reports</p>	<p>1. Draft Policy documents</p> <p>2.1 Decision document</p> <p>3.1 Publications and reports</p>	
<p>Activities</p> <p>1.1.1 Consultations with regulators and EAC policy makers on GMO trade and GMO food Policies</p> <p>1.1.2 Prepare Draft policies</p> <p>1.1.3 Stakeholder consultation on draft policies</p> <p>2.1.1 Consultations with scientist and regulators on safety standards to guide in risk assessment</p> <p>2.1.2 Prepare recommendations on safety standards</p> <p>3.1.1 Information generation, documentation and dissemination</p>	<p>1.1.1 Consultations completed</p> <p>1.1.2 Preparation of draft policies completed</p> <p>1.1.3 Draft policies endorsed</p> <p>2.1.1 Consultations completed</p> <p>2.1.2 Recommendations on Safety standards adoption</p> <p>3.1.1 Enhanced knowledge and informed Decisions</p> <p>3.1.2 Publications and reports</p>	<p>1.1.1 -2.12. Policy and recommendations documents</p> <p>3.1.1 Circulation list and reports,</p> <p>3.1.2 Publications and reports</p>	

Appendix 2.

Program for Biosafety Systems (PBS) Medium-Term Plan 2007-2009

Logframe matrix PROJECT: [Uganda PBS Project]

MANAGER: [UNCST and Theresa Sengooba]

Hierarchy of Activities/Objectives	Indicators/Milestones for Achievement	Means of Verification	Important Assumption
<p>Goal: The overall goal of the program, is to more effectively address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade and environment objectives</p>	<p>Enhanced use of modern biotechnology and biosafety integrated within relevant institutions</p>	<p>GM commodities in use</p>	<p>Demand for the Gm commodities</p>
<p>Intermediate Goals</p> <ol style="list-style-type: none"> 4. Approval of Uganda Biotechnology and Biosafety (BB) Policy and the legislation 5. Capacity in place for risk assessment and risk management 6. Conduct of confined field trials for transgenic banana and Bt cotton 7. Functional system for review and approval of commodity imports 8. Initial capacity for review of application for commercial release 	<ol style="list-style-type: none"> 1.1 Approved BB Policy 1.2 Biosafety Bill submitted to Parliament 1.3 Biosafety regulations ready for submission 2.1 Personnel trained in risk assessment and risk management 2.2 Risk assessment studies conducted 3.1 Approved applications for transgenic banana and cotton testing 4.1 Regulatory body for commodity imports fully functional 4.2 Applications for import of GM commodities processed 5.1 Application and review process documented 	<ol style="list-style-type: none"> 1.1 Published BB Policy 1.2 Draft Biosafety Bill and regulations 2.1/2.2/ Reports 3.1/4.1/4.2 Decision documents 5.1 Published Application Forms 	<ul style="list-style-type: none"> • Policy will be approved • Personnel qualifying for risk assessment training available • Successful consultation of stakeholders • Biosafety applications will be submitted and approved

Hierarchy of Activities/Objectives	Indicators/Milestones for Achievement	Means of Verification	Important Assumption
<p>Purpose To promote the judicious use of modern agricultural biotechnology in Uganda in order to (i) increase productivity leading to higher rural income, (ii) enable trade of GM commodities</p>	<p>3. Enabling policies and legal frameworks 4. Balanced media coverage 5. Field evaluation of GM plants 6. Policy recommendations on GM commodity trade</p>	<p>1. Published policies 2. Media coverage 3. Reports on evaluation trials</p>	<p>Policies' adoption</p>
<p>Outputs 1.3 Approved BB Policy 1.4 Draft Biosafety Bill 1.5 Regulations for implementing biosafety bill 1.6 Policy makers and the public sensitized about biotechnology/biosafety 2.1 Guidance for risk assessment and risk management 3.1 At least one CFT planted 4.1 Guidelines for GM commodity imports 5.1 Guidelines for commercial release of GM products</p>	<p>1.1.1 Policy lobbying process completed 1.1.2 Policy adopted 1.2.1 Draft Bill submitted to Parliament 1.3.1 Draft regulations ready for approval 1.6.1 Informed decisions and opinions 2.1.1 Recommendations for risk assessment and risk management 3.1.1 At least one biosafety application approved 3.1.2 Guidelines for conducting CFT implemented 6.1.1 Recommendations for GM commodity import developed 8.1.1 Recommendations for commercialization of GM products developed</p>	<p>1.1.1 Dialogue reports 1.1.2 Published policy 1.2.1/1.3.1 Draft Biosafety Bill and the regulations 1.4.1 Sensitization activities' report 2.1.1 Technical Publications 3.1.1/3.1.2 Decision documents 4.1.1/5.1.1 Reports,</p>	<ul style="list-style-type: none"> • Cabinet will table the policy • Successful consultations with stakeholders • Public will be interest in biotechnology • Biosafety applications will be submitted
<p>Activities 1.1.4 Dialogue with members of parliament and Sector specific policy makers on BB policy</p>	<p>1.1.4 Dialogues with MP completed 1.1.5 Implementation plan completed 1.2.1 Revised Bill</p>	<ul style="list-style-type: none"> • Reports • Implementations • Information 	<ul style="list-style-type: none"> • Successful consultation of stakeholders

Hierarchy of Activities/Objectives	Indicators/Milestones for Achievement	Means of Verification	Important Assumption
<p>1.1.5 Develop the implementation plan for the BB Policy</p> <p>1.2.1 Consultative review of Biosafety Bill</p> <p>1.3.1 Develop biosafety regulations</p> <p>1.4.1 Media training</p> <p>1.4.2 Assistance to spokespersons</p> <p>1.4.3 Information exchange and dissemination activities</p> <p>2.1.1 Conduct Risk Assessment studies on cotton, banana and cassava</p> <p>2.1.2 Conduct formal M. Sc. training</p> <p>3.1.1 Training for scientist, technicians, Phytosanitary Inspectors on requirements for CFT managements</p> <p>3.1.2 Assistance in biosafety application preparation and revision</p> <p>3.1.3 Technical backup in CFT establishment</p> <p>4.1.1 Consultative guidance to assess alternatives and draft regulations governing the review and approval of transgenic commodity imports</p> <p>4.1.2 Training in testing samples for the presence of transgenic materials</p> <p>5.1.1 Training for relevant regulatory bodies on reviewing applications for commercial release with special focus on Bt Cotton</p>	<p>1.3.1 Biosafety regulation final draft</p> <p>1.4.1 Media needs identified and incorporated in future action plan</p> <p>1.4.2 Spokespersons' needs identified and addressed</p> <p>1.4.3 Information material published</p> <p>1.3.3 Information material published</p> <p>2.1.1 Recommendations for risk assessment</p> <p>2.1.2 Progress reports and theses submitted</p> <p>3.1.1 Number of technical staff trained for CTF implementation</p> <p>3.1.2 Biosafety applications processed</p> <p>3.1.3 CFT conducted</p> <p>4.1.1 Consultative process completed</p> <p>4.1.2 Personnel with expertise to test for presence of transgenic materials</p> <p>5.1.1 Benefits and risks associated with commercial release discussed with regulators</p>	<p>documents</p>	<ul style="list-style-type: none"> • Public interest • Continued Government commitments for application of modern biotechnology

Summary Report on East African Workshop on Legal Issues Involved in Establishing National Biosafety Regulatory Systems -7th to 8th Dec 2005

By: Theresa Sengooba

Background

Countries throughout the world are establishing national biosafety regulatory systems that strive to be comprehensive, efficient, workable, transparent and participatory. Establishing such systems requires the balancing of numerous goals and the trading off of different interests and issues. It also requires analyzing and addressing difficult legal and regulatory problems.

Over the past several years, Kenya, Tanzania, and Uganda have made tremendous progress toward establishing functional and protective national biosafety regulatory systems. Each country has set forth interim regulatory processes and drafted legal instruments to implement more permanent regulatory structures. As those regulatory systems continue to evolve and mature, each country will confront difficult legal and regulatory issues that require decisions if their systems are to be transparent, understandable, fair, and workable.

In April, 2005, the International Food Policy Research Institute's Program for Biosafety Systems (PBS) co-sponsored with ASARECA an East Africa Policy Roundtable in Entebbe, Uganda. That roundtable brought together individuals from Kenya, Tanzania and Uganda who are involved in biosafety regulation to review and analyze different areas related to biosafety, including legal and regulatory issues. At that meeting, presentations were made on the regulatory frameworks in each country as well as a comparative analysis of the different regulatory systems.

Purpose and Objectives

As a follow-up activity to the East Africa Policy Roundtable and the policy paper entitled "Comparative Analysis of National Biosafety Regulatory Systems in East Africa" presented at that roundtable, a small meeting of legal and regulatory experts was organized. The purpose of the workshop was to explore a number of legal and regulatory issues that will be confronted by countries trying to establish comprehensive, efficient, and transparent regulatory systems. The "comparative analysis" paper produced by Greg Jaffe after consultations with a number of legal and regulatory officials in the region was used as the background document to the meeting. The specific objectives of the workshop were:

5. To convene a meeting of legal and regulatory experts to discuss in greater detail legal issues surrounding the establishment of national biosafety regulatory systems that were identified at the East Africa – PBS Roundtable in Entebbe, Uganda, in April, 2005.
6. To explore legal and regulatory issues that might arise when establishing biosafety regulatory systems that are comprehensive, efficient, workable, transparent and participatory.
7. To discuss cooperation and coordination among the national biosafety regulatory systems in EA.
8. To enhance legal and institutional capacity on biosafety in Kenya, Tanzania, and Uganda. To build a network

There were seven technical sessions where topics were presented and thoroughly discussed and the areas covered were:

1. Background on National Biosafety Systems in East Africa
2. Legal Authority for Biosafety System and Safety Standards
3. Proportionate Risk-Based Review Procedures
4. The Role of Socio-Economic Considerations
5. Addressing Food Safety Issues within the Biosafety Regulatory System
6. Public Participation and Transparency
7. Coordination and Cooperation among Biosafety Regulatory Systems in East Africa

Salient Observations Made On The EA Biosafety Legal Regimes

- All three countries approach Biosafety from agriculture, but it is important to note that there biosafety concerns in other fields, e.g. food, health, trade and this may necessitate changes in these laws future.
- Biosafety is a multifaceted discipline and thus there is need to look at the various disciplines involved and how the developed law caters for it. The regulatory regime should not be judged by the form it takes but the content and the capacity of attend to what is supposed to be addressed.
- If socio-economics, culture etc, have to be put in the law so that there are taken into account for approval they need to be defined clearly and the standards to be followed clearly spelt out. Parameters of legal authority need to be delineated.
- Promotion and regulation of Biotech by the same institution (UNCST in Uganda) may bring conflict of interest and this should be avoided.
- There is need to develop generic standards for the region. The CP gave members to set their own standards that may be higher than the minimum prescribed in a protocol. It is better to have one standard because the essence is to ensure safety of human health and the environment. Internal law does not allow the segregation in standards of indigenous and foreign products or processes.
- Institutional arrangements and legal systems are very important for biosafety. How are the lawyers, the judges aware and informed of all these issues? They are part of the legal system and the challenge is how to sensitize them because they will in future make binding decisions from uninformed points of view.

Summary:

- What kind of legal instrument and arrangement do we think fits the different countries?
- The whole question of whether the promoter should be the regulator? Issues of conflict interest?
- RF and procedural rules? How to assess risks, should we do risk assessment and EIA, these needs to be evaluated.
- Should we have generic standard for the region and leave the countries to fit in their national interests (Already the EAC is developing a document for shared ecosystems; SADC membership e.g. Tanzania etc)

- The whole question of socio economic and ethical consideration; do we set generic standards e.g. TZ radios broadcasting in vernacular are illegal, preaching in vernacular has been abolished etc)
- Public perception issues (delineating issues such as terminator gene technology) (TZ 18% use certified seed).
- What we should put clear is that the regulations and laws are to protect human health and environment

Salient Observations made on proportionate risk-based review procedures

Questions raised:

- Should commercial releases have the same requirements as CFTs?
- Should a CFT require a food safety assessment
- CFT should it require socio-economic impact assessment?

Biosafety Protocol: Based on LMOs (in general) and potential impact on the environment and human health. CFTs may not require a whole set of procedures provided for under the protocol given its limited applicability. The available regulator framework could suffice (i.e. may not require advance informed agreement procedures). It was further noted that different regulation paths and risk assessment may be needed for different organisms. Factors that contribute to the understanding of the risk have to be clear so that levels of acceptable risk are defined.

The issue of how to we generate public interest for CFTs and avoid asking information that may not be available at the time of application was discussed and the need to stress purpose of the trial (experimental) and the source of the genes pointed out.

On the question of risk assessment it was noted that is the technology developer that can do a risk assessment. The regulatory authority only does the risk assessment audit of a particular event they are interested in and otherwise review RA data. If the regulatory authority put it upon them to do risk assessment, it would mean that they are going to do the whole work and it would be a very big burden that may even require establishing a new institution. Minimum standards for risk assessment have been set up under the protocol and that is what Kenya National Biosafety Committee has followed in auditing the applications that have been received.

Salient Observations on socio-economic issues

- Socio-economic issues may be positive e.g. alleviating poverty, improving food security, economic development, treatment of diseases or development of vaccines or negative such as high cost of IPR issues and unknown sustainability issues. Socio-economic considerations should be part and parcel of the Biosafety regulatory systems but there is need to:
 - Consider which ones are important and relevant and define the scope
 - Who should conduct SE analysis?
 - When is it to be conducted e.g. does it make sense to do these at contained and CFT levels or at commercialization? Need to be defined and incorporated in the legal frame work

Suggested approach

- Use regulatory impact assessment at the stage of analysing the need for putting a regulation in place (should be justified why it is included)
- Assess cost and benefits of considering each of the SE consideration
- Look at other options and their impacts
- Consider regional, bilateral and international implications
- Cultural considerations (way of life of the people)
- Advise on the best decision to be taken at the time (what best fits as a law at the time of the formulation of that law)
- Leave room within the law for constant monitoring and review (esp. through regulations and guidelines)-New technologies less known at a given time and evolve at a fast rate.

It was noted that socio-economic factors are specific to each country; harmonizing them may be difficult and if they make part of the decision making process, what should be the entry point? (Science-based decision??). It was pointed out that:

- SE issues are not a safety issue but they have to be considered. E.g. some years back Bt cotton application in Uganda was not allowed due to economic factors. (Though lack of clarity between application CFT and commercial release was also a complication). The SE issues should thus not be ignored, they can be useful but may some times be redundant
- Economic drive marginalizes human safety (according to history). The approach is therefore is to tame the strong drive for socio-economic gain (essence of Biosafety).
- There is need to be careful about socio-economic consideration and balance socio-economic factors with other factors e.g. ethical, cultural etc. The tendency has been to ignore these factors in our legal systems. (not economic development at all costs)
- SE should be defined for different aspects of the technology (health, agriculture, environment) and addressed before commercialization stage. What is important is to establish how the ES have been catered for in the whole process. For example Tanzanians have in their law (Environ management act, 2005): Strategic environmental Impact assessment, health IA, Social IA and Economic IA.. They have provided a schedule on how to do Social impact assessment; it only needs to be adapted to issues of Biosafety Considerations.

Salient Observations on food safety issues with in a biosafety regulatory system:

It was emphasized that a potential risk exists though it is minimal or non existent but consumers care the most about this issue. The Cartagena protocol mentions safety of human health but the standards for food safety are not described. We therefore have to fall back to the CODEX Alimentarius where efforts are being made to incorporate standards for food safety.

Questions raised:

Does FS belong to the Biosafety Regulatory system?

What is the proper regulatory agency to conduct food safety risk analysis

What is the proper legal authority for review and an approval?

It was noted that:

- The element of Food safety is ignored in EA legal systems e.g. Biosafety Bills etc. It is only mentioned at the time of defining the term Biosafety (We should take it up now since we are still in the process of developing our laws)
- It may be too heavy to lump all the regulatory aspects in one regulation (If you lump everything in one law, it will mangle out issues). In Uganda for instance, there is the food and nutrition bill that puts into consideration the CODEX requirements.
- The region is very unclear about the regulatory procedure and institutional procedures for Food Safety and there is need to clarify at a policy level.

Salient Observations on public participation and transparency:

Key elements for effective participation process:

- Public participation should be taken as a precondition for public acceptance
- There is need to identify target audiences and package information specifically for them (Gov'ts may need to target intermediaries e.g. NGOs, CBOs etc)
- Lack of transparency may lead to suspicion and lack of trust in the regulatory institutions
- In the Law, there is need to define the time of the public participation and the procedures
- What types of information should be released to the public and at what point? y include
 - Information on the regulatory process? Information on specific applications? decision documents?

The Objective should be effective public participation putting into consideration social cultural issues. Information should be readily available for who ever is interested. What is important think through is the legal part of public participation. For the EA region what can be legally binding with respect to public participation and transparency.

Salient Observations Coordination and Cooperation

The session on Coordination and Cooperation was discussed in context of objectives 3 and 4 of the workshop. It was noted that while in the case of biosafety regulatory regimes each country is trying work individually there are several joint efforts such as Customs union, Inter University Council, E.A Legislative Assembly, Sectoral Councils, EA Anthem and several comparative studies under EU, USA, India (Populations and Cooperation) have been conducted. For Phytosanitary Rules 2003-similar procedures have been established for EA. There are other on-going efforts within the Judiciary, Education as well as Fast tracking for Union. All these developments demonstrate that some initiative of unity is happening. In the context of Biosafety, the question that arises are how to channel the issues to the powers above.

Something demanding/wanting in Biosafety. If you talk of coordinating, there needs to be cooperation and collaboration amongst the people. One person must take the responsibility. The role here will be of harmonization. We should explore the existing EAC Pathways. Existing possible institutions that can take the lead- include ASARECA, EAC, Councils for Science and Technology. Informally, the institutions may agree among themselves on who can take the lead.

Potential starting points in Biosafety in E.A

- Food safety- already an initiative through codex
- Documentation- how possible is it to simplify the data collection systems-checklists
- Regulatory pathways- can this be standardized, regional Biosafety comm.

ASARECA organized a national consultative meeting (3 years ago) to discuss the plan of action for collaboration in biotechnology and biosafety. This did not materialize because countries did not have frameworks. The countries have made milestones now and the coordination role can be comfortably undertaken by ASARECA. Legitimacy of ASARECA is strong as directors are appointed by their respective governments. ASARECA is prepared and capable to take up the harmonization role. This will go hand in hand with Program goal of ASARECA.

This group suggested possible areas of collaboration that can take in concurrence with official harmonization efforts.

Collaboration and joint training in the various potential areas.

Sharing of information

Existing institutions to more closely work together in biosafety areas of mutual interest.

GMOs do not know boundaries. People across the borders will want to use. Eg Maize that are safe and beneficial. Thus collaboration in data collection will be necessary.

Investors will look at the broader market thus target EA instead of a separate country.

Thus regional testing and certification will be easier and cheaper.

A document that is representative to the region should be developed.

Appointment of an interim committee to work on the documents

It will be a useful exercise to agree on some benchmarks and some acceptable standard of what to look at. Since most of our frameworks are still in draft form, it will be a good time to start now.

How should matters of e.g commercialization be handled at the broader policy level? Should we aim at a regional policy? This could be taken in steps ie Common terms/ definitions, Common document and eventually Regional policy

The meeting noted that It might take a bit of time to have some of these things in place, however certain areas of commonalities can easily be done without legal permission. For example Information exchange, standardizing of issues, harmonize procedures for CFTs.

Where next from here? How do we move the ideas forward?

The meeting noted that the need to harmonize at least certain aspects of the biosafety policy and regulations was recognized all concerned. ASARECA as a regional body was best placed to lead the process with PBS providing technical backstopping. Also legal advisers in the region need to be empowered and trained so as to be able to come up with good drafts. In order to ensure regional ownership of the process the NBCs should participate in identifying areas that need to be harmonized. An expert group would then draft the harmonized documents for endorsement or approval by the appropriate authorities. The paper prepared by Gerg to be finalized and presented to the NBCs and used as a background paper for the NBC workshop that may be designed to generate areas of biotechnology and biosafety policies that should be harmonized. The NBC conference planned for mid-2006 will be a good opportunity to have the background paper introduced and issues of harmonization raised. The output of the NBC conference will be important in shaping the way forward to harmonization. Hence a combination of NBC, PBS and ASARECA will provide leadership for the harmonization process in an informal way and the formal approach will follow.

Evaluation of this workshop indicated that the set objectives were met, in general terms 40% of the participants rated it as excellent while the other 60% reported it as good.

Proposed Follow up Activities included:

- Analysis of draft laws to develop draft regional document
- Implementation of recommendations
- Enhancing networking/collaboration
- Further capacity building of legal experts and regulators

This two-day meeting was held at Stanley Hotel, Nairobi, Kenya, December 7-8, 2005. The primary participants were 17 and included mainly lawyers and key regulatory officials from the region. The consultant Greg Jaffe originated the workshop. The USAID biotechnology advisor participated in the workshop.

Main accomplishment

The workshop brought together a critical mass of legal experts concerned with biosafety to share and discuss the legal comparison paper developed by Greg Jaffe. This provided participants with better insight of critical legal issues and how these may impact implementation of the regulatory regime for the individual country and the region as a whole. Concrete proposals on how to move forward the regional harmonizing effort were made.