



PBS Kenya Associate Award

Building a Functional Biosafety System in Kenya

Final Technical Implementation Report

April 1st 2007 to March 31st 2010

Kenya Associate Award Partners:

International Food Policy Research Institute (IFPRI)
National Council for Science and Technology (NCST)
International Service for the Acquisition of Agri-biotech Applications (ISAAA AfriCenter)

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1. Executive Summary

The Program for Biosafety Systems (PBS) Kenya Associate Award (AA) was awarded to the International Food Policy Research Institute (IFPRI) by the USAID/Kenya mission on March 19, 2007 for a 3-year period. The program supported by the AA was launched in April 2007 with the overall goal of enhancing the development of a functional national biosafety system in Kenya.

The core objectives formulated to realize the above mentioned overall goal were as follows:

1. To enhance the risk communication capacities of high level policy makers and regulators.
2. To strengthen mechanisms for implementing the biosafety system.
3. To facilitate the passage of the Biosafety Bill

The key partner implementing organizations in Kenya were the National Council for Science and Technology (NCST) and ISAAA AfriCenter. Biosafety policy and regulatory backstopping was provided by IFPRI and experts at the Donald Danforth Plant Science Center (St Louis, USA) who are part of PBS's team of international experts.

Significant achievements were realized during the implementation period. The legal and institutional components of the national biosafety system were considerably expanded and strengthened. One of the most outstanding milestones that the PBS/Kenya AA contributed to was the passage of the Biosafety Bill and subsequently its enactment into law in 2009. A set of implementing regulations, designed to operationalize the law, have been drafted and finalized for gazettment following endorsement by the recently established National Biosafety Authority (NBA). The National Biosafety Office at NCST was strengthened, capacity of biosafety regulatory agencies enhanced and coordination among them improved. PBS partnered successfully with the ISAAA AfriCenter, which provided leadership in executing risk communication and outreach/awareness activities in liaison with like-minded governmental and non-governmental organizations in Kenya. The communication and decision making capacities of senior policy makers were enhanced.

Generally, the Biosafety Act has transformed the institutional and legal governance of biotechnology and biosafety issues in Kenya. Continued and concerted efforts to sustain the momentum will be essential to respond to emerging needs, challenges and priorities presented by the new regulatory regime. Additional technical and financial assistance building on the foundation already laid is required to facilitate the effective functioning of the NBA and support full and timely implementation of the Biosafety Act.

2. An assessment of progress made towards accomplishing Strategic Objectives and results

Implementation of the PBS Kenya AA over a period of 3 years was designed to address the following objectives:

1. To enhance the risk communication capacities of high level policy makers and regulators
2. To strengthen mechanisms for implementing the biosafety system
3. To facilitate the passage of the Biosafety Bill

The above objectives were defined in more detail and translated to specific annual work plans in consultation with USAID/Kenya technical officers. Implementation of the AA in terms of work plan development, monitoring of project performance and evaluation was guided by the USAID Foreign Assistance Framework operational plan indicators. PBS contributed to the Framework's Program Element 5.1, "Agriculture Enabling Environment" under the Strategic Objective 7 on Increased Rural Household Incomes. The following performance indicators were tracked, as detailed in Performance Indicator Reference Sheets developed by USAID/Kenya and Abt Associates:

1. Number of individuals who have received USG supported short-term agricultural enabling environment training
2. Number of policies/regulations/administrative procedures analyzed as a result of USG assistance
3. Number of institutions/organizations making significant improvements based on recommendations made via USG supported assessment
4. Number of policy reforms presented for legislation/decreed as a result of USG assistance

The table below shows that extent to which the AA responded to USAID performance indicators over the past 3 years.

Table 1. PBS/Kenya expected deliverables and performance indicators

USAID indicator	PBS targets responding to the indicator	Remarks on progress
(1) Number of individuals who have received USG supported short-term agricultural enabling environment training	<ul style="list-style-type: none"> ▪ NBC, regulatory agencies, senior officers in the Ministries of Agriculture and Public Health and Sanitation (78) ▪ National Biosafety Office staff (2, at MSU) ▪ Parliamentarians trained (45) ▪ Agricultural Sector Coordination Unit (13) <p>Total: 83 male and 55 female</p>	The short courses have greatly contributed to capacity strengthening, and fully involving the variety of regulatory institutions. The demand for similar, tailored courses is still very high.
(2) Number of policies/regulations/administrative procedures analyzed as a result of USG assistance	<ul style="list-style-type: none"> ▪ Draft Biosafety Bill (1) ▪ Draft biosafety implementing regulations (5) ▪ Crop biology documents (4) 	Supported consultations, reviews of Biosafety Bill (and alternative proposed Bill). Regulations on contained use, environmental release, import, export and transit were drafted and reviewed. Work with KEPHIS in progress for crop biology documents.
(3) Number of policy reforms presented for legislation/decree as a result of USG assistance	<ul style="list-style-type: none"> ▪ Biosafety Act 2009 (1) ▪ Biosafety Act implementing regulations finalized for gazette (5) 	Biosafety bill signed into law in 2009. Five implementing regulations finalized. Future assistance is required to draft regulations on handling, packaging, transporting and labeling of GMOs
(4) Number of institutions/ organizations making significant improvements based on recommendations made via USG supported assessment	<ul style="list-style-type: none"> ▪ NBC secretariat/NBO under NCST ▪ National Environment Management Authority (NEMA) ▪ Department of Veterinary Services (DVS) ▪ Kenya Plant Health Inspectorate Services (KEPHIS) ▪ Pest Control Products Board (PCPB) ▪ Kenya Bureau of Standards (KEBS) ▪ Public Health Department ▪ Ministry of Agriculture/BioAWARE 	The 8 institutions under this indicator were strengthened in terms of: <ul style="list-style-type: none"> – Communication and information technology equipment and facilities. – Enhanced coordination and delineation of responsibilities – Enhanced capacity for conducting confined field trials. – Improved risk communication skills and tools – Mechanisms for implementation of the national biotechnology awareness strategy

The results achieved and impact made as per the various strategic objective is as follows.

2.1 Enhance the risk communication capacities of high level policy makers and regulators (*objective 1*)

In support of the policy and regulatory framework development, the AA supported a set of communication and outreach activities under the leadership of ISAAA AfriCenter in collaboration with the NCST. The activities accomplished and the results are as follows:

2.1.1 Training courses in communicating the risks and benefits of modern biotechnology

During the life of the AA, 4 demand-driven courses on communicating the risks and benefits of modern biotechnology were held. All the courses were organized in response to requests from the various institutions. The courses benefited a total of 78 participants (33 female and 45 male) with a fair consideration of gender balance. The participants were drawn from regulatory agencies, the NBC and senior policy makers from the Ministries of Agriculture and Public Health and Sanitation. The training courses were rated by the participants as beneficial and relevant. As Kenya moves closer to commercialization of biotech crops, the challenge is to influence and change negative mindsets among policy makers and the general public. Building trust, confidence and eventually acceptance in the potential benefits and safety of the technology is critical. This can only be realized by disseminating, accurate, balanced and reliable information through appropriate channels.

The target institutions and individuals have an important role to play in communicating biotechnology and biosafety issues to various categories of stakeholders (including the media, farmers and consumers). However, they faced several challenges including high degree of ignorance and lack of skills and tools for communicating and engaging with all the stakeholders. The courses therefore enhanced their biosafety communication capacities, sharpened their interaction skills and strengthened their confidence and capabilities to design and implement communication strategies tailored to address specific concerns. The main outcome of this activity has been creation of a team that can respond to emerging issues and concerns rapidly, confidently and authoritatively. A sample report on such a course is included as [Annex 1](#).

2.1.2 Development and dissemination of information, education and communication materials

Over 5,000 copies of focused and targeted information, education and communication (IEC) materials on biosafety including policy briefs, a hand book for policy makers, message maps, fact sheets and a video documentary on biotechnology and biosafety capacity in Kenya were produced to respond to the information needs of policy makers, parliamentarians and regulators. Some of the materials informed parliamentary debates and influenced passage of the Biosafety Bill. The key ones include policy briefs on “*Applying Biotechnology in a Safe and Responsible Manner: Justification for a Biosafety Law in Kenya*” (see [Annex 2](#)) and “*GMOs and Exports: Demystifying Concerns in Africa*”.

2.1.3 Support for implementation of BioAWARE

In 2008, a National Biotechnology Awareness Strategy (BioAWARE) was launched by the Ministry of Agriculture in Kenya as a mechanism for improving public understanding and awareness of biotechnology through dissemination of accurate, timely and balanced information. PBS made a contribution towards implementation of BioAWARE in various ways. The nature of PBS support entailed development of policy outreach and communication materials in collaboration with BioAWARE secretariat for dissemination at various levels. A poster on the “Status of agricultural biotechnology in Kenya” was produced for wider dissemination to the provincial and district agricultural offices. A newspaper supplement on the “Facts about safety of modern biotechnology” was produced to mitigate negative propaganda and demystify public concerns associated with biotechnology food products. PBS contributed towards generating contents of the documents as well as printing costs. PBS in collaboration with ISAAA and BioAWARE facilitated a briefing session for senior policy makers in the Agricultural Sector Coordination Unit (ASCU) Ministries in December 2009. The session provided a good forum for deliberations on biotechnology and biosafety developments in Kenya and mechanisms for the institutionalization and implementation of BioAWARE.

The development of an English-Kiswahili biotechnology and biosafety glossary was completed during the reporting period. The work entailed translating from English to Kiswahili some of the commonly used terms in biotechnology and biosafety. The glossary will be an important tool in the implementation of BioAWARE especially at the grassroots level. It will be of relevance/benefit to farmers, agricultural extension officers and other stakeholders. The glossary, included as [Annex 3](#), will be pre-tested and customized for use by various target groups.

2.1.4 Open Forum on Agricultural Biotechnology (OFAB)

The Open Forum on Agricultural Biotechnology in Africa (OFAB) was launched in Nairobi in September 2006 as a joint venture between AATF and ISAAA AfriCenter. OFAB facilitates interactions between scientists, journalists, the civil society, industrialists, lawmakers and policy makers. It seeks to ensure that a critical mass of knowledge possessed by scientists is made available to policy makers and the public. It has emerged as an important forum to stimulate constructive debate on various aspects of biotechnology and biosafety. Some of the outstanding OFAB presentations include “Examining Concerns about GMOs” by Prof. Robert Paarlberg and “Science and Innovation in Africa: The Case for Policy Preparedness” by Prof. Calestous Juma”. Early in 2010, PBS started supporting partially the cost of managing planned OFAB events. PBS will also provide speakers for select OFAB forums to inform and influence policy debates and science-based decision-making in Kenya. PBS is also represented on the OFAB programming committee which is responsible for strategic planning and agenda setting of the Forum’s activities.

2.2 Strengthen mechanisms for implementing the biosafety system (*objective 2*)

The primary focus of this objective was establishing and strengthening implementation mechanisms for a fully functional biosafety system. The following results were accomplished.

2.2.1 NBC secretariat's coordination and information support functions strengthened

The support provided under this component aimed at strengthening the capacity of the secretariat in executing both administrative and information support functions. It sought to strengthen the National Biosafety Office, secretariat to the NBC, through procurement of additional office facilities including furniture and IT equipment (computers and a printer), following competitive bidding procedures. The National Biosafety Office's website was managed and updated regularly to reflect the support provided by PBS and recent changes in regulatory system as stipulated in the Biosafety Act 2009.

In line with the goal of strengthening the National Biosafety Office, PBS supported two NCST National Biosafety Office staff (Jane Omari and Roselida Owour) to participate in the International Environmental Biosafety short course held at Michigan State University in August 2009. The course equipped the participants with hands-on experience in biosafety policy development, risk analysis and program implementation to ensure safer application of biotechnology products. The course also covered environmental safety issues associated with products developed through biotechnology and genetic engineering.

2.2.2 Development of a coordination structure

One of the major challenges identified at the inception of the Associate Award was poor coordination among regulatory agencies. PBS provided leadership in the drafting of a coordination framework for regulatory agencies. The framework aims at fostering a coordinated and harmonized biosafety regulatory system that delineates the regulatory mandates and defines the decision-making procedures of the various regulatory agencies. It also spells out the areas of interaction in regulatory approvals of different types of GM products. The document contains GM product approval flow diagrams designed to provide guidance to applicants on the decision making channels followed in the approval of GM products under their mandate. The structure was approved for publication and it will inform the transition process from the National Biosafety Committee (NBC) to National Biosafety Authority (NBA). The coordination structure was posted on the NBO website (<http://www.biosafetykenya.co.ke/frontpage.php>) to facilitate access by various interested parties including potential applicants.

2.2.3 Creation of biosafety web pages for regulatory agencies

The main purpose of this activity is to enhance access to information on the biosafety regulatory mandate of the various agencies and provide useful links to other institutions involved in biotechnology and biosafety. With the support of PBS, web pages were created and uploaded on the websites of the six key regulatory agencies. The contents of the web pages (derived from the coordination structure) were discussed and harmonized in several meetings held with regulatory agencies. The process of updating and improving the web pages will be continuous to improve on the contents and layout.

Department of Public Health-
Department of Livestock-
Kenya Bureau of Standards-

<http://www.publichealth.go.ke>
<http://www.livestock.go.ke>
<http://www.kebs.org>

Pest Control Products Board- <http://www.pcpb.or.ke>
Kenya Plant Health Inspectorate Services- <http://www.kephis.org>
National Environment Management Authority- <http://www.nema.go.ke>

2.2.4 Development of implementing regulations

PBS/Kenya initiated the process to develop implementing regulations under the then draft Biosafety Act in June 2008, facilitating a training workshop that introduced Kenyan scientists and regulators to models of functional biosafety regulations being applied in various regions of the world and assessing requirements under the proposed Biosafety Act. Biosafety implementing regulations were identified and prioritized and a drafting team made up of Kenyan lawyers and scientists constituted. PBS supported several retreats organized by NCST to facilitate the actual drafting and revision process. Technical assistance and guidance was provided in the drafting, analyzing and reviewing the regulations. Substantial comments and inputs for improving the drafts were provided by PBS experts. Five sets of regulations have been finalized for gazettment. They include regulations on contained use experiments, environmental release, import/export and transit of GMOs. The regulations will ensure that there is adequate legal authority to enforce the Biosafety Act and facilitate imports, exports, transit of GM products and commercialization of potentially beneficial GM crops in a science-based manner.

2.2.5 Development/revision of Crop Biology Documents

Under the Kenya AA, PBS liaised with KEPHIS in the development of crop biology documents. This activity mainly targeted key priority crops that are currently undergoing trials in Kenya and those in the pipeline of approval. They include sweet potato, banana, cotton and maize biology documents. PBS prepared drafts of sweet potato and banana biology documents and organized a review meeting in 2008 to obtain feedback from Kenyan crop experts. PBS also facilitated the process of reviewing drafts of cotton and maize biology initially prepared by KEPHIS. These documents spell out biosafety considerations that should be followed in conducting confined field trials (CTFs). The trials are necessary to collect agronomic and ecological data required to complete the environmental safety assessment of transgenic crops. The final versions of these documents will be formally adopted by KEPHIS.

2.3 Facilitate the passage of the Biosafety Bill (*objective 3*)

The focus of this objective was to support a range of strategic activities associated with catalyzing passage of the Biosafety Bill. To ensure that the Bill was appreciated and supported, PBS worked closely with ISAAA and other like-minded institutions to implement a number of communication and outreach activities. The activities organized include briefing sessions to sensitize parliamentarians and tours to biotechnology and biosafety R&D facilities including the Kenya Agricultural Research Institute (KARI) Biotechnology Centre, the Tree biotechnology programme, tissue culture projects and the Bt cotton confined field trials site. Publication and dissemination of focused materials to enhance understanding of the main provisions of the Bill and the importance of getting it passed was undertaken. Emphasis was placed on strategic and influential parliamentary committees mainly the ones responsible for Education, Science and

Technology, Health, Environment, Trade, Finance and Agriculture. Senior policy makers in the various key line Ministries were also brought on board and actively engaged.

The passage of the Biosafety Bill in 2008 and its enactment into law in 2009 was a major milestone in Kenya's biosafety regulatory system. It marked the end of a protracted process that commenced in 2002 and went through the life of the three parliaments. The entire process was characterized by several challenges and setbacks. Strong opposition and heightened negative from anti-biotechnology lobby groups aimed at jeopardizing the process emerged as a formidable challenge. Coalition building and joint strategy development between ISAAA AfriCenter, PBS and like-minded organizations was essential in providing timely responses.

3. An assessment of progress made during the Associate Award

The goal of the PBS Kenya Associate Award at inception was to strengthen the development of a functional national biosafety system in Kenya. During the implementation of the Award, PBS forged and maintained strong and close linkages with the National Council for Science and Technology (NCST), biosafety regulatory agencies, ISAAA AfriCenter and the Ministry of Agriculture through the National Biotechnology Awareness Programme (BioAWARE).

The crucial milestone during the period was enactment of the Biosafety Act. PBS worked closely with ISAAA and like-minded stakeholders to build a strong consolidated force that spearheaded the process of getting the biosafety bill passed and enacted into law in 2009.

In line with the specific objectives responding to the goal of the AA, PBS worked successfully with partners in enhancing the communication and decision making capacities of senior policy makers. PBS has also responded adequately to the specific needs of the regulatory agencies. Strategic interventions of PBS contributed to among others (i) enactment of a biosafety law, (ii) drafting of implementing regulations, and, (iii) strengthening biosafety regulatory agencies and coordination among them.

The linkages were sustained through the PBS/Kenya Advisory Committee, regularly convened by NCST, in which the key regulatory agencies are represented. Capacity building needs and priorities of the various agencies were addressed systematically. Direct collaborations were implemented on a case by case basis, such as with KEPHIS on crop biology documents, the Ministry of Agriculture on activities associated with BioAWARE, the National Environment Management Authority (NEMA) and the Department of Veterinary Services (DVS) on the development of institutional biosafety guidelines.

Beyond the strict scope of the Associate Award, but nevertheless important for this report, being part of a global program and network such as PBS brings significant benefits for Kenya. In all activities implemented to date, Kenyan partners had easy access to relevant expertise through PBS through our US-based and other in-country partners. For example, PBS/Philippines organized a study and fact-finding tour for a delegation of Kenyan and other East African scientists and regulators involved in the AATF-led WEMA (Water Efficient Maize for Africa) project. Also, PBS facilitated Kenya's active participation in COMESA's initiatives to come up

with common policies and guidelines regarding GMOs for its member countries. In turn, Kenya's involvement in PBS benefits other countries in the region; e.g., by providing resource persons (from ISAAA AfriCenter and KARI) during training events in Ethiopia, Uganda and Malawi.

In conclusion, the resulting regulatory framework and skills base in Kenya are expected to facilitate commercial release of potentially beneficial products such as insect resistant maize and cotton and other relevant GM products in the pipeline. In the absence of the legislation, protracted delays in commercializing products whose efficacy and safety have been scientifically proven, would deny Kenyan farmers the opportunity to gain higher incomes and increased agricultural productivity.

The Biosafety Act has transformed the institutional and legal governance of biotechnology and biosafety issues in Kenya. A continued and concerted effort will be essential to respond to emerging needs and challenges presented by the new regulatory regime under the Biosafety Act. PBS/Kenya demonstrated its leadership role throughout the duration of the Associate Award, and is keen to continue its partnership with USAID/Kenya. Successful implementation of PBS/Kenya as a model project has informed establishment of similar in-country initiatives in Africa and Asia.

4. Overview of Expenditures

A detailed financial report has been submitted separately by IFPRI. An overview of expenditures by main budget line items is presented below. This excludes the financial contributions from PBS core resources (USAID/EGAT).

	ACTIVITY LINE	AMOUNT (US\$)
1	Biosafety framework, regulatory coordination (excl. policy specialist, policy advisor)	34,570
2	Technical guidelines, training	120,962
3	NBC Secretariat, biosafety clearinghouse and database	51,561
4	Policy outreach and communication	137,063
5	Program management support, international travel (IFPRI, NCST)	35,694
6	Advisory group Kenya, other meetings (NCST)	33,232
	Sub-Total	413,081
	Indirect costs	65,919
	GRAND TOTAL	479,000

5. Annexes

Annex 1: Proceedings of the Training Course on Communicating the Risks and Benefits of Modern Biotechnology Organized for Senior Ministry of Agriculture Officials held on June 22-23 2009 in Nairobi.



Annex1_proceedings
.doc

Annex 2: Policy brief on “Applying Biotechnology in a Safe and Responsible Manner



Biosafety Bill 2008
brief.pdf

Annex 3: English-Kiswahili Biotechnology and Biosafety Glossary



Annex3_glossary.do
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