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EVALUATION

Performance Evaluation of the Program for Biosafety Systems

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Cover photo: Confined field trial of genetically engineered rice in the Philippines. Photo credit: International Rice Research Institute

PERFORMANCE EVALUATION OF THE PROGRAM FOR BIOSAFETY SYSTEMS:

SUPPORTING PARTNER COUNTRIES BY FACILITATING USE OF BIOTECHNOLOGY FOR THE EVENTUAL DEPLOYMENT OF BENEFICIAL AGRICULTURAL PRODUCTS

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CONTENTS

ACRONYMS

AATF	African Agricultural Technology Foundation
ABNE	African Biosafety Network of Expertise
ABSPII	Agricultural Biotechnology Support Project II
BCGEP	Biosafety Commission for Genetically Engineered Products (Indonesia)
COMESA	Community for East and Southern Africa
ECOWAS	Economic Community for West and Central Africa
GM	Genetically Modified
ICGEB	International Centre for Genetic Engineering and Biotechnology
IFPRI	International Food Policy Research Institute
ISAAA	International Service for the Acquisition of Agribiotech Applications
ISBGMO	International Society for Biosafety of Genetically Modified Organisms
M&E	Monitoring and Evaluation
NBRC	National Biosafety Regulation Committee (Malawi)
NGO	Non-Governmental Organization
OECD	Organization for Economic Cooperation and Development
OFAB	Open Forum for Agricultural Biotechnology
PBS	Program for Biosafety Systems
SIAB	Society for Indonesian Agricultural Biotechnology
SOP	Standard Operating Procedure
UBBC	Uganda Biotechnology and Biosafety Consortium
USAID/BFS	U.S. Agency for International Development/Bureau for Food Safety

EXECUTIVE SUMMARY

EVALUATION PURPOSE AND EVALUATION QUESTIONS

The purpose of this external evaluation of the Program for Biosafety (PBS) is to assess the performance of the preceding 5-year period, and to identify ways in which the program can be improved during the next 5-year period. The scope of this review isthe entire range of PBS activities, including policy research and all in-country programs, but excluding programs that just began in FY2013. The primary audience for this evaluation is USAID/BFS and IFPRI staff. The evaluation will identify successes and lessons learned over the past 5 years of program implementation, and help guide the design of the new IFPRI award to continue PBS activities.

Questions were posed on five topics by USAID to guide the evaluation:

1. PBS Country Programs Staff and Support from International Technical Consultants

Are the roles and responsibilities of the in-country country lead appropriate compared with international short-term consultants? Should the mix be adjusted to support program expansion and sustainability of provider support in the next PBS award?

2. Policy Research

Has the policy research carried out by PBS been relevant to the technical support and capacity development activities being conducted by PBS? Provide specific examples of where PBS policy research has made a direct and measurable contribution to the achievement of PBS country-level objectives. Are the research products developed by the PBS team of high quality and contribute to a literature base that is being utilized by partners and stakeholders?

3. Project Management

How effectively have the PBS Director and Africa and Asia regional program leads supported learning and ensured quality across countries? How could these roles be strengthened in the next PBS award? How useful is the current PBS monitoring and evaluation system for program management, results reporting and learning? Given that many outcomes are outside the manageable interest of the program, are impacts being captured appropriately across all aspects of the program? How might the M&E system be strengthened in the next PBS award?

4. Financial Management

Given the goals of the projects as outlined in project documentation, how appropriately have BFS central resources been allocated amongst countries, partners and activities, to supplement and complement Mission funding and to support global technical leadership?

5. Communications, Outreach and Partnerships

Has PBS effectively responded with appropriate and timely communications products and outreach directed to the appropriate audiences as technical and political issues arise? What could be improved? Is PBS effectively collaborating and working with other biosafety and biotechnology programs in the regions where these projects are active?

PROJECT BACKGROUND

USAID has been funding efforts in biotechnology and the regulation of agricultural biotechnology for nearly two decades across several partners and host countries in Africa and Asia. The Program for Biosafety Systems (PBS) is the largest of USAID's investments that support the development of science-based regulatory systems that govern the application of these new agricultural technologies. PBS has been supported for 10 years by both USAID Washington and USAID field missions through a contract with the International Food Policy Research Institute (IFPRI).

PBS is active in seven countries in Africa and three in Asia, although this number has changed over time and remains flexible based on funding and the situation in countries in these regions. PBS supports partner countries by facilitating use of biotechnology for the eventual deployment of beneficial agricultural products. The indirect outcome is sustainably enhanced productivity and climate resilience in agricultural production systems to reduce poverty, enhance nutritional status and improve quality of life for resource-poor farmers and consumers.

The USAID Bureau for Food Security (BFS) supports the PBS core budget. This budget includes management staff, technical consultants, global policy research, participation in international meetings and in-country program and staff costs for some PBS countries and regions. USAID missions support PBS to strengthen and deepen programmatic activities in their respective countries. PBS currently receives mission funding from Ghana, Indonesia, Malawi, Nigeria, Tanzania and Uganda.

EVALUATION DESIGN, METHODS AND LIMITATIONS

Data were collected using two methods: document review and semi-structured interviews with key informants. Field visits to Indonesia, Uganda and Malawi allowed for interviews with key informants at a country level as the program is based around country activities. This was supported by interviews with regional and global collaborators, as well as interviews with senior PBS staff and long-term consultants.

The evaluation team conducted a preliminary desk review of relevant project documents and key sector background material in order to gain a thorough understanding of the specific activities over the 5 year period of the project (2008-2013), together with the country context in which each program is operating. Key informants were identified by the contractor in-country staff in addition to others identified during the data collection process. Based on a review of project documents the evaluation team identified several stakeholder groups that are the focus of program activities. These stakeholder groups comprise (i) USAID and other US Government agencies, (ii) PBS Implementing staff in both the headquarters and the countries visited, (iii) Government regulatory agencies as well as research institutes and universities acting as agents of regulators, and (iv) Partners/collaborators (including technology development groups and the private sector). For each such stakeholder group, specific questions were designed that focus on their interest in the PBS project. The same base sets of questions were asked of all interviewees.

In the initial planning of the review and for the first of the three field visits, a specialist in Monitoring and Evaluation was accompanied by a specialist in biotechnology regulatory affairs as the review team. Due to the inability of the monitoring and evaluation specialist to continue with the review, the second and third field visits and the overall drafting of the review were completed by the regulatory affairs specialist, using the template and methods developed by the monitoring and evaluation specialist as much as

possible.

It should be stressed that this review is based on the responses to questions posed to a large number of different stakeholders, many of whom may not be completely aware of the full range of activities performed by PBS. Statements in this document include common responses, even if these are not completely factual, as they represent the understanding and perception of certain stakeholders.

FINDINGS AND CONCLUSIONS

1. PBS Country Programs Staff and Support from International Technical Consultants

The role of the country coordinator was reported as being the key to the success as this person is the main interface with the various stakeholders in each country. The technical consultants were highly praised for their technical ability, but there was a common request for more diversity and more use of experts from within the region. To date, the technical focus of PBS is well served by the country staff and experts, however the demands are now moving from primarily technical support to advocacy and there are different skills required. The value of having external experts from a wider source than just the United States is tempered by the need to have well-qualified experts and to have them involved in PBS activities over a long enough period to be familiar with and accepted by local stakeholders. Development of local expertise, through training and joint research studies, can provide a resource for the region as well just the country in which they are working.

2. Policy Research

The PBS Policy team, working within and through IFPRI, has played an important role in producing a body of work recognized globally as being critical to the understanding of biosafety policy and regulation. However, there seems to be little recognition of this by country stakeholders and there appears to be some conflict between IFPRI demands for publications in peer-reviewed journals and products which can be used to help countries develop practical regulatory systems. This is recognized by PBS management and attempts are being made to use the research more widely and also to conduct more country-level studies. The challenge for PBS is to work within IFPRI to allow for recognition of more practical studies for implementation as a valid output. With regard to recognition of the role of PBS research by local collaborators, it is less important that these studies are identified as IFPRI publications than that PBS is seen as a source for documents relevant to the local policy and planning needs. The PBS summaries and short briefs are where there needs to be "brand recognition" as this is where most of the government regulators and policy makers will be getting their information.

3. Project Management

Annual work plans and semi-annual reports appear deficient in many respects for proper management, results reporting and learning. The main problems include:

- Exclusive focus on inputs (and outputs), rather than on outcomes and results.
- Milestones should be reviewed and refined using USAID standard definitions and differentiated from inputs.
- There is a need to present realistic time frames for achievement of critical milestones, outputs, and outcomes, so that program progress can be measured and monitored for decision-making.
- Project level intermediate outcomes and results need to be identified. USAID Feed the Future standard indicators do not capture outcomes and results in sufficient detail to know whether the inputs are achieving the desired impacts.
- Previous project indicators for capacity building within government agencies should be reviewed

for potential utility. The time for an application to progress through each step of the regulatory process can be used as a measurement of the effectiveness of the regulatory system, as can the responsiveness of the various committees to applicants.

4. Financial Management

PBS has been successful to date in juggling the demands on the core budget to provide services and support in a number of countries which have USAID mission support as well as operating in some key countries which don't have such support. There was no suggestion that lack of funds was a key factor in those cases where political changes have become a road-block to further progress.

A challenge for PBS lies in how much they can expand into new countries, given the demands on the core budget, recognizing that for each country funding is not only required for country level staff, but also to support the country activities with external experts and central PBS activities. There is the potential to reduce effectiveness over the whole program by stretching core staff and external consultants too far.

5. Communications, Outreach and Partnerships

PBS has entered into partnerships with a number of collaborators to increase the reach of PBS outreach activities, in some cases forming formal or semi-formal consortia. A number of issues concerning targeting, the role of communications and outreach and the professionalization of advocacy and PR need to be addressed. Answers to the following will be helpful in defining and implementing a strategy:

- For whom do the in-country consortia speak? The tighter the connection to PBS, the more the group becomes a proxy for the US government, which could backfire if PBS loses the trust of local stakeholders.
- Is there a long-range plan for engagement and institutional support? A clear plan is needed to determine the relationship in both short and long term financial terms and otherwise.
- What is the capacity of the consortia to do public relations and policy work?
- What is the appropriate target group(s) for the consortia to focus on, what clear and measureable results are expected from their outreach, and how will they be measured?
- Is policy outreach an appropriate direct PBS role, using respected policy experts both international and national?
- Are professional communications services needed to complement and support PBS local staff and volunteers?
- What results are desired, and what indicators will measure the impact of different inputs on different stakeholders?

PROJECT BACKGROUND

USAID has been funding efforts in biotechnology and the regulation of agricultural biotechnology for nearly two decades across several partners and host countries in Africa and Asia. Amongst these programs are those that support Research and Development (R&D) and deployment of new agricultural technologies using biotechnology and a separate set of programs that support the development of reasonable, science-based regulatory systems that govern the application of these new agricultural technologies. The Program for Biosafety Systems (PBS) is the largest of USAID's investments in this latter group. PBS has been supported for 10 years by both USAID Washington and USAID field missions through a contract with the International Food Policy Research Institute (IFPRI).

The role of biosafety systems and facilitative policies to insure that Agency-funded research yields practical benefits cannot be underestimated since it is widely recognized that biosafety considerations and concerns, especially in developing countries, can be a primary limiting factor in biotechnology adoption.

PBS is currently active in six primary countries in Africa and three in Asia, although this number has changed over time and remains flexible based on funding and the situation in countries in these regions. PBS supports partner countries by facilitating use of biotechnology for the eventual deployment of beneficial agriculture products, such as new genetically-modified (GM) varieties of crop plants that are resistant to a variety of biotic and abiotic stresses (e.g. insect resistant cowpeas and drought tolerant maize) or GM varieties with enhanced nutrient profiles (e.g. Vitamin A enriched cassava). The indirect outcome is sustainably enhanced productivity and climate resilience in agriculture production systems to reduce poverty, enhance nutritional status and improve quality of life for resource-poor farmers and consumers.

The objective of PBS's support for developing functional biosafety systems is to ensure that countries have and evidenced-based legal framework and the laws in place which are consistent with global best practices employed by other countries who have opted to adopt the use of biotech crops as part of their agriculture system.. PBS support and guidance is intended to provide sustained, credible, and impartial biosafety legal and policy advice and to enhance capacity of decision-makers. Coupled with this, targeted, practical/technical support is supplied to regulators so that a system is in place to evaluate products for eventual distribution to farmers.. In parallel with the increased number of GM products approaching release in developing countries, ongoing public debate and legal challenges are more frequently emerging as obstacles to progress. PBS has strategic, multi- stakeholder outreach activities, coupled and integrated to the work it does on the regulatory front, to confront the challenges of misinformation and to to avoid backpedaling to more precautionary policies.

The final outcome of the layered support and integrated approach provided by PBS is to establish a science-based regulatory system and local capacity to insure that products are evaluated from a point of evidence. Developing a country's capacity would impact and further its national goal of increased food security, poverty reduction and also better climate resilience.

The PBS program works with local agricultural organizations and stakeholders to build functional science-based regulatory pathways for the adoption of new biotechnology products. Its diverse team of

scientific, legal, commercial and communications experts builds biosafety capacity through an integrated program of policy analysis, development and implementation for practical, achievable results. Activities are designed and implemented through a country-led approach with local PBS country leads. Further, the ability to draw on an in-house independent policy research team at IFPRI is expected to bring added value and academic credibility for informed decision-making. IFPRI is a public international organization and member of the Consultative Group on International Agricultural Research.

USAID Bureau for Food Security (BFS) supports the PBS core budget. This budget includes management staff, technical consultants, global policy research, participation in international meetings and in-country costs for some PBS countries (Malawi, the Philippines, Vietnam) and regional activities within the Common Market for Eastern and Southern Africa (COMESA) and the Economic Community for West and Central Africa (ECOWAS). USAID missions support PBS to strengthen and deepen programmatic activities in their respective countries. PBS currently receives mission funding from Ghana, Indonesia, Nigeria, Tanzania and Uganda.

PBS's approach to biosafety capacity development is unique among a variety of biosafety service providers (most of which are funded by other donors) in several aspects, as it emphasizes:

- A comprehensive approach to biosafety framework development, including the development of workable implementing regulations, detailed operating procedures, and guiding biosafety dossier development and reviews, among others;
- A sustained and consistent on-the-ground presence in the form of local country coordinators who facilitate discussions of needs and concerns between local decision-makers and the project's technical and managerial experts;
- Development of biosafety frameworks by involving international and local legal and scientific expertise in support of effective functioning biosafety decision-making;
- Supportive outreach and communications strategies for national competent authorities and the broader stakeholder community that is a pre-emptive, guiding and responsive to complement the technical work that is undertaken by the project;
- Capacity development, including hands-on training, around a specific product, policy/legal instrument, or GM application in the pipeline in partner countries;
- De novo, targeted research to inform the decision-making process and effect policy development, adoption and implementation.

EVALUATION PURPOSE & EVALUATION QUESTIONS

EVALUATION PURPOSE

The purpose of this external evaluation of the Program for Biosafety Systems (PBS) is to assess the performance of the preceding 5-year period (2008-2013), and to identify ways in which the program can be improved during the planned next 5-year period. The scope of this review will be the entire range of PBS activities, including policy research and all in-country programs, but excluding programs that just began in FY2013 (Ghana, Tanzania and ECOWAS).

The primary audience for this evaluation is USAID/BFS and IFPRI staff. The evaluation will identify successes and lessons learned over the past 5 years of program implementation, and help guide the design of the new IFPRI award to continue PBS activities.

EVALUATION QUESTIONS

1. **PBS Country Programs Staff and Support from International Technical Consultants** Are the roles and responsibilities of the in-country country lead appropriate compared with international short-term consultants? Should the mix be adjusted to support program expansion and sustainability of provider support in the next PBS award?

Sub-questions to consider: Is the skill set of the in-country country leads appropriate to achieve PBS objectives? In what areas of their essential job functions have country leads been effective and where have they struggled? Do stakeholders feel country leads have enough/the right technical expertise, as compared to skills required to initiate and keep activities moving forward, and to communicate, advocate and build consensus among national stakeholders? Has the support provided by international consultants been effective in achieving the objectives of their STTA and overall PBS country objectives?

2. **Policy Research**

Has the policy research carried out by PBS been relevant to the technical support and capacity development activities being conducted by PBS? Provide specific examples of where PBS policy research has made a direct and measurable contribution to the achievement of PBS country-level objectives.

Are the research products developed by the PBS team of high quality and contribute to a literature base that is being utilized by partners and stakeholders?

3. Project Management

How effectively have the PBS Director and Africa and Asia regional program leads supported learning and ensured quality across countries? How could these roles be strengthened in the next PBS award?

How useful is the current PBS Monitoring and Evaluation (M&E) system for program management, results reporting and learning? Given that many outcomes are outside the manageable interested of the program, are impacts being captured appropriately across all aspects of the program? How might the M&E system be strengthened in the next PBS award?

4. Financial Management

Given the goals of the projects as outlined in project documentation, how appropriately have BFS central resources been allocated amongst countries, partners and activities, to supplement and complement Mission funding and to support global technical leadership?

5. Communications, Outreach and Partnerships

Has PBS effectively responded with appropriate and timely communications products and outreach directed to the appropriate audiences as technical and political issues arise? What could be improved?

Is PBS effectively collaborating and working with other biosafety and biotechnology programs in the regions where these projects are active (including AATF, ABNE, ICGEB and OFAB communications programs)

EVALUATION METHODS & LIMITATIONS

EVALUATION DESIGN

The scope of this review is the entire range of PBS activities over the past five year period including research and in-country programs but excluding those activities that just started in 2013. As the time and evaluation budget did not allow for visits to all participating countries or of a review of every research document produced, a purposive sampling method was used.

Field visits to Indonesia, Uganda and Malawi allowed for interviews with key informants. The three countries have different characteristics such as length and depth of assistance, and stage of preparedness and institutional capacity in biosafety regulation. Furthermore, in each country there are specific cultural and political factors which influence outcomes. Three different cases allow for an assessment of the impact of outside factors and variables on outcomes and results and enable a comparison of how the program is being implemented in each country and the effect this has on meeting objectives. Each country will be summarized as a separate case study, tracking the processes and mechanisms that led to specific results to understand causality, and from which relevant lessons can be generalized and applied to the design and management of the project in other countries as recommendations. In addition, global policy research inputs have been considered and compared with outputs in policy and regulatory changes with the countries to determine the extent of causality and usefulness.

In the initial planning of the review and for the first of the three field visits, a specialist in Monitoring and Evaluation was accompanied by a specialist in biotechnology regulatory affairs as the review team. Due to the inability of the monitoring and evaluation specialist to continue with the review, the second and third field visits and the overall drafting of the review were completed by the regulatory affairs specialist, using the template and methods developed by the monitoring and evaluation specialist as much as possible.

DATA COLLECTION AND ANALYSIS METHODS

DATA COLLECTION

The project's design is based on assisting country-specific institutions to develop successful and fully functioning regulatory frameworks and methods for assessing biosafety of products, and implementing the associated directives with appropriate measures, laws and regulations. As this is a process evaluation, it focuses mainly on the effectiveness of the processes and the inputs in producing project success, rather than on the specific outputs or results. Therefore, a large part of the data collection has involved gathering information to assess the extent to which the different activities of the program and its management have contributed to achieving the general program objectives and specific country objectives. To a great extent the answers to the evaluation questions involve subjective opinions,

however, by employing the techniques of cross- verification and triangulation between respondents and with existing secondary data, objective findings are derived. Data was collected for this evaluation using two methods: document review and key informant semi-structured interviews.

DOCUMENT REVIEW AND SECONDARY SOURCES

The evaluation team conducted a preliminary desk review of relevant project documents and key sector background material in order to gain a thorough understanding of the specific activities over the 5 year period of the project, together with the country context in which each program is operating. Document review is an important source of data on project activities that can be used to triangulate interview data, derive qualitative information and continually inform the data collection process.

KEY INFORMANT INTERVIEWS

Key informants - identified by the contractor in-country staff in addition to others identified during the data collection process – were interviewed either face-to-face or by telephone conference. Based on a review of project documents the evaluation team identified several stakeholder groups that are the focus of program activities. These stakeholder groups comprise (i) USAID and other US Government agencies. donors, (ii) PBS Implementing staff in both the headquarters and the countries visited, (iii) Government regulatory agencies as well as research institutes and universities acting as agents of regulators, and (iv) Partners/collaborators, including technology development groups such as USAID's Agricultural Biotechnology Support Project (ABSPII), the African Agricultural Technology Foundation (AATF) and regulatory groups such as the International Centre for Genetic Engineering and Biotechnology (ICGEB), and the private sector. Attempts were made to interview representatives of all stakeholder groups in each country visited, including representatives of those who have received training through PBS. Initially, two additional stakeholder groups were included – policy makers and media, however discussions during field work with USAID and the implementers were used to better define the target groups and individuals to interview and there were not enough individuals in these two groups to maintain them as separate groups. There is considerable cross-over in the roles of certain stakeholders and parliamentarians, government officials and members of media organizations were included in either the collaborators or regulators group based on initial discussions with the interviewee. The full list of key informants is included in Annex IV, with affiliations and the stakeholder group in which they were included.

For each such stakeholder group, specific questions were designed that focus on their interest in the PBS project. The same base sets of questions were asked in all three sample countries visited - see Annex III for interview instruments. Questions were asked in the same order where possible. In Indonesia, key informant interviews were conducted with both evaluation experts present, however this was not possible in Uganda and Malawi.

Data collection was aided by the use of an Excel workbook to organize and store data culled from interviews. At the end of the interview day, interview notes were synthesized and entered into the data collection spreadsheet. A separate sheet in the excel workbook was maintained for each of the stakeholder groups identified above. Each of these sheets contained all potential interview questions to be asked to that stakeholder group. Each interview respondent was listed in one sheet of the excel workbook to allow recording information from each protocol question from each interviewee. Confidentiality of respondents was maintained by anonymizing the data (i.e. removing names, titles, and other information that specifically links a participant with a specific response).

This method of organizing and assembling interview information allowed for the identification of patterns in the responses and common themes that are supported by evidence in the data. To ensure that the data are internally valid and reliable, interview data was triangulated between respondents and between sources such as work plans, performance reporting, research reports, financial reports, or other secondary data.

Data collected and transcribed into the excel workbook was systematically analyzed to answer the five evaluation questions. This content analysis process involved review of the data in the excel workbook for emergent themes. Attempts were made to quantify the prevalence of certain themes in the data and indicate the frequency that represents the prevalence of any given theme for one or more stakeholder groups or respondents. The identified and analyzed themes allow for the formulation of findings for each of the evaluation questions.

The evaluation report will be structured on the basis of these questions – i.e., the discussion of each evaluation question, by itself, forms the basis of a complete section, based on analysis of the themes and response across the range of stakeholders.

METHODOLOGICAL LIMITATIONS

PARTICIPANT SELECTION AND BIAS

Key informant interviewees were selected non-randomly based on availability and engagement with program activities and as such, there were no comparison groups. A non-random selection is standard for qualitative "purposive" evaluations. As there is a small universe of stakeholders in each country, it was not be possible to randomly select interviewees. Attempts were made to interview representatives of every organization that was a recipient or object of the PBS project in the three sample countries, as well as with regional organizations whose own interests and work coincide with the donors. However as most interviewed beneficiaries are direct participants in the project and were recommended by either USAID or the contractor, it can be expected that they will say positive things about the project.

Where possible, to minimize bias informants were sought who represent "public stakeholders" with different 'causal distances' from the activities to qualitatively triangulate/check information from beneficiary organizations and who cannot be perceived as "friendly" or biased stakeholders but who have sufficient knowledge to comment.

RECALL BIAS

To minimize recall bias, the interview questions were designed to draw upon specific knowledge or viewpoints that the organization or the individual acquired from direct association with the project. As the project is currently actively being implemented recall issues should be minimal.

INTERVIEWEE RESPONSE BIAS

All participants come with biases. An attempt was made to organize a sample of organizations with different perspectives and playing different roles to provide different viewpoints. The degree to which there is agreement/disagreement in viewpoints is indicated and assertions are triangulated with other data sources and with other stakeholder groups.

Undoubtedly a larger problem, difficult to assess, is that of deliberately inaccurate responses because the respondent wants to keep a good relationship with the implementer and donor. This shortcoming will be mitigated through triangulation of what was said by different organizations, comparison with known facts, and the interviewer's perceptions of points of view.

ABILITY TO GENERALIZE FROM THE DATA

The method of organizing the data by question and respondent through an excel workbook allowing for coding for recurrent themes, opinion agreements and disagreements allow the identification of areas where the data clearly justifies generalizations. Where possible the number of respondents is quantified although the quantification is subject to interpretation since often the respondents' answers to "open-ended questions" are imprecise and opinion-related, and it is difficult to get explicit answers or examples. Hence the development of recurring themes and concurrence across different types of respondents provides the best source of data. USAID Evaluation Policy is followed, placing emphasis on anchoring conclusions in 'findings of fact,' and not in individual interviewee or evaluator opinions or second-hand reports. Clear, reproducible evidence for findings and conclusions, supported by specific examples and quotes, have been used to tie findings to conclusions, and from there to recommendations.

FINDINGS, CONCLUSIONS & RECOMMENDATIONS

As described in the methodology, the findings are arranged in the order of the questions which form the basis of the evaluation. Separately, a summary of the situation, progress and impacts in each of the three countries visited are included as a set of cases, which are then used together with the findings as the basis for conclusions.

FINDINGS

1. PBS Country Programs Staff and Support from International Technical Consultants

- *Are the roles and responsibilities of the in-country country lead appropriate compared with international short-term consultants? Should the mix be adjusted to support program expansion and sustainability of provider support in the next PBS award?*

Interview responses from the implementers are in agreement that the role of the country coordinator is key to the operations of PBS, with the country staff supplying both the direct implementation of PBS programs and providing critical insight into the political situation in their respective countries. USAID and other US government stakeholders support the role that the country staff play, with comments noting the connections that country staff have with policy makers and other stakeholders who have influence.

There is also no disagreement about the role played by external consultants, who are seen as providing valuable expertise and a focal point for activities. At the same time, there is a broad feeling that the range of consultants could be increased, with specific note that consultants from within their region would be appreciated by stakeholders. High marks were consistently given for the level of expertise of the outside consultants, but the only ones named were those with long term staff affiliation with PBS and not short term experts. Criticism was voiced by several interviewees of the ability of consultants to present information and examples of how developing countries achieve goals, with more emphasis desired on non-US models and examples. Other individuals commented that the external consultants were all from the US and a broader source would be appreciated.

- *Sub-questions to consider: Is the skill set of the in-country country leads appropriate to achieve PBS objectives? In what areas of their essential job functions have country leads been effective and where have they struggled? Do stakeholders feel country leads have enough/the right technical expertise, as compared to skills required to initiate and keep activities moving forward, and to communicate, advocate and build consensus among national stakeholders? Has the support provided by international consultants been effective in achieving the objectives of their STTA and overall PBS country objectives?*

Implementers all agree that a certain level of technical expertise is required (a science or agriculture background), but that biosafety expertise *per se* is not a pre-requisite given that all country staff receive training from PBS and experts can be called on when needed. However, it appears that to the majority of country-level collaborator and regulatory contacts, the level of technical expertise exhibited by the

country coordinators is adequate or above what is required – perhaps reflecting the lower level of experience in these interviewees. Some less favorable comments were noted in other areas often relating to specific failings with certain Ministries in certain countries i). One theme noted across the three countries visited was a lack of the requisite skills for outreach and communications. This changing focus of the type of role played by the country level staff was also mentioned by implementers and a stronger focus on this aspect – either through staff training or even bringing in new supporting staff - would be an option to consider. There was almost unanimous support for the expertise and work-rate of the coordinators which could be a result of selection bias, but does seem to reflect a genuine appreciation of their activities and achievements.

Consultant support was highly rated, with the previously noted caveat of some interviewees that consultants were US-centric. Where specific outcomes were accomplished through PBS activities (approval of field trial applications, legal reviews, development/adoption of guidelines and SOPs etc.) the input of external consultants was acknowledged by the stakeholders involved as being a key factor.

2. Policy Research

- *Has the policy research carried out by PBS been relevant to the technical support and capacity development activities being conducted by PBS? Provide specific examples of where PBS policy research has made a direct and measurable contribution to the achievement of PBS country-level objectives.*

There is a general lack of awareness of PBS policy research among stakeholders, unless they are already familiar with and working in the area of the research. There is more familiarity with IFPRI as a research organization, which suggests that some of this is a confusion of the role of PBS within IFPRI with few people appreciating that related research published by IFPRI is a PBS activity. However, a bigger issue seems to be the level at which policy research is published/presented makes it less relevant to the actual stakeholders involved in the country level activities. A few specific examples of PBS policy research were cited, most notably the socio-economic study and the environmental risk analysis done for eggplant. On the other hand, when asked how policy research has proven useful to their organization and to meeting PBS objectives, respondents referred to exposure to the US and Brazilian regulatory system and OECD guidelines (which may not have come from research but from workshops), in addition to socio-economic studies.

The contribution of the policy research is hard to measure directly, given that its impact occurs in combination with other factors, however it was reported by PBS implementers that research on labeling thresholds had had a noted impact in Vietnam. In addition, the work on socio-economic benefits was recognized by a number of stakeholders as being useful in getting policy makers to understand the role that biotechnology can play in increased agricultural productivity. In Indonesia, the development of a socio-economic assessment as part of the national regulatory system was reported by three interviewees as being helped by research from PBS detailing how this was done elsewhere.

In Indonesia, the most frequently noted contribution to the technical committee's work were the workshop which led to establishing the socio-economic team and the workshops on technical assessment from which committees drafted their regulations (which presumably included the research that was used as background information). For members of the biosafety commission a better understanding of the issues surrounding biosafety regulation influenced them in understanding and acceptance of findings of the technical committees. Probing for how workshops led to actions, the

technical committees acknowledged that they were able to prepare their own guidelines based on the workshop inputs, but there was little differentiation from policy studies. Respondents noted that the examples from other countries cited in workshops are useful, but it is was not stated whether anyone read the publications.

In Uganda there is awareness and use of the research by some of the collaborators. However some respondents understood that the research was focused on trade issues and was therefore not relevant at the present time to Ugandan researchers who are involved in early-stage development of modified crops. In Malawi, the interest was in socio-economic benefits, but there was a call for specific data on benefits within Malawi directly. There were few examples of direct impact of the research studies in these countries, but it was also stated that they expected these to be more relevant as modified products moved further along the development pathway.

A common theme in responses was that the research was not directly relevant to the respondents own country and that there was an (unmet) demand for research done within the country, especially on potential benefits at the country level for specific crops. PBS is addressing this to some extent, with studies under way in Indonesia on policy and legal issues, but this issue of showing relevance of policy research at the country level seems to be an important aspect.

- *Are the research products developed by the PBS team of high quality and contribute to a literature base that is being utilized by partners and stakeholders?*

Where stakeholders were aware of the research being done by IFPRI, there was almost unanimous agreement that papers were of high quality. As noted above, there is little awareness that the research is part of the PBS program and the regional collaborators in particular look to IFPRI research as being the major source of academic information. More common than awareness of the research publications, however, was exposure to the research through shorter policy briefs and training workshops where participants were presented with data from the research rather than papers themselves. These types of exposure were regarded as useful and shorter documents – such as the policy briefs – were used by collaborators and government regulators for their own use.

One issue raised by implementers was the conflict between meeting IPFRI requirements for high-level publications in peer-reviewed journals and the needs of PBS collaborators and government regulators for simpler policy advice and also more locally-relevant studies. Although the Director noted that PBS is used as a positive example within IFPRI with regard to "policy impact", there is still an issue with addressing country-level demands for research which may not be compatible with IFPRI publication standards.

3. Project Management

- *How effectively have the PBS Director and Africa and Asia regional program leads supported learning and ensured quality across countries? How could these roles be strengthened in the next PBS award?*

Interviews with the Director and regional coordinators detailed the management structure being followed in PBS – with a combined role in developing the workplans, but more reliance on the regional coordinators for day to day implementation. Quality control for individual activities is provided by the external experts, once the central management team (Director and regional coordinators) have approved these activities in the workplan. As the external experts operate across the program and are

responsible for delivery of the individual activities, this should ensure that standards are maintained across the countries. The role of the country coordinators in providing the links to stakeholders and determining the political situation within each country was noted as a positive aspect by the implementers. Attempts are being made to develop more independence in the country programs and more direct connections between them, with direct communication between the country coordinators in West Africa being encouraged by the Director. However, a combination of factors such as the level of experience of the in-country teams and budgetary constraints reducing the scope for independent actions, mean that most budgetary decisions affecting programs are taken at a higher level. Although this does support the quality control aspects, this will make it difficult to expand the program into more countries without an expansion of the core staff.

Very few respondents were able to assess the effectiveness of the PBS Director and the Regional Program Leads as most reported little interaction with this level of PBS management. Those that did report interaction gave high marks to the Regional Program Leads and the communications advisor, noting that they are easy to communicate with and respond quickly to emails. Positive feedback cited recent communications and outreach oversight and quality control, including assistance on developing focused stakeholder targeting, and supervision of newly developed outreach products and methods of delivery. There was more familiarity with the senior PBS staff in their role as technical experts, which was addressed in relation to question 1 above.

- *How useful is the current PBS monitoring and evaluation system for program management, results reporting and learning? Given that many outcomes are outside the manageable interested of the program, are impacts being captured appropriately across all aspects of the program? How might the M&E system be strengthened in the next PBS award?*

The USAID Feed The Future criteria provide a very basic set of M&E requirements that are not considered by the implementing staff to be useful in assessing the impact of the PBS Program. The reports made available to the evaluation team include the numbers of people attending training events, (this is higher than the indicator, which call for the number of people trained due to a small number of people who attend more than one training event, but this is estimated at around 5% by the program staff). However, this number does not provide any measure of impact and there needs to be some way to capture the progress countries have made in developing a cadre of scientists who have had experience in the regulatory arena. In both Indonesia and Uganda, the various technical committees are now operating to review and make decisions on applications submitted to them. Ugandan scientists have been used as resources for training workshops both in Uganda and in other countries in the region. Even in Malawi, it was noted that although the National Biosafety Regulation Committee has only reviewed two applications for confined field trials, there was already a noted increase in confidence among the members about their role. This capacity building impact does not appear to be being captured in the progress reports submitted to USAID and it is difficult to provide quantifiable measures. Measurement of the operational effectiveness of the government committees (time between receipt of applications to approval of field trials, for example) would be possible, but will require the monitoring of agencies not directly under the authority of PBS. Reference was made to the previous monitoring framework which PBS operated under as having broader indicators (number and types of government organizations strengthened) and there would be value in re-assessing whether the previous indicators were more relevant.

Project monitoring currently rests on conference calls between different levels of PBS staff at set periodic intervals, and country lead reports on activities and semi-annual country reporting. Reporting to USAID Washington is made under two indicators: *4.5.2(7): Number of individuals who have received USG supported short-term agricultural sector productivity or food security training;* and *4.5.1(24): Numbers of Policies/Regulations/Administrative Procedures in each of the following stages of development as a result of USG assistance in each case: (Stage 1/2/3/4/5)* in addition to a narrative which is more qualitative and focusses more on activities than outcomes. The USAID mission in Uganda have an on-line reporting system for monitoring, but other USAID missions rely on reports from Washington and presence at PBS events to provide oversight. In Malawi, the US Embassy relies specifically on such presence and prefers not to receive detailed reports. Although this is adequate in the sense that the directly responsible project officers are satisfied, there is little scope in this system to quantify impacts across the project and to use the impacts as an illustration of the value of the project to other potential investors.

4. Financial Management

- *Given the goals of the projects as outlined in project documentation, how appropriately have BFS central resources been allocated amongst countries, partners and activities, to supplement and complement Mission funding and to support global technical leadership?*

Reviewing the financial documents supplied by PBS showed a complex funding situation requiring quite some effort to manage successfully. Interviews with the Director and regional coordinators confirmed the complicated nature of the financial situation which arises from a number of different USAID donors (Missions) being combined into a single line grant to IFPRI, but these funds often requiring managing and reporting separately. As mission funds are rarely more than single year grants, the challenge has been to maintain a constant presence in countries where continuity is considered to be important. Balancing core funds to be able to support all of the country programs, regardless of whether mission funds are available, is a key role of the Director.

The countries where PBS supports activities from core funds are included for a number of reasons, although it was explained that there are no fixed criteria. Continuity of presence is a key factor, and this is supported by the fact that a number of stakeholders credited the impact of PBS to this continuity. In fact, three regional collaborators commented that it is the long term presence of PBS and the contacts that PBS had built up in certain countries that are among the most useful aspects that PBS brought to the collaboration. Other factors considered in funding decisions are the political climate in a country, for example in Malawi, PBS considered that the situation was positive towards biotechnology and that the demand for external regulatory help would have support from within the country.

Some issues with availability of funds has caused problems in recent years. Delays in confirming funding from USAID have meant delays in disbursements from IFPRI to country operations as IFPRI management are cautious in committing funds to PBS operations until they receive the confirmation from USAID. In addition, retaining a pipeline of funds in the core to cover potential delays in availability of new funding results in an apparent under-spending by the project and risks reduction in funding from USAID. Better financial management by USAID and IFPRI would improve the running of PBS by preventing uncertainty over the availability of funds.

5. Communications, Outreach and Partnerships

- *Has PBS effectively responded with appropriate and timely communications products and outreach directed to the appropriate audiences as technical and political issues arise? What could be improved?*

The PBS program originally concentrated communications activities on high level information sharing and technical training of a targeted group of decision-makers most related to implementation of regulatory policy, namely the various biosafety commissions and the technical committees who support them and the policy-makers and influencers who set the agenda for biotechnology. Outreach to technical and academic collaborators appears to have been accomplished through small scale training activities. In recognition of the fact that communications and outreach is important to the policy development process, and to insure that a range of stakeholders understand the policies and policy decisions, the program has expanded its communications work to include an exapanded group of stakeholders who figure prominently in the both policy creation and implementation. The approach is more strategic-- to better inform the policy process, and to anticipate issues which may impact policy development and implementation. he program emphasis has, as a result, evolved to focus on building partnerships with a wider group of collaborators and providing information to sensitize stakeholder groups who can influence policy-makers to make biosafety a policy priority and insure that evidence-based biosafety policy is enacted and implemented. This represents a much broader outreach and communications program, which has been recognized by the hiring of a communications specialist as a long-term consultant, who assists in guiding this work, in addition to a number of other roles.

With the small resources that PBS has in each country it is not possible to operate alone - even if this were considered desirable - and so in each country PBS has either developed or associated itself with a broad consortium of government agencies, academic and government scientists and industry organizations to perform the broad scale sensitization that is required. The role of PBS in all of these efforts or organizations is to provide a conduit for science-based, accurate information of biosafety. In Indonesia, communications and messaging is currently being done by the Society for Indonesian Agricultural Biotechnology (SIAB). The group was established with some guidance and ongoing technical support from PBS. In Uganda, the Uganda Biotechnology and Biosafety Consortium (UBBC) and the Open Forum for Agricultural Biotechnology (OFAB) (a consortium established with AATF and which operates in a number of countries in Africa) are the main vehicles for this and PBS guidance was useful in helping these groups organize and develop, especially with respect to building their capacity to respond to regulatory issues.. In Malawi, PBS works with a number of local organizations including working with an association of agricultural journalists to insure that they receive evidence-based information about regulatory issues and practices. This certainly has an effect in multiplying the reach that PBS can have, with a far greater number of people able to be contacted than could be achieved with PBS funding alone. At the same time, however, there is a potential that the message is harder to control and the goals and targets of the partners may not be in alignment with PBS goals. In many cases, the partners are as interested in information and education about biotechnology itself and the message about the biosafety aspects of the regulation of biotechnology products may be diluted or missed altogether.

Furthermore, there is no consensus among the various respondents on who would be prime target groups for PBS as the various collaborators all have slightly different goals. While all respondents seemed aware of outreach and communication as a tactic, their targets of choice for PBS varied depending on where they themselves stand. Government regulators express interest in increasing focus on messaging on policy makers in government, believing that knowledge of biosafety is still restricted to

a very limited policy group. The non-governmental groups want to work with a wide variety of target groups including university and secondary school students, farmer groups that may benefit as users of agricultural biotechnology products, and also elected and appointed officials - diverse groups and widespread across each country. The private sector often have their own programs to target farm groups and farmers and would prefer that PBS should take advantage of its close ties with key government officials, drawing on the stature that experts bring to bear on policy makers, rather than with farmers whom industry can reach and with whom PBS has no connections. Hence, the issue of what is the appropriate audience or set of target groups for the future is not resolved and currently efforts appear to be going in many directions.

Another issue is the sustainability of these organizations should the program cease to operate in these countries. Transitioning to expanded and diverse funding sources and development of a mature management structure is a goal, but progress in this respect is dependent on the development of local skill sets for fund raising and management. These are in process. This will result in less guidance provided by PBS and therefore less quality control with respect to the regulatory messages and information, especially as other donors may have different goals.

It is not known what, if any, of the past and current efforts have been effective because there are no criteria to apply or methods for assessing impact (other than the "body count" of participants at outreach activities). Several respondents mentioned that the communications training has helped them to interact in public with journalists and to communicate with lay public, but at the same time, several others stated that PBS needs to bring in competent local PR experts to guide the process. Impact has been assessed through results in other areas, such as passing bills and/or regulations and approval of field trials, although the role of broad outreach in these outcomes is hard to estimate. There have been examples of publicly stated changes of opinion of influential individuals – such as the public support of one religious group in Indonesia and the change of position (from negative to positive) of the major consumer activist in Malawi, but it was noted that much effort is needed just to maintain current positions and prevent "backsliding" among prominent stakeholders and this may not be captured in assessment of impact. A more explicit monitoring of public awareness and opinion, through direct surveys is an option, however these are expensive and require repeating to determine the impact of PBS activities. Collecting and analyzing media reports would address the impact that the program is having on the press and could be used as a proxy, especially if there is also monitoring of feedback on websites etc.

Internally, PBS has a relatively large number of front-line staff (at least one in each country) and works with as number of different organizations both in individual countries as well as regionally and – in some cases – globally. Ensuring a coherent message across these is a major effort and responding to issues as they arise requires a number of capabilities. For the most part, response is through the expert consultants who rely on the rapid communications that they are able to achieve using electronic media. It is an aim stated by a majority of the PBS implementers (country staff and experts) that PBS should try to get ahead of the issues rather than reacting to issues as they arise.

PBS has not tried to garner a high profile for itself (a position noted by several US government interviewees) and works more with and through partners with regard to communications and outreach. Sets of frequently asked biosafety questions have been prepared by some partnering organizations, sometimes using PBS documents where applicable. To the extent that a common set of answers can be useful to show a united front, this is a valid aim and could be expanded more explicitly.

- *Is PBS effectively collaborating and working with other biosafety and biotechnology programs in the regions where these projects are active (including AATF, ABNE, ICGEB and OFAB communications programs).*

Direct collaboration with regional organizations is an expanding theme, but some non-formal collaboration has been going on for a longer period and has been the subject of a more recent, formalized effort since 2011 which marked the start of an annual biosafety service providers meeting) and more recently evidenced by closer joint programs in countries where numerous potential collaborators exist (such as the joint workshop between PBS and ICGEB which took place in March 2014). Close links with ISAAA have been established over a relatively long time and links with AATF at the country level through OFAB have also been a feature. The noted issues with such collaboration is the somewhat different goals and mandates of these organizations, with some being explicit promoters and/or developers of agricultural biotechnology products (AATF and ISAAA) and ICGEB targeted towards training more than policy.

Interviewees from all collaborating organizations reported benefit from their collaboration with PBS, often with respect to visibility within a country and access to the relevant stakeholders. The fact that PBS has been on the ground in many of their target countries for a number of years is seen as a major positive factor by the collaborators.

COUNTRY CASE STUDIES

Although the main themes noted in the interviews have been collected and reported across all of the countries in the sections above, the actual situation in each of the three countries visited was quite different. The individual situation reports below illustrate the broad range - in terms of the status of biosafety regulations - in the countries where PBS operates. These snapshots are included to provide some country specific analysis.

Case 1- Indonesia

Snapshot of Situation

- In Indonesia, the USAID Mission has provided significant funding for the past 3 years in tandem with a re-launch of the program which had fallen dormant due to negative publicity over BT-cotton and low perceived interest on the part of the government to proceed.
- In 2010 the Government of Indonesia appointed the Biosafety Commission for Genetically Engineered Products (BCGEP) based on a Presidential Decree (Government regulation 3910) whose role and authority is to advise government on importation and marketing of GM commodities including locally developed GM products. The thrust of PBS program activities has been to support the knowledge of biosafety and to advise in preparation of regulations for reviews and approvals by three technical committees (food, feed and environmental safety) that advise the Commission. Technical workshops have provided support to develop such regulations for technical committee review and advice to the Commission.
- There are strong undercurrents of negative feeling about international biotech industries - mainly US companies - as well as worries about food safety on the part of a small part of the population. This is manifested in negative publicity by NGOs. The Ministry of Environment has conducted its own outreach campaign on the guidelines for environmental risk assessment independent of PBS and they worry about the diverse issues surrounding GM crop cultivation.
- In mid-2013 the BCGEP mandate expired and the Ministry of Environment, the responsible agency, has not appointed (or re-appointed) a Commission that meets with the agreement of President's office. In addition, biotechnology and biosafety is a contentious issue, especially as it relates to the role of multi-national companies and especially sensitive in an election year. Thirteen food products have been approved for import using newly developed regulations, while regulations for feed regulations are awaiting ratification by the new Commission when it is appointed. Since the BCGEP has no formal authority at this time, no further formal approvals may be made by the Commissioners until the impasse over re-appointing the Commission is resolved, although technical committees continue to function. In the case of the one product developed, a drought-tolerant sugar cane, a dossier has been prepared, but the product cannot be approved in the absence of a functional Commission. In the meantime PBS is looking to develop an outreach strategy working with a locally based coalition to share information about the regulatory process for the GM sugarcane and other GM products.
- USAID Indonesia has preferred to keep a low profile on biotechnology because of past and potential future bad publicity. The new USAID Country Strategy will eliminate agriculture as an

intervention area and mission support for PBS in the future is in question as the program objectives may not be consistent with the Mission strategy.

Analysis

- The signal for programming and for USAID interest was the renewed interest in biotech through the Presidential Decree establishing the BCGEP. However, in retrospect, the foundation for the Commission was not sufficiently strong to keep it free of political manipulation and electoral pressures. This demonstrates the importance of a clear and firm institutional basis for regulation of biosafety so that progress is not dependent on waxing or waning political will or driven by outside factors. In Indonesia, the stakeholder interest in biotech does not appear to be strong enough to maintain the momentum in the face of negative pressure.
- PBS must determine whether it can, or should, attempt to develop more stakeholder support for biosafety and continue to support the government of Indonesia in the next project period and without, potentially, the active collaboration of a Mission program after the next year. The program success to date has been in the technical arena dependent on outside experts. As key products near commercial release, one might expect the need for more effort in outreach to materialize, while needing to maintain a continued level of technical support. The support of the country mission would be an important asset for policy outreach, not only from a funding perspective but also in enabling access to decision-makers. Without mission support, biosafety policy outreach efforts might be more difficult.

Case 2 – Uganda

Snapshot of Situation

- In Uganda the USAID Mission has provided significant support since 2004 through an Associate Award which was closed in 2013 and a new Associate Award which will run until 2017. During this period, the local development of expertise in biotechnology research has progressed and field trials of a number of GM crops have been carried out. PBS was instrumental in developing the capacity of Ugandan regulatory authorities to review applications, approve and manage these field trials.
- The system for confined field trials is functional and a number of locally developed and external GM events are currently being developed towards commercial deployment. PBS played a large role in developing SOPs for confined field trials and training staff to manage and inspect the trials. PBS has contributed to the development of a significant Ugandan capacity in biotechnology and biosafety, such that Ugandan scientists are now involved as resource for training in the region as well as in Uganda.
- A bill has been submitted to Parliament to cover the commercial approval of GM crops. This Bill was introduced by the government, but is currently awaiting a second reading and proponents of the bill are concerned that in the current climate it will not pass and are anticipating that a second reading will be delayed.. Although it is a government-sponsored Bill, outside interests and coalitions are providing most of the technical and outreach backstopping related to passage of the Bill. With an election approaching, the Bill may be contentious; as a result, momentum and support for passing the Bill has stalled.
- PBS has been focused on insuring that those in Parliament have access to technically sound information to support an informed decision making process with respect to passage of this Bill.

Visits to the confined field trials and international study tours to visit commercial plantings of GM crops have been effective, via a "seeing is believing" approach, to expose key policymakers to regulatory progess in both Uganda and other countries. This is regarded as successful, but only limited numbers of people can be exposed.

- Stakeholders remain confident that the Bill will be passed, but there is currently no timetable. Attention appears to have been so focused on getting the Bill passed that there is a worry among some stakeholders that little consideration has been given to what is needed to implement the Bill. There needs to be planning now for the next stage of support to get the Bill fully implemented and operational.

Analysis

- PBS has been successful in gaining support of individual MPS though targeted activities, but this support does not seem sufficient to ensure passage of the Bill. Although this is a Ministry of - Planning sponsored Bill, support for the bill among some government Ministries is not consistent within and between ministries.
- PBS should support those working on the Bill should by providing analytical direction regarding the various stakeholders who can impact the Bill to insure that they have accurate information about the purpose of the Bill, its contents, and the implications for agriculture productivity and safe deployment of new GM varieties in Uganda.
- Consideration is needed on what PBS role will be once the Bill is passed.

Case 3 – Malawi

Snapshot of Situation

- In Malawi, PBS has no current support from the USAID Mission and is operating on core funding, but is in receipt of funds from the US Embassy in Lilongwe to do outreach related to the regulatory work This situation is likely to change in the near future as AATF are planning to apply for field trials of an insect-resistant cowpea event and the USAID Mission is willing to support this under the Feed the Future program.
- PBS was instrumental in developing implementing regulations under the original Biosafety Act which was passed in 2002, but had not been implemented. Technical and financial support was provided by PBS to put in place Biosafety Regulations and guidelines under which field trails can take place.
- Confined field trials with insect resistant cotton are under way in Malawi. This is the second season and funding for the trials (in three locations) is being provided by Monsanto as the technology developer with Bunda College. PBS has provided support in the form of infrastructure and training of regulatory staff, inspectors and the National Biosafety Committee. Progress on capacity development of the National Biosafety Regulation Committee (NBRC) has been made – with the approval of the second round of cotton trials much more straight forward than the first round of trials and the Biosafety Registrar speaking of increased confidence within the NBRC as to their role.
- The confined field trials have provided an opportunity to sensitize a wide range of stakeholders in addition to those who were given the opportunity of international visits. Lack of interest by the Ministry of Agriculture has meant that the trials are being sponsored by Bunda College of Agriculture; support from the Department of Agricultural Research (under the Ministry of Agriculture) is lukewarm although some research sites have been used for trial work. In contrast,

there is enthusiastic support from the Ministry of Environment and Climate Change, which houses the Biosafety Registrar.

Analysis

- The "seeing is believing" visits to the confined field trials have increased interest in the technology and the challenge is to maintain this momentum. At present, there is only one potential new product on the horizon and insufficient local resources and projects for public sector GM research
- PBS needs to consolidate the gains (a regulatory system that has approved two rounds of confined field trials) by encouraging other developers to work in Malawi and thus increase the experience of the local regulatory system.

CONCLUSIONS AND RECOMMENDATIONS

1. PBS Country Programs Staff and Support from International Technical Consultants

To date, the technical focus of PBS is well served by the country staff and experts, however the demands are now moving from primarily technical support to advocacy and there are different skills required. The value of having external experts from a wider source than just the United States is tempered by the need to have well-qualified experts and to have them involved in PBS activities over a long enough period to be familiar with and accepted by local stakeholders. Development of local expertise, through training and joint research studies, can provide a resource for the region as well just the country in which they are working.

2. Policy Research

The PBS Policy team, working within and through IFPRI, has played an important role in producing a body of work recognized globally as being critical to the understanding of biosafety policy and regulation. However, there seems to be little recognition of this within the country stakeholders and there appears to be some conflict between IFPRI demands for publications in peer-reviewed journals and products which can be used to help countries develop practical regulatory systems. This is recognized by PBS management and attempts are being made to use the research more widely and also to conduct more country-level studies. The challenge for PBS is to work within IFPRI to allow for recognition of more practical studies for implementation as a valid output. With regard to recognition of the role of PBS research by local collaborators, it is less important that these studies are identified as IFPRI publications than that PBS is seen as a source for documents relevant to the local policy and planning needs. The PBS summaries and short briefs are where there needs to be "brand recognition" as this is where most of the government regulators and policy makers will be getting their information.

3. Project Management

Annual work plans and semi -annual reports appear deficient in many respects for proper management, results reporting and learning. The main problems include:

- Exclusive focus on inputs (and outputs), rather than on outcomes and results. The work plans do not indicate what outcomes (except USAID standard measures which are of little value) are

expected from a given input (activity) and provide no adequate measure of whether the activity resulted in expected and desired outcomes (which are often not defined). Hence, the planning and reporting do not give a clear picture of what objectives and outcomes were expected or achieved in the given period.

- There is considerable confusion over what a milestone is, what is an input and what is an output. These should all be reviewed and refined using USAID standard definitions with critical milestones clearly defined, and differentiated from inputs.

- There is a need to present realistic time frames for achievement of critical milestones, outputs, and outcomes, so that program progress can be measured and monitored for decision-making, both from the standpoint of financial cost benefit analysis and allocation of funds against expected progress, but especially for Missions that need clarity on what they have paid for and what is being achieved from year to year leading to desired outcomes.
- Project level intermediate outcomes and long term outcomes and results need to be identified, with clearly defined indicators for measurement (based on USAID indicator development methodology) so that achievements can be measured at the project level for better reporting, and learning from experience. USAID Feed the Future standard indicators do not capture outcomes and results in sufficient detail to know whether the inputs are achieving the desired impacts; as for one of the two indicators used, the number of people trained, the raw number of attendees at a seminar or a lecture is meaningless for project management and planning purposes (these are outputs) because it does not reveal what the attendees did with the information. A similar problem is found with use of indicators such as number of regulations produced or reviewed (which are inputs and outputs) that tell nothing about results. Carefully refined indicators and means of measurement are needed to capture project impacts and goal achievement.
- Previous project indicators for capacity building within government agencies should be reviewed for potential application. The time for an application to progress through each step of the regulatory process can be used as a measurement of the effectiveness of the regulatory system, as can the responsiveness of the various committees to applicants.

4. Financial Management

PBS has been successful to date in juggling the demands on the core budget to provide services and support in a number of countries which have USAID mission support as well as operating in some key countries which don't have such support. Based on interviews and assessment of country situations, progress has been made in all countries in which PBS operates and there was no suggestion that lack of funds was a key factor in those cases where political changes have become a road-block to further progress. It is not possible to speculate on whether PBS would have been more successful by focusing only on countries where there were mission funds as there are examples of success both with and without mission funds. However, the interest of the country mission is valuable and in the case of Indonesia and Uganda has provided more than simply funding such that - for the most part PBS – should concentrate on those countries where there is USAID country mission support.

One challenge for PBS lies in how much they can expand into new countries, given the demands on the core budget, recognizing that for each country funding is not only required for country level staff, but also to support the country activities with external experts and central PBS activities. There are many

demands on the core budget and hard decisions need to be taken about when to stop funding activities in a country or even to turn down mission funds to begin working in a new country if this would stretch core funds too thinly. There does not appear to be any formal benchmarking of different countries with respect to the return on investment of core funds and this would be very difficult, given the very different situations (and funding levels) in the countries where PBS operates. However, some understanding of what is needed from the core budget to support a useful country program - over and above the costs for the country team itself is – is required to determine how many countries PBS can productively support from the existing core budget. There is the potential to reduce effectiveness over the whole program by stretching core staff and external consultants too far.

5. Communications, Outreach and Partnerships

A number of issues concerning targeting, the role of communications and outreach and the professionalization of advocacy and PR are pending. Answers to the following will be helpful in defining and implementing a strategy:

- For whom do the in-country consortia (SIAB, UBBC, OFAB etc.) speak? Is it the mouthpiece of PBS? The tighter the connection, the more the group becomes a proxy for the US government and PBS, which could backfire if PBS loses the trust of local stakeholders.
- Is there a long-range plan for engagement and institutional support? PBS is providing partial support to a few of these consortia in addition to funding travel costs of speakers and venues. USAID has a long history of supporting and financing NGOs that eventually fail when financial support is withdrawn. A clear plan is needed to determine the relationship in both short and long term financial terms and otherwise.
- What is the capacity of the consortia to do public relations and policy work? Neither the members nor PBS country staff are advocacy or PR professionals nor are they receiving professional advice at present.
- What is the appropriate target group(s) for the consortia to focus on, what clear and measureable results are expected from their outreach, and how will they be measured? To date PBS considers "results" the number of persons attending a lecture. It is not clear what result or outcome has been defined as the goal for speaking to high school students, or a farmers groups, for example.
- Who should focus on other target groups, and is PBS involvement needed or desirable? Is policy advocacy an appropriate direct PBS role, using respected policy experts both international and national?
- Are professional communications services needed to complement and support PBS local staff and volunteers?
- What results are desired, and what indicators will measure the impact of different inputs on different stakeholders?

CONCLUDING REMARKS

The country visits have confirmed this reviewer's previous experiences of biosafety regulation in other developing countries in that there is often a lack of real commitment by governments to developing a regulatory system for products of biotechnology. The fact that there is no government budget for the various committees, in certain cases, and little government support for a bill originating with the

ministry of Agriculture in Uganda, indicates that biosafety regulations are still not seen as critical to the functioning of governments. In this atmosphere, international commitments to biosafety regulation (chiefly the Cartagena Protocol) become something to address at the minimum level required and only where external funds can be obtained. The fact that it is largely overseas agencies which are involved in both developing biotechnology products and supporting the implementation of a regulatory system compounds the erroneous perception that these things are being pushed onto a country, rather than addressing an internal need or being a positive factor in the country's development.

Within this difficult political environment, PBS has been an effective force in increasing the technical capacity of countries to handle the regulatory aspects of agricultural biotechnology up to the stage of confined field trials. In all three of the countries visited, PBS can take considerable credit for the fact that there is a system for the application, review, approval and monitoring of confined field trials of transgenic plants, together with some form of regulations and standard operating procedures to ensure that these are carried out with minimal risk to the environment and human or animal health. There is even noted progress in addressing the technical aspects of risk assessments for approval of foods and feeds and environmental release in both Indonesia and Uganda. However, taking this to the next step – getting products approved for commercial cultivation – has not been achieved and remains elusive in many countries across the globe. This failure is not a criticism of PBS as there are still relatively few countries which have approved transgenic plants for cultivation (and even some of these cannot be described as having a functional regulatory system as there is just a single modified crop being grown with approval being given as a one-off dispensation). It is simply a recognition that more than technical expertise and support are needed to develop and implement a functional regulatory system to the stage of approving GM products for commercial cultivation. In order to achieve such commercial level approval, there needs to be a broader political commitment, supporting the passage of enabling law(s) and/or the establishment of a permanent government system for implementing cultivation approvals. It is the opinion of this Reviewer that promoting this broader commitment will require a different strategy to that taken by PBS in the past.

In achieving the success that it has in the technical areas, PBS has focused quite narrowly on the relatively few people who need to be involved in the process of implementing confined field trials and addressing the technical aspects of risk assessment. This has been successful because the governments in the selected countries were supportive of the technology – as long as there was relatively little political cost. While the funding was from external sources and there was little negative public reaction, the activities in implementing a confined field trial system had little downside to government officials or politicians. However, as the products moved further towards commercial approval, decisions on legal frameworks (potentially requiring laws to be passed) and funding for regulatory activities now have the potential to be controversial. As the situation evolves, PBS has become more focused on broadening its outreach to other stakeholders that may impact the regulatory system. This has required an augmentation of communication skills, expertise and resources in the program.program and has resulted in a more integrated approach such atht technical capacity building and communications capacity building are now developed in tandem. PBS has a challenge to effect this change in their focus – while at the same time retaining the credibility and trust which has been built up during the technical training and development.

As the situation is changing, the future role of PBS could be considered through how to strike a balance between two extreme options, detailed below. It is not suggested that PBS chooses one of these two extreme positions, and in reality, it is expected that some course between these two will be chosen, but in choosing the particular course, the potential for conflict between these goals needs to be recognized.

Option 1. PBS remains an agency for technical support, narrowly focused on getting a relatively small number of people trained in the review and monitoring of confined field trials and risk assessment of applications for commercial release, staying away from the political advocacy areas needed to get such cultivation applications approved. PBS is certainly good at this – and has a track record in a number of countries. This would retain the reputation of PBS as an honest broker and might even have benefit for USAID as it will be seen not to be an arm of big US companies. However, this will miss the major goal of USAID – giving farmers in these countries more options to improve their productivity and profitability and thus not be compatible with the Feed the Future mandate.

Option 2. PBS converts to an advocacy organization, utilizing its linkages and contacts to push for an enabling environment through the adoption of (possibly) new laws, regulations and the setting up of regulatory agencies. This will require quite a large alteration in the make-up of PBS staff and also – quite likely – a different kind of budgetary system, given the potential need for increased funds to be spent on public relations and – possibly – covering the funding of positions within local government agencies to facilitate the process. This is something which will more directly advance the Feed the Future goals, but is quite different to the current PBS structure and may be difficult to operate within the current system of an award to IFPRI.

One of the problems for PBS is that it is operating in countries which are at different stages along the pathway towards a functional regulatory system. Countries such as Malawi are still at the stage of needing technical support to handle applications and manage confined field trials, while Indonesia has a set of technical committees which are now actively involved in handling approvals for food use and environmental release. Even as each country moves towards the commercial end-point and advocacy becomes a bigger part of the PBS role, there will still be a need for technical support to regulators and – possibly – developers and so PBS will need to retain the technical expertise and, to a large extent, an un-aligned non-partisan stance.

The need to be essentially neutral and outside the government means that PBS will never have full control over the outcomes in relation to getting government procedures in place and products approved. Thus there will always be a need to have other measures of impact than a simple counting of bills and regulations put in place by governments. In both planning and monitoring, the inability of PBS to control many of the factors which are directly related to its success needs to be understood and milestones and their attendant criteria developed to incorporate this.

ANNEXES

ANNEX I: EVALUATION STATEMENT OF WORK

Aug 1, 2013

STATEMENT OF WORK
Performance Evaluation of the Program for Biosafety Systems

Complete Title: Performance Evaluation of the Program for Biosafety Systems
Begin Work Date: 08/10/13
End Work Date: 10/30/13
Total Days: 64

1) BACKGROUND

A. Problem Addressed by PBS

USAID has been funding efforts in biotechnology and the regulation of agricultural biotechnology for nearly two decades across several partners and host countries in Africa and Asia. Amongst these programs are those that support R&D and deployment of new agricultural technologies using biotechnology and a separate set of programs that support the development of reasonable, science based regulatory systems that govern the application of these new agricultural technologies. PBS is the largest of USAID's investments in this latter group. PBS has been supported for 10 years by both USAID Washington and USAID field missions.

The role of biosafety systems and facilitative policies to insure that Agency-funded research yields practical benefits cannot be underestimated since it is widely recognized that biosafety considerations and concerns, especially in developing countries, can be a primary limiting factor in biotechnology adoption.

B. Target Areas and Groups

PBS is currently active in the following countries:

Africa

- Kenya
- Uganda
- Nigeria
- Malawi
- Mozambique
- Tanzania (new in 2013)
- Ghana (new in 2013)

Asia

- Indonesia
- The Philippines

- Vietnam

Regional Organizations
- COMESA
- ECOWAS (new in FY13)

C. Identifying Information

- Activity Title: Program for Biosafety Systems (PBS)
- Grant No: AID-EEM-A-00-03-00001
- Implementing Partner: International Food Policy Research Institute (IFPRI)
- Award Dates and Amounts:

Leader Award:	05/14/2003 to 09/30/2013	$25,762,721
Leader Award Funding from:		
USAID/BFS	05/14/2003 to 09/30/2013	($23,451,154)
USAID/Ghana:	10/01/2012 to 09/30/2013	($250,000)
USAID/Tanzania:	10/12/2012 to 09/30/2013	($200,000)
USAID/Indonesia:	10/01/2010 to 09/30/2013	($931,567)
USAID/Malawi:	10/01/2007 to 09/30/2013	($300,000)
USAID/Nigeria:	03/22/2007 to 09/30/2013	($550,000)
USAID/Mozambique:	10/01/2006 to 09/30/2013	($80,000)
Associate Awards:		
USAID/Kenya:	10/01/2010 to 09/30/2013	$600,000
USAID/Kenya	03/12/2007 to 03/11/2010	$479,000
USAID/Uganda:	08/03/2004 to 01/31/2013	$2,419,284
USAID/Ghana:	03/01/2005 to 04/30/2008	$750,000

D. PBS Theory of Change and Intended Results

PBS supports partner countries by facilitating use of biotechnology for the eventual deployment of beneficial agriculture products, such as new genetically-modified (GM) varieties of crop plants that are resistant to a variety of biotic and abiotic stresses (e.g. insect resistant cowpeas and drought tolerant maize) or GM varieties with enhanced nutrient profiles (e.g. Vitamin A enriched cassava). The indirect outcome is sustainably enhanced productivity and climate resilience in agriculture production systems to reduce poverty, enhance nutritional status and improve the quality of life for resource poor farmers and consumers.

The theory of change in PBS's support for developing functional biosafety systems is to ensure that countries have the legal framework and the laws which facilitate development and adoption of biotech crops. PBS initial support and guidance is required for sustained, credible and, impartial biosafety legal and policy advice and capacity building of decision-makers. Coupled with this, targeted, practical/technical support will be essential to actualize the benefits of these products for farmers and consumers alike. In parallel with the increased number of GM products approaching release in developing countries, ongoing public debate and legal

challenges are more frequently emerging as obstacles to progress. PBS has strategic, multi-stakeholder outreach activities, coupled and integrated to the work it does on the regulatory front, to confront these challenges “head on” and to avoid backpedaling to more precautionary policies.

The final outcome of the layered support and integrated approach provided by PBS is to enhance adoption of biotech crops, coupled to an increased understanding of the underlying science by decision makers in order to withstand negative influences of anti- GM groups which might affect eventual product adoption and limit impacts. Developing a country’s capacity would impact and further its national goal of increased food security, poverty reduction and also better climate resilience. Figure 1 presents PBS’s Impact Pathway, which describes the Inputs and Outputs for which PBS is responsible, and the Outcomes and Impacts that should result in part due to PBS successfully implementing planned inputs and producing planned outputs.

Input	Output	Outcome	Impact
National policy and regulatory framework development a. Legal training and small drafting team retreats to lawyers and regulators b. Support to legal and regulatory actors to review and approve commercial product applications c. Educate regulators about the biosafety regulatory system and facilitate the establishment of policies and guidelines that allow for simultaneous use of overlapping data and analysis to satisfy other legal obligations d. Train regulators on how to write better legal language into the laws and defend these regulatory decisions against potential challenges e. Socio economic analysis of major crops or traits in the regulatory pipeline *Strategic outreach and communications* a. NetMapping to orient, update and refresh the country strategies b. dynamic use of the PBS website as a capacity building, information sharing and regulatory services tool c. systemize communications training for regulators d. establish a more formal network mechanism whereby	1. Regulatory framework developed 2. Biosafety law passed 3. First products submitted for CFT 4. Competent biosafety officials in place; 5. Draft law developed; 6. Regional harmonization framework developed 7. Analysis of biosafety decision-making options for CPB 8. Research used to inform biosafety frameworks 9. Communication materials developed and disseminated 10. Advocacy of biotechnology as a science for enhancing support within the country 11. Implementation of enabling regulations (e.g., circulars, guidance documents)	Functional biosafety systems established in partner countries Commercial release of GM crops Coalition built at various levels within the agriculture value chain of people knowledgeable about the benefits of biotechnology Capacity within country to counter pressures from anti-GM lobbies Better understanding of the science of biotechnology for enhanced food security and poverty reduction Sustainably enhanced productivity and climate resilience	Enhanced food security in partner countries and the region Reduction of agriculture loss from climate change effects Poverty reduction in adopting countries due to increased yields and better trade Expand producer choice Inspire consumer confidence Facilitate trade Promote agricultural R&D

developing country regulators can share information, best practices, lessons learned and issues across countries *Regulatory and technical support* a. support in the development and implementation of enabling regulations b. Assist regulatory agencies in developing policies surrounding food and feed safety c. Assist regulatory agencies in defining and implementing insect resistance management practices d. Assist regulatory agencies and technology providers e. Foster partnerships between in-country R&D institutions and regulatory agencies *Supportive decision-making research* a. Inform decision-makers on the socio-economic consequences of various policy options b. Assess existing constraints and policy obstacles that impact the development and implementation of functional biosafety systems c. Analyze current and upcoming issues at a global scale and determine the impacts of sub-regional, regional, and global regulatory instruments and trade considerations on national regulatory systems d. Analyze the impacts of GM regulatory policy on product access from a gender sensitive perspective	12. Capacity developed in food-feed safety assessments 13. Reconciliation of biosafety laws and procedures with other laws and across ministries 14. More positive political climate and enabling policy system across ministries 15. GM plants/products tested and evaluated in compliance with national guidelines 16. System for commercial release incl. IRM guidelines	in agriculture production systems developed	

Figure 1. Impact pathways of the Program for Biosafety Systems

E. Approach and Implementation

The PBS program works with local agricultural organizations and stakeholders to build functional science-based regulatory pathways for the adoption of new biotechnology products. Its diverse team of scientific, legal, commercial and communications experts builds biosafety capacity through an integrated program of policy analysis, development

and implementation for practical, achievable results. Activities are designed and implemented through a country-led approach with local PBS country leads. Further, the ability to draw on an in house independent policy research team at IFPRI brings added value and academic credibility for informed decision-making. IFPRI is a public international organization and member of the Consultative Group on International Agricultural Research.

BFS supports the PBS core budget. This budget includes management staff, technical consultants, global policy research, participation in international meetings (i.e. Cartegena Protocol, ISBGMO) and in-country costs for some PBS countries (Malawi, the Philippines, Vietnam, COMESA and ECOWAS). USAID missions support PBS to strengthen and deepen programmatic activities in their respective countries. PBS currently receives additional mission funding from Ghana, Indonesia, Kenya, Nigeria, Tanzania and Uganda.

PBS's approach to biosafety capacity development is unique among a variety of biosafety service providers (most of who are funded by other donors) in several aspects, as it emphasizes:

- A comprehensive approach to biosafety framework development, including the development of workable implementing regulations, detailed operating procedures, and guiding biosafety dossier development and reviews, among others;
- A sustained and consistent on-the-ground presence in the form of local country coordinators who facilitate discussions of needs and concerns between local decision-makers and the project's technical and managerial expertise;
- Development of biosafety frameworks by involving international and local legal and scientific expertise in support of effective functioning biosafety decision-making;
- Supportive outreach and communications strategies for national competent authorities and the broader stakeholder community that is a pre-emptive, guiding and responsive to complement the technical work that is undertaken by the project;
- Capacity development, including hands-on training, around a specific product, policy/legal instrument, or GM application in the pipeline in partner countries;
- De novo, targeted research to inform the decision-making process and effect policy development, adoption and implementation.

F. Existing Documents

PBS will provide the evaluation team with the following documents at the beginning of the assignment:

- Original Grant
- Performance Management or Monitoring and Evaluation Plan

- Annual workplans and reports
- Publications and Major communications pieces produced by PBS
- Any additional technical reports
- Yearly Summary Financial Reports from period of FY2008-FY2013

2) TASKS

A) Evaluation Purpose

The purpose of this external evaluation of PBS is to assess the performance of the preceding 5-year period, and to identify ways in which the program can be improved during the planned next 5-year period. The scope of this review will be the entire range of PBS activities, including policy research and all in-country programs, but excluding programs that just began in FY2013 (Ghana, Tanzania and ECOWAS).

B) Audience and Intended uses

The primary audience for this evaluation is USAID/BFS and IFPRI staff. The evaluation will identify successes and lessons learned over the past 5 years of program implementation, and help guide the design of the new IFPRI award to continue PBS activities.

C) Evaluation Questions

1) PBS Country Programs Staff and Support from International Technical Consultants
   (a) Are the roles and responsibilities of the in-country country lead appropriate compared with international short-term consultants? Should the mix be adjusted to support program expansion and sustainability of provider support in the next PBS award?
   Sub-questions to consider: Is the skill set of the in-country country leads appropriate to achieve PBS objectives? In what areas of their essential job functions have country leads been effective and where have they struggled? Do stakeholders feel country leads have enough/the right technical expertise, as compared to skills required to initiate and keep activities moving forward, and to communicate, advocate and build consensus among national stakeholders? Has the support provided by international consultants been effective in achieving the objectives of their STTA and overall PBS country objectives?

2) Policy Research
   (a) Has the policy research carried out by PBS been relevant to the technical support and capacity development activities being conducted by PBS? Provide specific examples of where PBS policy research has made a direct and measurable contribution to the achievement of PBS country-level objectives.

(b) Are the research products developed by the PBS team of high quality and contribute to a literature base that is being utilized by partners and stakeholders?

3) Project Management
   (a) How effectively have the PBS Director and Africa and Asia regional program leads supported learning and ensured quality across countries? How could these roles be strengthened in the next PBS award?
   (b) How useful is the current PBS monitoring and evaluation system for program management, results reporting and learning? Given that many outcomes are outside the manageable interested of the program, are impacts being captured appropriately across all aspects of the program? How might the M&E system be strengthened in the next PBS award?

4) Financial Management
   (a) Given the goals of the projects as outlined in project documentation, how appropriately have BFS central resources been allocated amongst countries, partners and activities, to supplement and complement Mission funding and to support global technical leadership?

5) Communications, Outreach and Partnerships
   (a) Has PBS effectively responded with appropriate and timely communications products and outreach directed to the appropriate audiences as technical and political issues arise? What could be improved?
   (b) Is PBS effectively collaborating and working with other biosafety and biotechnology programs in the regions where these projects are active (including AATF, ABNE, ICGEB and OFAB communications programs)

D) Evaluation Design

This is a performance evaluation of PBS that focuses on PBS's implementation processes and efficiency. There are no comparison groups or randomized assignment involved, nor is there an expectation that the evaluation team will be able to attribute outcomes or impacts to PBS activities. USAID anticipates the team will use a combination of three evaluation designs:

1. Snapshot: Looks at a group receiving an intervention at one point in time during the intervention. Most of the performance evaluation questions will be answered with this design (Questions #1,3-5)
2. Before and After: Aggregate measure of outcomes for a group before and after the intervention. This design will be useful to document policy and regulatory changes as a result of PBS policy research (Q#2)
3. Case Study: Used to gain in-depth understanding of a process event or situation and explain why results occurred – from the perspective of a case, a cultural context, the

lived experiences of recipients. The evaluation team may consider using this design to document particularly useful and informative successes or lessons learned.

E) Data Collection and Analysis Methods

The evaluation questions are descriptive in nature and the evaluation team will rely largely on qualitative methods to collect the data required to answer them. Likely methods include individual and group structured interviews with, among others, USAID BFS and Mission staff, PBS team members, host country government officials, technology researchers and developers, and civil society participants in advocacy and communication activities; desk reviews of project and other documentation to understand the biotechnology and biosafety policy climate and changes in policy and regulatory decisions made over the previous 5 years in PBS countries; and possibly network analysis to understand how information is communicated and whether the right people are being involved to reach the desired project audience.

The evaluation team will be required to submit an evaluation plan that describes in detail the data collection methods, including triangulation, that will be used for each evaluation question, and how unbiased information will be assured (see evaluation plan template in Annex 1.) The evaluation plan should also detail the analytical methods to be used for each data collection method. The plan should specifically address how qualitative interview information will be analyzed, including transcription, coding and interpretation/theory development, and what types of validity checks will be used.

The evaluation should be based entirely on the data collected (interviews or documents) for the evaluation. No personal opinions should be included and no inferences made. All conclusions in the evaluation report should be based on objective data; biased or subjective statements and opinions should not be included in the report.

All statements/conclusions on performance/progress should be linked to project objectives (and objective measures), such as those outlined in a project document or work plan, and measured against objective standards for performance. Performance should be measured first and foremost by the goals and objectives laid out in project planning, and statements about performance provided by respondents can be included as additional supporting information.

The evaluation team should develop written instruments for structured interviews and systematic document review in advance of field work, and share them with USAID and PBS for review and comment prior to initiating fieldwork. All instruments must be included in an annex in a final report.

F) Methodological Strengths and Limitations

Qualitative methods can be relatively flexible and adjusted as the evaluation team gains understanding of the PBS context and approach. The methods can provide very

accurate information if appropriate qualitative validity checks were employed, and will be useful for understanding how PBS interventions and project management operates and what fosters and hinders their success. Limitations of qualitative methods in general include difficulty in replicating (NB: USAID does not intend to replicate this evaluation); and in generalizing beyond the specific activity being evaluated (NB: USAID intends to use the findings of this evaluation in the design of the next round of PBS, not more generally).
Quality depends heavily on skills of the individual evaluation team members and the use of non-biased methods. Team member qualifications include experience with evaluation of these types of programs using these types of methods.

G) Reporting Guidelines

The evaluation team must ensure that the final report meets USAID's Criteria to Ensure the Quality of the Evaluation Report (see Attachment 2). The team should also reference PPL's How To Note on preparing evaluation reports http://www.usaid.gov/sites/default/files/documents/1870/How-to-Note_Preparing-Evaluation-Reports.pdf, and, to the extent feasible, submit the report using the USAID Evaluation template http://usaidlearninglab.org/library/evaluation-report-template.

All findings and statements of conclusions must be based on data, not opinion. Paragraphs or sections should be written primarily to provide a summarized finding, followed by an explanation of the supporting evidence that substantiates the finding.

There should be no personally identifiable information in the report. Do not include names, including in the list of interviewees in the annex. Do include titles or positions of interviewees.

H) Logistics

Three one-week field visits are anticipated, to Indonesia, Uganda and Kenya. Both team members will participate in all three visits. The review team will consult with PBS staff and USAID for logistic arrangements and contacts in host countries. PBS will be responsible for assisting the team to organize the field visits, including scheduling individual interviews, arranging for any necessary in-country lodging and travel, and making work space available to the team, if available. The costs of all travel and in-country activities will be covered by the USDA/FAS contract as will the per diems and reimbursements for time spent.

Scheduling

The following schedule is suggested with a begin date in mid-late September 2013.

Tasks	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10
Organizational meetings										
Work and Evaluation plans										
Document review										
Field visits/consultations										
Write and present draft report										
Write final report										
Present final report										

3) DELIVERABLES

Deliverable	Due
Initial Meeting with USAID and PBS	Within two days of start date
Evaluation Team Meeting (internal)	Within two days of start date
Work Plan	Within one week of start date
Evaluation Plan	Within one week of start date
Draft Report	Within three weeks of completion of field visits
Presentation on Draft Report (conference call or in person)	Within three weeks of completion of field visits
Written comments from USAID and PBS	*Within two weeks of receiving draft report*
Final Revised Report	Within two weeks of receiving comments

4) QUALIFICATIONS

The review team will be composed of 2 senior consultants, an evaluation specialist and a biosafety expert in the technical areas listed below.

The Evaluation Specialist will be the Team Leader. His/her responsibilities will be to coordinate all activities and ensure all aspects of the review are covered by the team. The Team Leader/Evaluation Specialist is responsible for developing the evaluation plan, and ensuring the technical team member uses appropriate data collection and analytical techniques as defined in the evaluation plan. The Team Leader/Evaluation Specialist will ensure that the report is completed according to the plan above.

Final decisions on which team member is responsible for which evaluation question will be determined by the team based on composition and expertise. However, illustratively, the team Leader/Evaluation Specialist could be primarily responsible for evaluation questions 3 and 4, while the technical team member focus on questions 2 and 5. The team would jointly be responsible for question 1.

Education and Experience: All members of the team will hold advanced degrees in relevant fields. The team will have combined work experience in the following areas:

research management and/or administration, regulatory compliance, product stewardship, human and institutional capacity building – particularly in biosafety/regulation/law, and international development program evaluation of similar types of projects.

Knowledge and Ability Requirements: Team members will possess expertise in: (1) biosafety regulation; (2) agriculture biotechnology and its applications; (3) international agriculture development issues; (4) research methodology and implementation; (5) human and institutional capacity building; and (6) performance evaluation design, and data collection and analysis methods.

5) PERIOD OF PERFORMANCE

Activities under this Statement of Work will be implemented in two (2) months or until 11/30/2013.

ANNEX II: EVALUATION METHODS AND LIMITATIONS

DATA COLLECTION

The project's design is based on assisting country-specific institutions to develop successful and fully functioning regulatory frameworks and methods for assessing biosafety of products, and implementing the associated directives with appropriate measures, laws and regulations. As this is a process evaluation, it focuses mainly on the effectiveness of the processes and the inputs in producing project success, rather than on the specific outputs or results. Therefore, a large part of the data collection has involved gathering information to assess the extent to which the different activities of the program and its management have contributed to achieving the general program objectives and specific country objectives. To a great extent the answers to the evaluation questions involve subjective opinions, however employing the techniques of cross- verification and triangulation between respondents and with existing secondary data objective findings are derived. Data was collected for this evaluation using two methods: document review and key informant semi-structured interviews .

DOCUMENT REVIEW AND SECONDARY SOURCES

The evaluation team conducted a preliminary desk review of relevant project documents and key sector background material in order to gain a thorough understanding of the specific activities over the 5 year period of the project, together with the country context in which each program is operating. Document review is an important source of data on project activities that can be used to triangulate interview data, derive qualitative information and continually inform the data collection process.

KEY INFORMANT INTERVIEWS

Key informants - identified by the contractor in-country staff in addition to others identified during the data collection process – we interviewed either face-to-face or by telephone conference. Based on a review of project documents the evaluation team identified several stakeholder groups that are the focus of program activities. These stakeholder groups comprise (i) USAID and other US Govt. donors, (ii) PBS Implementing staff in both the headquarters and the countries visited, (iii) Government regulatory agencies as well as research institutes and universities acting as agents of regulators, and (iv)Partners/collaborators (including technology development groups such as ABSPII, AATF and regulatory groups such as ICGEB, and the private sector). Attempts were made to interview representatives of all stakeholder groups in each country visited, including representatives of those who have received training through PBS. Discussions during field work with USAID and the implementers were used to better define the target groups and individuals to interview.

For each such stakeholder group, specific questions were designed that focus on their interest in the PBS project. The same base sets of questions were asked in all three sample countries visited - see Annex III for interview instruments. Questions were asked in the same order where possible. In Indonesia, key informant interviews were conducted with both evaluation experts present in order to assure two independent sources, however this was not possible in Uganda and Malawi.

Data collection was aided by the use of an Excel workbook to organize and store data culled from interviews. At the end of the interview day, interview notes were synthesized and entered into the data collection spreadsheet. A separate sheet in the excel workbook was maintained for each of the stakeholder groups identified above. Each of these sheets contained all potential interview questions to be asked to that stakeholder group. Each interview respondent was listed in one sheet of the excel workbook to allow recording information from each protocol question from each interviewee. Confidentiality of respondents was maintained by anonymizing the data (i.e. removing names, titles, and other information that specifically links a participant with a specific response).

This method of organizing and assembling interview information allowed for the identification of patterns in the responses and common themes that are supported by evidence in the data. To ensure that the data are internally valid and reliable, interview data was triangulated between respondents and between sources such as work plans, performance reporting, research reports, financial reports, or other secondary data.

Data collected and transcribed into the excel workbook was systematically analyzed to answer the five evaluation questions. This content analysis process involved review of the data in the excel workbook for emergent themes. Attempts were made to quantify the prevalence of certain themes in the data and indicate the frequency that represent the prevalence of any given theme for one or more stakeholder groups or respondents. The identified and analyzed themes allowed the formulation of findings for each of the evaluation questions.

The evaluation report is structured on the basis of these questions – i.e., the discussion of each evaluation question, by itself, forms the basis of a complete section, based on analysis of the themes and response across the range of stakeholders.

PARTICIPANT SELECTION AND BIAS

Key informant interviewees were selected non-randomly based on availability and engagement with program activities and as such, there were no comparison groups. A non-random selection is standard for qualitative "purposive" evaluations. As there is a small universe of stakeholders in each country, it was not be possible to randomly select interviewees. Attempts were made to interview representatives of every organization that was a recipient or object of the PBS project in the three sample countries, as well as with regional organizations whose own interests and work coincide with the donors. However as most interviewed beneficiaries are direct participants in the project and were recommended by either USAID or the contractor, it can be expected that they will say positive things about the project.

Where possible, to minimize bias informants were sought who represent "public stakeholders" with different 'causal distances' from the activities to qualitatively triangulate/check information from beneficiary organizations and who cannot be perceived as "friendly" or biased stakeholders but who have sufficient knowledge to comment.

RECALL BIAS

To minimize recall bias, the interview questions were designed to draw upon specific knowledge or viewpoints that the organization or the individual acquired from direct association with the project. As the project is currently actively being implemented recall issues should be minimal.

INTERVIEWEE RESPONSE BIAS

All participants come with biases. An attempt was made to organize a sample of organizations with different perspectives and playing different roles to provide different viewpoints. The degree to which there is agreement/disagreement in viewpoints is indicated and assertions are triangulated with other data sources and with other stakeholder groups.

Undoubtedly a larger problem, difficult to assess, is that of deliberately inaccurate responses because the respondent wants to keep a good relationship with the implementer and donor. This shortcoming will be mitigated through triangulation of what was said by different organizations, comparison with known facts, and the interviewer's perceptions of points of view.

ABILITY TO GENERALIZE FROM THE DATA

The method of organizing the data by question and respondent through an excel workbook allowing for coding for recurrent themes, opinion agreements and disagreements allow the identification of areas where the data clearly justifies generalizations. Where possible the number of respondents is quantified although the quantification is subject to interpretation since often the respondents' answers to "open-ended questions" are imprecise and opinion-related, and it is difficult to get explicit answers or examples. Hence the development of recurring themes and concurrence across different types of respondents provides the best source of data. USAID Evaluation Policy is followed, placing emphasis on anchoring conclusions in 'findings of fact,' and not in individual interviewee opinions or second-hand reports. Clear, reproducible evidence for findings and conclusions, supported by specific examples and quotes, have been used to tie findings to conclusions, and from there to recommendations.

ANNEX III: DATA COLLECTION INSTRUMENTS

USAID

- Do you suggest policy research topics to PBS staff?
- Do you receive requests for publications from any of the stakeholder groups you work with (regulatory agencies, policy makers or collaborators)?
- Are you aware of communications products or messaging from PBS? Have you used PBS communications products in your own contact with media or in explaining the PBS program or in other USAID programs?
- Are there specific communications products which you have either developed jointly with PBS or which PBS have developed which you use? In either case, how have they been used and what has been their impact on targeted groups ?
- In your opinion (on a scale of 1-5) how effective has PBS been in targeting influential groups to change attitudes about GM? Are there groups they have not targeted or methods unused?
- How timely has PBS been in providing messaging when there is a political issue?
- Describe the monitoring information you get from PBS and please rate how satisfactory it is to your needs for monitoring and decision making about the program, its funding, and its coherence within the USAID country portfolio.
- What is the basis (criteria) for deciding whether to fund PBS out of Mission funds? What information do you rely on from PBS?
- Would USAID want more information on outcomes and impacts (in addition to outputs)?
- How effective is the country staff at performing their duties? Do they have the appropriate skills to deal with policy makers and regulatory agencies?
- How effectively is the communication between the Mission and PBS country staff and experts?

Implementers

- Can you describe what systems you have in place for communications, consultation and information flows between field and home staff and experts? What are the strengths and weaknesses of the current system? Are there gaps and how do you address them?
- Who ensures quality control of inputs and products within and across different countries?
- How do you see the role of the director and two regional team leaders compared to Technical Consultants for quality control and programming?
- How do you define the role of the in-country leads? How do you define their role compared to that of technical Consultants and/or to country advisors (where present)?
- To what extent is technical background necessary or important for country leads? What other qualities and experience have you found important?
- Please rank on a scale of 1-5 the capacity of the in country leads to fulfill the following functions: advocacy, outreach, logistics, management, technical direction. What makes you rank them so high/low?
- Is the mix of staff and consultants adequate for needs? Are there gaps that need to be filled?
- What is the Country Team? What is its role?
- Do you have country-specific indicators? Are the indicators the same throughout the projects? Are there indicators for regional programs and if not, how do you measure outcomes?
- In your reporting, how do you differentiate between milestones and outputs? Where (and how) do you track outcomes and results and relate this to programming decisions?
- What are the definitions for your indicators and how do you assess meeting definitions?

- For what purposes do you use the information in your monitoring plan (budget decision, programming, reporting to USG)?
- Do you benchmark in any way amongst the countries where you actively have projects, for example annual central grant amount, inputs provided such as consultant days, outputs achieved, targets from your indicators?
- Who decides topics for policy research? Where do ideas come from and what is the input of USAID Missions, collaborators including international or national groups, country leads, Consultants, policy makers and regulatory agencies? What are the criteria for selecting topics?
- How (and who) determines the likely audience for policy research and how to target this audience? Who is tasked with the promotion and dissemination of policy research products and according to what plan?
- Please rank the general usefulness of policy research in promoting the project objectives on a scale of 1-10. If applicable, what makes you rank them so high/low?
- What do you see as the most effective dissemination methods for different types of research, with most payback?
- Is there research to determine the effectiveness and influence of different policy research and on what target groups?
- Can you cite examples where the research has clearly contributed to achieving a program goal or objective or outcome? What did it achieve and what factors made it useful or influential? Can you cite examples of where research was not relevant?
- How (and for what) do you use the research for training and capacity development activities? Where has it been of direct application?
- What criteria do you use in allocating central program resources? Is this a function of need, based on amount of mission support, or lack thereof or other criteria?
- What constraints are placed on funds from different sources (USAID missions etc.)?
- If a mission stops its funding, what are the financial consequences? Do you shift more core funds into the country to make up the deficit ? Reduce activities?
- Are there instance you can cite where the funding was not sufficient to meet the objectives the PBS program was committed to achieving? Has funding level been an issue?
- What kind of collaboration with regional governmental bodies on harmonization has proved most successful? Had the most impact? What has proved less-useful? In what way has association with these bodies improved or added to the impact of your program success? What work with other, global organizations, has proved successful and had an impact?
- Do you collaborate with other groups on communications and outreach activities and has this been useful and in what way?
- What has been the impact of the communications activities in the past? Do you do any research to determine what the impact has been on the groups you target?
- What gaps have been identified in outreach and how do you plan to improve communications to reach relevant target groups in each country?
- Is there a demand for communications and outreach materials from local sources? Which sources have requested this and how have you responded?
- Do you have a communications plan for specific occurrences – such as a set of prepared responses etc.?
- Are there any anti-GM groups active in your country and what has been their effect on public opinion? How has PBS addressed their views?
- **To ask of country leads**: what do you find most challenging in your assignment? How do you define your role and responsibility compared to that of the experts? Is the support of the international consultants adequate to your needs? Is more in country assistance needed? Is the

support of central staff adequate to your needs? Does your scope of work reflect the real job requirements?

- **To ask of consultants (consulted)**: Is the support of the country staff adequate to your needs? If not what is needed? Do you get sufficient time in-country, or to do the necessary quality control or communications and technical support?

Regulatory agencies

- What is the nature of your interaction with the country program staff? With the central PBS staff?
- On a scale of 1-10 can you assess the adequacy of the country program staff experience in biosafety issues? If applicable can you explain the reason for your high/low score?
- On a scale of 1-10 asses how well program staff manages the activities in which you collaborate with them? If applicable, can you explain the reason for your high/low score?
- Are sufficient staff consultant or expert time and input available to meet needs that country leads cannot fill? What are significant contributions of staff consultants?
- Please rate the usefulness of the expert technical assistance on a scale of 1-10. Please rate the professional level of the assistance on a scale of 1-10.
- What technical assistance or training has proven most useful to your organization and had the most impact? What in your view was not useful? Why?
- Have expert technical assistance inputs been sufficient in (terms of time and presence) to meet your needs? Are there unmet needs?
- What policy research are you aware of from the PBS? How do you know about research that is done through the PBS program - through publications, directly through the assistance or through other means?
- What has been your input into determining policy research topics or products?
- Do you see policy research outputs in publications?
- How do you rate the quality of the research on a scale of 1-10?
- To what extent has the policy research related to or added to the technical support or training that was given. (rarely, mostly, always)
- Can you cite examples where the policy research has clearly contributed to achieving one of your organizations' biotechnology or regulatory objectives or activities? How have you used research, what did it achieve and what factors made it be influential or useful?
- Do you work with PBS on communications activities?
- Are there specific communications products which you have either developed jointly with PBS or which PBS have developed which you use? In either case, how have they been used and what has been their impact on targeted groups?
- Has awareness of biosafety regulation changed over the period of PBS? In your view has the training and outreach through PBS had an effect and if so on what groups?
- Do you think the outreach and communications messages reached the right target groups? Are there any agencies or groups which you think should be included in outreach and communications which have not been included? Are there gaps?
- Are there any anti-GM groups active in your country and what has been their effect on public opinion? How has PBS addressed their views and the issues they raise?

Collaborating Organizations

- Do you interact directly with the country program staff and/or the central PBS staff?

- If so, do you find the country program staff to be adequately trained/experienced in biosafety issues to be of assistance to you?
- How effective is the country program staff at managing the activities in which you collaborate with them?
- Please evaluate the quality of PBS experts with whom you have collaborated (scale 1-10) If applicable can you explain the high/low score?
- What has been your input into deciding policy research topics that PBS has funded?
- How do you rate the quality of the research on a scale of 1-10?
- In your view, has the PBS policy research contributed to achieving a program goal or objective or outcome of your organization? What in particular? What did it achieve and what factors made it influential?
- Have you been in receipt of funds from PBS for joint activities? If so for what?
- Are there constraints on what the funds can be used for?
- Do you have specific reporting rules for jointly-funded projects?
- What collaboration with PBS has been most useful to advancing joint goals?
- In what way has association with PBS improved or added to the impact of your program success? What is the added value of association?
- Do you work with PBS on communications activities? Do you have your own target groups?
- Are there specific communications products which you have either developed jointly with PBS or which PBS have developed which you use?
- Do you operate joint outreach activities, or do you have input into PBS outreach activities? (Does PBS involve other agencies when conducting communications activities either at the central management level , at the level of USAID or within countries where the project is active?)
- Are there organizations which you think should be included in outreach and communications which have not been included?
- Can you evaluate on a scale of 1-10 the effectiveness of their targeting messaging and communications? If applicable can you explain the high/low score? Are they reaching key groups (differentiate by country)? What evidence do you use to evaluate?
- Do you have a communications plan for specific occurrences – such as a set of prepared responses etc.?

ANNEX IV: SOURCES OF INFORMATION

NAME	AFFILIATION	COUNTRY	GROUP
John McMurdy/ Saharah Moon Chapotin	USAID, Washington DC	USA	USAID
Thom Wright/ Ali Absi	USDA-FAS, Jakarta	Indonesia	USAID
Brian Dusza/ Donal Tambunan	USAID Indonesia Mission	Indonesia	USAID
Simon Byabagambi	USAID – Uganda Mission	Uganda	USAID
Cybill Siegler	USAID – Malawi Mission	Malawi	USAID
Heather Dresser/ Piston Msika	US Embassy, Lilongwe	Malawi	USAID
Mark Petry	USDA-FAS, Washington DC	USA	USAID
Sidi Asmono	PBS Country Coordinator	Indonesia	Implementer
Jeff Stein	PBS Regional Coordinator	USA	Implementer
Donna Ramaeker Zahn	PBS External Consultant	USA	Implementer
Herbert Oloka/ Theresa Sengooba	PBS Country Team	Uganda	Implementer
Boniface Mkoko	PBS Country Coordinator	Malawi	Implementer
Jose Falck-Zapeda	PBS Policy Team Leader	USA	Implementer
Greg Jaffe	PBS External Consultant	USA	Implementer
John Komen	PBS Regional Coordinator	Netherlands	Implementer
Judy Chambers	PBS Director	USA	Implementer
Prof. Bambang Sugiharto	University of Jember	Indonesia	Collaborator
Prof. Sugiono Mulyoprawiro	Crop Life Indonesia	Indonesia	Collaborator
Herry Krisanto	Monsanto	Indonesia	Collaborator
Dr Widodo Hadisaputro	Society for Indonesian Agricultural Biotechnology (SIAB)	Indonesia	Collaborator
Prof. Mohammed Herman	ABSPII Country Coordinator	Indonesia	Collaborator
Hon. Beatrice Anywar	Member of Parliament, Uganda	Uganda	Collaborator
Imelda Kashaija	National Research Organization	Uganda	Collaborator
Andrew Kiggundu	National Agricultural Research Laboratory, Kawanada	Uganda	Collaborator
Peter Wamboga	SCIFODE	Uganda	Collaborator
Dr Peter Ndemere	Uganda National Council for Science and Technology (UNCST)	Uganda	Collaborator
Dr Tushemereirwe	National Agricultural Research Laboratory, Kawanada	Uganda	Collaborator
Tilahun Zeweldu	ABSPII Country Coordinator	Uganda	Collaborator
Erostus Nsubuga	Uganda Biotechnology and Biosafety Consortium	Uganda	Collaborator
Dr David Mutekanga	Uganda national Academy of Sciences	Uganda	Collaborator
Prof. Rubaihayo	Makerere University	Uganda	Collaborator
Dennis Kibirige/ Susan Nakabuye	Ministry of Justice and Constitutional Affairs	Uganda	Collaborator
Paul Nampala	Regional Universities Forum for Acapacity Building in Agriculture	Uganda	Collaborator

NAME	AFFILIATION	COUNTRY	GROUP
	(RUFORUM)		
Prof. Kwapata	Bunda College of Agriculture	Malawi	Collaborator
Anthony Muyepa-Phiri/ Pongolani Msakambewa/	National Commission for Science and Technology	Malawi	Collaborator
Dt Wisdom Changadeya	Biotechnology-Ecology Research and Outreach Consortium (BioEROC)	Malawi	Collaborator
Felix Jumbe	Private sector (seed production)	Malawi	Collaborator
Duncan Warren	Famers Union of Malawi, Cotton Development Trust	Malawi	Collaborator
Alick Maulawo	Monsanto-Malawi	Malawi	Collaborator
Wendy Craig	ICGEB	Italy	Collaborator
Craig Rickerd	CropLife International	USA	Collaborator
Adelaida Harries	BIGMAP	Argentina	Collaborator
Nancy Muchiri	AATF	Kenya	Collaborator
Dr Agus Pakpahan	Biosafety Commission for Genetically Engineered Products (BCGEP)	Indonesia	Regulator
Yusra Egayanti/ Siti Maemunati/ Saffian Dewi/ Desy Fasta Waty	National Agency for Food and Drugs Control (NAPDCP	Indonesia	Regulator
Dr Antung Deddy	Ministry of Environment	Indonesia	Regulator
Dr Karden Mulya	Indonesian Center for Agricultural Biotechnology and Genetic Resources (ICABIOGRAD)	Indonesia	Regulator
Prof Bahagiawati Amir Husin	Indonesian Center for Agricultural Biotechnology and Genetic Resources (ICABIOGRAD)	Indonesia	Regulator
Dr Satya Nugroho	Indonesian Institute of Sciences (LIPI	Indonesia	Regulator
Dr Erna Maria Lokollo	Indonesian Center for Agriculture Socio-Economics and Policy Studies	Indonesia	Regulator
Dr Friday Agaba	National Drug Authority	Uganda	Regulator
Dr Isa Katwesigye	Ministry of Water and Environment	Uganda	Regulator
Prof. Opuda-Asibo	National Council for Higher Education	Uganda	Regulator
Dr Yona Baguma	National Crops Resources Research Institute, Namulonge	Uganda	Regulator
Caroline Thaka	Environmental Affairs Department	Malawi	Regulator
Dr Yanira Ntupanyama	Ministry of Environment and Climate Change Management	Malawi	Regulator
Dr Mackson Banda	Ministry of Agriculture	Malawi	Regulator

ANNEX VI: DISCLOSURE OF ANY CONFLICTS OF INTEREST

Name	Robert Potter
Title	Dr
Organization	Robert Potter Consulting
Evaluation Position?	☒ Team Leader ☐ Team member
Evaluation Award Number *(contract or other instrument)*	
USAID Project(s) Evaluated *(Include project name(s), implementer name(s) and award number(s), if applicable)*	
I have real or potential conflicts of interest to disclose.	☐ Yes ☒ No
If yes answered above, I disclose the following facts: *Real or potential conflicts of interest may include, but are not limited to:* 1. *Close family member who is an employee of the USAID operating unit managing the project(s) being evaluated or the implementing organization(s) whose project(s) are being evaluated.* 2. *Financial interest that is direct, or is significant though indirect, in the implementing organization(s) whose projects are being evaluated or in the outcome of the evaluation.* 3. *Current or previous direct or significant though indirect experience with the project(s) being evaluated, including involvement in the project design or previous iterations of the project.* 4. *Current or previous work experience or seeking employment with the USAID operating unit managing the evaluation or the implementing organization(s) whose project(s) are being evaluated.* 5. *Current or previous work experience with an organization that may be seen as an industry competitor with the implementing organization(s) whose project(s) are being evaluated.* 6. *Preconceived ideas toward individuals, groups, organizations, or objectives of the particular projects and organizations being evaluated that could bias the evaluation.*	

I certify (1) that I have completed this disclosure form fully and to the best of my ability and (2) that I will update this disclosure form promptly if relevant circumstances change. If I gain access to proprietary information of other companies, then I agree to protect their information from unauthorized use or disclosure for as long as it remains proprietary and refrain from using the information for any purpose other than that for which it was furnished.

Signature	
Date	22 April, 2014

ANNEX VI: STATEMENT OF DIFFERENCES

(1) Background

PBS is pleased to offer its comments on the findings of the External Performance Evaluation of the Phase II Program for Biosafety Systems (Grant No. AID-EEM-A-00-03-00001 for the period 2008-20013). In general, we were very appreciative of the reviewer's comments and regard this review as a positive assessment of the program, its works and its staff. We believe the review identifies a number of issues and recommendations that will assist our program in its next phase of funding (2013-2019). However, in the interest of accuracy, there are a few points which require additional comment and clarification. A summary of our general concerns is shown below. Individual and specific comments are presented, in addition, referencing the topic or issue in question by page and paragraph.

(2) General Comments Related to Conclusions and Recommendations

Structure of the review: We believe that the review could have benefited from a larger team, with varying expertise, to better inform the project. While it is imperative that at least one member of the review team have a technical understanding of the subject matter (as was the case here), a diverse team comprised of those with understanding of policy and/or legal challenges in a development context and as well as those with specialized skills set in impact analysis, specifically for policy interventions, would have been additionally helpful to the project.

Program Staff and Technical Consultants: The review accurately identifies the need to balance use of a strong technical team to maintain consistency and quality of results across the program and to insure technical accuracy vs. the need to build capacity among country level personnel to assume this role in the future. Unfortunately, for most of the countries in which we work, the capacity of local experts is still evolving, and building the capacity of such experts is a significant part of the program's long term objectives. To a certain extent, PBS has used the Philippines study tours to address this need and one member of our team was formally a regulator in Argentina and has been a valuable resource to this end. However, it is quite possible and reasonable to cast a wider geographical net for advisory expertise (i.e. Brazil, Australia) and the program has begun to identify and engage experts beyond those that reside in the United States. Nevertheless, PBS appreciates the concern about the reliance on the use of US-based consultants. Capacity building to further develop local resources will continue, and the use of other global and locally placed consultants will be pursued to augment the existing core of primarily US-based consultants.

Policy Research Issues: Significant strides have been made in recent years to conduct policy research that is more relevant to the decision-making challenges faced at the country level. This has been an evolution in the program, and the need to do so is certainly recognized by senior management and the PBS policy team. From a branding perspective, PBS is less concerned about whether the research is seen as PBS research or IFPRI research: our greater concern is to insure the research is used and impactful on the setting evidence-based regulatory policy.

Plans are underway to develop the appropriate format and locally relevant materials to insure that research findings are accessible to key decision makers. A number of country level policy papers

have been developed or are underway to specifically address the national decision making challenges, such as socio-economic impact studies on Bt cotton (Uganda, Kenya and Malawi) or labeling threshold impacts (Vietnam). We recognize that the format for the presentation of this information is often in academic journals or somewhat technical policy briefs. An identified goal of the program going forward is to insure that information is appropriate packaged for audiences which may have an authoritative role in policy formation but may lack detailed technical knowledge.

Project Management: Many of the points raised with respect to project management, reporting and measuring of impacts are very useful suggestions which we will incorporate into future reporting structures and documents. PBS intends to acquire expertise to assist our Monitoring and Impact work to insure that we develop more appropriate metrics to measure project success. We agree that fine tuning is needed in work plans and progress reports that differentiate between inputs and outcomes and that **realistic** milestones should be developed to track our work progress, manage expectations and more effectively guide resources and expenditures. In general, impact measurements and reporting will benefit from the hiring of an M&E specialist. There is a need to reconcile overall reporting requirements to Mission needs for monitoring and evaluation and we are hopeful an M&E specialist can also assist in that area.

Financial Management: Delays in our annual obligation from USAID place an extraordinary administrative and financial burden on the project. To date, the project has managed to cope by using reserve funds to support operations, although at a reduced level of effort during the intervening time until new program funds arrive. However, this has the undesirable effect of needing to preserve pipeline funds in order to protect the program against these delays. The effect, when funds finally arrive, is pressure to accomplish a year's work plan of activities in a shortened time frame (6-9 months). The pressure on consultants and collaborators is also increased due to funding delays as contracts cannot be executed due to IFPRI policy until the obligation is in place. On a related note, retaining focus only on those countries where mission support is provided is also note tenable, as mission interests can change (e.g Indonesia). Instead, we believe the project should continue to focus on those countries where there is ample interest and need for the project's support. Benchmarking of country progress, while an enviable goal, is also not entirely realistic due to the fact that countries are starting from a different place on the regulatory progress continuum; this is not always reflective of the product environment or political will. All of these factors are taken into consideration, in addition to the possibility of mission support, when considering PBS engagement in a given country.

Communications, Outreach and Partnerships: Consortiums speak for the range of interests and stakeholders which are members of the consortium. The role of PBS is to provide technical, evidenced-based formation to allow the development and implementation of science-based regulatory systems.

(3) Specific Point by Point Comments Related to Specific Review Topics and Issues Raised

Evaluation Methods & Limitations

Page 15, Key Informant Interviews
Incomplete Review Team, para 2: Given that the reviewers were not standardized across all three countries, caution should be exercised in any attempt to compare and evaluate across the three considered – Indonesia, Uganda and Malawi.

Findings, Conclusions & Recommendations

1. PBS Country Programs Staff and Support from International Technical Consultants

Page 18
Use of US-based models, para 2: The use of examples in PBS training and capacity building work has been somewhat dictated by the fact that regulatory case studies and examples for most of the commercially released GM varieties come from the US (a majority) or other developed counties (i.e. Canada, Australia). As more developing countries, in addition to the Philippines, South Africa, Brazil and India, pursue commercial adoption of GM crops (such as Bangladesh recently did), the availability of non-US/developed country examples will increase and will be incorporated into PBS's work.

Expertise of PBS Country Coordinators, para 3: It is not necessarily a fair assumption to state that PBS coordinators are perceived to have a high level of competency due to the relative low level of competency of their government counterparts. PBS coordinators are chosen for their scientific competency, to start, and then are given extensive and constant training and, by virtue of working with the senior technical staff, have consistent and repetitive exposure to best regulatory principles and practices.

2. Policy Research

Page 19
IFPRI vs. PBS Acknowledgement for Policy Research, para 1: This is essentially an issue about branding and not necessarily germane to the quality and the impact of the work. To some extent, the fact that the research findings are considered to be those of IFPRI actually raises the visibility and credibility of the work, as IFPRI is well known among most of the government policymakers. There is a need to better "package" the research in a user-friendly format, and to insure a more targeted outreach plan to those who can most benefit from having the information generated from the research conducted by the PBS policy team. This is a major focus for the next phase of PBS funding.

Page 20
Relevance and Balance of Policy Research, para 3-5: Considerable progress has also been made in Phase II over Phase I funding to insure that the research actually conducted is more client driven, and focused on addressing key decision making issues related to national biosafety discussions. To some extent, this is also a funding related issue. The PBS policy team is only partially supported by PBS funding. The team has other research objectives which they pursue with other funds. Current

PBS funding levels in the leader award do not permit the "luxury" of a full time policy research team which can respond to all of the needs presented by the operational side of the program.

3. Project Management

Page 21

Familiarity with Senior Management, para 2: Less familiarity with the PBS Director and regional directors is a function of project design. The in-country coordinators are expected to be the first line and most consistent, face of interaction with the government. This should be interpreted as a neutral comment.

M and E Assessments, para 3**:** The Feed the Future criteria for M&E were not in place at the time this award was developed and initially funded. PBS has been responding to impact measurements based on guidance we have received from USAID, especially for capacity building, which is captured via proscribed, quantitative reporting guidance. The project agrees that the current methodologies and metrics for evaluating PBS impact are insufficient to fully account for project performance. With the addition of staff expertise in M&E for the new award period, we expect to revisit M & E reporting along lines which are more consistent with both quantitative and qualitative program-level impacts. Any additional guidance to assist in this from USAID, in terms of specific parameters that should be considered, would be welcome by the project management team.

4. Financial Management

Page 22,

Mission Funding and Obligation Delays, para 2&3: The delays in PBS's yearly obligation from USAID (which were extensive in FY 2013) cannot be underestimated in terms of the negative impacts it can potentially have on program success. This is compounded by the fact that CGIAR centers no longer have "core " funds to cover temporary project shortfalls and therefore lack flexibility to address the problem. This pattern of delay with respect to the yearly obligation has necessitated that the project operate with an intention of retaining some reserve funding so that project operations can continue, if even at a reduced level of effort, until the USAID obligation is received. This however, results in criticism from USAID with respect to the project pipeline. The program is caught in the middle and ability to complete a 12 month work plan in a compressed 6-9 month effective time frame puts unnecessary stress on program staff, contractors and in-country collaborators. In addition, unless a separate contracting mechanism is employed, the mission "buy-in" mechanism of funding creates added stress as missions typically base commitments on a year by year time frame. PBS remains hopeful that these trends will not continue for the remainder of the Phase III award.

5. Communications, Outreach and Partnerships

Page 23

Shift in Communications and Outreach, para 1: Added emphasis on this function stems from a heightened awareness of the importance that good communications and outreach functions have in policy enactment and implementation. The project consultant was hired for a number of reasons, not just this one. The consultant's role, as a member of the senior management team, is also to assist on internal communications across a complex and growing program, to establish standards

and quality control in our training programs and communications materials, and to also build capacity of regulators to enunciate their policies and policy decisions with clarity and confidence. The role of this position extends beyond outreach.

Coalitions, para 2: The role and interaction of PBS with these various coalitions needs some clarification. These groups are, for the most part, self-assembled and self-identified and have a variety of functions and activities which go beyond the PBS interests in regulatory policy. Other aspects of biotechnology are also a target of coalition work but PBS stays focused on the regulatory issues. Some guidance and administrative support has been initially provided by PBS, as well as program support specific to the activities which are directly in line with the PBS mission. We remain engaged with these groups to support the work that they do in bringing a technical and evidenced-based voice to biosafety policy discussions.

Page 24

Public Relations vs. Evidenced-based Communications and Outreach, para 3: Public relations, and therefore hiring of a PR (local or otherwise) expert, is not really the role of PBS, as our efforts in this area are relegated to providing sound technical information about the regulatory process and safety issues, and we believe the channels to do so are fairly obvious and exist (with media being only one such channel). Monitoring of sentiment, particularly of those who are in a position to influence the regulatory process, is achievable. While this may have been expressed by some who were interviewed, this is not our role and is indicative of the nuanced differences between working on the establishment of sound regulatory policy vs. advocating for the technology, per se.

PBS Low Profile, para 5: The fact that PBS has maintained a low profile is not an issue from our perspective. We are not seeking accolades for the work that we do. We are instead focused on providing credible information, advisory services, research and capacity building in support of effective national regulatory systems. PBS believes our credibility is enhanced by our low key approach.

Country Case Studies

(1) INDONESIA

Election Cycles and political appointments: The situation with respect to delays in appointments as a result of the election cycle is somewhat overstated. These appointments are often political appointments, as is the case in many developed countries, including the US. It is not unreasonable to expect that a Presidential election may have impacts on this type of appointment. It does not mean that the regulatory system is necessarily flawed or weak. The key thing to consider is to assess whether or not the regulatory functions proceed, along expected lines commensurate with policy, once such appointments are made. Also, it is not possible at this point to judge the impact of stakeholder interest in the face of negative pressure. To date, except for an understandable delay in the appointments made due to an electoral process, the system has been functioning, in spite of negative pressure.

Indonesia Mission Support: The issue of mission support for PBS in Indonesia is an area of critical concern, but not necessarily for the reasons cited in the review. There is strong Government of Indonesia interest, expressly stated in many policy briefs and pronouncements, to use this

technology to address issues related to food security and agriculture productivity likely to be impacted by climate change. With this as a clear policy pronouncement, it is imperative that the country builds a regulatory system that is based on sound science, global best practices and includes a staff that is skilled and confident in its regulatory authority. PBS has made great strides in assisting the government in this regard in a fairly short period of time (3 years). However, significant capacity building needs remain, especially as the first generation of public and private sector products approach general, commercial release. Without continued mission support, additional pressure will be placed on the PBS core funds to maintain a robust level of activity in Indonesia, a large, strategic country with many food security demands. This will generate the need for stock taking across the entire program, with the result that an Indonesia program may be funded at a lower level, resulting in less progress, or another PBS program may need to be eliminated, with local consequences for that country.

(2) UGANDA

PBS has continued to provide technical support while progress on the Bill continues. We have been focused on guidelines for commercial release, and updating the training of the National Biosafety Committee.

PBS has given consideration to our role and plans upon passage of the Bill. We expect to provide significant technical expertise in training and capacity building for the new regulatory authority and to finalize various guidelines and requirements needed to implement the Bill, including support to various Ministries and Agencies who will have a defined regulatory role.

(3) MALAWI

PBS has been effective in encouraging others to engage in Malawi. Other regulatory service providers are offering assistance (the African Biosafety Network of Expertise) and the Bt cowpea project will begin work in Malawi in late 2014 via USAID Malawi mission support. The historically slow developments of the regulatory system and delays in the first field trial have been factors in the lack of more robust mission involvement. It is likely that in the face of continued regulatory progress, other donor-funded or commercial efforts in biotechnology will develop in Malawi.