



The Partnership for Biosafety Risk Assessment and Regulation

2015 Summary Report

Introduction to the Partnership

The Partnership for Biosafety Risk Assessment and Regulation (PBRAR) was a US \$1.2 million program, funded through the World Bank's Development Grant Facility (DGF), which ran from July 1, 2011 to December 31, 2014.

The Partnership was comprised of the ILSI Research Foundation's Center for Environmental Risk Assessment, the Environment Directorate of the Organisation for Economic Co-operation and Development (OECD), the World Bank, and eight developing countries that have adopted, or are considering the adoption of, agricultural biotechnology: Bangladesh, Vietnam, Kenya, Tanzania, Uganda, Colombia, Paraguay, and Uruguay. These countries represent a range of geographic areas in different stages of economic development and with varying capacity in agricultural biotechnology, regulatory systems and environmental risk assessment.

The PBRAR addressed the important global issue of ensuring science based risk assessment and regulation of genetically engineered (GE) crops. Partners worked together to strengthen the technical capacity of stakeholders engaged in biosafety risk assessment and regulation to facilitate evidence-based decision making.



**Successful global partnership
links agriculture and
environment to strengthen
the capacity of developing
countries in biosafety risk
assessment and regulation.**

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International Partners



The World Bank is a vital source of financial and technical assistance to developing countries around the world. The World Bank's Development Grant Facility (DGF) saw the potential for improving the delivery and impact of capacity building support and technical assistance in biosafety by sponsoring this partnership of international expert organizations that would deliver targeted support for environmental risk assessment to a handful of countries at the cusp of adopting agricultural biotechnology.

The program was managed by the Center for Environmental Risk Assessment (CERA), which is part of the non-profit International Life Sciences Institute Research Foundation. CERA is dedicated to developing and applying sound science to the environmental risk assessment of agricultural biotechnologies so their contributions to the sustainable production of food, fuel and fiber may be safely realized. CERA's technical competence and experience, when combined with its independent status, made it uniquely qualified to successfully manage and implement the PBRAR.

CERA maintains an extensive tripartite network of subject matter experts in government, academia, and the private sector, and taps into this network to leverage resources as it undertakes big projects



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with substantial impacts. For example, Iowa State University, USDA-ARS Corn Insects and Crop Genetics Research Unit and DuPont Pioneer were technical partners in the Partnership, and co-hosted two regional training workshops on risk assessments with non-target organisms.

The OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology focuses on the environmental risk and safety assessment of transgenic plants and other genetically engineered organisms. The OECD's Task Force for the Safety of Novel Foods and Feeds deals with the products derived from them. Their work aims to ensure that the types of information used in biosafety assessment are as similar as possible amongst countries in order to promote mutual understanding and harmonized practice, which in turn, increases the efficiency of the risk/safety assessment process and limits duplication of effort. PBRAR provided a vehicle to enable both OECD member countries and targeted developing and emerging economies to participate in the OECD technical discussions and to elaborate assessment tools, with a view to greater international harmonization on evidence-based approaches to the regulation of agricultural biotechnology.

The Approach

The Partnership used a flexible and responsive approach to meet the specific needs of the eight targeted countries. The PBRAR included a combination of activities involving knowledge sharing, as well as technical assistance on environmental risk assessment and regulatory system design and implementation. It also encouraged greater harmonization of biotechnology regulations, particularly through partner country engagement with OECD's technical working groups on these topics. Direct interactions at regional workshops and training courses were complemented by a range of PBRAR communication products, including a website, quarterly newsletters and online learning courses.

**The goal of the Partnership:
To enable client country
stakeholders to better promote
harmonization and rationalization
of biosafety regulations in their
countries, which can in turn facilitate
evidence-based decision making
when considering the adoption
of agricultural biotechnology.**



Case Study on Kenya

Kenya was selected in the first year of the PBRAR because it was uniquely positioned to benefit from technical capacity building in environmental risk assessment: Kenya demonstrated an early commitment to the safe adoption of GE crops, being the first signatory of the Cartagena Protocol on biosafety; it had a well-developed regulatory system; and Kenya's public sector scientists would soon be ready to release new GE crops to meet the challenges faced by Kenya's small holder farmers. Kenyan regulators lacked specific experience in performing risk assessments for agricultural biotechnology and in determining data needs for the commercialization approval process.

The PBRAR worked to provide Kenya's regulatory staff with training in a science-based risk assessment process and the use of problem formulation to identify the risk hypotheses they would need to address and the specific data needed to test those hypotheses. Through participation in the Partnership, Kenya's regulatory staff received training in problem formulation, risk characterization and assessment, and risk communication. They were also the first

country to take advantage of the online learning courses generated through the PBRAR.

A specific capacity building need identified by Kenya was the training of their network of subject matter expert consultants. The regulators had been working with a group of over twenty university researchers, who provided technical advice on applications for confined field trials of GE crops. However, these researchers had never received formal training in environmental risk assessment, and as the time approached when the regulators would receive their first application for commercial release of a GE crop, Kenyan regulators wanted the researchers to be "speaking the same language" when undertaking risk assessments. To address this, the Partnership facilitated a workshop, in which the Kenyan regulatory staff and the expert consultants met face-to-face for the first time. Kenyan regulators acted as the instructors and led the researchers through a series of exercises to show them how risk assessments were performed, what the goals of the assessment were, and how they used data and the experts' opinions, to complete the assessments. As a result of this workshop,

the relationship between the regulators and the researchers was restructured to better meet the needs of the risk assessment. In the future, the regulators would be presenting the experts with specific risk hypotheses, and the experts would identify relevant data in the application and the scientific literature that would test each hypothesis. As a result, Kenyan regulators would get the specific advice they needed to proceed, and the experts' time would be used more effectively and efficiently.

“The symposium was of great interest because apart from giving a theoretical background it also provided an opportunity to ask questions on various areas. It also provided a chance to meet, interact and network with other players in the industry of biotechnology.” -Mr. Eric Korir, Biosafety Inspector, National Biosafety Authority, Kenya

Case Study on Paraguay

Paraguay was incorporated into the Partnership because of a timely need to reinforce technical capacity and build additional biosafety resources. The agricultural sector is one of the economic pillars of Paraguay, and the rapid adoption of GE crops has led to an interest from the Government in ensuring their regulatory systems are up to date and functioning well. Farmer's interest in adequate access to products derived from biotechnology and the Government's interest in ensuring the safe and sustainable incorporation of GE crops into domestic production highlighted this need (CERA 2013, 2014). Paraguay has made significant progress with establishing and implementing the National Agricultural and Forestry Biosafety Commission (CONBIO) as well as responding to applications for experimental and commercial releases. Using stakeholder input, the Government has prioritized technical capacity needs regarding its biosafety regulatory system, and a strategic plan was developed for Paraguay's participation in the Partnership.

The Partnership activities for Paraguay included developing practical skills in problem formulation for the environmental

risk assessment of GE crops; analyzing key regulatory procedures for each stage in the development of a transgenic crop; and building a knowledge base focused on special considerations for non-target organisms, crops with stacked traits, and the safety assessment of foods derived from GE plants. Workshops, courses and symposia were targeted to different audiences, including regulators, inspectors, researchers and graduate students in Paraguay.

One specific outcome of the Partnership was the preparation of guidelines for the application processes for confined field trials and commercial authorizations of GE crops.

The time for decision making by the national regulatory authority in Paraguay was reduced from 2 years to 3 months.

The unifying concepts used in risk assessments for transgenic plants reinforced through the Partnership have helped to facilitate regulators' decision-making procedures in addition to improving communication

between applicants and regulators.

“There has been an improvement of the capabilities of a large number of participants and the updates of the regulatory framework that are being implemented as a result of the activities that are being developed in the framework of the Partnership Program.” -Mr. Santiago Bertoni, Director, Unidad De Comercio Internacional E Integración Del Ministerio De Agricultura Y Ganadería Del Paraguay, Paraguay

References:

CERA. [2013]. The Partnership for Biosafety Risk Assessment and Regulation June 2013 Newsletter. Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, Washington DC. <http://bit.ly/PBRARJune2013>

CERA. [2014]. The Partnership for Biosafety Risk Assessment and Regulation September 2014 Newsletter. Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, Washington DC. <http://bit.ly/PBRARSept2014>

Outcomes



The Partnership for Biosafety Risk Assessment and Regulation:

- Improved the efficiency of national regulatory systems in several targeted countries through establishing effective partnerships with national regulators to share technical expertise on environmental risk assessment and procedures to enable more efficient decision making within national regulatory systems.
- Increased the evidence-base for regulatory decision making by producing and disseminating technical publications.
- Enabled regulators from several developing countries to participate substantively in regional and global policy deliberations on biosafety regulations, notably within OECD

2

OECD biology consensus documents were developed to inform risk assessments of Cassava and Common Bean

2

e-Learning courses were developed on relevant biosafety topics

26

national and regional workshops focusing on biosafety, risk assessments, confined field trials and regulatory harmonization were held

>600

biosafety regulators, risk assessors and other scientists received technical support and training

- technical working groups and in meetings of the parties to the Convention on Biological Diversity Cartagena Protocol on Biosafety.
- Provided opportunities to assess the net economic benefits likely to be gained from improving the efficiency of regulatory systems to enable more timely decisions to be made on the introduction and commercial use of new agricultural biotechnologies. This was most clearly demonstrated in Paraguay and Vietnam, where both countries moved ahead to obtain earlier access to new technologies, specifically the approval for new soybean cultivars in Paraguay and new maize cultivars in Vietnam, in an environmentally sound manner.

Reasons for Success

The success of the PBRAR can be attributed to the idea at its core, that the program represented a true partnership between the countries engaged, the World Bank, CERA and the OECD. Instead of trying to impose a pre-formed idea of effective biosafety regulation on partners, the program focused on cooperative engagements to identify areas where partners felt a need for assistance in developing or strengthening their regulatory programs. This means that no two countries' participation in the PBRAR was the same. In this spirit of collaboration, the PBRAR is one of the few biotechnology and biosafety programs that has successfully created bridges between the agricultural sector and the environmental sector. These bridges are essential if countries are going to have a coherent and effective biosafety regulatory system that considers the context of agricultural biotechnologies. Involving key stakeholders early in the process rather than trying to address their concerns after the fact ensures that programs stay on the right track.

Strong program leadership by the Director of the Center for Environmental Risk Assessment and senior technical and communications staff leading the PBRAR's various activities contributed to the success of the program. By facilitating

open dialogue with partner countries to identify areas of mutual interest while maintaining clear boundaries around the scope of the project, program leaders were able to keep the energy and effort focused in productive directions.

“The Partnership on Biosafety Risk Assessment and Regulation was a well led and well managed program on environmental risk assessment and regulation in agricultural biotechnology. The Partnership was both effective and efficient in providing technical assistance on environmental risk assessment and enhancing regulatory systems in several developing countries.”

–Dr. Gabrielle Persley, Lead Author, PBRAR External Review



Sustainability

The Partnership succeeded in working across the agriculture and environment sectors in several countries. It provided an opportunity to strengthen linkages between stakeholders within partner countries and external organizations. This collaborative approach allows regulation to fulfill its function as an enabling factor and not a barrier to the safe and environmentally sustainable use of new agricultural biotechnologies.

At least five of the participating countries (Bangladesh, Colombia, Kenya, Paraguay and Vietnam) have incorporated the content of the PBRAR technical assistance on environmental risk assessment and regulatory procedures into their regulatory systems. In at least two instances (Paraguay and Vietnam), this has contributed to more timely decision making in the regulation of biotechnology products and, where deemed safe for use, in their commercial release. The sustainability of the benefits of PBRAR will depend on the continuation of this evidence-based decision making in the national regulatory systems of partner countries.

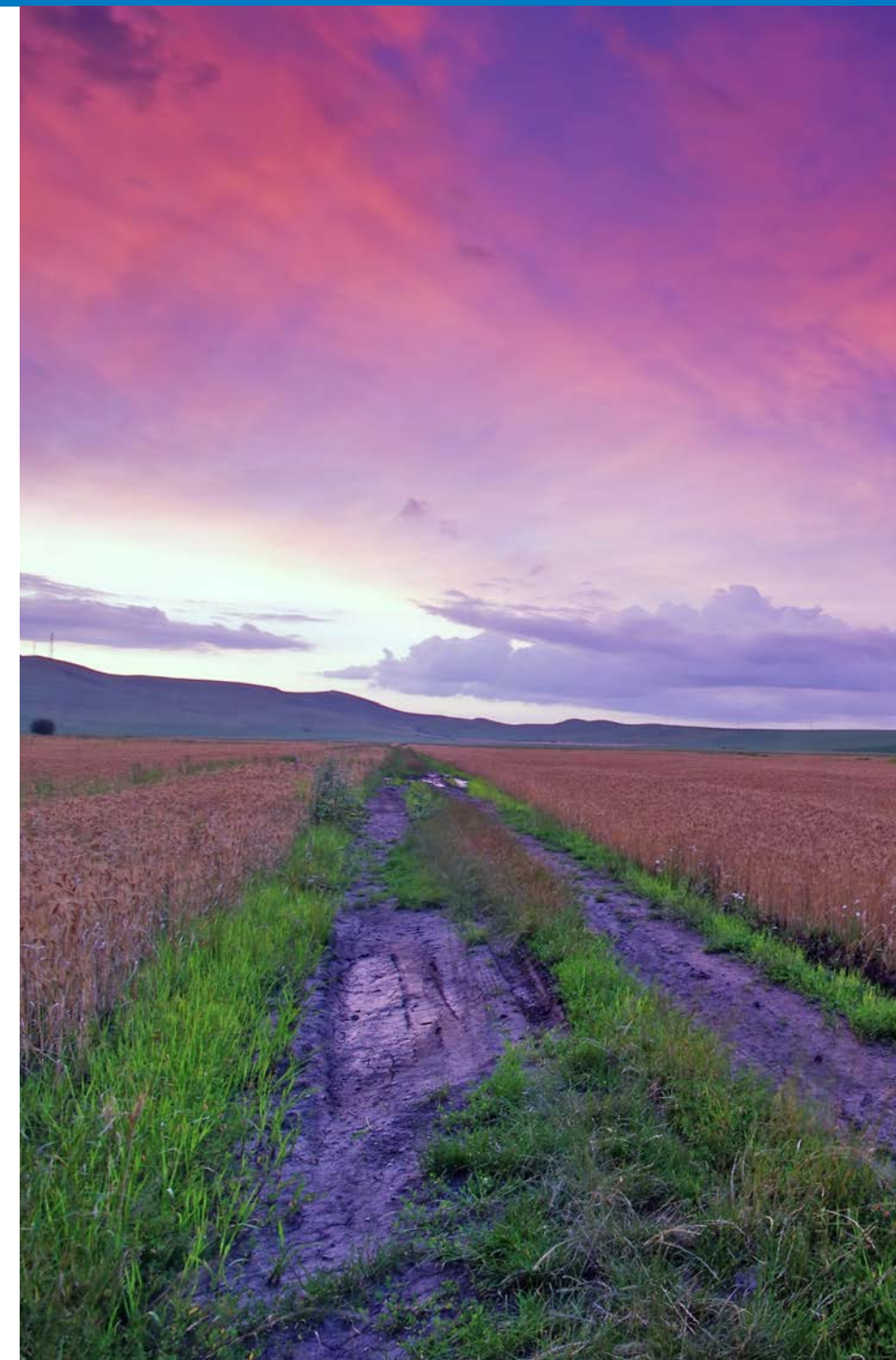
The continued engagement of developing countries and emerging economies in the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology is another means

to ensure that the regulators and policy makers can share experiences with their peers and also to be aware of new developments in biosafety. This engagement will also offer an opportunity to find ways to improve the future efficiency of regulatory systems.

A continued partnership between CERA and the OECD will be valuable in terms of ensuring the global sustainability of the PBRAR results. For example, the OECD could expand its range of crop biology documents to include other important food security crops, making them available as guidance to regulatory systems in a large number of countries. This would build on the success of the crop biology documents for cassava and common bean that were prepared as a result of the PBRAR partnership with the OECD.

For all the partner countries, the benefits of the PBRAR at the national level are more likely to be sustained if CERA is able to maintain contact with the national regulators to keep them abreast of new scientific developments that will influence evidence-based regulatory decisions. Ideally, this would be through ongoing professional development programs for biosafety regulators and policy makers.

“Biosafety risk assessment is a dynamic, scientific exercise that requires significant technical capacity. While the PBRAR has largely met its performance and outcome objectives in this regard, its lasting impact will be dependent on sustained commitments by our country partners to continue to implement and improve upon the gains made under the program. Tools like the e-Learning platform and country-specific microsites will continue post-PBRAR but, more importantly, it is our hope that the community of practice established through the PBRAR will continue.”
–Dr. Morven McLean, Executive Director, ILSI Research Foundation





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