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South Asia Biosafety Program

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Featuring Plenary Sessions on:

- Perspectives on the Regulation of Genetically Engineered Organisms in South Asia
- Research and Development of Genetically Modified Organisms in South Asia
- Biosafety and Regulation of Genetically Engineered Insects
- Tools for Science Communicators
- Agricultural Biotechnology and Adaptation to Climate Change
- Regional Harmonization of Risk Assessment Approaches in Agricultural Biotechnology

Show your work during the Poster Session!

The 2nd Annual South Asia Biosafety Conference Poster Program is a new opportunity for individuals to share their research, findings and achievements, with colleagues at the conference. Presenting a poster is a noteworthy way to share expertise or accomplishment and poster presenters will have a dedicated time to present and discuss their work with the diverse group of attendees.

Information for registering for the conference and submitting poster abstracts, coming soon.

Key Messages from the Workshop on Strengthening the Culture of Responsibility

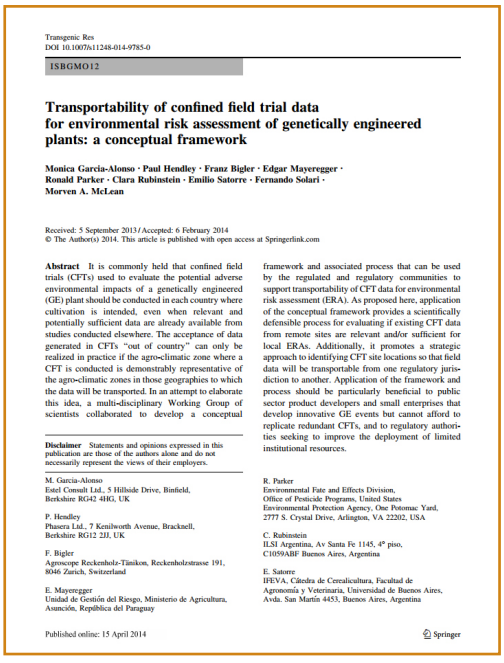
ZABTA SHINWARI & FOUZIA MIRZA, DEPARTMENT OF BIOTECHNOLOGY, QUAID-I-AZAM UNIVERSITY, ISLAMABAD

The workshop on "Strengthening the Culture of Responsibility: Dual Use Research and Biosecurity" was held in the auditorium of the Abdul Wali Khan University Chitral in Khyber Pakhtunkhawa on May 23-24, 2014. It was organized by Shaheed Benazir Bhutto University (SBBU) Shringal and its Chitral Campus in collaboration with Quaid-I-Azam University Islamabad. The workshop was co-sponsored by the Pakistan Academy of Sciences. The basic aim of the workshop was to create awareness about dual use of research in biosciences among university students of the remote areas of Pakistan such as Chitral, Dir, and Swat.

In this workshop, Dr. Anwar Nasim, Secretary General of the Pakistan Academy of Sciences, Dr. Zabta Khan Shinwari, Chairman of the Department of Biotechnology, Quaid-I-Azam University, Dr. Khan Bahadar Marwat, chief organiser of the event, and other intellectuals briefed the students about biosecurity/biosafety issues and the responsibility of the scientists for the safe conduct of science. The workshop also stressed the importance of the role of youth in the development of a responsible nation in terms of dual use aspects of research. The other important highlights of the event included a questionnaire to evaluate the students before and after the workshop; an interactive learning session where students were encouraged to design their own posters with the help of the teacher; and students' poster presentations on topics such as collaborative science and research on infectious diseases.

The majority of the students gave positive feedback about the outcome of workshop. Participants shared that the interactive session and the group activity of the students was the most interesting part of the event. Students appreciated the teachers' help in the interactive learning sessions and were impressed by the speeches and presentations of the guest speakers who conveyed their message in a simple but effective way.

NEW PAPER ON TRANSPORTABILITY OF CONFINED FIELD TRIAL DATA FOR ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY ENGINEERED PLANTS: A CONCEPTUAL FRAMEWORK



Transgenic Res
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ISBGMO12

Transportability of confined field trial data for environmental risk assessment of genetically engineered plants: a conceptual framework

Monica Garcia-Alonso · Paul Hendley · Franz Bigler · Edgar Mayeregger · Ronald Parker · Clara Rubinstein · Emilio Satorre · Fernando Solari · Morven A. McLean

Received: 5 September 2013 / Accepted: 6 February 2014

Abstract It is commonly held that confined field trials (CFTs) used to evaluate the potential adverse environmental impacts of a genetically engineered (GE) plant should be conducted in each country where cultivation is intended, even when relevant and potentially sufficient data are already available from studies conducted elsewhere. The acceptance of data generated in CFTs "out of country" can only be realized in practice if the agro-climatic zone where a CFT is conducted is demonstrably representative of the agro-climatic zones in those geographies to which the data will be transported. In an attempt to elaborate this idea, a multi-disciplinary Working Group of scientists collaborated to develop a conceptual framework and associated process that can be used by the regulated and regulatory communities to support transportability of CFT data for environmental risk assessment (ERA). As proposed here, application of the conceptual framework provides a scientifically defensible process for evaluating if existing CFT data from remote sites are relevant and/or sufficient for local ERAs. Additionally, it promotes a strategic approach to identifying CFT site locations so that field data will be transportable from one regulatory jurisdiction to another. Application of the framework and process should be particularly beneficial to public sector product developers and small enterprises that develop innovative GE events but cannot afford to replicate redundant CFTs, and to regulatory authorities seeking to improve the deployment of limited institutional resources.

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ABSTRACT: It is commonly held that confined field trials (CFTs) used to evaluate the potential adverse environmental impacts of a genetically engineered (GE) plant should be conducted in each country where cultivation is intended, even when relevant and potentially sufficient data are already available from studies conducted elsewhere. The acceptance of data generated in CFTs "out of country" can only be realized in practice if the agro-climatic zone where a CFT is conducted is demonstrably representative of the agro-climatic zones in those geographies to which the data will be transported. In an attempt to elaborate this idea, a multi-disciplinary Working Group of scientists collaborated to develop a conceptual framework and associated process that can be used by the regulated and regulatory communities to support transportability of CFT data for environmental risk assessment (ERA). As proposed here, application of the conceptual framework provides a scientifically defensible process for evaluating if existing CFT data from remote sites are relevant and/or sufficient for local ERAs. Additionally, it promotes a strategic approach to identifying CFT site locations so that field data will be transportable from one regulatory jurisdiction to another. Application of the framework and process should be particularly beneficial to public sector product developers and small enterprises that develop innovative GE events but cannot afford to replicate redundant CFTs, and to regulatory authorities seeking to improve the deployment of limited institutional resources.

LINK TO ACCESS THE PAPER: http://bit.ly/1wlD5fP

Status of the Implementation of the National Biosafety Framework Project

MOHAMMED SOLAIMAN HAIDER, DEPUTY DIRECTOR, DEPARTMENT OF ENVIRONMENT & PROJECT DIRECTOR, INBF PROJECT, AGARGAON, DHAKA

On May 29, 2014, the Inception Workshop of the Implementation of the National Biosafety Framework (INBF) project supported by the Global Environment Facility (GEF) through United Nations Environment Programme (UNEP) was held. The workshop was the first of its kind that offered an opportunity of outreach to stakeholders, informing them of all the components and outcomes of the project. The workshop was held at the RDEC Conference Room of LGED Bhaban, Agargoan, Dhaka, Bangladesh. Approximately 100 participants from different stakeholder groups, including scientists from different NARS institutes, academics from various universities, the planning commission, the Ministry of Environment and Forests, NGOs, private sectors and representatives from the Department of Environment attended this workshop.

The workshop was comprised of an inaugural ceremony followed by a group exercise on various project components. The outcomes of the group exercise were presented during the concluding session of the workshop.

The technical session started with the formation of four groups. Group members for individual groups were selected based on the expertise and interest of the participants. Group I was assigned to discuss and formulate recommendations on the biosafety policy issues. Group II worked on the existing biosafety guidelines and biosafety rules. Group III worked on the capacity building needs. Group IV discussed the updating needs of project documents for review of the GEF planned budget and activities of the work plan. The outcomes of the group exercise were reported by the members of the individual group.

During the concluding ceremony the Director General of the Department of Environment thanked the participants for their comments. As the chair of the event, he closed the meeting by stating that we have already accomplished some progress and now we are moving towards further actions to finish the remaining jobs. The biosafety guidelines were created in 2008 and the biosafety rules were made in 2012. Now, we will move forward by making the biosafety policy. If stakeholders, researchers, and scientists use the Biosafety Clearing House and give innovative ideas and suggestions, then the database will be enriched. He emphasized that long term research and effective monitoring is essential to get to the final result. He also added that adequate training is essential for farmers and regulators on the biosafety issues.

The Director General also shared that the implementation of the National Biosafety Framework (INBF) is very crucial, which could be accomplished through development of regulations and soft laws, capacity building in technical training, an improved infrastructure for monitoring and detection of LMOs and enhancing public awareness and capacity to a level of active participation in decision-making on LMOs notifications. All of these steps are essential but are presently lacking because of resource constraints. The INBF project will pave the way to institutionalize the biosafety regulations and policy as well as strengthen infrastructural facilities for risk assessment and management of LMOs, including decision-making which would provide global environmental benefits on the safe use of modern biotechnology and conservation of the endemic uniqueness of Bangladesh's biodiversity.




IN JUNE 2014, THE CENTER FOR ENVIRONMENTAL RISK ASSESSMENT (CERA), IN COOPERATION WITH THE AGRICULTURAL RESEARCH SERVICE, UNITED STATES DEPARTMENT OF AGRICULTURE AND DUPONT PIONEER, CONVENED A TECHNICAL TRAINING WORKSHOP ON NON-TARGET ORGANISM TESTING OF TRANSGENIC CROPS. THE PURPOSE OF THE WORKSHOP WAS TO PROVIDE REGULATORY SCIENTISTS AND ENVIRONMENTAL RISK ASSESSORS WITH AN EXPERIENTIAL LEARNING OPPORTUNITY IN LABORATORY AND FIELD TESTING OF NON-TARGET ORGANISMS. THE 5-DAY WORKSHOP TOOK PLACE IN AMES, IOWA AND INCLUDED PARTICIPANTS FROM INDIA, BANGLADESH, PAKISTAN, MALAWI, UGANDA, NORTHERN GHANA AND CHINA.

HEAR FROM DR. MUKESH DHILLON (BELOW) AND DR. ELIZABETH BANDASON (PAGE 5) ON THEIR PERSONAL EXPERIENCES AT THE WORKSHOP.

INDIA

Knowledge Gained from the Environmental Risk Assessment Workshop

DR. MUKESH K. DHILLON, SENIOR SCIENTIST, DIVISION OF ENTOMOLOGY, INDIAN AGRICULTURAL RESEARCH INSTITUTE, NEW DELHI

Environmental risk assessment of genetically modified crops to non-target organisms is a basic requirement for their release in the environment. The week-long CERA workshop held during June 23-27, 2014, in Ames, Iowa, offered me a unique experience to work and interact with GE plant developers, environmental risk assessors and regulatory scientists from Asia, Africa and the USA. The resource persons, course curriculum, lectures, workshop material, lab and field based activities and hospitality were all awesome.

The workshop contents viz., test organisms and biosafety protocols; planning and designing non-target organisms; selection of surrogate species and life stages; environmental risk assessment of genetically engineered plants for non-target organisms through tiered testing using laboratory bioassays and field techniques; installation of sticky and pitfall traps in the maize field; target and non-target insect bioassays; evaluation procedures for non-target organism groups; discussion on limits of non-target organisms testing, field test sample processing, data collection, species identification, result interpretation and group discussion on the results were found highly relevant and of practical utility for the environmental risk assessment of transgenic crops for commercial cultivation.

The knowledge gained from this workshop will be helpful for me in planning and designing experiments related to environmental risk assessment of non-target organisms in transgenic crops for their environmental release. As an entomologist, my approach for non-target testing of genetically engineered plants for environmental risk assessment used to be from a research perspective, however, this workshop broadened my vision about what kind of data is necessary and needs to be generated, and how to look at the environmental risk assessment data on non-target organisms from the GE developer and regulator perspective, because of my experience with the evaluation of non-target organisms case studies.

The visit to the Lost Lake Nature Trail of the Des Moines River was a good opportunity to see one of the Cicada species emerging after 17 long years of dormancy. Our visit to the DuPont Pioneer research facilities was another opportunity to see the mega molecular genotyping, transgenic and bioassay facilities, and controlled environment automated greenhouses.

I am grateful to the Center for Environmental Risk Assessment, ILSI Research Foundation for the invitation and kind support for this workshop, and the faculty involved in organizing this workshop for sharing their excellent knowledge and experiences.

Lessons Learned on Non-Target Organism Testing through Hands-On Workshop

DR. ELIZABETH BANDASON, LECTURER, ENTOMOLOGY, LILONGWE UNIVERSITY OF AGRICULTURE AND NATURAL RESOURCES, BUNDA COLLEGE CAMPUS, LILONGWE, MALAWI

Since time immemorial, humans have been fighting against insects and other pests to rescue their crops. Most of the time, careless sprays of insecticides and other harmful chemicals were inevitable, especially when farmers wanted to produce marketable goods. In such instances, it was very rare for them to consider protecting the non-target organisms, considering the risk adverse outcomes of their practices. Discovery of *Bacillus thuringiensis* (*Bt*) insecticidal proteins, which would kill specific insects and spare some non-target organisms, revealed a cutting edge research in science, that would definitely reduce the adverse effects of intensive use of chemical substances on the environment. But are *Bt* toxins really safe? What science and art would prove their safety on non-target organisms? If *Bt* toxins kill only specific insects, then why does the risk assessment on non-target organisms matter anyway? These were some of the questions that I had before I had the opportunity to participate in the Environmental Risk Assessment Workshop on Non-Target Organism Testing, in Ames, Iowa. Obviously, my school of thought represented some scientists in my country, Malawi, who are tirelessly working hard to find innovative solutions to protect farmers' crops and thinking less of the likelihood of unintended adverse outcomes of the technologies.

My experience in Ames evolved my thinking right from the first day of the workshop, especially keeping in mind my countries' efforts to introduce *Bt* cotton, which was said to have less likelihood or probability of causing harmful environmental effects than conventional cotton. I wondered whether our confined trials on *Bt* cotton were done using good laboratory practices, how certain we would be, and whether we were doing the right thing or not. Intuitively, we were certain that farmers would produce more yields in *Bt* cotton than conventional cotton, there would be reduced insecticide sprays in cotton growing areas, and the environment and other non-target organisms were safe.

By the end of the workshop, I did not leave with lots of questions the way I came in. By attending this event, most of my questions were answered right there! I am now aware of the basic techniques and methods that I would use to do a risk assessment because the training was hands on. We did not just talk about risk assessment, we "walked the talk"! Practical sessions formed the most important part of the training workshop.

Having had this exciting time in Ames, Iowa, the only question that I had tasked myself to answer was, I have done this training workshop, so what? Revising my work schedule to accommodate this important task was something that could not be avoided. Empowered with this knowledge and the "power to do", I am compelled to do this training with colleagues so that we build a team. But more importantly, I am working on starting to collaborate with the Commission of Science and the Department of Environmental Science in Malawi, to make environmental risk assessment an integral part of agricultural production. Soon, Malawi will be rolling out *Bt* cotton in most parts of the country. This training program came at the perfect time because a plan to initiate an environmental risk assessment on non-target organisms is inevitable.

Highlights from the "Risk Assessment: The Role of Science in GMO Decision-Making" Workshop

DR. MICHAEL WACH, SENIOR SCIENTIFIC PROGRAM MANAGER, THE CENTER FOR ENVIRONMENTAL RISK ASSESSMENT (CERA), WASHINGTON, DC, USA

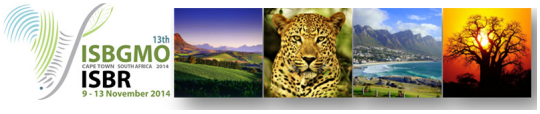
Participants from Bangladesh, Pakistan, and India attended a workshop entitled "Risk Assessment: The Role of Science in GMO Decision-Making," held June 30–July 4. The workshop was sponsored by the International Centre for Genetic Engineering and Biotechnology (ICGEB), and it was held at ICGEB headquarters in Trieste, Italy. In addition to six representatives from South Asia, there were participants from Argentina, Brazil, Colombia, Costa Rica, Cuba, Egypt, Hong Kong, Iran, Mexico, Kenya, Nigeria, Panama, the Russian Federation, Slovenia, Sudan, and the Ukraine, making this a truly international workshop. I served as a lecturer and resource person at this event.

The workshop covered a broad range of topics relating to the commercial authorization of genetically engineered crops and foods made from them, including the processes of environmental risk and food/feed safety assessments, and the "pathway to harm" method to analyze causal links between the commercial use of GE crops and specific environmental and food safety harms. Socio-economic considerations were also discussed. Participants learned the difference between "need to know" and "nice to know" data and how to effectively use data from dossiers as well as publicly available information to determine the likelihood of potential harms.

The workshop provided multiple opportunities for the participants to practice what they had learned. Each of the countries represented at the workshop has a unique approach to the regulation of genetically engineered crops. Small group exercises, focusing on a case study involving a drought-tolerant, nutritionally enhanced maize variety, enabled the participants to compare their regulatory programs, discuss the challenges each of them face, and share ways to resolve those challenges. Participants included both government regulators as well as researchers, which provided a more diverse perspective on the question of GE crop commercialization. The workshop ended with a day-long session on risk communication, including a writing exercise in which the participants drafted a portion of a regulatory decision document that presented a risk hypothesis, the data that was considered in testing the hypothesis, and the final decision.

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
New Frontiers in Hybrid Seed Production and Genetic Purity Testing Summer School	Anand Agricultural University	August 5-25, 2014 Anand, Gujarat	http://aau.in/sites/default/files/summer_school_baca_aau_anand_may_2014.pdf
Advanced Course on Novel Approaches in Pest and Pesticide Management in Agro-Ecosystem	CCS Haryana Agricultural University	August 19 - September 8, 2014 Hisar, Haryana	http://www.hau.ernet.in/ento1529.pdf
INTERNATIONAL			
Theoretical and Practical Course "Plant Tissue Culture: Tool for Genetic Engineering of Plants"	ICGEB and National Biotechnology Development Agency, Abuja, Nigeria	August 10-23, 2014 Abuja, Nigeria	http://www.icgeb.org/meetings-2014.html
13th IUPAC International Congress of Pesticide Chemistry	IUPAC and ACS-AGRO	August 10-14, 2014 San Francisco, California United States	http://www.iupac2014.org/
South Asia Biosafety Conference	South Asia Biosafety Program	September 15-17, 2014 Colombo, Sri Lanka	http://cera-gmc.org/Upcoming_Meetings_&_Events
12th Asian Conference and Expert Consultation on Maize for Food, Feed, Nutrition and Environmental Security	Asia-Pacific Association of Agricultural Research Institutions (APAARI), International Maize and Wheat Improvement Center (CIMMYT) and Vietnam Academy of Agricultural Sciences (VAAS)	October 27-29, 2014 Hanoi, Vietnam	http://www.apaari.org/events/12th-conference-on-maize.html
13th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO13)	International Society for Biosafety Research (ISBR)	November 9-13, 2014 Cape Town, South Africa	http://isbr.info/ISBGMO13



THE 13TH ISBGMO IS COMING TO SOUTH AFRICA

REGISTER TODAY!

The International Society for Biosafety Research (ISBR) and the Local Organising Committee are pleased to announce the conference theme for ISBGMO13 is advancing the environmental risk assessment of GMOs to address biosafety in a global society. Registration and abstract submissions are now open! Register by August 19 to receive early-bird rates. For more information on ISBGMO13, please visit the official conference website at http://isbr.info/ISBGMO13 or email the conference secretariat, Centeq Events, at isbgmo2014@allevents.co.za.

SOUTH ASIA BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international developmental program implemented in India, Bangladesh and Pakistan with support from the United States Agency for International Development. SABP aims to work with national governmental agencies and other public sector partners to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds, and environmental protection.

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