4TH ANNUAL SOUTH ASIA BIOSAFETY CONFERENCE

September 19-21, 2016
Taj Krishna, Hyderabad, India
The South Asia Biosafety Program (SABP) is dedicated to assisting India and Bangladesh in further strengthening institutional governance of biotechnology. Managed by the ILSI Research Foundation, SABP works with its in-country partners to:

- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Facilitate systems for permitting the safe conduct of experimental field trials of new crops developed using biotechnology so that scientists and farmers can evaluate them.
- Raise the profile of biotechnology and biosafety on the policy agenda within Bangladesh and India and to address the policy issues within the overall context of economic and agricultural development, international trade and environmental sustainability.

The South Asia Biosafety Program would like to acknowledge USAID for its continued support.
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AGENDA

September 19, 2016

08:00  Delegate Registration
09:30  Inaugural Ceremony

Welcome Address: Dr. Vibha Ahuja, Biotech Consortium India Limited, India
Introduction to the South Asia Biosafety Program: Dr. Andrew Roberts, ILSI Research Foundation, United States
Address: Mrs. Amita Prasad, Ministry of Environment, Forest and Climate Change (MoEF&CC), India
Keynote Address: Dr. Trilochan Mohapatra, Indian Council of Agricultural Research (ICAR), India
Keynote Address: Dr. Anupam Varma, National Academy of Agricultural Sciences and Advanced Centre for Plant Virology, Indian Agricultural Research Institute
Remarks: Dr. Naiyyum Choudhury, Bangladesh Academy of Science, Bangladesh
Vote of Thanks: Dr. Andrew Roberts, ILSI Research Foundation

10:30  Tea

Plenary Session I: Regulation of Biotechnology in South Asia

Chair  Mr. Gyanesh Bharti, MoEF&CC, India

11:00  Strengthening Environmental Risk Assessment in Indian Biosafety Regulations
Dr. K. Veluthambi, Madurai Kamaraj University, India
11:20   Update on Biosafety Regulation in Bangladesh
Mr. Mohammed Solaiman Haider, Department of Environment, Bangladesh

11:40   Update on the Biosafety Regulatory Framework in Bhutan
Mr. Jamyang Phuntsho, Bhutan Agriculture and Food Regulatory Authority (BAFRA), Bhutan

12:00   Update on Biosafety Regulation in Pakistan
Dr. Kauser Abdulla Malik, Forman Christian College, Pakistan

12:20   Update on Biosafety Regulation in Sri Lanka
Ms. Himali De Costa, Ministry of Mahaweli Development & Environment, Sri Lanka

12:40   There and Back Again: Reversal by the Supreme Court on the Constitutionality of GM Crop Regulations and the New Challenge to the Philippine Biosafety System
Mr. Abraham Manolo, Biotech Coalition of the Philippines, Philippines

13:00   Lunch

Parallel Session I: Biotechnology Research and Development in South Asia
Chair  Dr. J.S. Sandhu, Indian Council of Agricultural Research, India

14:00   Nematode Resistant GM Crops Based on RNAi - Research and Regulation
Dr. Uma Rao, Indian Agricultural Research Institute (IARI), India

14:30   Experiences for Approval of Bt Brinjal in Bangladesh
Dr. G.P. Das, Feed the Future South Asia Eggplant Improvement Partnership, Bangladesh

14:50   Recent Advances in Breeding Golden Rice in Bangladesh
Dr. Partha Biswas, Bangladesh Rice Research Institute (BRRI), Bangladesh

15:10   Potato Transgenics in India: Status and the Way Forward
Dr. S.K. Chakrabarti, Central Potato Research Institute, India

15:30   Tea

Parallel Session II: Research Efforts to Address Climate Change
Chair  Dr. Ravindra Babu, ICAR-Indian Institute of Rice Research, India

14:00   National Innovations in Climate Resilient Agriculture
Dr. Srinivasa Rao, Central Research Institute for Dryland Agriculture (CRIDA), India

14:30   Developing Plant Resources for Stress Tolerant Molecular Breeding in Rice
Dr. Zeba Seraj, University of Dhaka, Bangladesh

14:50   Transgenic Strategies for Enhanced Abiotic Stress Tolerance in Grain Legumes: Retrospect and Prospects
Dr. Pooja Bhatnagar, International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), India

15:10   Water Efficient Maize for Africa
Dr. Sylvester Oikeh, African Agricultural Technology Foundation (AATF), Kenya

15:30   Tea
16:00  **Lightning Round**  
Students and Young Scientists

17:30  **Poster session**  
Dr. Monica Garcia-Alonso, Secretary, International Society for Biosafety Research (ISBR) Board of Directors  
The poster session is sponsored by ISBR. Conference participants are encouraged to share their work with colleagues by preparing a poster for this session. All posters must convey relevance to biosafety research, environmental risk assessment of genetically modified organisms (GMOs), or the regulation of GMOs—plants, animals, arthropods, or microorganisms. First and second place prizes will be awarded for the most outstanding posters.

19:30  **Dinner**

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**September 20, 2016**

**Plenary Session II: New and Emerging Technologies for Genetic Engineering**

*Chair  Dr. Monica Garcia-Alonso, Estel Consult, United Kingdom*

09:00  Introduction to New Technologies  
Dr. Andrew Roberts, ILSI Research Foundation, United States

09:15  CRISPR-Cas Enabled Advanced Breeding Technology  
Dr. Amitabh Mohanty, DuPont Pioneer, India

09:40  Biosafety Considerations for the Use of Gene Drives in *Anopheles gambiae* for Malaria Control  
Dr. Andrew Roberts, ILSI Research Foundation, United States

10:05  Genetic Biocontrol for Snails Utilizing a Cas9-Mediated Gene Drive  
Dr. John Teem, ILSI Research Foundation, United States

10:30  **Tea**

11:00  Plant Breeding Innovation: Towards Consistent Global Policy  
Dr. Usha Barwale Zehr, Mahyco, India and International Seed Federation, India

11:45  Panel Discussion

12:30  **Lunch**

13:30  **Facility Visit to ICRISAT or Cultural Tour of Hyderabad (Optional)**

Participants are invited to attend an optional facility visit to the ICRISAT Global Headquarters, located in Patancheru near Hyderabad, Telangana, India. The research station offers an insight into the integration of agricultural sciences and research-for-development activities across the whole value chain—high end science using germplasm from the genebank, genomics laboratory, phenotyping and genetic engineering facilities, through to the agribusiness center, watershed management and crop production field experiments. Alternatively, participants have the opportunity to enjoy a cultural tour of Hyderabad.
September 21, 2016

Plenary Session III: Meeting Regulatory Challenges and Approaches to Regulatory Support

Chair  Dr. Alex Owusu-Biney, United Nations Environment Programme, Kenya

09:00  South Africa's Evolving Biosafety Regulatory System
       Dr. Hennie Groenewald, Biosafety South Africa, South Africa

09:30  India's Regulatory Framework: Evolution and Reforms
       Dr. S.R. Rao, Department of Biotechnology, India

10:00  Biosafety Regulatory Framework in Kenya: Challenges and Approaches
       Dr. Willy Tonui, National Biosafety Authority, Kenya

10:30  Guidance for the Biosafety Regulatory Process in Bangladesh
       Ms. Khorsheda Yasmeen, Ministry of Environment and Forests, Bangladesh

11:00  Tea

11:30  Regulatory Challenges for Small Companies
       Dr. Keith Redenbaugh, Arcadia Biosciences, United States

12:00  Addressing Regulatory Challenges in a Federated System: An Australian Plant Science Industry Perspective
       Mr. Osman Mewett, CropLife Australia, Australia

12:30  Panel Discussion

13:00  Lunch

14:00  Keynote
       Dr. David Bergvinson, International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), India

14:30  Poster Session Awards
       Dr. Monica Garcia-Alonso, International Society for Biosafety Research

Plenary Session IV: Dossier Preparation: Planning and Generation of Regulatory Data

Chair  Dr. P.K. Chakrabarty, Indian Council of Agricultural Research, India

14:45  Regulatory Data Generation, Analysis, and Interpretation
       Dr. Donald MacKenzie, International Rice Research Institute (IRRI), Philippines

15:15  Writing Regulatory Dossiers: Good Reports, Good Dossiers, Good Stories
       Dr. Monica Garcia-Alonso, Estel Consult, United Kingdom

16:00  Tea

16:30  Development of a Genetically Engineered Virus Resistant Fruit Tree - From Concept to Product Release
       Dr. Ralph Scorza, United States Department of Agriculture (Retired), United States

17:00  Testing of GE Silk Moths: Challenges in Interpreting Regulatory Requirements
       Dr. P.J. Raju, Andhra Pradesh State Sericulture Research and Development Institute, India
       Dr. V. Satyavathi, Centre of Excellence for Genetics and Genomics of Silkmoths, Centre for DNA Fingerprinting and Diagnostics, India

17:30  Building Support for our Science: Four Keys to Successful Stakeholder Engagement and Communication
       Ms. Jill Kuehnert, Seed Stories, United States

18:00  Panel Discussion

18:30  Closing Remarks and Adjournment
Usha Barwale Zehr, Ph.D.

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Dr. Usha Barwale Zehr is the Director and Chief Technology Officer at Maharashtra Hybrid Seeds Company Private Limited (MAHYCO), India. She received her Ph.D. from the University of Illinois at Urbana-Champaign. Subsequent to her formal education, she worked at Purdue University in the sorghum improvement program. For the last 18 years, she has been utilizing new technologies and tools including biotechnology, for improving the quality and productivity of seeds and agriculture. In addition, Dr. Zehr serves as Director of Barwale Foundation, a non-profit research foundation. She also serves on the Board of the Donald Danforth Plant Science Center and Alliance for Green Revolution in Africa. Dr. Zehr chairs the Breeder’s Committee of the International Seed Federation.

David Bergvinson, Ph.D.

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Dr. David Bergvinson is the Director General of the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT). He oversees the formulation and implementation of actionable plans to develop and deliver farmer-preferred products and services in the semi-arid
tropics in Asia and Sub-Sahara Africa. He is specialized in management of grants and digital innovation for agriculture; geospatial resources to support ecological intensification and database architecture to target agriculture innovations. He has developed and managed grants in partnership with national and international research and development organizations that have reached over 9 million farmers in Asia and Africa. He has received awards from the CGIAR and the International Maize and Wheat Improvement Center (CIMMYT) for his work in maize research to support smallholder farmers in the developing world.

Pooja Bhatnagar-Mathur, Ph.D.

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Dr. Pooja Bhatnagar-Mathur is a Senior Scientist at the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), currently leading the theme on cell, molecular biology and genetic engineering. She holds a basic degree in Horticulture, with a Post Graduate (M.Sc.) and Doctorate (Ph.D.) in Biotechnology. Dr. Bhatnagar-Mathur has over 12 years of expertise in genetic engineering of various legumes and cereals such as groundnut, chickpea, pigeon pea and sorghum. She has been actively involved with research aimed at reconciling the best of biotechnological approaches to integrate useful traits including enhanced resistance to diseases and pests, tolerance to abiotic stresses and nutritional enhancement in these crops. Dr. Bhatnagar-Mathur is also involved with the “Platform for Translational research on Transgenic Crops” (PTTC) at ICRISAT, a unique concept aimed at facilitating collaborative and coordinated approaches for translation of the transgenic concepts to product development by addressing biosafety, intellectual property (IP) and technology transfer issues through public-private partnerships. She has to her credit, several advanced certifications from the World Intellectual Property Organization (WIPO) on several components of IP management for commercialization of biotech products. Dr. Bhatnagar-Mathur has published over 60 research communications in various international peer reviewed journals and books besides several popular articles in various newsletters.

Partha Biswas, Ph.D.

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Dr. Partha Sarathi Biswas was born in 1971 in Bangladesh. He completed his Ph.D. in Plant Breeding and Genetics from the Bangladesh Agricultural University in 2011. Currently, he is working at the Bangladesh Rice Research Institute (BRRI) as a Principal Plant Breeder. During his service at BRRI since 1998, he was involved in the development of rice varieties for favourable and unfavourable ecosystems. Since 2002, he has been working on the development of nutritionally enriched rice varieties. His research team has already developed seven rice varieties; four of them are zinc enriched rice. Now, he is leading the research activities at BRRI for the development and evaluation of locally adapted pro-vitamin A enriched golden rice varieties. He regularly participates in the developmental process of biosafety guidance documents in the country. His expertise is in both conventional and molecular breeding. Marker assisted breeding and
QTL mapping work for different traits of interest in rice are on-going under his supervision. He has published more than 30 research articles in national and international journal. He has supervised six M.S. thesis researchers and one Ph.D. thesis researcher from different universities in Bangladesh.

S.K. Chakrabarti, Ph.D.

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Dr. Swarup Kumar (S.K.) Chakrabarti is the Director of the Indian Council of Agricultural Research (ICAR)-Central Potato Research Institute, Shimla. He had been the country leader of the Potato Genome Sequencing Consortium, comprising of 26 international institutes belonging to 14 countries. The consortium deciphered the complex genome of potato (844 Mb) that has been published in the high impact journal Nature in 2011. He has worked on transgenics, genomics, molecular breeding and plant pathology for potato improvement through biotechnological interventions. In brief, his achievements in terms of products, technologies and patents include functional genomics of late blight resistance; genomes sequencing of potato leaf roll virus; molecular profiling of potato pathogens; QTLs mapping for late blight resistance; genetic variability during micropropagation; Bt-brinjal for management of fruit and shoot borer; transgenic potatoes for late blight resistance, improved protein and quantity, and tuber moth; diagnostic for potato viruses; and many others.

He has been credited with several honors and awards, including the L.C. Sikka Endowment Award, the S. Ramanajuam Award and the Dr. J.P. Verma Memorial Award, to name a few. He is the fellow of many societies, including the National Academy of Agricultural Sciences. He has more than 200 publications, including research articles in peer-reviewed journals of national and international levels. He has served in several committees and handled many projects at the national and international levels. Prior to his work at this institute, he was the Director of the ICAR-Central Tuber Crops Research Institute, Thiruvananthapuram, Kerala.

G.P. Das, Ph.D.

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Dr. G.P. Das is the Agricultural Biotechnology Support Project II (ABSPII) Country Coordinator for Bangladesh. His main responsibilities are to facilitate all ABSPII related activities in Bangladesh. Dr. Das holds a Ph.D. from the University of the Philippines at Los Banos (UPLB). Prior to joining ABSPII, he worked with the Bangladesh Agricultural Research Institute (BARI) for about 25 years and was involved in a number of projects aiming at the development of the Integrated Pest Management (IPM) strategies against the major insect pests of tuber crops. Biopesticides, among others, were components of this IPM. Other experiences include the full responsibility of research management in the context of a donor funded (DANIDA) project as well as teaching at the University level. He also worked with the Bangladesh Agricultural Research Council (BARC) as the Director of the Agricultural Information Centre. He has over 35 years of experience
including as a senior research scientist, university teaching, extension approaches, Director of BARC, project management, etc. Dr. Das has over 50 publications in referred journals of national and international origin. He has also authored two books and supervised several Ph.D. and M.S. students. He is a member of over 20 professional societies at home and abroad.

**Himali De Costa**

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Ms. W.A. Himali De Costa is a Post Graduate in Geoinformatics. She is presently working as an Environment Management Officer (I) at the Ministry of Mahaweli Development and Environment, Government of Sri Lanka. She is actively engaged in the Ministry of Mahaweli Development and Environment, which is the focal point for implementation of the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety in Sri Lanka.

**Monica Garcia-Alonso, Ph.D.**

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Dr. Monica Garcia-Alonso is an independent consultant and is the owner of Estel Consult Ltd, based in the UK. Her main areas of expertise are environmental risk assessment and regulatory affairs for agricultural biotechnology products and agrochemicals. Dr. Garcia-Alonso studied her degree in Biology at the University of Barcelona from 1985 to 1990. She then did her M.Phil. at the Centro Superior de Investigacione Scientificas (CSIC) in Barcelona on insect physiology and ecology from 1990 to 1992. She then moved to the UK where you started working at the Entomology Department of ICI, conducting studies on insects and nematodes. In 1993, she started to works as a scientific officer at the biochemistry department at Zeneca, as part of the electrophysiology team, studying the mode of action of insecticides. In 1994, Zeneca sponsored her Ph.D. in neurobiology at the University of Reading. The project aimed at cloning insect receptors for expression in a mammalian cell line to develop a high throughput screening method for the discovery of new insecticides. On completion of her Ph.D. in 1997, she started to work at the Environmental Sciences Department at Zeneca, where she was part of the terrestrial ecology team, working as an environmental risk assessor.

**Hennie Groenewald, Ph.D.**

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Dr. Jan-Hendrik (Hennie) Groenewald has a Ph.D. in plant biotechnology and more than 20 years’ experience in research and development, teaching, business development and innovation management. He is currently the executive manager of Biosafety South Africa, a national biosafety service platform, under the auspices of the national Department of Science and Technology. It forms part of the national
biotech innovation system and ensures that the regulation, research and development, and commercialisation of biotech products are done in a safe, sustainable and effective manner. Dr. Groenewald is a member of and has served on various international, national and institutional organisations, boards and committees tasked with biosafety, risk analysis, risk governance, biotech and agricultural innovation.

M. Solaiman Haider

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Mr. M. Solaiman Haider is the Deputy Director of the Department of Environment (DoE) under the Ministry of Environment and Forests of the Government of the People’s Republic of Bangladesh. He received a B.Sc (Hons.) and an M.Sc in Botany. He did his Professional Masters in Natural Resources Management at the International Institute for Geo-information Science, the Netherlands. He also received a Postgraduate Diploma in Biosafety from the University of Malaya, Kuala Lumpur, Malaysia.

He joined the Department of Environment in 1996 and since then has served in various capacities in the areas of pollution management, environmental impact assessment, climate change, biodiversity conservation and biosafety issues. He is the Member Secretary of the National Committee on Biosafety (NCB) and Biosafety Core Committee (BCC). He has wide experience with attending international trainings, seminars, workshops, negotiation meetings on environment, biodiversity and biosafety issues in countries such as the United States, Canada, Germany, France, Switzerland, the Netherlands, Egypt, Jordan, South Korea, Tanzania, Kenya, India, Sri Lanka, Nepal, Bhutan, Thailand, Cambodia, Vietnam, China, Hong Kong, Indonesia, Malaysia and Japan. As an environmental expert, he possesses vast experience on presenting papers as a resource person in various topics related to environment, biodiversity, biosafety, and climate change issues. As a focal person on Biosafety issues in DoE, he has been very keenly associated with the development of the Updated Biosafety Guidelines of Bangladesh, National Biosafety Framework, Biosafety Rules of Bangladesh, Food Safety Assessment Guidelines, SOPs for confined field trials of GE plant and Data Recording Formats. He is also the Project Director of UNEP-GEF funded Implementation of Biosafety Framework of Bangladesh.

Jill Kuehnert

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Ms. Jill Kuehnert is a communications and outreach advisor focused on agriculture in developing countries. Through Seed Stories, her international consulting practice, Ms. Kuehnert helps build greater understanding and support for agriculture research and development within complex science, technology and policy environments. Her hands-on work with clients encompasses development of core content, stakeholder engagement strategies, and proactive issue management. She is an experienced presenter and trainer on these topics.
Ms. Kuehnert has engaged actively in research partnerships in Asia and Africa throughout her career, contributing management, capacity-building and communications expertise to projects in banana, cassava, rice and other crops. Clients have included the African Agriculture Technology Foundation, CropLife, the Donald Danforth Plant Science Center, the Global Industry Coalition, Helen Keller International, and the International Rice Research Institute. Ms. Kuehnert established Seed Stories in Singapore in 2008, and currently works from the US and South Africa. Her prior experience includes a decade with Monsanto Company, including leadership of the company’s government, industry and public affairs team in Asia, and several years at the World Bank in Washington, DC. Ms. Kuehnert holds a Bachelor of Arts degree in International Affairs and a Master of Arts degree in Philosophy and Social Policy from the American University in Washington, DC.

Donald MacKenzie, Ph.D.

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Dr. Donald MacKenzie leads regulatory affairs and stewardship for the Golden Rice Project on behalf of the International Rice Research Institute. In this role, Dr. MacKenzie is responsible for developing and executing regulatory strategies to continue the timely advancement of Golden Rice in Bangladesh, Indonesia, and the Philippines.

Prior to taking on this assignment, Dr. MacKenzie was a global registration manager and regulatory leader for Canada on behalf of DuPont Pioneer. Over his career, Dr. MacKenzie has held government posts with Agriculture and Agri-Food Canada’s Research Branch, the Canadian Food Inspection Agency and he was the head of Science Policy Division within Health Canada’s Health Protection Branch. As the executive vice-president of AGBIOS, Dr. MacKenzie was involved with numerous US Agency for International Development funded agricultural biotechnology development projects that focused on working with governments, regulatory authorities, and biotechnology stakeholders to develop science-based policies and the professional capacity of scientists and regulators to conduct risk assessments.

From 2005 through 2008, Dr. MacKenzie led the USAID-funded South Asia Biosafety Program in Bangladesh assisting with BARC and the Ministry of Environment and Forests in the development of biosafety guidelines and compliance management practices for the conduct of confined field trials in Bangladesh and approaches to environmental risk assessment.

Abraham Manalo

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Mr. Abraham (Abe) Manalo is a Policy and Planning Specialist. His work includes biotechnology and biosafety policy, environment and biodiversity policy, reorganization, and governance of the bureaucracy, and formulation of national development plans. He has wide experience in providing management and technical support in coordinating activities related to policy formulation, development planning and design, institutional strengthening, capacity and constituency building, advocacy and public awareness. He took his political science undergraduate course and
graduate (Masters) courses in statistics and in public administration from the University of the Philippines Diliman, and is currently pursuing his doctorate at the National College of Public Administration and Governance (NCPAG) from the same university. As an Associate Professor at the New Era University, he teaches major political science subjects, algebra and statistics. Mr. Manalo is the current Executive Secretary of the Biotechnology Coalition of the Philippines (BCP), Inc., a non-profit organization working for the safe and responsible use of modern biotechnology in the Philippines to serve national development goals.

Osman Mewett

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Mr. Osman Mewett joined CropLife Australia in December 2011 and brought with him extensive knowledge of the plant science regulatory system. Mr. Mewett is a plant molecular biologist and lawyer who leads CropLife’s activities relevant to the Crop Biotechnology Sector. Prior to joining CropLife, Mr. Mewett held the position of Scientist – Biosecurity and Farm Analysis Branch with the Australian Bureau of Agricultural and Resource Economics and Sciences. Prior to this appointment, he held a number of senior scientific, regulatory and policy positions with the Federal Department of Agriculture, Fisheries and Forestry and the Office of the Gene Technology Regulator. He has authored a number of journal papers, government reports and publications relevant to his areas of expertise. Mr. Mewett possesses a Bachelor of Science (First Class Honours) and a Bachelor of Laws from the Australian National University. Mr. Mewett is a member of the Australian Society of Plant Scientists and represents CropLife on the Agricultural Biotechnology Council of Australia.

Amitabh Mohanty, Ph.D.

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Dr. Amitabh Mohanty joined DuPont Pioneer in 2007 as a Group Leader, Genetic Discovery group at DKC and currently serves as a Senior Research Manager, Trait Discovery and Optimization. Dr. Mohanty is part of the global Trait Discovery & Optimization Leadership Team (TDOLT). Currently, his group focuses on lead discovery, characterization and optimization for yield and yield stability programs, insect protection and hybrid systems. In addition, his group is involved in developing tools/technologies, such as genetic element discovery, as well as CRISPR Cas enabled advance breeding technologies. He also oversees the native traits group, which works collaboratively with product development teams and develops new assays for traits, uses association mapping and map based cloning for imparting defensive traits to DuPont Pioneer elite lines. He was instrumental in building a world class competency in lead discovery using model system Arabidopsis. This includes a state-of-the-art phenotyping facility at DKC. Dr. Mohanty completed his Ph.D. in Plant Molecular Biology from University of Delhi South Campus, New Delhi India in 2000. Subsequently, he got trained in high-throughput rice genomics at Rice Genome research Program (RGP, Tsukuba, Japan) and helped to jump start
the Indian rice genome sequencing program (IRGSP), which was part of the International Rice Genome Sequencing Program (IRGSP).

Before joining DuPont Pioneer, Dr. Mohanty did his post-doctoral studies (2002-2007) with Professor Dave Jackson at the Cold Spring Harbor Laboratory, New York, USA. During this time, he worked on two NSF funded multi-million dollar projects on Arabidopsis and maize on cell biology and genomics.

Dr. Mohanty is currently the site leader for the DuPont Pioneer group at the DuPont Knowledge Centre and he is also part of the Asia Pacific Leadership Team for research. He also serves as the Chair of the Institutional Biosafety Committee (IBSC) at DKC.

**Jamyang Phuntsho**

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Mr. Jamyang Phuntsho, currently serves as the Chief Certification Officer at the Bhutan Agriculture and Food Regulatory Authority (BAFRA), Ministry of Agriculture and Forests, Thimphu, Bhutan. Mr. Phuntsho has a background in food science and technology from University of Bologna, Italy. He has experience in laboratory analysis of food and agricultural products and implementation of standardization, inspection and certification for quality management systems. He was involved in the establishment and operation of the first food testing laboratory of Bhutan.

Mr. Phuntsho is involved in activities that work towards ensuring food safety and implementation of biosecurity measures in Bhutan. He coordinates the analytical and certification activities in Bhutan including the implementation of Bhutan Organic Certification and Good Agricultural Practices. During the implementation of National Biosafety Framework Project, a UNEP-GEF Biosafety Project, he was involved in the development of biosafety legislations, administrative and technical guidelines and establishment of the GMO (biotechnology) laboratory.

**Sylvester Oikeh, Ph.D.**

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Dr. Sylvester O. Oikeh for the past seven years has been coordinating the operational management of the Water Efficient Maize for Africa (WEMA) project that was recently rated as the “most successful public-private partnership in the agricultural research sector of the tropical world”. Dr. Oikeh has more than 30 years of interdisciplinary experience in research-for-development projects on natural resources and crop management, and plant nutrition. He joined AATF from the Africa Rice Centre, WARDA, where he worked for five years, as a Principal Scientist/Soil Fertility Agronomist and Project Leader. As a Principal Scientist, his key duties included conducting strategic and applied research on integrated soil fertility management and plant nutrition to improve natural resources management and increase rice production in smallholder farming systems.
Between 1990 and 2003, Dr. Oikeh held various positions at the International Institute of Tropical Agriculture (IITA), including as a GTZ Research Fellow, a consultant agronomist; and a visiting maize scientist involved in collaborative research investigating micronutrient enhancement of tropical maize. He was a Postdoctoral Fellow for two years at Cornell University, Ithaca, New York, USA, in the HarvestPlus project where he established for the first time, the link between enhanced iron and zinc in maize grains with improvement in human nutrition using an in vitro technique (model gut-system).

Dr. Oikeh attained his doctorate in Soil Science specializing in Soil Fertility and Plant Nutrition from the Ahmadu Bello University, Nigeria, in 1996. He obtained a Master’s degree in Crop Science from the University of Nigeria, Nsukka, the same university from where he had graduated with a Bachelor of Agriculture degree in Horticulture. He holds a Postgraduate Diploma in Irrigation Engineering from the Centre for Irrigation Engineering of the Katholieke universiteit, Leuven, Belgium. Besides research, he has lectured in Nigeria at the University of Benin (Soil Science) and Anambra State College of Education.

Dr. Oikeh is a Certified International Project Manager (CIPM™) of the American Academy of Project Management. He has authored over 60 publications including hand books for upland and lowland rice production. Dr. Oikeh is a national of Nigeria.

P.J. Raju, Ph.D.

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Dr. Poosapati Jagannatha (P.J.) Raju is the Director of the Andhra Pradesh State Sericulture Research and Development Institute (APSSRDI), Hindupur. He is involved in research and development, including the transfer of sericulture technologies in particular the new silkworm hybrids for different agro-climatic zones of Andhra Pradesh. He is heading the APSSRDI component of the Centre of Excellence (CoE) for Genetics and Genomics of Silkmoths in association with the Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad, India.

The epoch making technology of transgenic silkworms/hybrids resistant to BmNPV are under limited field trials, which is a first of its kind in India. Dr. Paju is instrumental in mobilizing grants for several of the research and development activities, including field oriented projects through national and international funding. He has to his credit significant publications, which are relevant to field applications and also has authored several books. He has taken the lead in foraying into research on non-textile purposes of silk.

In addition, he and his team are instrumental in reviving the Silkworm Seed Sector in a scientific approach. Dr. Raju’s contributions in alleviating the socio-economic empowerment of tribals through state-of-the-art technologies is well appreciated by the Government and equally recognized by the tribal communities.
S.R. Rao, Ph.D.

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Dr. S.R. Rao is an Adviser in the Department of Biotechnology (DBT) at the Ministry of Science & Technology, Government of India. He has served in various positions in the department since 1989. He was associated with the implementation of several national level programs on research and development (R&D), technology development and commercialization of biotechnology. Currently, his main responsibility is the regulation of genetically engineering products, including biosafety and biosecurity. He is the Scientific Member Secretary of the statutory body, “Review Committee on Genetic Manipulation”, which was mandated with scientific risk assessment and management under Rules, 1989 of Environmental Protection Act, 1986 of India. He is also serving as the Chairman of the “Scientific Panel on GM Foods” of the Food Safety Standards Authority of India (FSSAI), dealing with risk assessment of GM Foods. He is also responsible for the establishment of the Biotechnology Regulatory Authority of India through the enactment of legislation, which replaces the existing regulatory framework. He specializes in core and cross-sectoral policy issues of biotechnology policy, development, regulation, safety, public private partnership, international relations, biotech R&D innovation and development, public concerns and consensus building. He has published more than 50 scientific papers and is the chief editor of the Journal of Biosafety Research, which launched in 2016.

Srinivasa Rao, Ph.D.

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Dr. Srinivasa Rao, Cherukumalli, is working as the Director of the Central Research Institute for Dryland Agriculture (CRIDA), Hyderabad, India. He completed his M.Sc. (Agriculture) from the Agricultural College, Bapatla. He received his Ph.D. in Soil Science from the Indian Agriculture Research Institute (IARI), New Delhi.

He has 25 years of experience in the fields of soil carbon sequestration, climate change, agriculture contingency planning, climate resilient villages, participatory soil health management, development of resilient indicators. Dr. Rao has worked extensively in rain fed-dryland production systems of India, carbon sequestration potential, and critical carbon inputs for maintenance of soil organic carbon at antecedent levels under different cropping systems. Through these efforts, various soil health improved strategies were demonstrated in a large number of farmers’ fields in several agro-ecosystems.

Dr. Srinivasa Rao has contributed in the development of climate resilient model villages across the country in about 150 villages. This work included rain water management such as in-situ and farm pond technologies; efficient irrigation systems; integration models of national resource management (NRM) technologies with stress tolerant crop cultivars; crop diversification; integrated farming system models; intercrops; establishment of custom hiring centre’s of farm implements and institutions like the Village Climate Risk Management Committee (VCRMC); village seed banks; village level carbon balance with implementation of various climate resilient interventions.
The development of agriculture contingency plans for 614 districts of India was done in association with National Agriculture Systems, Agriculture Knowledge Centres and Agriculture Departments. Updating these plans required sensitization by organizing state level and regional interface meetings for enhanced preparedness to manage climate variability and extreme climatic events such as droughts (early, mid-season and terminal), floods, cyclones, heat waves, frosts, sea water intrusions, etc. These plans address all the agriculture sub sectors like field crops, horticulture, livestock, poultry, fishery, etc. Currently, he is coordinating the “National Innovations in Climate Resilient Agriculture (NICRA)”, a mega flagship program of the Indian Council of Agriculture Research (ICAR).

Dr. Srinivasa Rao was part of the global climate change negotiations, as a member of Indian delegation at UNFCCC, SBSTA-42 and 44 at Bonn, Germany during 2015 and 2016. He contributed to organizing a side event on climate resilient agriculture in the Indian pavilion at CoP-21, Paris. He was recently nominated as the Executive Member of IDDC. He has received approximately 20 awards from national and international organizations for his significant contributions in NRM. He is involved in several organizations, including as a Fellow of the National Academy of Agricultural Sciences (NAAS); Fellow of the Indian Society of Soil Science; President of Indian Society of Dryland Agriculture and Development; Member of the Standing Technical Committee of National Mission for Sustainable Agriculture (NMSA) which is one of the 8 missions under Prime Minister of India. Under his leadership, CRIDA received the prestigious Sardar Patel Outstanding Research Institute Award of ICAR in 2015.

Uma Rao, Ph.D.

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Dr. Uma Rao is presently working as Head of the Division of Nematology, and as the Coordinator of School of Plant Protection, ICAR- Indian Agricultural Research Institute (IARI) in New Delhi. She obtained a B.Sc. (Horticulture) and M.Sc. (Agriculture) in Plant Pathology from the University of Agricultural Sciences, Bangalore. She completed her Ph.D. in Nematology from IARI, New Delhi. She joined the Indian Council of Agricultural Research as an ARS Scientist in 1989 and joined the Division of Nematology in 1990. Since then, she has been working in different positions and involved in post graduate teaching, research and extension activities. Dr. Uma Rao has worked on various aspects of applied and basic research in Plant Nematology. She had post-doctoral training in Molecular Nematology from the University of North Carolina, USA and the University of Leeds, UK. Her present research focus is on the genomics of important plant parasitic nematodes of India and nematode functional genomics for identifying potential nematode genes as targets for designing nematode resistant crops. Her present work includes development of nematode tolerant crops by knocking down critical nematode genes particularly in root knot and cyst nematodes. She has been guiding post graduate students and published research papers in national and international journals.
Keith Redenbaugh, Ph.D.

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Dr. Keith Redenbaugh is the Senior Regulatory Manager and Director of Analytical Science & Regulatory Support at Arcadia Biosciences, Inc., Davis, California. During his 25+ years in regulatory affairs of genetically engineered plants, Dr. Redenbaugh has obtained crop approvals in the United States, Canada, Mexico and the United Kingdom for a variety of crops, including tomato, canola, cotton, squash, soybeans and safflower.

Prior to coming to Arcadia, Dr. Redenbaugh was the Associate Director Regulatory Affairs for Biotechnology, Variety Registration and Research Contracts at Seminis Vegetable Seeds (later Monsanto); Biotechnology Industry Liaison at Iowa State University; and Manager Regulatory Affairs at Calgene, Inc. Dr. Redenbaugh received his Ph.D. in Forest Genetics from the State University of New York College of Environmental Science and Forestry and completed a post-doctorate study under Melvin Calvin and James Bassham at University of California, Berkeley. He has given over 150 invited talks on plant genetic engineering, food safety, regulatory affairs, plant cell biology, technology transfer, intellectual property, and variety registration. Dr. Redenbaugh has authored two books, 10 major regulatory submissions, 21 refereed papers and 37 book chapters and other publications. He holds 8 patents on artificial seeds and encapsulation.

Andrew Roberts, Ph.D.

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Dr. Andrew Roberts joined the ILSI Research Foundation in December 2009 as the Deputy Director of the Center for Environmental Risk Assessment (CERA), where his first tasks included developing tools and materials for use in training and capacity building related to the problem formulation approach to environmental risk assessment. He also authored the first in what has become a series of protein monographs reviewing the biosafety information available for proteins commonly used in genetically engineered plants.

Dr. Roberts serves as the coordinator of CERA’s capacity building projects under the USAID-funded South Asia Biosafety Program and the World Bank-funded Partnership for Biosafety Risk Assessment and Regulation in Bangladesh, Pakistan, and Vietnam. He also provides technical support for capacity building work in Brazil, India, Japan, Chile, and South Africa. Dr. Roberts is currently leading CERA’s scientific initiatives in the areas of ERA under low-exposure conditions and RNA interference. As of January 2015, Dr. Roberts was promoted to the position of Director of both CERA and CSAFF (Center for Safety Assessment of Food and Feed), with the goal of continuing collaboration between the centers, identifying opportunities to work with new partners both within and outside the ILSI family, and expanding the work of both CERA and CSAFF to applicable scientific areas beyond agricultural biotechnology.

Prior to joining the ILSI Research Foundation, Dr. Roberts worked at the U.S. Department of Agriculture in several different capacities, all related to the regulation of agricultural
Dr. Roberts received his Ph.D. in Cell and Developmental Biology from Rutgers University where he worked on signal transduction in the model nematode C. elegans.

V. V. Satyavathi, Ph.D.
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Dr. V.V. Satyavathi holds a Ph.D. from India. She is presently serving as a Technical Officer in the Centre of Excellence for Genetics and Genomics of Silkmoths and also in-charge for the APEDA CDFD Centre for Basmati DNA Analysis. She ventured into the field of genetic engineering and used the technology extensively to develop disease resistant crops during her post-doctoral research at the Indian Institute of Science, Bangalore and at the Agriculture Research Station, United States Department of Agriculture, USA. She has successfully engineered various crops for resistance against virus, fungus and insects, and developed genetically modified pigeon pea as a source of edible vaccine against Rinderpest and Peste des Petits viruses that cause diseases in ruminants and standardized Agrobacterium-mediated transformation technology for various crops like cotton, black gram and durum wheat. After joining the Centre of Excellence for Genetics and Genomics of Silkmoths at CDFD, she diversified her research towards understanding the molecular mechanisms underlying insect immune responses and was involved in the generation of baculovirus resistant transgenic silkworms. Towards this goal, she has actively been involved in taking forward the technology of transgenic silkworm lines that produce dsRNA for essential Bombyx mori Nucleopolyhedrosis virus (BmNPV) genes to combat baculovirus infection. She has been active in conducting multilocational field trials on transgenic silkworms with the help of collaborating institutes to establish efficacy of the transgenic lines and to generate data on biosafety related issues. She is a recipient of Department of Biotechnology BioCare award.

Ralph Scorza, Ph.D.
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Dr. Ralph Scorza was a research horticulturist, fruit breeder and leader of the Genetic Improvement of Fruit Crops Research Unit at the USDA-ARS Appalachian Fruit Research Station, Kearneysville, West Virginia, USA for 36 years. He received his B.Sc. and M.S. degrees in agronomy and plant physiology, respectively, from the University of Florida, and received his Ph.D. in plant genetics and breeding from Purdue University. His peach and plum breeding programs combined classical and molecular approaches to improve tree form, disease resistance, and fruit quality. Dr. Scorza and colleagues
developed the genetically engineered Plum pox virus resistant plum cultivar ‘HoneySweet’, approved for commercialization in the U.S., and he currently leads an international team that is working to submit ‘HoneySweet’ for cultivation approval in the European Union. He has consulted with researchers and governments in a number of countries on the development of and regulatory approval of genetically engineered horticultural crops. He is a co-developer of the ‘FasTrack’ breeding technology, a novel breeding approach that uses genetic engineering to reduce the time required for developing new fruit tree varieties at least by half. Taking fruit tree growing beyond our planet, he worked with NASA to adapt miniature fruit trees for long distance space flight and for Mars colonization.

Dr. Scorza is the recipient of the Flemming Award for “Exceptionally creative and useful research and leadership in the area of stone fruit breeding and genetics,” a recipient of an USDA-ARS Senior Research Scientist of the Year Award, and has been co-recipient of three U.S. Secretary of Agriculture Honor Awards. He is a recipient of the USDA Foreign Agricultural Service Distinguished International Service Award, and the U.S. National Peach Council Carroll R. Miller Award. He has developed and released 12 stone fruit cultivars that are currently marketed in the U.S. Dr. Scorza is the co-inventor of four biotech patents, and authored over 200 research publications. He is a Fellow of the American Society for Horticultural Science and in 2015 he was inducted into the USDA Science Hall of Fame.

Zeba Seraj, Ph.D.

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Dr. Zeba I. Seraj is a Professor of Biochemistry and Molecular Biology at the University of Dhaka. She works on the molecular biology of salinity tolerance in rice. In collaboration with both national and international institutes such as the Bangladesh Rice Research Institute (BRRI), the International Rice Research Institute (IRRI) and the International Centre for Genetic Engineering and Biotechnology (ICGEB), her plant biotechnology laboratory has produced saline tolerant rice using DNA-marker-assisted selection as well as genetic transformation. Some of these lines are under trial at ACI and BRRI. Recently her team has engaged in genomic selection, with the University of Texas, Austin, using modern sequencing technologies. Her lab and the International Centre for Diarrhoeal Disease Research (ICDDR) have produced stable mucosal vaccines using rice as a delivery system.

John Teem, Ph.D.

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Dr. John Teem was formerly a professor in the Biological Science Department of Florida State University where he worked on the human genetic disease cystic fibrosis. He subsequently left biomedical research to join the Florida Department of Agriculture and Consumer Services as an invasive species biologist. Seeing opportunities to apply molecular biology and genetics to eradicate invasive species, he has proposed, modeled and tested genetic methods for causing the directed extinction of
exotic species. His research led to a novel method for eradicating invasive fish by the use of a Trojan Y Chromosome strategy. His recent work involves development of genetic biocontrol for aquatic invasive species utilizing CRISPR/Cas9-mediated genome editing to eradicate invasive fish and snails in Florida. Dr. Teem joined the ILSI Research Foundation as a Senior Scientific Program Manager in 2016.

Willy Tonui, Ph.D.
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Dr. Willy Kiprotich Tonui is Chief Executive Officer at the National Biosafety Authority (NBA), Nairobi, Kenya. He is responsible for the day to day management of the Authority. The role of NBA is to regulate research and commercial activities involving GMOs in Kenya. Before joining NBA, he helped to establish a Biorisk Management and Dual Use Research (BIORISK-DUR) programme and Office of Health Safety and Environment (OHSE) at the Kenya Medical Research Institute (KEMRI).

Dr. Tonui currently serves as the Chair of the newly formed Association of National Biosafety Agencies in Africa (ANBAA). He has also served as the Chair of the Board of Directors for the global International Federation of Biosafety Associations (IFBA). He is also the Founder Member and Past President of the African Biological Safety Association (AfBSA), a professional association that seeks to congregate practitioners of biological safety, promote biosafety and biosecurity as a discipline through awareness and to facilitate the sharing of biosafety and biosecurity information in the African region.

Dr. Tonui studied for his B.Sc. in Biological Sciences and Chemistry at Kurukshetra University in India and his M.Sc. and Ph.D. in Immunology with a specialty in vaccine development from Kenyatta University in Kenya. He completed his post-doctoral training at the School of Veterinary Medicine at Colorado State University, United States. He has a career-long history of consistently supporting national programmes, regulations and policies in Kenya. He is a registered Expert on Environmental Impact Assessment and Audit (EIA/EA) by the National Environmental Authority (NEMA); and a Registered Biosafety Professional (RBP) ABSA. He is also an author of Laboratory Safety Handbook and three other books on Fire Safety and Prevention. For his distinguished service, he was recently decorated with the “Elder of the Order of the Burning Spear (EBS)” by the President of Kenya.

K. Veluthambi, Ph.D.
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Dr. K. Veluthambi is currently a UGC-BSR Faculty Fellow, of the Department of Plant Biotechnology, School of Biotechnology, Madurai Kamaraj University, Madurai, India. He completed his Ph.D. in 1981 at the Indian Institute of Science, Bangalore. He worked as a Postdoctoral Fellow in the United States during 1981-1988. During this period, he carried out research in the National Institutes of Health...
(Bethesda), Washington State University (Pullman) and Purdue University (West Lafayette).

After joining as a Faculty Member in Madurai Kamaraj University in 1988, he developed a strong teaching and research programme in Plant Biotechnology in Madurai Kamaraj University. His research interests are, (1) Mechanism of agrobacterium T-DNA transfer, (2) Molecular biology of geminiviruses, (3) Genetic engineering of rice for fungal disease resistance, (4) Selectable marker elimination in transgenic plants, (5) Gene targeting and (6) Transgene silencing and suppression of silencing. He superannuated from his services at Madurai Kamaraj University in June 2013.

Dr. Veluthambi is an Elected Fellow of the Indian Academy of Sciences (Bangalore), the Indian National Science Academy (New Delhi), the National Academy of Sciences – India (Allahabad) and an Elected Member of the Guha Research Conference. He is currently the co-chair of the Genetic Engineering Appraisal Committee (GEAC).

Ms. Khorsheda Yasmeen completed her B.Sc. Honours and Master of Science degrees in Geography from the University of Dhaka, Bangladesh. She also completed a Master of Science in Environmental Studies from the University of New Castle, NSW, Australia. She started her career as a Lecturer of Geography at the Government College under BCS (Education) cadre. After that, she joined as an Assistant Commissioner and Magistrate under BCS (Administration) cadre at the district level. She works primarily in the areas related to disaster management issues in different capacities, either policy making or implementing them at the local level. She is involved with the formulation of the Biodiversity Act, the Ecologically Critical Area Rules, and the Tanguar Haor Management Rules.

Ms. Yasmeen was also involved in developing course curricula for diploma and degree courses in Disaster Management. She prepared training modules on Disaster Management and has delivered presentations on climate change and management of aftermath: rehabilitation and reconstruction after a disaster as resource person in different public universities and training institutes under the Comprehensive Disaster Management Programme (CDMP).

At present, she is holding the position of Deputy Secretary at the Ministry of Environment and Forests (MOEF), Government of the People's Republic of Bangladesh. She is also working as the Member Secretary of the National Committee on Biosafety (NCB) at MOEF, alongside with other tasks including agricultural biotechnology and biosafety related issues. Before joining MOEF, she worked in various positions at the Cabinet Division, Ministry of Agriculture, Ministry of Education and Local Government Division.

During her career, she has attended different meetings and training courses held in Australia, Thailand, Kenya, Germany, India and France. She is also an active member of different professional societies, namely, a member of the resource pool in the area of ‘Disaster Management’ constituted by the Ministry of Public Administration, Bangladesh; an executive member of 13th Bangladesh Civil Service Administration Cadre; a member of the ad-hoc committee of the Bangladesh-Australia Alumni Association.
Strengthening Environmental Risk Assessment in Indian Biosafety Regulations

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Biosafety regulations in India are based on the “Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/Genetically engineered organisms or cells, 1989” notified under the Environment (Protection) Act, 1986. These rules are supported by series of guidelines issued by the Department of Biotechnology (DBT) and Ministry of Environment, Forest and Climate Change (MoEFCC). These guidelines address aspects related to research in contained facilities, confined field trials, food safety assessment, Institutional Biosafety Committees etc. and provide guidance to both applicants and regulators in dealing with biosafety issues.

In continuation to these efforts, MoEFCC in association with the Department of Biotechnology (DBT) have prepared a set of three documents to strengthen the environmental risk assessment of genetically engineered (GE) plants in India. These include Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016; Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders and Risk Analysis Framework, 2016.

The ERA Guidelines for GE Plants provide a comprehensive and science-based framework for identification of potential harms, collection of relevant scientific data pertaining to the nature and severity of any harm, and characterize the level of risk posed by GE plants. The accompanying Guide for Stakeholders has been prepared to provide additional explanatory material, illustrative examples, and references to scientific literature to provide a better understanding. The Risk Analysis Framework (RAF) describes the principles of risk analysis to
be used by the Regulatory Agencies to protect human health and safety, and the environment. RAF also includes concepts related to risk management, and risk communication in addition to risk assessment. The three documents put together provides a practical elaboration of risk assessment framework included in the Indian regulations in conjunction with Annex-III of the Cartagena Protocol on Biosafety, to which India is a Party. This presentation will highlight the salient features of these documents.

**Update on Biosafety Regulation in Bangladesh**

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The economic potential of modern biotechnology in agriculture, health, energy and the environment is well recognized. However, there are concerns that the genetically modified organisms (GMOs) derived from biotech may pose risks to human health and the environment. Moreover, mixing of genes from unrelated organisms might create an imbalance in the natural integrity of the living world. The policy of the Government of Bangladesh is address the potential risks arising from any kind of use of GMOs with utmost importance.

To address the issues of health and environmental safety associated with modern biotechnology, its products or its applications, Bangladesh has already put in place biosafety regulatory systems in accordance with the obligations under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD). The country is a party to the Protocol as it was ratified on 24 May 2000. The Ministry of Environment and Forest (MOEF) is the designated National Competent Authority and the focal point for implementing the Protocol.

The biosafety system in Bangladesh has been built upon transparent procedures for receiving applications, evaluation and decision making. A mechanism for monitoring, enforcing and providing information to the stakeholders as well as public awareness and participation has also been incorporated in the National Biosafety Framework. The biosafety system is comprised of various authorities, mainly, the National Committee on Biosafety (NCB), Biosafety Core Committee (BCC) and the Institutional Biosafety Committee (IBC).

The Biosafety Guidelines of Bangladesh were created to safeguard the interests of Bangladesh in relation to the potential risks associated with the use of GMOs and their introduction into the country. The Guidelines became a legal document with the enactment of the Biosafety Rules of Bangladesh. MOEF has already institutionalized the NCB that is responsible for decision making and overseeing the biosafety of GMOs. The BCC has also been operationalized to assist the NCB in terms of safe management of biotechnology activities in the laboratories and in the field, as well as during the commercialization of biotech products. IBCs and biological safety officers (BSO) are in place in the research establishments. Field level biosafety committees (FBC) have been formed for specific cases of confined trials with GM crops.

The concerned ministries that are working on the research and development of GMOs have operationalized National Technical Committees (NTC) in their respective areas of biotechnology. Such technical committees can review the technical merits of the applications and forward them to the NCB for final consideration. The technical committees working on promoting research and development of biotech are: the National Technical Committee on Crop Biotechnology (NTCCB) in the Ministry of Agriculture; the National Technical Committee
Update on the Biosafety Regulatory Framework in Bhutan

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Bhutan ratified the Cartagena Protocol on Biosafety (CPB) in 2002 and as fulfillment of the obligation to the Protocol, the Biosafety Act of Bhutan 2015 has been drafted with financial and technical support from UNEP-GEF through the National Biosafety Framework (NBF) Project from 2010-2014. The Bhutan Agriculture and Food Regulatory Authority (BAFRA) is the national competent authority for implementing of the NBF Project.

The application of economic potentials of modern biotechnology in agriculture, health, energy and environment are relatively new to Bhutan. However, some biotechnological applications are modestly used in various departments within the Ministry of Agriculture and Forests to address issues in the agriculture and livestock sector. Bhutan’s major concern is ensuring safety of the citizens and safeguarding its pristine environment and to address the biosafety concerns. Biosafety regulatory frameworks have been developed. A technical advisory group has been instituted to address national biosafety concerns. The Biosafety Act of Bhutan, passed in July 2015, addresses the Kingdom’s current interest and food security needs through the regulation of GMOs and GM products. This presentation provides an update on the regulatory frameworks for biosafety regulation in Bhutan, including the current biosafety scenario and the process for application handling and the administrative system.

The Current Status of Biosafety in Sri Lanka

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Sri Lanka is a small island in Asia which is classified as a biodiversity hotspot by Conservation International (CI). Its varied climate topographical conditions have given rise to rich species diversity, distributed in a wide range of ecosystems which can be broadly categorized in to forests, grasslands, aquatic, coastal, marine and cultivated. Therefore, it is vivid that Sri Lanka is wealthy in its biodiversity and its conservation is exclusive.

Modern biotechnology is applied to numerous fields in Sri Lanka, including agriculture for
increasing food production which should be adequate for the increasing population. But, there may be adverse effects from modern biotechnology on both biological diversity and human health. The term which addresses the prevention of large-scale loss of biological integrity, focusing both on ecology and human health is “biosafety”.

The Cartagena Protocol on Biosafety is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity. It was signed on 24th May, 2000 and it was ratified by Sri Lanka on 28th July 2004. The Biodiversity Secretariat of the Ministry of Environment acts as the national focal point in the implementation of the biosafety protocol in Sri Lanka.

In order to maximize the benefits and legitimacy of modern biotechnology by minimizing its potential risks, the Government of Sri Lanka implemented the "National Biosafety Framework Development Project" (2003-2005) which was funded by UNEP/GEF. The National Policy on Biosafety, which has been available since 2005, is a result of the National Biosafety Framework (NBF) and includes the commitment of the government to ensure adequate levels of protection in the safe use of modern biotechnology.

Based on the NBF and the National Policy on Biosafety, the Biodiversity Secretariat initiated the process for the development of the Biosafety Act in 2012 and formulated it in 2014. It is currently being reviewed at the Legal Draftsman’s Department. The draft Act stipulates that release of LMOs or GMOs should be undertaken in a manner that prevents or reduces risks to biological diversity and human health. It requires any exporter to notify the National Competent Authority in writing prior to the transboundary movement of LMOs/GMOs. It is a legal requirement to provide complete and accurate information of all required particulars in the application. The National Competent Authority, if it is deemed necessary, requires Sectoral Competent Authorities to carry out risk assessments on a case by case basis.

At the moment, until the Biosafety Act is enacted, some provisions in existing laws are used to control the introduction of GMOs.

The National Coordinating Committee on Biosafety (NCCBS) is comprised of relevant ministries as well as representative from NGO, and coordinates all matters related to biosafety including risk assessment. Six government organizations were proposed to serve as the Sectoral Competent Authorities (SCAs), namely; Department of Agriculture, Department of Animal Production and Health, Department of Health, Department of Fisheries and Aquatic Resources, Department of Wildlife Conservation, and Ministry of Industry. Qualified personnel from those departments are requested to conduct risk analysis when application of importation of LMOs is submitted. The Ministry of Health, in particular, is mandated to enforce regulations related to GM food under the Food Act and it also conducts inspection of GMOs for human consumption through random sampling by inspectors. The Customs Department and National Plant Quarantine Service also plays a significant role in controlling and the monitoring import of LMOs/GMOs to the country.
There and Back Again: Reversal by the Supreme Court on the Constitutionality of GM Crop Regulations and the New Challenge to the Philippine Biosafety System

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Seven months after the Philippine Supreme Court (SC) nullified in December 2015 the national regulations for the commercial development and use of genetically modified (GM) crops, it completely reversed itself and declared that said regulations are not unconstitutional. Meantime, during this period, five executive departments (ministries) drafted and issued new guidelines for the regulation of GM crops, which took into consideration supposed legal infirmities stated in the original SC decision. The new regulations remain fundamentally science-based but are relatively more stringent in terms of the conduct for environmental impact assessment, public consultations, and socio-economic considerations. How all these developments will play themselves in the currently evolving Philippine regulatory system for GM crops will be a challenge for both government regulators and technology developers in the future.
Nematode Resistant GM Crops Based on RNAi - Research and Regulation

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Globally, plant parasitic nematodes are responsible for considerable yield losses amounting to an estimated $173 billion annually. One of the most widely used approaches like chemical control is restricted due to government restrictions/prohibition of nematicides, owing to the harmful effects on environment and human health. Likewise, development of resistant plants also has limitations due to the restricted availability of resistant genes in majority of plant species and also lack of information on the resistance loci. Alternatively, nematode genes which are involved in infection, establishment and reproduction can be good targets for the development of resistant crop plants. Due to the inadequacies of current control measures, there is an ample opportunity for development of environmentally fitting and durable new generation management approaches tailor-made for controlling various plant parasitic nematodes, particularly for the most damaging species of root knot and cyst nematodes.

Recent efforts in sequencing of free living nematodes-Caenorhabditis elegans, C. briggsae- and several plant, animal and human parasitic nematodes has resulted in the availability of 21 whole genome sequences, EST derived transcriptomes of 62 species comprising more than 679,480 ESTs and 250,000 genes. The momentum also resulted in the completion of sequencing five important plant parasitic nematodes. The genomic information has been demonstrated to be useful for identifying genes involved in vital pathways of nematode life and disease cycles that served as potential targets for designing transgenic plants with required field tolerance or developing novel nematicidal molecule. There are different avenues for engineering plant resistance. RNA interference is one of them and silencing of nematode...
genes involved in infection, establishment and reproduction can be a plausible alternative for the development of resistant crop plants.

With the recent advent of gene expression control via small interfering RNA (siRNA) and micro RNA (miRNA) molecules, RNAi based transgenics have emerged as a strong alternative to suppress the menace of plant parasitic nematodes (PPNs). Demonstration of utility of RNAi by delivering double-stranded RNA (dsRNA) in the model non-parasitic nematode, C. elegans, has provided a great impetus for its application in PPNs. dsRNA delivery was accomplished by soaking the nematodes with dsRNA solution mixed with the neurotransmitters like resorcinol, octopamine, serotonin etc. Using in vitro dsRNA delivery approaches, down regulation of various housekeeping genes led to reduced parasitic ability, delayed egg hatching, impaired motility, and ability to locate and invade roots, demonstrated in root-knot, cyst, lesion, pine wilt and burrowing nematodes. The success of the in vitro dsRNA ingestion and down-regulation of the target genes inspired the in planta delivery of dsRNA to the feeding nematodes. The most convincing success of in planta delivery of dsRNA to feeding nematodes came from root-knot nematodes. Limitations of existing nematode management practices have paved the way for RNAi based approach for nematode suppression. Peptide based transgenics produce functional proteins which could have off target effects on non-target organisms but RNAi based transgenics are superior to that as it does not produce any functional proteins and targets organism in a sequence specific manner. Although RNAi based transgenics are still in the preliminary stage, it offers novel management strategies for the future. In this endeavour, our laboratory has undertaken identification and validation of several gene targets in Meloidogyne incognita involved at various stages of disease cycle comprising nematode infection, development and reproduction. These genes have been functionally validated by in vitro RNAi and potential ones expressed in planta for developing nematode resistant brinjal and tobacco. Similar studies have been also undertaken in cereal cyst nematode, Heterodera avenae infecting wheat. As the next important step, primary biosafety analysis done revealing the absence of unintended effects for demonstrating the safety of the transgenic brinjal events will also be discussed in the light of the existing/proposed global requirements.

**Experiences for Approval of Bt Brinjal in Bangladesh**

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Brinjal is a popular vegetable in Bangladesh. It is grown throughout the year and is consumed by both the rich and the poor. The main constraint for successful cultivation of this crop is the brinjal fruit and shoot borer (BFSB), *Leucinodes orbonalis* Guenee, that causes 30-70% loss of the crop. Generally, farmers use insecticides over 80 times in one cropping season to control this insect without significant success. Brinjal varieties resistant to this insect are not available.

Given the situation, the Bangladesh Agricultural Research Institute (BARI) under the aegis of the Agricultural Biotechnology Support Project II (ABSPII) led by Cornell University and with funding support from USAID, introgressed Cry1Ac gene (received from Mahyco) into nine local brinjal varieties. Backcross breeding continued for several cycles and BARI applied to the government for approval in connection with the commercial cultivation of four Bt brinjal varieties (BARI Bt brinjal-1, BARI Bt brinjal-2, BARI Bt brinjal-3, BARI Bt brinjal- 4). Bt brinjal went through the research and development (R & D) phases following the rules and
regulations of the country and got approval (four varieties) for limited scale commercial cultivation on 30th October, 2013. Upon approval, through its On-Farm Research Division (OFRD), BARI distributed seedlings to farmers of different districts for demonstration of the Bt technology under farmers’ conditions along with product stewardship. The technology has shown its promise under farmers’ fields. Bt brinjal showed zero to negligible infestation by the BFSB, while the non-Bt brinjal suffered heavy damage by the BFSB. Monitoring the performance of Bt technology at farmers’ fields is being done by BARI and the field level monitoring committee of the government. A follow up project of ABSPII called Feed the Future South Asia Eggplant Improvement Partnership led by the same university and same donor is facilitating the dissemination of the Bt brinjal to the large scale farmers.

The approval process that was followed for Bt brinjal will be discussed. Experiences gathered from R&D to limited scale commercialization of Bt brinjal will be highlighted.

**Recent Advances in Breeding Golden Rice in Bangladesh**

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Vitamin A deficiency (VAD) is a serious public health problem in south and south-east Asian countries, where rice, which lacks any of the vitamin A precursors, makes up nearly two-thirds of caloric intake. Golden Rice is a new type of rice that produces beta-carotene in the endosperm giving it a unique yellow-orange colour. Thus, Golden Rice can be a complementary, sustainable, food-based, approach to reducing VAD in high rice-consuming countries like Bangladesh. The Bangladesh Rice Research Institute (BRRI) is working for the development of locally adapted Golden Rice varieties in collaboration with the International Rice Research Institute (IRRI). In 2015, BRRI imported backcross introgression lines of Golden Rice event GR2E BRRI dhan29 from IRRI and tested these in contained screen-house facilities following approval by the National Committee on Biosafety (NCB). The purpose of this testing was to evaluate agronomic and phenotypic properties in comparison with conventional BRRI dhan29, and to measure carotenoid expression levels in the grain. Selected lines from the screen-house test were further evaluated in a confined field trial during the boro season in 2016. The tested lines were found to be very uniform in phenotype, with the majority of lines were quite similar to the recipient parent in nearly all traits. Phenotyping for kernel colour and genotyping with event-specific DNA markers showed that all the entries tested in this trial were homozygous for the GR2E locus. The transgenic lines yielded 6.2 t/ha to 7.7 t/ha with average of 7.0±0.38 t/ha, while the non-transgenic BRRI dhan29 yielded 7.0 t/ha. Total carotenoid content in milled rice after two months of storage at ambient temperature ranged from 8.4 – 14.4 ug/g with an average value of 11.2±1.12 ug/g. A short list of elite lines, selected on the basis of target carotenoid content in milled rice and agronomic performance, will be evaluated further in multi-location confined field trials, subject to regulatory authorization by the NCB. BRRI is also working to introgress the GR2E locus into other popular varieties. To help better adaptation, backcross introgression lines are being developed keeping all agronomic traits and resistance to major diseases and insect pests similar to those of the recipient varieties.
Potato Transgenics in India: Status and the Way Forward

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Potato (Solanum tuberosum L.) is the third most important food crop in the world. Though potato was introduced to India from Europe about 400 years ago, it has now emerged as a principal crop of the country. Today, India produces approximately 45 million tonnes of potatoes annually, thus making it the second largest producer in the world after China. Potato is perhaps the best example of a crop plant to which biotechnology has been most extensively applied in all aspects of production, germplasm handling and genetic improvement. ICAR-Central Potato Research Institute has a policy of using genetic transformation techniques for improving those traits that cannot be manipulated by conventional breeding. Intractable traits like late blight resistance, reduction of cold-induced sweetening, protein quantity/quality enhancement, and resistance to apical leaf curl virus were identified for developing transgenic varieties in potato. Event selection has been completed for each of the above four traits and permission for the BRL1 trial is pending from the Review Committee on Genetic Manipulation (RCGM).

For late blight resistance, the RB gene from the wild species S. bulbocastanum has been used and five promising clones (KJ-16, KJ-21, KJ-65, KJ-66, and KJ-77) showing a very high level of late blight resistance along with good agronomic characters and yield have been identified and advanced to the eighth clonal generation. Availability of RB transgenic potato varieties will be a benefit for resource-poor small and marginal farmers.

For reduction of cold induced sweetening, RNAi technology targeting vacuolar invertase was developed in the cultivar Kufri Chipsona 1. A confined field trial was conducted with seven such transgenic lines and one line possessing similar yield potential to non-transgenic control and desirable cold-chipping attributes after 90 days of cold storage, which was selected for further evaluation. Similarly, the grain storage protein gene (AmA1) of Amaranthus hypochondriacus has been used for enhancement of protein quantity and quality in potato. The AmA1 gene was transferred into eight Indian potato cultivars viz. Kufri Chipsona 1, Kufri Chipsona 2, Kufri Badshah, Kufri Sutlej, Kufri Jyoti, Kufri Pukhraj, Kufri Bahar, and Kufri Sindhuri. Yield of the transformed lines were at par with the control but protein content increased by 23-54%. For managing apical leaf curl disease in potato, RNAi technology targeting the replication-associated protein gene (AC1) of the virus was used to obtain pathogen-derived resistance. The glass house evaluation identified three transgenic lines of Kufri Pukhraj, that showed complete resistance to the Tomato Leaf Curl New Delhi Virus- Potato, causing apical leaf curl disease in potato. The status of the evaluation of the above transgenic lines will be discussed and a road map for biosafety and food safety evaluation will be elaborated during this presentation.
Climate change has become a major concern for India to ensure food and nutritional security. It is evident from the recent weather aberrations like droughts, floods, cyclones, heat waves, cold waves, and hail storms hitting one or the other parts of the country with more intensity and frequency. To meet the challenges of sustaining domestic food production in the face of changing climate and generate information on adaptation and mitigation in Indian agriculture and also to contribute to global fora like UNFCC, it is important to make concerted efforts. With this background, the Indian Council of Agricultural Research (ICAR), Department of Agricultural Research and Education, Ministry of Agriculture and Farmers Welfare launched a mega network project ‘National Innovations in Climate Resilient Agriculture’ (NICRA). Objectives of this project are to enhance the resilience of Indian agriculture to climatic variability and climate change through development and application of improved production and risk management technologies; to demonstrate the site specific technology packages on farmers’ fields for adapting to current climate risks; and to enhance the capacity of scientists and other stakeholders in climate resilient agricultural research and its application. The scheme involves 4 major components, specifically (1) strategic research (40 ICAR Institutes) (2) sponsored and competitive grants (16 + 20 Projects), (3) technology demonstration (121 KVKs, 25 AICRIPAM, 23 AICRIPDA Centers), and (4) capacity building and knowledge management. The entire program is coordinated and monitored by ICAR-Central Research for Dryland Agriculture, Hyderabad.
For strategic research component, programs have been taken up to identify the most vulnerable districts in the country to climate change. This includes assessing climate change impacts on livestock, fisheries, poultry and Natural Resource Management (NRM) and evolving adaptation and mitigation strategies. One of the major thrusts of the scheme was to build a state-of-the-art infrastructure for climate change research, such as High Throughput Plant Phenomics, Free Air Temperature Enrichment (FATE), Free Air Carbon Dioxide Enrichment (FACE), CO2 Temperature Gradient Chamber (CTGC), Eddy Covariance Towers, a network of 100 Automatic Weather Stations, Exclusive Satellite Data Reception System, Rainout Shelters, Animal Calorimeter, CO2 Environmental Chambers, Research Shipping Vessel etc. A simulation modeling approach is used to understand the climate change impacts on crops and livestock at national level. Significant achievements of the project so far include extensive field phenotyping of large number of germplasm in rice, wheat, maize, pigeonpea, and tomato to multiple abiotic stresses. The first ever Vulnerability Atlas of India at a district-level for all the 572 rural districts has been prepared. NRM interventions including biochar and conservation agriculture (CA) experiments have been initiated across the country. Emission reduction through efficient energy management is being attempted. Quantification of carbon sequestration by agroforestry, measurement of GHG emissions in the rice-based system and marine ecosystem is underway. Unique traits for thermal tolerance in livestock has been mapped. Heat care mixtures for poultry is ready for commercialization. The relationship was established between an increase in Sea Surface Temperature (SST) and catch and spawning in major marine fish species.

Location specific technologies developed so far by the National Agricultural Research System (NARS), which can impart resilience against climatic vulnerability, are being demonstrated under the technology demonstration component (TDC). This is being implemented in 121 climatically vulnerable districts through Krishi Vigyan Kendras (KVKs), along with the 25 All India Coordinated Research Improvement Project on Agro-Meteorology (AICRPAM) and the 23 All India Coordinated Research Improvement Project on Dryland Agriculture (AICRIPDA). A representative village in each district was selected for implementation as a model climate resilient village. An institutional arrangement in the form of the Village Climate Risk Management Committee (VCRMC) has been established for sustaining the activities envisaged and scaling up of interventions. NRM interventions included site specific rainwater harvesting structures in drought affected areas; recycling of harvested water through supplemental irrigation to alleviate moisture stress during midseason dry spells; improved drainage in flood-prone areas; artificial groundwater recharge and water saving micro-irrigation methods. Through these interventions, over 500 rain water harvesting structures were constructed/renovated/repaired and cropping intensity was increased by about 20% in several NICRA villages. Under the crop production module, demonstrations consist of drought and flood tolerant crop varieties, community nurseries for delayed monsoons, water saving paddy cultivation methods (System Rice Intensification and direct seeding), advancement of planting dates of rabi crops in areas with terminal heat stress, promotion of location-specific and risk-reducing intercropping systems with high sustainable yield index. Under the livestock and fishery module demonstrations on fodder production, especially under drought/flood situations, improved shelter for reducing heat stress in livestock, silage making methods for storage of green fodder and feeding during the dry season, breed selection and stocking ratios for fish production in farm ponds and monitoring of water quality in aquaculture and integrated farming system models in diverse agro-ecosystems are being taken up. Custom hiring centers were established to improve the timeliness of operations during the limited window periods of moisture availability in rain fed areas and to promote small farm
mechanization for adoption of climate resilient practices. These interventions helped farmers to reduce the yield losses and enhanced their adaptive capacity against climatic variability.

Massive capacity building programs were organized at the local and national level by the NICRA project partners across the country to sensitize climate change issues, provide information and empower various short-term and long-term strategies to combat climate change in the agriculture sector. The stakeholders include farmers, agricultural extension workers, NGOs, researchers and policy makers. The NICRA project supported implementation of some of the policy issues viz., Broad Bed Furrow (BBF) Technology in Maharashtra; million farm ponds in Andhra Pradesh & Telangana; ground water recharge initiatives in the Southern states; NABARD action plans; NICRA model village expansion in Assam etc. The Vulnerability Atlas developed under NICRA is being used by different Ministries and NGOs/CBOs. The NICRA partner institutes are contributing to the Biennial Update Report (BUR) of UNFCCC. The annual contingency planning workshops coordinated by CRIDA, in different states involving different stakeholders, helps in preparedness to face weather aberrations. NICRA is also contributing to national missions like NMSA, the Water Mission, the Green Fund and INDC.

**Developing Plant Resources for Stress Tolerant Molecular Breeding in Rice**

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The coastal areas of Bangladesh are home to many salt tolerant rice landraces, including both indica and aromatic subgroups, which showed allelic diversity at several genetic loci associated with the tolerance of common donors like Pokkali and Nona Bokra. One of these rice landraces, Horkuch, was previously characterized as salt tolerant at the seedling stage and reproductive stages, while was recently shown to cluster within the aromatic group of rice. Due to their allelic diversity, these rice landraces are likely candidates for contribution of alternate functional genes for salt tolerance as well as for pyramiding of additional loci to existing ones. The introduction of new sources of salt tolerance in breeding programs for rice are essential to ensure food security not only for the increasing rice-eating global population, but also the steadily rising levels of salinity inwards from coastal regions due to rising sea levels as a consequence of climate change. Horkuch was therefore used as source of tolerance in reciprocal crosses with the sensitive but high-yielding IR29 variety for discovering genetic loci as well as transcriptional variation associated with salt tolerance at the seedling and reproductive stages in the resulting populations. This was to find markers associated with multiple tolerance traits/QTLs, validate them using e-QTLs and to combine these in breeding lines for an enhanced level of tolerance.

An SNP linkage map was produced by ddRAD sequencing and associated QTLs were identified by model-based mapping. Traits and their associated QTLs like root dry weight, total chlorophyll, K/Na ratio and panicle architecture originated from Horkuch, while leaf senescence and yield related characteristics originated from IR29. A number of seedling and reproductive stage-specific tolerance QTLs were identified in single individuals of the population. These can now be used as donors directly or after further recombination. Gene-expression variation using RNAseq showed that tolerant plants uniquely showed upregulation of superoxide dismutase response, photosynthetic electron transport as well as K transport in seedlings and signaling and root membrane potential at the reproductive stage. e-QTL validation of these findings are underway.
In order to discover the uniqueness of Horkuch, we have also attempted to re-sequence its whole genome and that of IR29. The complete transcriptome of each of the parents under control and stress conditions was also analyzed to correlate unique genomic regions with gene function. Our future goal is to super-impose identified QTLs when the genome will be assembled for locating specific genes functioning in the tolerance mechanism of Horkuch.

Partnership for enhanced engagement in research-PEER-USAID funds and MBBISP fellowship to SME is acknowledged for this collaborative work.

Transgenic Strategies for Enhancing Abiotic Stress Tolerance in Grain Legumes: Retrospect and Prospects

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Restricted water resources and ever changing climatic conditions over the recent years are posing major challenges for producing more food on limited, arable land. Various forms of drought, including lack of sufficient irrigation, unpredictable rainfalls and terminal water stress alone, are responsible for major losses to global crop production, thereby affecting millions of small-scale and resource-poor farmers in the semi-arid tropics.

While developing drought tolerant cultivars could alleviate the economical strain of losses from these important crops, genetic improvement through conventional means is difficult because of their highly self-pollinating characteristics and highly conserved genomes with low polymorphism. Lack of understanding on the response of crop plants to varying water limiting conditions also is factor. To generate additional genetic diversity that may not be available in the crop germplasm, we attempted to enhance its drought tolerance in chickpea and peanut crops through genetic engineering options. The independent transgenic events with high transpiration efficiencies (TE) and desirable root and shoot traits were selected for further evaluations. The performance of transgenic plants was examined under a series of environments, including under glasshouse and confined field trials, to comprehensively study the component traits of drought, not only to evaluate but also to understand the stress adaptive mechanisms in these transgenic plants. The relationship between TE and its surrogate traits were explored, in addition to studying the role of biochemical changes in the anti-oxidative machinery under water-limiting conditions. Evaluations of the transgenic plants were based on their effectiveness in capturing the water, using the captured water for producing biomass via photosynthesis, and converting assimilate into a harvestable yield. Accordingly, a critical assessment of drought tolerance and yield under contained field conditions proved the effectiveness of these transgenic events that showed substantial yield improvement of at least 17% under drought stress without any accompanying yield penalty under irrigation. Details on various strategies to develop drought tolerant transgenic plants, and the results and scope of our own studies will be discussed.
Developing Climate-Smart Technologies for Smallholder Farmers in Africa: Recent Developments with WEMA Maize and NEWEST Rice

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Frequent droughts are a major element of climate change and a persistent challenge to African agriculture, making farming risky for millions of smallholder farmers who rely on rain fed crop production, thus threatening food security in Africa. Droughts have contributed to reduced crop yields, particularly maize, a major African staple food crop for over 300 million people, and rain fed rice a staple for over 20 million smallholder farmers. Identifying ways to mitigate drought-risk, stabilize yields, and encourage smallholder farmers to adopt best agronomic practices is fundamental to realizing food security and improving livelihoods for Africa.

The Water Efficient Maize for Africa (WEMA) partnership was formed to bring together expertise and technologies from public and private sector institutions for the benefit of smallholder African farmers. AATF leads the partnership that includes CIMMYT, Monsanto Company, and the National Agricultural Research Systems (NARS) of Kenya, Mozambique, South Africa, Tanzania, and Uganda. The partnership focuses on three approaches: a) developing new varieties using conventional breeding techniques including the production and use of doubled haploid technology; b) using molecular markers-assisted breeding including marker assisted recurrent selection (MARS), genomic selection and molecular marker discovery breeding; and c) the introduction of drought-tolerance and insect-pest transgenes into adapted varieties.

The Nitrogen-use Efficiency, Water-use Efficiency and Salt Tolerance (NEWEST) is a P-P-P-P project aimed to develop and disseminate farmer-preferred and locally-adapted rice varieties with triple stacked traits for drought-tolerance, nitrogen-use efficiency, and salt-tolerance. The partners led by the African Agricultural Technology Foundation (AATF), include Arcadia Biosciences, Public Intellectual Property Resources for Agriculture (PIPRA), International Center for Tropical Agriculture (CIAT) and the national agricultural research systems (NARS) of Uganda, Ghana and Nigeria. The climate-smart products of both projects will be deployed royalty-free to farmers through seed companies. To date, over 70 conventional drought-tolerant maize hybrids trademarked as DroughtTEGO® have been released in the WEMA countries and four are fully commercialized; while the introduction of the first transgenic Bt insect-pest protection hybrids trademarked TELA™ is scheduled for later in 2016 and the stacked transgenic drought-tolerant and Bt maize hybrids will be in 2017. The transformation of NERICA 4 rice has resulted in the development of fifteen N-Use Efficient (NUE) and 18 triple-stacked NEWEST events. The NUE events have been evaluated in 11 Confined Field Trials (CFTs) at three locations in Ghana, Uganda and Colombia. Details of the partnerships, strategies being used, and progress made in developing these Climate-Smart maize and rice varieties will be discussed.
Biosafety Considerations for the Use of Gene Drives in *Anopheles gambiae* for Malaria Control

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“Gene Drive” is a generic term for any genetic element that defies the rules of Mendelian inheritance and increases in prevalence in a population without selection pressure. Natural examples include transposons and other “selfish” genetic elements that are common in Eukaryotic genomes. Recent advancements in molecular biology, and particularly the development of the CRISPR/Cas9 gene editing tool, have made the use of artificial gene drives to alter populations in order to address human health and environmental protection goals a practical possibility. But before these technologies are developed and released into the environment they will need to be assessed for their potential to cause harm.

Dr. Roberts will review a three day workshop conducted by the ILSI Research Foundation, bringing together public health and human disease researchers, biotechnology regulators, entomology and mosquito biology experts in order to identify useful areas of investigation around the use of gene drives in *Anopheles gambiae* for controlling malaria.
CRISPR-Cas Enabled Advanced Breeding Technology

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CRISPR-Cas is one of the most important new technologies for advanced plant breeding, enabling us to help feed a growing global population. The superior properties of CRISPR-Cas allows DuPont Pioneer scientists to develop innovative and sustainable seed products for growers similar to those realized through marker-assisted plant breeding, but with even greater efficiency, accuracy and quality. Pioneer is leading the application of this tool to develop customized agriculture solutions that help solve the real challenges farmers around the world face in growing healthy and productive crops. Plant breeders have been creating new plant hybrids and varieties through plant breeding methods for many generations. CRISPR-Cas represents a more targeted way to evolve improved varieties using the best native characteristics available within the crop using prior knowledge of gene:phenotype relationships. This presentation will share how Pioneer scientists have applied CRISPR-Cas as an advanced breeding tool to efficiently develop Waxy corn hybrids directly in elite genetic backgrounds. Waxy corn produces a high amylopectin starch content, which is milled for a number of everyday consumer food and non-food uses. This next generation of elite waxy corn hybrids is expected to be available to U.S. growers within five years, pending field trials and applicable regulatory reviews. Other potential product targets of this promising technology will also be discussed.

Genetic Biocontrol for Snails Utilizing a Cas9-Mediated Gene Drive

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A “gene drive” is an application of the CRISPR-Cas9 genome editing tool that can be used to control or eradicate a pest species. By appropriately designing the configuration of both cas9 and its associated guide RNA in the genome of a pest organism, a genetic trait can be “driven” into a target population. The technique is presently being considered to genetically modify insect pests associated with agriculture or human disease, however, it can also be applied to snail pests causing harm to agriculture or human health. Potential applications of a cas9-mediated gene drive for the control of aquatic snails will be presented with a focus on reducing the transmission of the human parasitic disease schistosomiasis (involving the intermediate host snail Biomphalaria glabrata). An application of a gene drive for the control of invasive apple snails (Pomacea canaliculata) affecting rice production will also be considered.

Plant Breeding Innovation: Towards a Consistent Global Policy

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Internationally, there is a patchwork of national genetically modified organism (GMO) regulations. Some countries regulate specific technologies through GMO definitions. Other countries regulate based on the characteristics of the final product. Additionally, definitions for ‘GMO’, ‘biotechnology’, ‘genetic engineering’ and ‘bioengineering’ are not consistent across
countries. Due to these differences, products developed through newer breeding methods may be subject to different requirements for pre-market assessments and other requirements, such as labeling. Across countries this is negatively affecting research collaborations and hindering the movement of seed globally, and could lead to commodity trade disruptions. Enforcement issues are likely to increase because seeds and commodities developed with the aid of some newer breeding methods are indistinguishable from those derived from traditional breeding methods or natural occurring genetic variation.

Consistent government policies for products of newer breeding methods, such as gene editing, would facilitate the development and uptake of advanced, innovative breeding applications by both industry and public breeders in developed and developing countries. Plant breeders need legal certainty so they can reliably plan their breeding programs, their product development and market potentials. Disproportionate regulatory hurdles mean higher costs, especially for registration and approval which limit the access of small and medium sized enterprises (SME) and public plant breeding institutions to the latest plant breeding innovation tools. The seed industry is therefore focused on achieving a consistent approach to the scope of regulatory oversight for products of plant breeding innovation. The first step in this process is agreement among countries on the criteria that would be used to determine the scope of regulatory oversight. Once countries agree on the criteria, they may need to implement them differently, given the differences in current regulations around the world. For example, some countries will need to interpret definitions and others may need to redefine regulatory triggers.
South Africa’s Evolving Biosafety Regulatory System

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South Africa’s biosafety regulatory system has its origins in the now defunct South African Committee on Genetic Experimentation (SAGENE), initiated and led by the research community, which governed R&D on genetically modified organisms (GMOs) from 1979. The biosafety regulatory framework was formalised in 1999 in the form of the GMO Act (Nr 15 of 1997), which allowed South Africa to be an early adopter of GM technology, with the first commercial planting of a GM crop in 1998. The Act and regulations have since been amended to accommodate the provisions of the Cartagena Protocol on Biosafety and the overall biosafety regulatory system expanded to include aspect regulated under health, environmental and trade legislation.

It is fair to say that the spirit of the South African biosafety system is accurately captured in the aim of the GMO Act that was defined as being “to provide for measures to promote the responsible development, production, use and application of genetically modified organisms”. Positive attributes of the South African biosafety system include good representation, collaboration across diverse perspectives, a fair amount of adaptability to allow for extraordinary circumstances and the pro-active consideration of problematic and emerging issues. Matters that require improvement include communication, clarity regarding some protection goals and the unintentional discrimination against local innovators. These concepts will be further explored in the presentation with the aim to develop clear recommendations on how the South African biosafety regulatory system should continue to evolve to allow sustainable biotech innovation as envisaged in the national bio-economy strategy.
Indian Regulatory Framework – Evolution and Reforms

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India has been the pioneer to notify rules under the Environmental Protection Act 1986, for regulation of research, manufacture, use/import/export and storage of hazardous microorganisms/ genetically modified (GM) organisms or cells since as early as 1989. These rules provided a clear regulatory approval process at the Institutional level, State Governments level, and Central Governments level. The rules address scientific risk assessment in the Ministry of Science and Technology and accord final approval for environment release in the Ministry of Environment and Forestry. Interestingly, the rules also included constitution of an independent rDNA Advisory Committee of multidisciplinary experts to advise on biosafety issues with emerging technologies. Several guidelines, such as standard operating procedures (SOPs) for field trials, have been also published from time-to-time through a consultative process in harmony with international best practices. So far, 5 different versions of insect resistant GM cotton have only been approved; while several food crops are in pipeline. Following the approval of BGII cotton, during the period from 2005 -2016, the regulatory system experienced several challenges, including political, public policy, technical and socio-economic issues. Some examples include activist movement particularly on Bt Brinjal; the debate on a proposal to establish a separate “Biotechnology Regulatory Authority” through an act of Parliament; the Centre-State relationship in conducting field trials and adoption of GM crops; and the Supreme Court case questioning the credibility of the regulatory system. Many reforms have been implemented to address these challenges, particularly related to risk assessment and management, capacity building, infrastructure development and organizational restructuring. In this presentation, the developments in the Indian Regulatory Framework shall be discussed with the context of public perceptions as well as research and product development.

Biosafety Regulatory Framework in Kenya: Challenges and Approaches

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Globally, genetically modified organisms (GMOs) and specifically genetically modified (GM) crops are subjected to regulatory oversight during development, transfer, handling and use. In Africa, most GM crops regulations are based on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD). Kenya was the first country to sign the protocol and later domesticated it by publishing the National Biotechnology Development Policy in 2006. The Policy led to the development and enactment of the Biosafety Act No. 2 of 2009 which provided the legal and regulatory framework for the safe application of modern biotechnology. The Act established the National Biosafety Authority (NBA) to exercise supervision and control over the transfer, handling and use of GMOs with a view to ensuring safety of human and animal health as well as the provision of an adequate level of protection of the environment. The Authority has also published four Biosafety Regulations and other enabling tools to exercise its mandate. Whereas the process has been progressive, it hasn't been devoid of challenges. These include: submission of incomplete dossiers by some applicants; delayed feedback by some expert reviewers during review of the applications; policy decisions; limited
coordination among agencies regulating GMOs; limited public awareness and misconception on GMOs; biosafety laws that focus on crops with less attention to animals and biological materials; limited budgetary allocation; limited GMO detection capabilities; among others. This presentation will highlight the approaches that the NBA has employed to ensure seamless regulation of GMOs in Kenya.

Guidance for the Biosafety Regulatory Process in Bangladesh

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Bangladesh has had biosafety regulation for more than a decade, starting with the first publication of the Biosafety Guidelines in 2009 and carrying through subsequent revisions to those guidelines and the publication of Biosafety Rules in 2012. As the development of genetically modified crops in Bangladesh has advanced to include more research and development as well as the introduction of commercial products, beginning with Bt Brinjal in 2014 and more products in the pipeline, it has become clear that parts of the regulatory process are not always clear to stakeholders. As a result, there can be confusion about the processes and requirements for conducting research, importation of material and other regulated activities in Bangladesh.

The Ministry of Environment and Forests, in collaboration with the South Asia Biosafety Program and supported by the Department of Environment began a stakeholder consultation process in 2014 to better understand the needs of the regulated community with respect to regulatory process documentation. These efforts will culminate in the publication of Guidance for Biosafety Regulatory Process in Bangladesh. This does not reflect a new policy, but simply an enhanced effort to communicate regulatory procedure through a flexible and readily editable document that is simple and easy for stakeholders to understand.

Regulatory Challenges for Small Companies

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Since the launch in 1994 of the first, commercial, genetically engineered crop (Calgene’s FLAVR SAVR tomato), the agricultural biotechnology industry has consolidated from dozens of companies to six large ones (BASF Plant Science, Bayer CropScience, Dow AgroSciences, Dupont Pioneer, Monsanto and Syngenta), with further consolidation likely resulting in just four. Although small companies played major roles early in the development of agbiotech and the commercial launch of some of the first products, very few small companies are able to do this today. Two of the most significant hurdles are the high cost of obtaining global approvals and meeting the necessary stewardship requirements. This talk will focus on small companies and strategies for dealing with these hurdles. Examples will include a global crop and an identity-preserved crop.
Addressing Regulatory Challenges in a Federated System: An Australian Plant Science Industry Perspective

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Australia has a nationally consistent regulatory system for gene technology, comprised of the Commonwealth Gene Technology Act 2000 and corresponding State and Territory legislation. The federal laws were enacted to protect the health and safety of people, and to protect the environment, by identifying risks posed by, or as a result of, gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

The Federal Act does not take into account trade and marketing considerations, which are at the discretion of the states. This means that even when GM crops are approved by the Federal Regulator, each state and territory can decide, for trade and marketing reasons only, whether or not they are allowed to be grown within its borders. In 2003, licences were issued for the commercial release of two types of GM canola. All state and territory governments, except Queensland and the Northern Territory, subsequently enacted moratoria legislation to delay the release of GM canola until perceived trade and marketing concerns could be addressed. Since 2003, Ministerial exemptions to the moratoria to allow field trials of GM crops to take place have been granted in all states except Tasmania; and commercial production of GM canola has been permitted in Victoria and New South Wales since 2008, and Western Australia since 2010.

The Australian Government Productivity Commission has recently recommended that all state and territory governments repeal their legislation that puts in place moratoria on the commercial cultivation of GM crops. Ensuring there is a clear path to market and freedom to operate in Australia for developers of agricultural biotechnology products is an ongoing challenge for peak industry associations such as CropLife Australia.
Regulatory Data Generation, Analysis, and Interpretation

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The submission of regulatory applications for pre-commercial review of food, feed, and environmental safety represents the culmination of several years of product safety testing for genetically engineered plants. This presentation will focus on considerations for staging different types of regulatory studies throughout a typical product development process so that data are obtained as early as possible to inform relevant product advancement decisions. This includes discussion of the timing and usual approaches to studies on molecular-genetic characterization, assessment of the potential toxicity and allergenicity of expressed gene products, determining likely exposure pathways and magnitudes of dietary and/or environmental exposure to newly expressed proteins, and comparative nutrient and phenotypic analyses. The application of appropriate statistical methods and the interpretation of data within the safety/risk assessment framework are also discussed.

Writing Regulatory Dossiers: Good Reports, Good Dossiers, Good Stories

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The development of a genetically modified crop (GM) product is a long and involved process. The very last stage is the gathering of data for regulatory dossiers that will be submitted to gain approval for importing or releasing the product into the environment. Thus, it is very
important to ensure that all relevant data gathered are properly recorded and that regulators are provided with dossiers that clearly describe the product, the data collected, what the data mean and whether the proposed use of the product could pose any risks to humans, animals or the environment. This talk will describe the basis that form the foundation of good regulatory dossiers and the main considerations to take into account for preparing and presenting good dossiers.

**Development of a Genetically Engineered Virus Resistant Fruit Tree: From Concept to Product Release**

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Genetic engineering (GE) can target specific genetic improvements and allow for the development of novel, useful traits. In spite of the potential utility of GE for fruit tree improvement, the technology has not, to date, been widely exploited for cultivar development due, in part, to the reticence of researchers to become involved in the regulatory process. Over the past 20 years an intensive international research project focused on the development of GE resistance to Plum pox virus (PPV) the causative agent of Sharka, one of the most destructive diseases of plum and other stone fruits. This effort resulted in the development of the ‘HoneySweet’ plum, a GE variety that has proven to be highly resistant to PPV, as demonstrated in over 15 years of field testing in the U.S and Europe. In order to make this variety available to breeders and growers in the U.S., dossiers were submitted to the U.S. regulatory agencies. This process ultimately led to the U.S. regulatory approval of ‘HoneySweet’. The work with ‘HoneySweet’ demonstrates that the regulatory process, while a significant effort, can be successfully navigated by public institution researchers. Nevertheless, the few examples of success demonstrate a need for public institutions to find ways to encourage, support, and reward researchers who pursue deregulation efforts. The long-standing successes of virus control in squash and papaya, and the current work with plum demonstrate the power and the safety of GE for horticultural crop improvement. The commitment of researchers, institutional support, clear, science-based regulatory frameworks that build upon a developing knowledge base, industry support, and public outreach are components that are now necessary to move this technology forward to improve agricultural production and its sustainability.

**Testing of GE Silk Moths: Challenges in Interpreting Regulatory Requirements**

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RNA interference (RNAi) technology has emerged as a potential tool for the protection of hosts against various pathogens, and probably requires fewer biosafety issues as no transgene
protein is expressed. However, the progression of a proof of concept to its final implementation in the field includes many technical challenges before the application can pass through the regulatory process.

Using RNAi, the Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad, has previously generated genetically engineered baculovirus resistant silkworm (Bombyx mori) lines expressing double-stranded RNA (dsRNA) for multiple essential viral genes using piggyBac mediated germline transgenesis. Despite the fact that silkmoths are domesticated, do not fly, and are reared only indoors, the implementation of regulatory requirements for compliance management of transgenic silkmoths represents a challenge as an internationally acceptable dossier is required to ensure safety for humans and the environment before commercialization of the product. The development of genetically modified B. mori lines began in the laboratory and then passed on to user dependent sericulture centres for maintenance. After deliberate testing by repeated viral infections, the transgenic lines with the best event were selected for further testing under different environment conditions. The implementation and moving forward such a technology as RNAi includes conducting studies as per the guidelines of the regulatory authorities, testing of efficacy of the transgene at multiple locations followed by farmer’s field trials, compilation of the data for seeking other regulatory approvals, dossier preparation and consultations with experts in multiple disciplines.

This presentation will review existing guidance on the safety assessment of genetically modified insects, identify the differences with methods that would be applicable to silkmoth, detail the challenges with respect to interpreting regulatory requirements and assess risk factors.

**Building Support for our Science: Four Keys to Successful Stakeholder Engagement and Communication**

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Communications opportunities and challenges emerge at each stage of a biotechnology project – from basic research through field trials to regulatory review and commercialization. Keeping a low profile seems prudent early on, when results are not yet published and other tasks have higher priority. Many project teams do not have dedicated resources or expertise in communications. Eventually, however, stakeholders must be informed. Public notifications or comment periods may be required, often in environments where other projects or the technology itself is already subject to debate. There are four keys to successful stakeholder engagement and communication at every stage of biotechnology projects – Messaging, Visibility, Allies, and Issues. Case studies from projects in Asia and Africa show that even basic plans in each of these areas, evolving as the project progresses, can reduce risks and contribute to the success of core research and development activities. Proactive communication and outreach supports our science and helps ensure that we reach those most in need of improved crops.
The 4th Annual South Asia Biosafety Conference Poster Program is an opportunity for individuals to share their research, findings and achievements with colleagues at the conference. The 1st Place Winner will be sponsored to participate in the 14th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO), to be held in Guadalajara, Mexico in 2017 along with a two-year membership to the International Society for Biosafety Research (ISBR). The 2nd Place Winner will receive a two-year membership to ISBR and a USD $100 cash prize.

Baseline Susceptibility to Bt Cry1Ac Protein of Eggplant Fruit and Shoot Borer (EFSB), Leucinodes orbonalis Guenée (Lepidoptera:Crambidae) in the Philippines

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The use of Bt technology is one of the innovative options for the management of the eggplant fruit and shoot borer (EFSB), the major insect pest of eggplant in Asia. Bt eggplant from event EE-1 produces the insecticidal crystal protein (Cry1Ac) from Bacillus thuringiensis (Bt) that has been shown to be highly effective in preventing damage by EFSB. To ensure the durability of this product, one of the requirements for resistance management is to determine the sensitivity of EFSB to Cry1Ac over time. Nine EFSB field populations were collected during growing the seasons of 2012 to 2013. Neonates were exposed to artificial diet treated with increasing Cry1Ac concentrations and dose-response curves for lethality and growth inhibition, evaluated after 7d, were determined. Median lethal concentrations
(LC50) for the different populations ranged from 0.12 to 0.18 ppm (0.07-0.51, 95% fiducial limit) for nine populations of EFSB. Although interpopulation variation in susceptibility to Cry1Ac was observed, the magnitude of the differences was small (< 2-fold). Interpopulation susceptibility to Cry1Ac indicated by growth inhibition was measured in terms of molting inhibitory concentration (MIC50). Results ranged from 0.04 to 0.21 ppm, also a small (5-fold) variation. These bioassay results document that the EFSB populations tested were very susceptible to Cry1Ac prior to commercial deployment of Bt eggplant in the Philippines.

**Biosafety Resource Kit for Genetically Engineered Plants**

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Enhancing public awareness on biosafety issues is one of the key thrust areas of the Phase II Capacity Building Project on Biosafety. As part of the project activities, a Biosafety Resource Kit for Genetically Engineered (GE) Plants has been developed by the Ministry of Environment, Forest and Climate Change in association with Biotech Consortium India Limited to provide basic information on GE plants, confined field trials, regulatory framework in India, Cartagena Protocol on Biosafety and useful resources for safety assessment. The Biosafety Resource Kit has been prepared with an objective to serve as a useful resource tool for promoting public understanding about biotechnology and biosafety among various stakeholders by information dissemination.

The Biosafety Resource Kit consists of five brochures: (1) Cartagena Protocol on Biosafety: An overview; (2) Regulatory Framework for GE Plants in India; (3) Frequently Asked Questions about GE Plants; (4) Confined Field Trials of GE Plants; (5) Accessing Information/Databases: Useful Resources for Safety Assessment of GMOs.

**Communicating Biotechnology and Biosafety to Grass Root Level: Strategies for Information Dissemination**

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Phenomenal scientific progress has been made globally in the last decades yet, most of the research information is not translated into workable knowledge for the non-scientists. Science communication and public awareness are two independent systems, which allow the unilateral flow of information from science to society. For scientific outreach, the communication should address the needs of the audience, using appropriate language and information levels. The interactive and informative tools including print, electronic and social media should be explored to reach the end user and stakeholders. Also, dedicated capacity building programs should be designed for large scale dissemination.

The outreach and public awareness in multilingual-multicultural countries like India is difficult, owing to the prevailing diversity. To bridge the gap between lab research, journal publications and non-scientific stakeholders, CABI and MoEFCC have prepared a resource catalogue for awareness generation on GMO for a wide variety of stakeholder groups as a part of the Public Awareness component of the MoEFCC implemented UNEP-GEF funded ‘Capacity Building..."
Project on Biosafety’ Phase II. The catalogue has been carefully designed to addresses the barriers of language, literacy and dialect by making the use of electronic and print media and translation of the documents in local regional languages of key agricultural-states. Strictly peer reviewed, the contents of the catalogue aim to deliver a simplified, scientifically validated and actionable information to various stakeholders exploring the use of print and electronic media with diversity of deliverables. These include an animation on GM crop production, infographics, brochures, pocket guide, etc. Through these deliverables, an attempt has been made to establish a two-way, unimpeded flow of information which is imperative for strengthening scientific facts but also to maximise the impact and reach of research to people.

**Comparative Analysis of Nutritional and Anti-Nutritional Composition of Bt Eggplants and their Non-Bt Counterparts Grown in Field and Greenhouse Trials in the Philippines**

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One of the requirements for food safety analysis of genetically modified (GM) crops is documenting the substantial equivalence of nutritional and anti-nutritional contents in a GM crop compared to its non-GM counterpart, or to those that have historically been regarded as safe. Eggplant (=brinjal), like potato, is part of the Night shade family, which are glycoalkaloid producing plants. Bt eggplant containing event ‘EE-1’ produces the Cry1Ac protein to prevent major damage and yield loss caused by the eggplant fruit and shoot borer (EFSB), Leucinodes orbonalis Guenée, the most serious pest of eggplant in SE Asia. In this study, Bt eggplant F1 hybrid marketable fruits from field and greenhouse trials in Laguna, Philippines were harvested. Oven-dried ground slices of marketable fruits from the field were sent to service laboratories for proximate, mineral and total dietary fiber analyses while freeze-dried ground marketable fruits from both field and greenhouse were sent for amino acid composition, anti-nutrient, and specific glycoalkaoid (solasonine and solamargine) analyses. Higher potassium levels were measured in Bt eggplants compared to non-Bt counterparts in marketable fruits from the field, but were within the tolerance interval of the non-Bt counterparts and within published literature ranges of eggplant compositions. Other analytes measured in Bt eggplants, including glycoalkaloids, were not significantly different from the non-Bt counterparts in both field and greenhouse samples. Based on the eggplant fruits produced and collected from the field and greenhouse trials, the chemical compositions of Bt eggplants are substantially equivalent to their non-Bt counterparts.

**Comprehensive Biosafety Analysis of Transgenic Brinjal Expressing Dsrna to Silence Critical Genes of Meloidogyne Incognita**

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Root knot nematodes belonging to the genus Meloidogyne are the most devastating group of plant parasitic nematodes and the key economically important species is M. incognita whose genome has been sequenced along with stage specific transcriptome. This sequence information has become invaluable for comparative genomics to identify and select a plethora
of gene targets involved in both life and disease cycle of the nematode. Gene silencing using RNA interference is one of approaches to utilize the nematode genes for developing tolerant crops to overcome the nematode inflicted yield losses. In this direction, we have identified and demonstrated in brinjal that RNAi silencing of msp1, a gene expressed in the esophageal glands and two neuropeptides (FMRF amide like peptides) of M. incognita provide significant promise to reduce the nematode population densities in the field. These transgenic brinjal events have exhibited a great potential in reducing the nematode reproduction due to which, they will be highly promising to bring down the nematode population buildup in fields thus is a great advantage to reduce the initial nematode population pressure for the successive crop under field conditions. In view of this, demonstration of safety of these transgenics to both the humans and the environment becomes a prerequisite for commercial exploitation. Framing risk assessment strategies is challenging in the case of RNAi transgenics due to the lack of protein expression. Based on the deliberations in this direction, we have emphasised mainly on the effect on off-targets and the non-targets. Though information about this could have been generated prior to the development of these transgenics, stringent risk assessment is required based on the food chain components on a case by case basis. Standard operating procedures (SOPs) to check the off-target and non-target effects will therefore form a major criterion in risk assessment of transgenics developed through host delivered RNAi. However, preliminary in the pipeline would be selection of the transgenic events that are normal both phenotypically and physiologically. This refers to the transgenics being ‘substantially equivalent’ to its non-transgenic counterpart. A number of non-interactive procedures serve as means to ward off unintended effects in the events that could occur either due to the positional effect of the T-DNA integration or the dsRNA itself. Proteomic and metabolomic profiling measuring the metabolic end point quantification can be also used as tools that invariably decide the event selection. Any unintended effect can be easily identified by comparative proteomic profiling which also precisely identifies the protein that has resulted in producing the unintended effect. Risk analysis of the transgenics developed in our laboratory to silence the critical genes in M. incognita is being undertaken addressing these issues. Additionally, physical exposure of the dsRNA and its environmental persistence is equally important in case of RNAi transgenics. Therefore, the effect of the RNAi transgenics on the soil microflora in the vicinity of the plant has been done to establish the safety of the transgenic events.

Confined Field Trials of Genetically Engineered Plants in India: Overview of Compliance Requirements

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Confined field trials of genetically engineered (GE) plants are a crucial step in biosafety evaluation and data generation of a GE plant. As part of the ICAR project on “Biosafety Awareness and Compliance Readiness”, sequential steps to be undertaken by scientists for conducting CFTs have been outlined to ensure compliance during the conduct of confined field trials. The steps are in line with Guidelines and Standard Operating Procedures (SOPs) for conduct of Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008.
**CRISPR-Cas Gene Editing - Advanced Breeding Tools that Challenge the Regulatory Paradigm**

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Innovations in plant breeding have improved crop productivity several folds in last few decades. Recent developments in gene editing tools, specifically CRISPR-Cas enabled precise alterations are a next step in advanced breeding. CRISPR-Cas system creates breaks at specific, pre-determined locations in the host genome. This can be used to switch off the target gene, tweak its function favorably, replace with, or add an exact desired sequence. CRISPR-Cas gene editing tool has been shown to function effectively in a number of crop species including wheat, rice, maize, and sorghum. In this poster, we present global regulatory views on potential applications of CRISPR-Cas enabled advanced breeding. This advanced breeding technology may help in development of products for greater environmental resilience with characteristics like disease resistance and drought tolerance. This can be done directly in elite crop varieties thus helping in enhancing yield potential and decreasing time consuming back-crossing. CRISPR-Cas enabled products pose a paradigm shift in regulatory thinking and offer an opportunity to align on appropriate science-based regulatory policies for advanced breeding technologies. Many applications of CRISPR-Cas enabled advanced breeding are based on modifying plant’s own genes without introducing any foreign DNA sequences into the final organism. Furthermore, many of the CRISPR-Cas enabled products are indistinguishable from those that could be obtained from the inherent genome variability or produced via traditional breeding, albeit in much less efficient way. Global regulatory agencies continue to refine and develop regulatory policies for CRISPR-Cas enabled advanced breeding products. United States Department of Agriculture (USDA) has recently opined that specific CRISPR-Cas enabled corn and mushroom products produced by switching off the target gene of interest were not regulated by agency’s Biotechnology Regulatory Services. This poster will provide an overview on the current status of the regulatory agency activity in different countries with regard to advanced breeding technologies. A consensus among global regulatory bodies and a harmonized approach will help enable utilization of this breakthrough technology to its fullest.

**Crop Specific Biology Documents**

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Genetic engineering is being used as a tool for making crop improvements, more precisely by the plant breeders and scientists worldwide. The assessment of the risks associated with the genetically engineered (GE) crops is a prerequisite for qualifying towards approval for commercialization and being placed on the global market. The international best practices adopted for ensuring safety of GE crops is based on the comparative approach wherein the assessment evaluates any risks posed by GE crop in comparison to the risks posed by its counter non GE crop. The crop specific biology document provides information about the biology of the non GE crop to facilitate the comparative assessment and help risk assessors/regulator’s to identify any unintended effects that may have resulted due to genetic engineering.

The Ministry of Environment, Forest and Climate Change (MoEF&CC) initiated the preparation
of series of crop specific biology documents as resource documents to be used during biosafety evaluation of GE crops. Five biology documents viz., Brinjal, Cotton, Maize, Okra and Rice were prepared earlier by MoEF&CC in association with Department of Biotechnology (DBT). Now under the UNEP/GEF supported Phase II Capacity Building Project on Biosafety, MoEF&CC has prepared additional eight crop specific biology documents viz., Chickpea, Mustard, Papaya, Pigeon pea, Potato, Rubber, Sorghum and Tomato in association with the respective crop research institutions. These biology documents provide information about the nomenclature of the crop, geographical origin, reproductive biology, its related species including wild relatives, potential for gene introgression, important insect-pest & diseases etc. Such species specific information is expected to provide baseline information, to serve as a guiding tool for use in risk assessment of GE plants for comparisons with their non GE Comparator.

**DA-CPC: A Computational Method of Safe Target Identification for Development of Rationally Designed Agrichemicals and GMOs Expressing Toxins**

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Development of GMOs expressing toxins against pests and pathogens requires careful selection of the pathway or the protein in the target organism. Selection of a target protein that is directly or indirectly causing infestation or crucial for its survival would ensure effective control and its absence in the host plant eliminates the risk of phytotoxicity. However, for ensuring bio-safety, one has to go beyond the host-pest/pathogen system to the ecosystem with numerous beneficial as well as non target organisms including humans. In the context of availability of human genome and easiness to obtain the whole proteome of pests and pathogens through NGS platforms we envisioned a ‘Domain Architecture based Cross Proteome Comparison (DA-CPC)’ as a quick and handy method for identifying targets which are unique to the pest and therefore safe to humans. Here we present a cross proteome comparison between insects and human by assessing the similarities in structural domain compositions known as ‘Domain Architecture’ through a Domain Architecture Similarity Index. Using a program developed for a domain architecture comparison, we identified different sets of proteins which can be further evaluated for their suitability as a potential targets. First category is of the protein architectures that are unique to insects ie, none of them are present in human. They are unique in terms of their domain content and hence have the potential to be the safest targets provided they are essential for the biological functioning of the insect. Subsequently, two sets of protein domain architectures in insects with decreasing levels of similarity to that of human were identified. In future, this could be extended to the identification of unique protein pool of a specific insect pest in comparison with beneficial insects and other animals. Considering the simplicity of the computational approach like DA-CPC can be compulsorily undertaken as a pre-Genetic engineering activity when planning to express toxins against pest/pathogens in order to ensure maximum biosafety by minimizing off-target effects.
Development of Fungal Disease Resistant Peanut (Arachis hypogaea L.) through Agrobacterium-mediated Genetic Transformation

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Peanut is a major edible oil seed crop that is grown predominantly under rainfed conditions. It is one of the major legumes securing the third largest source of edible oil. Apart from the oil production, it is also used as a source of high nutritive supplements. In addition, peanut also contains good antioxidants. Although peanut is considered as an important legume crop for many parts of the world, its production in most countries is usually characterized by low yield potential. In Bangladesh, the cultivated peanut faces drastic yield loss every year due to fungal infection. The development of fungal-resistant varieties of peanut is a dire need to increase the productivity of this important crop. Previous reports indicated that apparently all attempts to develop disease resistant peanut using conventional breeding techniques did not yield the desired results. This was mainly due to the lack of genetic variability, which was caused by a predominantly high degree of self-pollination and absence of resistance gene/s of interest in the existing germplasm. To achieve this objective, the focus of this study was to pyramid fungus resistant traits in a high yielding peanut variety by over expressing an antifungal responsive gene through Agrobacterium mediated genetic transformation. Stable integration and expression of the antifungal gene was checked in the transgenic peanut plants by using PCR and RT-PCR, respectively. After analyses eight T0 transgenic lines were identified. These transgenic lines are being grown in the insect proof nethouse following biosafety principles applicable for contained condition. Further bioassay for the anti-fungal trait would be carried out in contained laboratory conditions by maintaining proper biosafety level. Finally, promising transgenic lines would be tested in confined field trial to generate relevant data for open field trial. Taken together, this strategy could be used to ascertain the feasibility of a trait pyramiding strategy for the development of an anti-fungal resistant peanut.

Development of Sugarcane Transgenics for Improved Water Deficit Stress Tolerance and Biosafety Related to Sugarcane Transgenics

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Drought is one of the most challenging agricultural issues limiting sustainable sugarcane production and can potentially cause up to 50% yield loss. Sugarcane is one of the high water demanding crops. Genetic improvement through conventional breeding for abiotic stress tolerance in sugarcane is constrained due to the complex nature of abiotic stress tolerance (timing, duration, intensity, frequency) along with the genetic complexity of the crop. Hence, abiotic stress related genes viz., heat shock protein 70 (HSP70), DREB2 and DNA helicase 45 were used to transform one of the most popular sugarcane variety (Co 86032) in tropical India through Agrobacterium-mediated transformation and pyramiding of these genes using particle bombardment. Expression of these genes in transgenic events was driven by Port Ubi 2.3 promoter cloned from wild rice (Porteresia coarctata). The transgene integration was confirmed through polymerase chain reaction. More than 100 transgenic events were screened for tolerance to soil moisture stress at the tillering phase by withholding irrigation. Our studies have shown that over expression of these genes enhanced the drought tolerance in the sugarcane variety Co 86032 under water deficit stress condition. Physiological, molecular and morphological parameters were used to assess drought tolerance. Transgenic events
were evaluated for cell membrane thermostability, relative water content, gas exchange parameters, chlorophyll content and photosynthetic efficiency compared to untransformed wild-type (WT). The overexpression of transgenes in sugarcane also led to the upregulation of downstream stress-related genes. Sugarcane is the central source of sugar or sucrose in India. In the process to obtain sugar, sugarcane juice is subjected to very high temperature that results in degradation of proteins. Therefore, sucrose is purified product free from proteins. In the present study, the genes of interest namely DREB2 and HSP70 were cloned from Erianthrus arundinaceus, a wild relative of sugarcane and DNA helicase was cloned from Pea. Therefore, it is expected that these transgenics could be safe to environment. Due to vegetative propogation, transgene could be fixed in the first generation. Moreover, no reports of pollen transfer from cultivated sugarcane to its wild relatives and rare natural seed sett occurs across the country. Hence, biosafety issues are relatively low with sugarcane transgenics and development of crop specific regulation would help in reaching the technology to the farming community.

**Development of Three Bt Eggplant Varieties as Genetically Engineered Crops in Bangladesh**

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Cry 1Ac gene was back crossed from EE1 in nine popular eggplant varieties of Bangladesh in 2004-05. Back crossing, selfing and multi-location trial were done from that time to till date to examine the varietal performance and efficacy of Bt eggplant on infestation by BSFB under open field conditions in comparison with non Bt versions. Standard procedures as suggested by National Biosafety Committee (NBSC) were followed during contained and confined field trial. At the field trial, number of non-infested fruit per plant and marketable fruit yield per plant were higher in Bt lines than that of non Bt version. Strip test and ELISA method were followed to test whether the presence of Cry1Ac gene in the Bt version. There was no incidence of eggplant fruit and shoot borer in Bt version. In the year 2013-14, BC3F8 generation have been developed from BC3F7 generation. Considering the homozygosity, three varieties viz., BARI Bt Begun 5, BARI Bt Begun 6, BARI Bt Begun 7 were proposed for release as more new genetically engineered eggplant variety. Generation advancement of these lines was carried out at the confined field trial of BARI, Gazipur. Oviposition preference test and direct infestation method were applied to determine the effectiveness of Bt transgenic lines against field collected BSFB populations. No infestation was observed during 2011-12 to 2013-14. Lowest infestation observed in bt lines compare to non-bt version in Direct infestation method. It was also evident that there was no significant difference in susceptibilities or resistant reaction to root-knot nematode infestation in Bt lines. Post-harvest soil analysis revealed that the bacterial population was significantly higher in all Bt eggplant varieties than non Bt eggplant varieties. The Rhizobial and Azotobacter population remained more or less same in both Bt and non Bt plot. It may be concluded that the Bt gene has no detrimental effect on soil microbial population. Distinctiveness, uniformity, stability and homozygosity etc. were considered in this trial. The plants of BARI Bt Begun 5 were found as erect type of plant stem with green colour, solitary type of flower, fruit oval and green colored with white spot at bottom end and glossy, prolific bearer (30-35 fruits/ plant) and yield is about 45-50 t/ ha, while BARI Bt Begun 6 were found as erect type of plant stem with purple colour, solitary type of flower, fruit cylindrical, purple colored and glossy, prolific bearer (30-35 fruits/ plant)
and yield is about 45-50 t/ha. BARI Bt Begun 7 having erect type of plant stem with purple colour, solitary type of flower, fruit cylindrical, deep purple colored and glossy, prolific bearer (35-40 fruits/plant) and yield is about 45-50 t/ha. No further varietal purification for these Bt lines are needed. Breeders expressed their satisfaction about the performance of Bt lines and proposed to release as three new genetically engineered varieties.

**DNA-Based Detection of Genetically Modified Maize Events: For Effective Risk Assessment and Management**

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The global area under cultivation of GM crops has reached 179.9 million hectares, out of which 29% of the area is of GM maize with the highest number of approved GM events (148 events). In India, the highest number of imports for research purposes are of GM maize, which account for more than 35% of the total imports. With the increased number of GM maize events and the diversity in transgenic elements, rapid, efficient and reliable methods for detection of GM maize events are necessary for risk assessment, management and post-release monitoring. GM diagnostics based on the matrix-multiplex PCR, real-time multiplex PCR and loop mediated isothermal amplification (LAMP) for screening of GM maize events have been developed. The GMO matrix for more than 140 GM maize events with 75 genetic elements has been developed as a decision support system and based on the information included in the matrix, tetraplex PCR assay was developed for screening of more than 90% of the maize events. This cost- and time-efficient approach can be employed by low resource GM testing laboratories, particularly in developing countries. SYBR® Green-based multiplex real-time PCR assay has been developed for rapid and simultaneous detection of selected GM maize events. Visual and real-time LAMP assays have also been developed for event-specific on-site detection covering 64% of stacked GM maize events commercialized globally. For risk assessment, management and post release monitoring of GM maize, these assays would facilitate the efficient screening of authorized GM events and the accidental occurrence of unauthorized GM events in farmers’ fields, ports of entry and supply chains.

**Documentation Requirement for Import of GM Crops for Contained Use in India**

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The Cartagena Protocol on Biosafety (CPB) to CBD, an international agreement governs the transboundary movement of LMOs. Article 18 of CPB sets forth rules for Handling, Transport, Packaging and Identification requirements of LMOs. Documentation requirements vary according to intended use of LMOs. Article 18 (2b) gives necessary documentation to accompany the shipment of LMOs for contained use. In compliance to this, import of GMOs/LMOs in India is governed by the provisions of Environment Protection Act, 1986 and Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/GMOs or Cells, 1989. Indian Council of Agricultural Research-National Bureau of Plant Genetic Resources (ICAR-NBPGR), New Delhi is the nodal organization for import and quarantine of transgenic planting material meant for contained use and is governed by provisions of
Import permit is issued subject to import Clearance issued by Review Committee on Genetic Manipulation (RCGM), Ministry of Science and Technology, Govt. of India. Documents, which should essentially accompany the consignment for contained use are: Import Permit (IP) issued by Director, ICAR-NBPGR as per PQ Form 09 of PQ Order 2003, giving information about common/scientific name of material, country of origin, name and address of exporter and importer, name and address of individual/ institution to whom GMOs are consigned, number of samples, type of material- trial/ germplasm etc., transgene/trait, additional declaration that material should be free from specific pests (as per PQ Order 2003); Import clearance from RCGM giving information about new/modified traits, transformation events, risk class, specification of use, specifies requirements, if any for safe contained use, handling, storage, transport; declaration by indenter that material is free from embryogenesis deactivator gene; Phytosanitary Certificate issued by country of origin, giving details of material and treatment as per format of IPPC, FAO; Commercial invoice giving details of material from the country of export; Red/White tag in PQ form 11. This information is very important for customs and plant quarantine officials for the safe import of GMOs into the country.

Genetically Engineered Plants in the Product Development Pipeline in India

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As part of compiling baseline information under the UNEP/GEF supported Phase II Capacity Building Project on Biosafety a questionnaire based survey was conducted on “Genetically Engineered Plants in the Product Development Pipeline in India”, in 2014. The questionnaire was circulated to scientists from approximately 350 public and private sector organizations involved in plant breeding research and development in India. There was 23% response to the survey.

Respondents identified over 85 different plant species currently being used in experimental work, including plants used for food, livestock feed, fibre fuel and dietary or medicinal purposes. Among the traits, extensive variations have been identified ranging from resistance traits for biotic stressors to abiotic stress tolerance (eg., drought, salt, heavy metals etc) to truly novel nutritional, medicinal or metabolic phenotypes. It has been indicated that 80 % of the on-going projects are limited to basic research, transformation, regeneration or early stages of event selection in contained conditions and only 20 % of the research has progressed to event selection in confined field trials.

Most of the on-going research on traits is relevant to mitigate the impacts of climate change on agriculture and would eventually improve agriculture productivity in case these reach the commercialization stage in the coming years.
ICAR Research Project with Genetically Engineered Plants in India: Ensuring Biosafety Compliance

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The Indian Council of Agricultural Research (ICAR), in association with the South Asia Biosafety Programme (SABP) and the Biotech Consortium India Limited (BCIL), is implementing a Programme on Biosafety Awareness and Compliance Readiness with an objective to improve ICAR’s institutional capacity in biosafety. As part of the project, the issues, suggested actions and resources that need to be referred under each step involved during the research and development of a GE plant have been compiled. The resources include relevant rules and the guidelines issued under the Indian biosafety regulatory framework and other internationally accepted documents.

Insecticide Susceptibility Tests Against Self-Limiting OX513A and Wild Type Aedes aegypti L. Strains

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Purpose: OX513A is an Aedes aegypti L. mosquito strain engineered with a self-limiting gene construct integrated with a fluorescent marker gene for efficient monitoring. This strain is considered to be one of the emerging effective vector control tools to suppress wild population of dengue vector Ae. aegypti. The strategy involves releasing non biting OX513A male mosquitoes in the environment, these OX513A males seek and mate with wild Ae. aegypti females. Offsprings of these mating inherit a copy of self-limiting gene and die before reaching functional adulthood. One of the biosafety assessments for implementation of such vector control tools is to analyze the strain for insecticide susceptibility. In the view, the present study was carried out to test OX513A and two wild type Ae. aegypti strains for insecticide susceptibility.

Method: The susceptibility tests were performed against both sexes of adult mosquitoes according to the WHO standard test procedure. The insecticides used for conducting susceptibility tests were DDT, malathion, deltamethrin and permethrin. Susceptibility of the strains were identified based on mortality percentage, as per the WHO criteria, 98-100% indicate susceptibility, <98% indicate resistance likely, and <90% confirm the presence of resistance.

Results: Observations indicated that male and female adults of all the strains were resistant to the DDT insecticide exhibiting mortality of 90.9, 87.4 and 44.4% for male adults and 70.1, 3.0 and 6.0%, for female adults of OX513A and wild type strains respectively. The malathion, deltamethrin and permethrin insecticides were found to be highly effective exhibiting mortality between 98 to 100%, thus indicating the three strains to be highly susceptible.

Conclusion: Based on the mortality values the strains were found susceptible for all the insecticides tested except DDT. However, the knockdown time values revealed that the magnitude of susceptibility was greater for OX513A strain for all insecticides.
In silico Allergenicity Study of Genetically Modified Rice (Oryza sativa L.) Containing BjAnn2 and BjAnn3 Annexin Genes for Assessment of Biosafety

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Transgenic crops, however, have not found ready acceptance among the public at large. The ability to transfer and express genes from any organism into plants transgressing the sexual barrier has raised concerns about the possible hazards to human beings and the environment. Therefore, transgenic crops are subjected to elaborate tests to assess the risks, and to ensure safety, before they are approved for commercial cultivation. These tests include assessment of hazards to humans (allergenicity and toxicity), animals, non-target organisms and the environment. Allergens are proteins or glycoproteins that are recognized by immunoglobulin E (IgE) which is elicited by the immune system of an individual. Allergenic proteins must bind specific IgE molecules that are present on the surface of mast cells and basophiles to elicit an immune response. Utilization of bioinformatics tools for assessment of allergenicity of recombinant protein(s) from transgene has seen significant progress over the last decade. Bioinformatics analysis has been considered a preliminary part of the safety assessment for GMPs because it is the first step in supporting an assessment of the biosafety with food allergy. Bioinformatics analysis for allergenicity assessment of proteins is performed using different allergen databases. Allergen databases and computational tools are becoming important in the assessment of allergenicity of recombinant protein(s) synthesized by the transgene(s) of the genetically modified plants. The novel proteins produced in the genetically modified (GM) crops need to be evaluated for its potential allergenicity before their introduction into the food chain to address the safety concerns of consumers. The present study aims at the evaluation for the potential allergenicity of transgenic proteins of genetically modified (GM) rice containing Brassica juncea annexin gene (BjAnn2 and BjAnn3) using bioinformatics tools. BjAnn2 and BjAnn3 proteins protected membranes from oxidative stress-mediated damage and positively regulated antioxidant gene expression for ROS detoxification and by counteract oxidative stress, maintain cell redox homeostasis, and enhance drought tolerance. The BjAnn2 [>gi|600971813 |gb|AHN63214.1| annexin 2 (Brassica rapa subsp. Rapa)] and BjAnn3 [>gi|229458366|gb |ACQ65866.1| annexin 3 (Brassica juncea)] annexin proteins contain 316 and 319 amino acids respectively. The amino acid sequences were aligned using allergen online program (http://www.allergenonline.org) employing the FASTA alogorithm in six allergen databases of FARRP, SDAP, ADFS, PSD, Allergome and Algpred. The sequence alignment was performed with the allergen proteins present in the biological databases by three approaches viz. the full sequence, the 80 amino acids, and the 6-8 amino. The results showed neither significant alignment nor similarity of BjAnn2 and BjAnn3 proteins at full sequence, domain, and epitope level with any of the known allergen proteins in the full sequence matching. Matching the 80 amino acid and matching of 8 amino acids illustrated no similarity to determine the epitope potential which confirmed that the transgenic rice plants do not have any allergenic effects and therefore safe for consumption.

Issues and Concerns of the Biosafety of Transgenic Crops: A Case Study of Castor (Ricinus communis L.)

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Castor (Ricinus communis L.) is an important non-edible oilseed crop that contains 40-55%
of oil rich ricinoleic acid, a unique hydroxy fatty acid, with great utilitarian value in industry, pharmaceuticals and agriculture. India supplies 80% of the global demand and is the leading producer of castor in the world. Profitable cultivation of the crop belonging to a monotypic genus is limited by the vulnerability of the improved cultivars to foliage feeders such as, castor semilooper, (Achoea janata L.) and Spodoptera litura, necessitating deployment of insecticidal genes (cry 1EC, cry 1Aa, cry 1Ab, cry 1Aabc) from the bacteria Bacillus thuringiensis (Bt) through biotechnological tools by different research groups in India. Transgenic Bt castor (cv. DCS-9) harboring cry 1EC and cry 1Aa genes were subjected to event selection trials in the field under confined net trials for two years and promising events with field tolerance to the major foliage feeders were selected. However, taking these events further is constrained by certain issues that are dealt in this presentation.

The main concerns are the toxicity of castor seeds due to ricin, an extremely toxic and water-soluble ribosome-inactivating protein which is also present in lower concentrations in other parts of the plant posing a problem in determining the toxicity and allergenicity of the transgenic castor events. The Bt genes for introduction in castor were selected based on the initial bioassays of the purified proteins against the target lepidopteran pests. Risk assessment studies necessitates testing of the transgenic events/cry proteins on the non-target and beneficial organisms. When assayed, purified Bt crystal proteins (Cry 1Aa, Cry 1Ab, Cry 1Ac) showed toxicity to silkworm (Samia cynthia ricini), which is an important economically beneficial insect in the production of eri silk (vanya silk). Furthermore, with the shift in sowing time and the changing pest scenario, the major pests on castor include capsule borer and sucking pests while the appearance of foliage feeders.

The present study represents the importance of long term perspectives and technical amenability of economic part of transgenic plant, for biosafety assay, in meeting the regulatory requirement for the successful and ecofriendly commercialization of transgenic crops.

Managing Late Blight Disease of Potato through Introgression of RB Gene in Indian Potato Cultivars

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Late blight of potato caused by Phytophthora infestans is still the single most important impediment to potato cultivation globally. Presently, the disease is managed through cultural practices, fungicides and host resistance. Management of late blight through host resistance will remain the most environmentally sustainable option.

The Event SP951 (in Katahdin genotype) contains the RB gene from wild potato species S. bulbocastanum which provides durable resistance to late blight diseases and was imported into India from the University of Wisconsin, USA. The bioefficacy of Event SP951 in both Katahdin as well as Kufri Jyoti was tested at our institute and found to be effective for late blight resistance. Hybrids (KJ-16, KJ-21, KJ-65, KJ66, and KJ-77) were developed by crossing between Kufri Jyoti × SP951 and were found superior in terms of late blight resistance and tuber yield.

The molecular characterization through PCR, RT-PCR, Southern Hybridization and Event specific PCR re-confirms the bioefficacy of the event in both Katahdin as well as Kufri Jyoti.
In order to move ahead in establishing biosafety of Event SP951, the Indian Biosafety Regulations prescribe protein toxicology studies to be carried out. The expression of RB protein, like other R proteins in plants, is extremely low. Our efforts in obtaining RB protein through heterologous expression in various systems such as E. coli and yeast have been futile. Thus, Rpi-blb1 is clearly an example of an intractable protein due to its very low level of expression. The need to perform a comprehensive safety assessment is questionable because the exposure is virtually non-existent. Considering this intractable nature of the RB protein, recent literature studies suggest testing of the RB protein in animal toxicology studies may not be required for the safety assessment of RB transgenic potato. On the issue of safety, regulators could treat it the same as a cisgenic line without any biosafety regulation in the future.

Mitochondrial cytochrome oxidase I (COI) DNA Sequence and Morphometric Traits of Eggplant Fruit and Shoot Borer, Leucinodes orbonalis Guenée (Lepidoptera: Crambidae) in Southern Luzon, Philippines

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The eggplant fruit and shoot borer (EFSB), Leucinodes orbonalis, is the most important insect pests of eggplant in the Philippines and many parts of SE Asia. A sample of 360 EFSB male adults and F1 4th instars were collected in six municipalities in two provinces in Southern Luzon, Philippines: Laguna and Quezon. Sequence analysis of mitochondrial DNA (mt) cytochrome oxidase I (COI) gene and the morphology of male genitalia of L. orbonalis were measured and analyzed to characterize the local EFSB population structure. This knowledge is important in designing an Insect Resistance Management plan for Bt eggplant. Both analyses confirmed that all EFSB samples from Laguna and Quezon belong to the L. orbonalis species. No statistically significant difference was observed among populations within a province in all genital traits measured. However, genital traits of Laguna EFSB were statistically larger than Quezon. The mtDNA sequence analysis revealed five haplotypes among Southern Luzon populations which were homologous (99~100%) with the published COI sequence of L. orbonalis from NCBI (KP260782.1). These haplotypes showed very low nucleotide diversity (π = 0.00021) and overall mean distance (0.003 ± 0.001). Topologies from neighbor-joining trees indicate all five haplotypes cluster in a single clade with populations from India, where L. orbonalis may have originated and been introduced to the Philippines by trade.

Monitoring Confined Field Trials of Regulated Genetically Engineered Plants: Monitoring Manual

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In the development and testing of genetically engineered (GE) crops, confined field trials (CFTs) are an important step for safety assessment and data collection. Being aware of the guiding principles and methodologies of CFTs, helps ensure regulatory compliance as well. In India, CFTs for GE crops are regulated as per the Rules for the Manufacture, Use, Import, Export

As an initiative towards building capacity of researchers, developers and regulators involved in conduct/review of CFTs, the Ministry of Environment, Forest and Climate Change has published a “Monitoring Manual: Monitoring of Confined Field Trials of Regulated GE plants”, under the Phase II Capacity Building Project on Biosafety. The monitoring manual presents information on the Indian regulatory systems relevant to CFTs, Standard Operating Procedures and monitoring practices for CFTs of GE crops. These are explained in detail for every step of conduct of CFTs along with the suggestions for corrective measures for managing the risks. An accompanying document entitled “Tools for Trainers: Monitoring of Confined Field Trials of Regulated GE plants”, has also been prepared to assist training of those engaged in monitoring of CFTs.

These two documents are expected to be used as guide for creating a pool of trained resource personnel’s to strengthen efforts by the regulatory agencies for efficiently monitoring CFTs of GE Crops. Two rounds of trainings have also been conducted using the above material, with a positive feedback.

**Multi-Generation Transgene Pea DNA Helicase 45 Expression in Rice Genotypes and Extent of Salinity Tolerance in Containment**

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Soil salinity is the primary limiting factor affecting the growth and production of rice worldwide. DNA helicase (PDH45) from the pea plant (Pisum sativum), is a member of the DEAD-box protein family and plays a vital regulatory role in abiotic stress tolerance in plants.

We previously reported that over-expression of PDH45 confers both seedling and reproductive stage salinity tolerance to a Bangladeshi rice landrace, Binnatoa (BA). In the current study, transgenic BA containing PDH45 was crossed with two different farmer popular BRRI Rice varieties, BRRI dhan28 (BR28) and BRRI dhan47 (BR47) in a contained net-house at DU. F1 plants with the recipient phenotype containing the transgene were selected by molecular tests and advanced from F1 to F5. Expression of PDH45 was detected in all generations. There were some differences in the level of PDH45 expression in donor and recipient genotypes without any effect on their salt stress tolerance ability in various assays. All rice genotypes showed vigorous growth, higher chlorophyll content, lower electrolyte leakage and lower SES score compared to their corresponding wild types. At the reproductive stage under continuous salinity stress, the cross-bred lines (BR28 and BR47) showed significantly better spikelet fertility and yield per plant than their corresponding wild types. We have also checked the downstream interactomes of the PDH45 transgene in all the rice genotypes and the expression of six salt stress related genes was significantly increased at 150 mM NaCl stress.

Our selected transgenic lines were sent to BRRI following the Biosafety Permissions and Procedures for further vigorous testing of their performance in contained greenhouse facilities. Here also the performance of the transgenic lines was better under salinity stress at the seedling stage and implementation is underway for further assessment of their yield potential under continuous salinity stress at the reproductive stage.
Regulatory Challenges and Approaches for Biosafety of Sorghum, Contribution of IIMR

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Biosafety for transgenic crops consists of capacity building to evaluate, assess and devise the precautionary measures for safe transport and handling of GMOs. Under the biotechnology network, set up jointly by the Indian council of Agricultural Research (ICAR) and the Biotech Consortium of India Limited (BCIL), several discussions and interactive sessions among the group of scientists, who are involved in transgenic crop production and evaluation, were organized to lay down procedures and increase the awareness for biosafety. As part of the capacity building at the institutional level, students, scientific colleagues and supporting staff are informed with the safety guidelines for handling transgenic research material. Lectures and discussions are included during different training programs at the Institute of Insurance and Risk Management (IIMR), Hyderabad, to increase the awareness of biosafety among different categories of the society. Careful labeling and storage of GMOs, especially during in-house transfers, and maintenance of transgenic seed in safe custody under restricted access is practiced. All the leftover transgenic material after the experimentation is incinerated. Genetic transformation experiments are conducted and putative transgenic plants are raised in containment facilities designed with biosafety level 1 and 2. Field trials for event selections are conducted in time and space isolations from sorghum crop. Safety guidelines are devised based on the crop biology of the species to conduct and monitor transgenic field trials. Learning through the ICAR-BCIL biosafety network contributed to train other staff and students involved in transgenic research. It is helpful to maintain the facilities, log books and reports; and to build up standard operation procedures (SOPs) for transgenic sorghum research in India.

Risk Assessment of Cry1AC in Non-target Soil Bacteria

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The risk assessment studies of genetically modified (GM) cotton demonstrate their impact on the ecosystem as well as non-target organisms (NTOs). Among the NTOs, plant growth promoting rhizobacteria (PGPR) is one of the most significant and least studied group of soil organisms. For this purpose, a comparative study of Bt with non-Bt cotton rhizosphere was conducted, regarding isolation of representative PGPR strains (Pseudomonas and Bacillus spp.), their biochemical characterization, auxin biosynthesis, analytical profiling (API NE) and molecular characterization to assess the risks of Cry proteins on non-target PGPR strains. The horizontal gene flow (HGT) of Bt gene (Cry1AC) was also observed in some of the experimental strains (03-N9, 01-1 and 03-N4) whereas no significant difference was observed in their colony morphologies, biochemical activities, auxin biosynthesis and API NE enzymatic reactions during this comparative analysis. Sequence homology searches of bacterial strains through 16S ribotyping showed ≥90% similarity to Pseudomonas and Bacillus spp. Our findings showed that neither the biochemical nor the molecular characteristics of PGPR strains are being affected by Cry1AC protein exposure.
Southern-by-Sequencing (SbS) as a Regulatory Molecular Characterization Tool

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Safety assessments of genetically modified (GM) crops for regulatory approval require a comprehensive molecular characterization of the inserted sequence and the insertion site in transgenic plants. In addition, molecular characterization plays a crucial role in event selection and advancement during product development. Typically, Southern blot analysis is used to characterize the inserted DNA copy number, intactness, and absence of the plasmid backbone sequences, as well as analyzing insert stability across breeding generations. Southern blot analysis can be time-consuming and comparatively expensive. Blot interpretation often requires considerable experience, and variability at multiple steps can lead to subjective interpretations. In this poster, we are introducing an efficient sequence-based application for molecular characterization called Southern-by-Sequencing (SbS). SbS utilizes sequence capture enrichment coupled with next-generation sequencing (NGS) technology and bioinformatics tools in a high-throughput environment for event selection and molecular characterization. It is conducted by hybridizing a whole genome DNA library from a GM plant to biotinylated probes designed to cover the transformation plasmid. The process enriches the DNA fragments of interest prior to sequencing. Data analysis uses the enriched library and next-to-target sequences that accompany the targeted construct sequences to identify all novel transgene-to-genome junctions, transgene-to-transgene junctions, and other potential construct rearrangements. SbS analysis provides nucleotide-level information about insertion copy number, number of insertion loci, transgene intactness, rearrangements, and additional linked or unlinked DNA fragments derived from the transformation plasmid. SbS can be reliably used to replace Southern blots as a molecular characterization tool for regulatory submissions on single events. SbS provides sequence level information to address key molecular characterization requirements in risk assessment analysis.

Standard Operating Procedures for Confined Field Trials of GE Cotton Plants in India

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Standard Operating Procedures (SOPs) for conducting confined field trials (CFTs) of regulated, genetically engineered (GE) plants have been devised. SOPs provide guidance for conducting CFTs of regulated, GE cotton plants in India. The given guidelines are to be followed for strict compliance that necessarily include a) transport of regulated GE plant material, b) storage of regulated GE plant material, c) management of confined field trials, d) management of harvest or termination of confined field trials, and e) post-harvest management of confined field trials. Both public and private sector organizations permitted to undertake the CFTs of GE plants are required to comply with SOPs and fill the relevant records as per the requirements indicated in each SOP. The following formats of records have to be maintained 1) record of transport and transport inventory list, 2) record of storage, 3) record of storage inspection and inventory, 4) record of planting 5) record of spatial isolation 6) record of harvest/termination, 7) record of post-harvest monitoring, and 8) record of corrective action. While conducting CFT,
all corners of each trial site should be clearly marked with reference to physical markers to permit identification of the trial site during the period of the trial and the post-harvest period. Any plant material removed during maintenance of the trial must be rendered non-viable by burning or burial on the trial site. All field trial sites of transgenic and their hybrids must be reproductively isolated at a distance of 50 meters from cotton or any other sexually compatible species that are not part of the trial by spatial isolation of cotton trial sites. Access to the trial site for the purpose of inspection should be provided to regulatory officials/monitoring committees upon request, for official use only and preferably during regular working hours. In the event of a confirmed accidental release of regulated cotton, all attempts shall be made to recover as much of the regulated material as possible and will be rendered non-viable by burning or burial on the trial site. The record of planting and map for each trial site should be retained by the Trial-in-Charge and one copy should be submitted to RCGM/GEAC within 7 days of planting. Cotton plant have growth stages (days after planting) emergence (5-15), 4th true leaf (20-30), 1st square (pinhead) (30-45), 1st bloom (50-80), cut out (80-120), defoliation (120-170), and harvest (130-180), which may be kept in mind while during CFTs. Practically cotton seeds do not have a dormancy period. There are no identified species outside the cotton family that are sexually compatible with cultivated cotton.

Standard Operating Procedures for Growing Transgenic Chickpea (Cicer arietinum L.) under Confined Field Trials

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Chickpea or gram (Cicer arietinum L.), Family: Fabaceae) is the world’s second most widely grown pulse crop, cultivated in more than 50 countries across continents. Chickpea seeds are an important source of dietary protein and its cultivation is essentially required for nutritional security. In India, chickpea ranks first in production and area. Chickpea is an annual, self-pollinated, diploid crop (2n=2x=16) with a genome size of approx. 738 Mb. Chickpeas are reported to have narrow genetic base, resulting from domestication and hence genetic engineering (GE) can be employed as a potential tool for improvement of this valuable pulse for traits unidentified in crossable gene pool. Insect resistance (IR) trait conferred by cry genes derived from bacterium, Bacillus thuringiensis (Bt) appears promising in controlling major insect pests of the lepidopteran class. Development and testing of a transgenic chickpea is an important activity of which confined field trials of requires meticulous biosafety considerations adhering to guidelines issued by MoEF&CC and other national competent authorities. Here, we present standard operating procedures (SOPs) for transgenic chickpea with special emphasis on the critical growth stages, feasible methods of reproductive isolation, list of sexually compatible species and dormancy of chickpea seeds in general. The details of the crucial parameters shall help researchers planning for confined field trials, evaluation field trials by the inspection team, post harvest monitoring and ensuring biosafety compliance for transgenic chickpea lines.
Standard Operating Procedures for Growing Transgenic Pigeonpea (Cajanus cajan L.) under Confined Field Trials

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Pigeonpea [Cajanus cajan (L.) Millsp.] or red gram (fam. Fabaceae) is an important grain legume of the tropical and subtropical regions of the world. It is an important source of dietary protein especially for the large vegetarian population in India, besides being used in diverse ways as a source of food, feed and fertilizers. In India, it ranks second after chickpea in production and area. Pigeonpea is an annual, often cross pollinated (10-30%), diploid crop (2n=2x=22) with a genome size of 858 Mb. Genetic engineering (GE) is a potential tool for improvement of this valuable pulse for traits unidentified in a crossable gene pool. An insect resistance (IR) trait conferred by cry genes derived from bacterium, Bacillus thuringiensis (Bt) appears promising in controlling major insect pest of the lepidopteran class. Pigeonpea is reported to be originated in India and hence confined field trials of transgenic pigeonpea needs meticulous biosafety considerations adhering to guidelines issued by MoEF&CC and other National Competent Authorities. Here, we present standard operating procedures (SOPs) for transgenic pigeonpea with special emphasis on critical growth stages of pigeonpea, feasible methods of reproductive isolation, list of sexually compatible species and dormancy of pigeonpea seeds in general. The details of the crucial parameters shall help researchers planning for confined field trail, inspection team for evaluation of trial and post-harvest monitoring, ensuring biosafety compliance of confined field trial for transgenic pigeonpea lines.

Strengthening Environmental Risk Assessment and Risk Management in India

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The environmental risk assessment (ERA) is a key component of the safety assessment to ensure the safe development and use of genetically engineered (GE) plants. In India, the Ministry of Environment, Forest and Climate Change (MoEF&CC) regulates the environmental release of GE plants as per the Rules for Manufacture, Use/Import/Export & Storage of Hazardous Micro-organisms/GE organisms or cells, 1989 (commonly called Rules, 1989).

As part of series of activities under the UNEP/GEF supported Phase II Capacity Building Project on Biosafety, the MoEF&CC has prepared guidelines, resource documents, supporting guidance documents and conducted various training workshops for strengthening risk assessment and risk management of GE plants in India. The Guidelines for ERA of GE plants, Stakeholders Guide: ERA of GE Plants and Risk Analysis Framework, prepared under the project have been adopted by the Genetic Engineering Appraisal Committee (GEAC). The resource documents prepared to provide baseline information for ERA guidance include (1) Multi-country comparison of information and data requirements for the ERA of GE plants, (2) Review of conformity of India’s regulatory system for GE plants with Cartagena Protocol on Biosafety, (3) Safety Assessment of GE plants containing Stacked Traits and (4) Post release monitoring of GE plants.
Sugarcane as a Potential Platform for Molecular Farming and its Biosafety Considerations

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Poster Abstract: Transforming plants as bio-factories or molecular farming for the production of different biomolecules is already an accepted technology. The model plants that were used are tobacco, potato, maize, alfalfa or rice. Very little attention has been made to transform sugarcane as a biofactory to produce novel biomolecules. A well-established tissue culture technique and with the standardized protocol for genetic transformation, the highest biomass producer, wide adaptability of the crop and a well-developed cropping system with very little biosafety issues make this crop as a potential candidate for the biofarming. Above all the expression of the biomolecules in the sugarcane juice which contain very little native proteins is the great advantage for the extraction of the valuable biomolecules from the plant. Perhaps the greatest advantage of transgenic sugarcane as a biofactory is for the developing nations, which may be benefited by providing valuable vaccines at a much cheaper cost. At ICAR-Sugarcane Breeding Institute, Coimbatore we have developed a technology that expresses and directs recombinant protein to the vacuoles of the stem parenchyma cells, which is the sugar storage site. We have generated transgenics that express GUS, GFP and aprotinin with the use of an in-house developed promoter* for higher expression in sugarcane clump(stem) and a vacuole localizing signal*. Our experiments have shown that GUS and aprotinin with his-tag could be isolated and partially purified from sugarcane juice without any loss of enzymatic activity and, in some selected events the r-protein yield was as high as 98 mg from a kilogram of sugarcane clum. Easy extraction and low protein juice content make downstream processing easier. With a definite advantage over the other crops, sugarcane holds promise as a new candidate crop for biofarming. Biosafety issues are relatively low because, a) commercially grown sugarcane is vegetatively propagated and sexual seeds are not used for commercial cultivation; b) it does not flower in many parts of the country and, even if it flowers, it does not set seeds; c) no reports of pollen transfer from cultivated sugarcane to its wild relatives; hence, no chance of transgene introgression to wild Saccharum spp; d) no weediness observed as sugarcane is vegetatively propagated and requires ideal conditions for establishment and growth; e) cane harvesting before flowering is possible. Above all for the purpose of molecular farming the transgenic sugarcane is not required to be released for large scale farming as it can be grown under contained/confined environments.

*Patent application pending with the Indian patent office.

The GMO Debate

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In the Cartagena Protocol on Biosafety, genetically modified organisms are defined as “living modified organisms”. The US Food and Drug Administration (FDA) has estimated that we need a 70% increase in food production by 2050. In order to maintain the demand along with providing safe and better quality food, genetically modified crops are essential. Recently, genetically modified mosquitoes have been developed by Oxitec to tackle the zika virus upheaval. Hence, we cannot ignore the necessity of using it today. The rationality behind tackling the matter needs to be examined. If the effects are benign or favorable, no regulation is needed. In case the effect is adverse, regulation is needed. Direct interactions may be favorable/ benign but this does not rule out the necessity of regulation because indirect...
interaction may be harmful irrespective of the effect of the direct interaction. Biomagnification is one such example. To produce more milk, genetically modified hormone supplement injections are used for dairy cows, but in the later stages we see that lactating mothers consuming milk/milk products rich in such supplements either develop mammary gland problems themselves or their offspring are affected. The Department of Biotechnology (DBT), under the Ministry of Science and Technology is the pivotal department for biotechnology in India. The various protocols on biosafety are enlisted under the Indian Biosafety Rules and Regulations. Despite a regulatory mechanism in place, there is no consensus reached by the public or among the scientists. In this poster, we hope to unravel the scope and extent of regulations arrived at, aimed at and some possible viable route through which the conflicting situation could be resolved.

The Journey of Bt Eggplant in Bangladesh

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Eggplant is a very popular vegetable which is grown year round all over Bangladesh. The eggplant shoot and fruit borer is the key pest of eggplant in this country. For eggplant production, farmers spray insecticides over 100 times in a season at 2-3 day intervals, which are most harmful for public health and the environment. The production cost of eggplant is increased due to frequent spraying of insecticides. The farmers cannot successfully control this insect by using conventional IPM methods. By this time, it was not possible to develop variety resistant to eggplant shoot and fruit borer by conventional breeding. So, to overcome this problem, the Bt gene (Cry1Ac) was introgressed in 9 popular eggplant varieties.

The Bangladesh Agricultural Research Institute (BARI) created a multidisciplinary team in 2005 with a biotechnologist, plant breeder, soil scientist, plant pathologist and entomologist under ABSP II Project which is led by Cornell University of USA and funded by USAID. Multi-location field trials were conducted in seven research stations of BARI (Joydebpur, Jamalpur, Jessore, Hathazari, Barisal, Ishwardi and Rangpur) from 2008-2013 according to the permission of the Ministry of Environment and Forests and Ministry of Agriculture and approval of Biosafety Committee and following the biosafety rules.

After conducting a series of research for more than 8 years following the existing rules of the country, BARI applied to National Technical Committee on Crop Biotechnology (NTCCB) to release Bt eggplant. With the recommendation from the NTCCB, the application was then sent to the National Committee on Bi-safety (NCB). Based on the proper assessments by the NCB and the recommendation from the Biosafety Core Committee, the Government approved the deregulation of four Bt eggplant varieties [BARI Bt begun-1 (Uttara), BARI Bt begun-2 (Kazla), BARI Bt begun-3 (Nayantara), and BARI Bt begun-4 (ISD 006)] on 30 October 2013 following the existing rules of the country.

On 22 January 2014, Bt eggplant seedlings were distributed among 20 farmers in Gazipur, Pabna, Rangpur and Jamalpur districts. The farmers successfully cultivated the distributed seedlings and sold the produce in the market. As a result, the farmers are economically benefited. In 2014-2015, Bt eggplant demonstrations plots were successfully established in 108 farmers’ fields across 19 districts. In 2015-2016, Bt eggplant demonstrations plots were conducted in 230 farmers’ field in 23 districts of Bangladesh. Shoot and fruit borer infestation was not observed anywhere. Due to no infestation of the insect, the production has increased
on an average 25-39 ton per hectare and farmers have benefited by selling the produce in
the market.

From the results, it is observed that the performance of Bt eggplant was better than non-Bt
eggplant in all districts. While the infestations by the insect in shoots and fruits in Bt eggplant
were only 0.00-0.05% and 0.04-0.88% respectively, the infestations in non-Bt eggplants were
30-40% and 48-57%, respectively. BARI Bt Begun-1, BARI Bt Begun-2, BARI Bt Begun-3 and
BARI Bt Begun-4 have brought with an average 66%, 68%, 40% and 100% higher yields,
respectively compared with non-Bt eggplant. Besides this, in this year the breeder seed is
being produced from the released four varieties at research stations. Such seeds will be
sold to the farmers following the government rate. The farmers were so pleased with the bt
eggplant because they produced eggplant free from eggplant shoot and fruit borers, can
produce and preserve the Bt eggplant seeds as Bt eggplant varieties are not hybrids, do not
need to depend on seed companies for seed every year, do not need to give any royalties
to foreign companies due to the limited use of pesticides, there will not be environmental
pollution and the health of farmers will remain good.

Towards Development of Environmentally Safe and Effective Technology for
Insect Resistance in Rice

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Purpose: Yellow stem borer (YSB; Scirpophaga incertulas) is a serious threat to all rice growing
ecosystems in the world. YSB infest plants from the seedling to maturity and causes 25%
yield loss. There are no resistant sources available for this deadly insect pest in primary and
secondary pool of Oryza germplasm. Hence, management is being generally done with
chemical pesticides, which is not environmental safe. Among the available options, RNA
interference (RNAi) has great promise for resistance and has low biosafety concerns.

Methods and Results: We targeted the three key genes of pests i.e Cytochrome P450 derivative
(CYP6), Amino peptidase N (APN) and Acetylcholinesterase (AChE) for silencing, which are
highly important for pest growth and metabolism. Several siRNAs from these three genes were
designed. The best siRNA was selected based on having very negligible off target effect on
non-target organisms as well as other mammals. For attaining effectiveness in RNAi, optimal
concentration of siRNAs was determined through insect feeding assays and was chosen
based on the desired concentration of larval mortality and abnormalities in growth and
development. To know the precise site of action, moment of dsRNAs in the larval body were
also examined by the fluorescence of the dye which was attached to dsRNA. Reduction in
transcripts expression of these genes was also found in treated larvae. To check the specificity
of RNAi, off-target effects of designed dsRNAs were tested on rice pink stem borer (Sesamia
inferens), which is a close non-target organism. There was no morality. Abnormalities were
observed in pink stem borer larvae. Artificial miRNA constructs were designed and the
transgenic plants were developed which were further confirmed molecularly and blot analysis.
The molecular analysis will be used in biosafety assessment and seeking regulatory approvals
as per the Indian biosafety regulations.

Conclusion: In our study, we conclusively proved the safety and effectiveness of RNAi for use
in insect resistance in rice.