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South Asia Biosafety Program

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BANGLADESH

Bangladesh National Committee on Biosafety Approved the Limited Field Release of *Bt*-Brinjal

The National Committee on Biosafety (NCB), the highest regulatory body for genetically modified (GM) crops in Bangladesh, officially approved the limited field release of four varieties of *Bt*-brinjal. This decision was made in the NCB meeting held on October 27 and 28 where the Secretary, Ministry of Environment and Forests (MOEF), chaired. The MOEF subsequently issued a Government order on October 31, 2013 (No.: 22.00.0000.073.003.2012-271; Dated: 31/10/2013) on this issue. Through this decision, Bangladesh became the first country in South Asia to cultivate the genetically modified food crop.

Bangladesh Agricultural Research Institute (BARI) had developed the *Bt*-brinjal varieties through the technical support of Maharashtra Hybrid Seeds Company (Mahyco), India. Mahyco had transferred its *Bt*-brinjal technology to BARI during 2005-2006 through a USAID-funded and Cornell University-managed Agricultural Biotechnology Support Project II (ABSP II).

Bt-brinjal contains a foreign Cry1Ac gene derived from a soil bacterium, *Bacillus thuringiensis* popularly known as *Bt*. This gene produces a protein which is toxic to the fruit and shoot borer (FSB), a destructive pest. The gene gives the crop a built-in resistance to FSB. Four *Bt*-brinjal varieties, namely, *Bt* brinjal-1, 2, 3 and 4, have been approved by the NCB for limited scale cultivation with some conditions. The conditions imposed by the NCB towards limited field release are as follows:

- Based on the proposal and recommendations by the Bangladesh Agricultural Research Council and Ministry of Agriculture (BARI) *Bt*-brinjal 1, 2, 3 and 4 may be released for limited scale field cultivation under a specific work plan.
- Before field release, the relevant ministry and organizations need to prepare the field production planning, field biosafety management planning, emergency response planning, safety measures, viz., isolation distance management planning, border row management planning, techniques for protection of local varieties, indigenous varieties and wild plants and inform the above planning to the NCB and BCC.
- BARI needs to send the proposal to NCB for forming a Field Level Biosafety Committee comprising a local officer of the concerned Agricultural Extension Department, a concerned scientist of the BARI research center, a district or divisional level officer of the Department of Environment and an officer of the local Upazilla administration to monitor the biosafety measures of the areas where the limited cultivation will be held.
- Farmers of the localities where the limited cultivation of the *Bt*-brinjal will be held need to be trained on the ecologically sound cultivation and biosafety related issues. Guidelines on the biosafety and cultivation practices of *Bt*-brinjal need to be supplied to the concerned farmers.
- The concerned applicant organization and ministry need to develop an emergency plan with immediate effect so that it may be possible to avoid any negative effects on human health and environment due to cultivation of *Bt*-brinjal. Under the authority of the Biosafety Rules, the applicant organization needs to bear all responsibilities if any negative effect arises due to release of Bt-brinjal in the environment.
- Under the direction of the Biosafety Rules, the applicant organization needs to maintain appropriate measures on the labeling issue during marketing of *Bt*-brinjal.
- It will be necessary to submit monthly reports to be posted in the Biosafety Clearing House on the biosafety measures taken post-release.

Food Security in Times of Climate Change

ZAHID ALI, ASSISTANT PROFESSOR, DEPARTMENT OF BIOSCIENCES, COMSATS INSTITUTE OF INFORMATION TECHNOLOGY (CIIT), ISLAMABAD

It is evident that changes in climate have significant effects on a variety of physical and biological systems. These harmful effects are global and have resulted in extreme weather events, such as rising temperatures and unpredictable rain fall.

In Pakistan, the increased climatic variability is causing a scarcity of water resources and soil degradation resulting in crop-yield losses. The frequency of climate-induced diseases and heat stress in agriculture is also on the rise. Similarly, marine and coastal ecosystems are being destroyed, forests are shrinking, flora and fauna face the threat of extinction. All of these are contributing to concerns with biodiversity in this country. The environment-associated pressure on natural resources is also negatively affecting economic development.

There is a dire need to address climate change and its effects, particularly on the sustainability and development of agriculture in Pakistan. Agriculture is the backbone of the Pakistan economy. The reduction in pressure on natural resources by improving management of environmental risks is a way to increase development. Water and agriculture sectors are the most vulnerable in this climate change scenario and require immediate attention for the nation. To address food security in Pakistan, it is essential to improve farming systems in order to produce more grain and biomass with smaller amounts of water, pesticides, fertilizers and arable land area requirements.

Keeping in mind the problems ahead, we have to rethink very clearly, devising our strategies and policies on how to increase the crop productivity under changing climatic conditions. This objective can be met by integrating approaches of crop improvement involving molecular biology, genetic engineering, breeding and stress physiology. The benefits of genetically modified (GM) crops include being able to breed disease and stress tolerant crops in addition to herbicide-resistant strains. GM crops can also be made to include vitamins that may be lacking in some staple varieties. Therefore, it is important to focus research on lowering environmental risks and increasing the potential of GM crops in Pakistan.

Presently, the range of GM crops in Pakistani fields is rather narrow even though these genetic engineering techniques will help the plants resist pests and agents causing harm and improve growth against abiotic stresses to assist in farm efficiency. The biotech crops introduced by local agencies or multinational companies include just four plants: soybean, maize, rapeseed and cotton. It is worthwhile to investigate the interconnections among climate change and other drivers of global change influencing plant health.

In this regard, the DAAD-HEC International Summer School titled "Food Security in Times of Climate Change: Bringing Translational Research from Bench to Field" was organized at COMSATS Institute of Information Technology-Islamabad. This initiative was financially supported by German Academic Exchange Service (DAAD) Germany, Higher Education Commission (HEC) Pakistan and Pakistan Academy of Sciences. The objective of this program was to review and discuss the recent advances in production and analysis of transgenic crops, gene insertion studies, gene silencing, factors effecting gene expression, post-translational analysis, molecular farming, field trial analysis, commercialization of modified crops and safety and regulatory affairs. The key note speakers from Germany, the United States, Austria, Bangladesh, Egypt and DAAD/German Alumni stressed that climate change is a challenge that needs to be addressed together with the several problems already faced in agriculture, forestry, landscape management and nature conservation. Thus, it was suggested that the interconnections among climate change and other drivers of global change effecting plant health need to be explored in-depth. The summer school gathered internationally recognized researchers, key note speakers, private sector, educators and decisions makers, to provide the recent developments and future research in agriculture for sustainable development.

Spotlight on the Biosafety Research in Pakistan Grants Program

The Biosafety Research in Pakistan Grants Program (BRPGP) supports laboratory, field, and literature research that will significantly advance knowledge relevant to environmental risk assessment of genetically engineered plants in Pakistan.

The Biosafety Research in Pakistan Grants Program is managed by the Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, as part of the biosafety component of the Pakistan Strategy Support Program (PSSP). The PSSP is financially supported by the US Agency for International Development (USAID) through the International Food Policy Research Institute (IFPRI), which manages PSSP. The Biosafety Research in Pakistan Grants Program recognizes the need for biosafety research as part of a broader effort to support science-based decision-making and policy development and will fund research aimed at addressing the effects of agricultural biotechnology, particularly transgenic crops, on the environment and biodiversity in Pakistan.

Grantees come from agricultural or environmental research institutions and universities in Pakistan.

All grantees work to:

- Address the effects of genetically engineered (transgenic) crops on the environment.
- Be relevant to Pakistan and take place in Pakistan.
- Demonstrate applicability to environmental risk assessment of transgenic plants and regulatory decision-making in Pakistan.

Over the next several newsletters, we will be introducing each of the grantees that are part of BRPGP. Learn about Dr. Fiaz Ahmad and Dr. Shaukat Ali, two of our grantees being highlighted this month!

BRPGP has awarded 13 grants to principal investigators at 5 separate research institutions in Pakistan over two funding cycles since 2012. To view all grant projects, visit the CERA website at: http://bit.ly/1hVizAM

2012 GRANTEE: Dr. Fiaz Ahmad

JOB TITLE: Head Scientific Officer, Physiology/Chemistry Section

ORGANIZATION: Central Cotton Research Institute Multan

PROJECT TITLE: "Effect of *Bt* cotton on chemistry, microbial community structure and enzymatic activity in the rhizosphere soil"

PROJECT DESCRIPTION:

The *Bt* toxin (e.g. Cry1Ac) produced within cotton plants enters into soil ecosystems through root exudates, senescent leaves and post-harvest residues which may influence microbial community and nutrient dynamics in the rhizosphere. This project is aimed at investigating the effects of *Bt* cotton on nutrient dynamics, microbial community structure and enzymatic activity in the rhizosphere. The studies will be accomplished by collecting rhizosphere soil samples from *Bt* and contiguous non-*Bt* cotton fields from Multan, Lodhran and Bahawalpur districts with varied soil texture and agroecology. The investigations will be confirmed by laying out replicated field trials with two *Bt* and non-*Bt* cotton varieties at CCRI, Multan, Shujabad, Lodhran and Bahawalpur. The parameters of the investigation include the soil pH, electrical conductivity, cation exchange capacity, nitrogen, total and extractable phosphorus, extractable-K and micronutrients (DTPA, -Fe & -Zn), total carbohydrates in soil and enzyme activity (phosphatase dehydrogenase).

2012 GRANTEE: Dr. Shaukat Ali

JOB TITLE: Principal Scientific Officer

ORGANIZATION: Natural Agriculture Research Centre, Pakistan Agricultural Research Council

PROJECT TITLE: "Potential risk for cross resistance development in cotton growing areas of Pakistan"

PROJECT DESCRIPTION:

In Pakistan, *Bt* cotton covers 90% of the total cotton area (2.81 million hectares), with no proper monitoring of farmer field conditions. The main goal of this project is to detect and quantify the *Bt* gene expression level in samples collected from farmers fields, cotton research institutions in Southern Punjab and glass houses that grow approved cotton varieties under different water deficit levels. This information will present a baseline to policy makers in Pakistan to formulate guidelines for the release of future *Bt* cotton varieties and their corresponding *Bt* toxin levels.

To date, samples from farmer fields and glass houses have been subjected to immunostrip for the detection of the *Bt* gene type and further confirmed through PCR. Later on samples are subjected to sandwich ELISA for *Bt* protein quantification. This bioassay test is designed to identify lethal doses of *Bt* toxin from farmer field samples in the terms of microgram per gram for target pests in Pakistan.

Highlights of the "Safety Assessment of Genetically Modified Crops" Workshop

International Crops Research Institute for Semi-Arid and Tropics (ICRISAT) and Biotech Consortium India Limited (BCIL) jointly organized a one day workshop on "Safety Assessment of Genetically Modified (GM) Crops" at the ICRISAT campus in Hyderabad on November 23, 2013. This was planned in addition to a two-week international workshop on "Genetic Engineering Applications in Grains and Legume Crops" being organized by ICRISAT.

The objective of the workshop was to discuss scientific, safety and regulatory aspects associated with biosafety evaluation and conduct of confined field trials. More than 80 participants, including 22 scientists from 11 countries, along with scientists from various public sector research institutions engaged in the development of GM crops, food safety assessment as well as those associated with conducting confined field trials participated in the workshop.

Dr. P. Ananda Kumar, Director, Institute of Biotechnology, ANGRAU, stated in his keynote address on the role of GM crops beyond *Bt* cotton that adoption of new technologies in agriculture is extremely important to address the ever increasing Indian population which is projected to reach 1.5 billion by the end of 2050. He mentioned that at present, GM crops are being grown in more than 17 million hectares in 28 countries. He shared that in India, *Bt* cotton is the only crop which has been commercialized in 2002 and since then, this technology has enabled India to transition from cotton importer to cotton exporter. Currently, India holds the 2nd position in cotton production globally with more than 95% area under cotton cultivation by *Bt* cotton.

Food safety assessment processes were explained by Dr. B. Sesikeran, former Director, National Institute of Nutrition (NIN) and Chairman, Review Committee on Genetic Manipulation (RCGM). He shared that Indian food safety standards are based on best international practices in accordance with the principles and guidelines of the Codex Alimentarius.

The Indian biotech regulatory framework and the role of various regulatory agencies and committees for research and commercialization of GM crops in India were explained by Dr. Rajalakshmi Muralidharan. The regulatory requirements, compliance management practices and monitoring mechanisms for conducting confined field trials were presented by Dr. S.J. Rahman, Principal Scientist & Head, AICRP on Biological Control of CropPests and Weeds, Acharya N.G. Ranga Agricultural University.

An e-Learning module on conducting confined field trials prepared by BCIL, under the aegis of South Asia Biosafety Program, was introduced to the participants. Presentations on ongoing research and development activities in various institutions in Hyderabad like Directorate of Rice Research, Directorate of Sorghum Research, ICRISAT and more were presented by principal scientists from their respective institutions. The presentations were followed by discussion and interaction with speakers.

Participants stressed the importance of communicating information and reaching out to different key players about scientific and regulatory aspects of GM crops. There is a need to increase communication to all concerned stakeholders, including government, scientists and industry. It was also indicated that similar e-Learning modules for various other regulatory guidelines and standard operating procedures in India should be prepared for ease in understanding and learning.

Biotechnology in the News: Journal Articles and Publications

The ILSI International Food Biotechnology Committee (IFBiC) Task Force 10: Mammalian Toxicology have published two new papers that are available online through the Critical Reviews of Toxicology.

TOXICOLOGICAL EVALUATION OF PROTEINS INTRODUCED INTO FOOD CROPS

BARTHOLOMAEUS A, PARROTT W, BONDY G, WALKER, K.

CRITICAL REVIEWS IN TOXICOLOGY. VOL 43, NUMBER S2 (NOVEMBER)

http://www.ilsi.org/FoodBioTech/Pages/Publications.aspx

This manuscript focuses on the toxicological evaluation of proteins introduced into genetically modified (GM) crops to impart desired traits. In many cases, introduced proteins can be shown to have a history of safe use (HOSU). Where modifications have been made to proteins, experience has shown that it is highly unlikely that modification of amino acid sequences can make a non-toxic protein toxic. Moreover, if the modified protein still retains its biological function, and this function is found in related proteins that have a history of safe use (HOSU) in food, and the exposure level is similar to functionally related proteins, then the modified protein could also be considered to be "as - safe - as" those that have a HOSU. Within nature, there can be considerable evolutionary changes in the amino acid sequence of proteins within the same family, yet these proteins share the same biological function. In general, food crops such as maize, soy, rice, canola, etc. are subjected to a variety of processing conditions to generate different food products. Processing conditions such as cooking, modification of pH conditions, and mechanical shearing can often denature proteins in these crops, resulting in a loss of functional activity. These same processing conditions can also markedly lower human dietary exposure to (functionally active) proteins. Safety testing of an introduced protein could be indicated if its biological function was not adequately characterized and/or it was shown to be structurally/functionally related to proteins that are known to be toxic to mammals.

THE USE OF WHOLE FOOD ANIMAL STUDIES IN THE SAFETY ASSESSMENT OF GENETICALLY MODIFIED CROPS: LIMITATIONS AND RECOMMENDATIONS

HAMMOND B, KOUGH J, HEROUET-GUICHENEY C, JEZ J.

CRITICAL REVIEWS IN TOXICOLOGY. VOL 43, NUMBER S2 (NOVEMBER)

http://www.ilsi.org/FoodBioTech/Pages/Publications.aspx

There is disagreement internationally across major regulatory jurisdictions on the relevance and utility of whole food (WF) toxicity studies on GM crops, with no harmonization of data or regulatory requirements. The scientific value, and therefore animal ethics, of WF studies on GM crops is a matter addressable from the wealth of data available on commercialized GM crops and WF studies on irradiated foods. Available GM crop WF studies were reviewed and considered the extent to which they add to the information from agronomic and compositional analyses. No WF toxicity study was identified that convincingly demonstrated toxicological concern or that called into question the adequacy, sufficiency, and reliability of safety assessments based on crop molecular characterization, transgene source, agronomic characteristics, and/or compositional analysis of the GM crop and its near-isogenic line. Predictions of safety based on crop genetics and compositional analyses have provided complete concordance with the results of well-conducted animal testing. However, this concordance is primarily due to the improbability of de novo generation of toxic substances in crop plants using genetic engineering practices and due to the weakness of WF toxicity studies in general. Thus, based on the comparative robustness and reliability of compositional and agronomic considerations and on the absence of any scientific basis for a significant potential for de novo generation of toxicologically significant compositional alterations as a sole result of transgene insertion, the conclusion of this review is that WF animal toxicity studies are unnecessary and scientifically unjustifiable.

The Center for Environmental Risk Assessment is pleased to share two papers that have recently been published on surrogate species and low exposure scenarios.

SURROGATE SPECIES SELECTION FOR ASSESSING POTENTIAL ADVERSE ENVIRONMENTAL IMPACTS OF GENETICALLY ENGINEERED INSECT-RESISTANT PLANTS ON NON-TARGET ORGANISMS

CARSTENS K, CAYABYAB B, DE SCHRIJVER A, GADALETA PG, HELLMICH RL, ROMEIS J, STORER N, VALICENTE FH, WACH M.

GM CROPS AND FOOD: BIOTECHNOLOGY IN AGRICULTURE AND THE FOOD CHAIN 2014; 5:0 - -1.

https://www.landesbioscience.com/journals/gmcrops/article/26560/

Most regulatory authorities require that developers of genetically engineered insect-resistant (GEIR) crops evaluate the potential for these crops to have adverse impacts on valued non-target organisms (NTOs), i.e., organisms not intended to be controlled by the trait. In many cases, impacts to NTOs are assessed using surrogate species, and it is critical that the data derived from surrogates accurately predict any adverse impacts likely to be observed from the use of the crop in the agricultural context. The key is to select surrogate species that best represent the valued NTOs in the location where the crop is going to be introduced, but this selection process poses numerous challenges for the developers of GE crops who will perform the tests, as well as for the ecologists and regulators who will interpret the test results. These issues were the subject of a conference "Surrogate Species Selection for Assessing Potential Adverse Environmental Impacts of Genetically Engineered Plants on Non-Target Organisms" convened by the Center for Environmental Risk Assessment, ILSI Research Foundation. This report summarizes the proceedings of the conference, including the presentations, discussions, and the points of consensus agreed to by the participants.

ENVIRONMENTAL RISK ASSESSMENT OF GE PLANTS UNDER LOW-EXPOSURE CONDITIONS

ROBERTS A, DEVOS Y, RAYBOULD A, BIGELOW P, GRAY A.

TRANGENIC RESEARCH 10.1007/S11248-013-9762-Z.

http://cera-gmc.org/index.php?action=publications

The requirement for environmental risk assessment (ERA) of genetically engineered (GE) plants prior to large scale or commercial introduction into the environment is well established in national laws and regulations, as well as in international agreements. Since the first introductions of GE plants in commercial agriculture in the 1990s, a nearly universal paradigm has emerged for conducting these assessments based on a few guiding principles. These include the concept of a case-by-case assessment, the use of comparative assessments, and a focus of the ERA on characteristics of the plant, the introduced trait, and the receiving environment as well as the intended use. In practice, however, ERAs for GE plants have frequently focused on achieving highly detailed characterizations of potential hazards at the expense of consideration of the relevant levels of exposure. This emphasis on exhaustive hazard characterization can lead to great difficulties when applied to ERA for GE plants under low-exposure conditions. This paper presents some relevant considerations for conducting an ERA for a GE plant in a low-exposure scenario in the context of the generalized ERA paradigm, building on discussions and case studies presented during a session at ISBGMO12.

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
National Conference of Plant Physiology 2013: "Current Trends in Plant Biology Research"	Directorate of Groundnut Research, Indian Society for Plant Physiology and Junagadh Agricultural University	December 13-16, 2013 Junagadh	http://www.nrcg.res.in/index.php?option=com_content&view=article&id=66&Itemid=67
Model Training Course on Integrated Pest Management in Vegetable Crops	Indian Institute of Vegetable Research	December 16-23, 2013 Varanasi	http://www.iivr.org.in/Training/BrouctureMTC16-23%20Dec.%202013.pdf
Winter School on "Molecular Breeding Approaches for Genetic Enhancement of Millet Crops"	Directorate of Sorghum Research	January 6-26, 2014 Hyderabad	http://www.sorghum.res.in/ad/Winter_school_DSR_Brochure.pdf
National Seminar on Recent Advances and Challenges in Sugarcane Research	Directorate of Research & Zonal Agricultural Research Station, Mandya and University of Agricultural Sciences, Bangalore	January 17-18, 2014 Bangalore	http://www.uasbangalore.edu.in/images/attachments/home/nssr-2014.pdf
National Symposium on Emerging Trends in Eco-friendly Insect Pest Management	Tamil Nadu Agricultural University & Sun Agro Biotech Research Centre	January 22-24, 2014 Coimbatore	http://www.uasbangalore.edu.in/images/attachments/home/national-seminar-on-sugarcane-2014.pdf
2nd International Conference on Agricultural & Horticultural Sciences	Omics Group	February 03-05, 2014 Hyderabad	http://www.omicsgroup.com/conferences/agricultural-horticultural-2014/
Bangalore India Bio	MM Activ Sci Tech Communications Pvt. ltd.	February 10-14, 2014 Bangalore	http://www.bangaloreindiabio.in/Index_New.php
International Conclave on Sugar Crops & SugarFest 2014: "Sweeteners and Green Energy from Sugar Crops : Emerging Technologies"	Society for Sugar Research and Promotion	February 15-17, 2014 Lucknow	http://www.iisr.nic.in/download/InternationalConclave.pdf
INTERNATIONAL			
2013 International Conference on Agriculture and Biotechnology (ICABT 2013)	Asia-Pacific Chemical, Biological & Environmental Engineering Society (APCBEES)	December 29-30, 2013 Kuala Lumpur, Malaysia	http://www.icabt.org

SOUTH ASIA BIOSAFETY PROGRAM

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

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