SOUTH ASIA
BIOSAFETY PROGRAM

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SABP

The South Asia Biosafety Program (SABP) is an international developmental program initiated with support from the United States Agency for International Development (USAID). The program is implemented in India and Bangladesh and aims to work with national governmental agencies 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.

SABP is working 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.
- Raise the profile of biotechnology and biosafety on the policy agenda within India and Bangladesh and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

ISBGMO-11: AN INSIGHT INTO BIOSAFETY RESEARCH

Dr. Vibha Ahuja, General Manager, Biotech Consortium India Limited, New Delhi

The 11th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO) was held November 15 – 20, 2010 in Buenos Aires, Argentina. ISBGMO is a biennial event organized by the International Society for Biosafety Research (ISBR). Since 1990 it has showcased environmental biosafety research and it has brought together scientific researchers, policy makers, regulators, non-governmental organizations (NGOs) and industry representatives to foster productive dialogue and multidisciplinary approaches while embracing diverse perspectives from all parts of the globe. The theme of ISBGMO 11 was The Role of Biosafety Research in the Decision Making Process. Its focus was the exchange of scientific experiences and ideas on how biosafety research supports regulatory processes especially risk assessments and ultimately science-based decisions. The plenary sessions covered topics such as problem formulation as a tool for environmental risk assessment; biosafety consideration for non food/feed uses; biofuels and energy crops; GM insect developments and biosafety; and biosafety aspects of GM based agronomic traits protecting against yield reduction due to abiotic stress. A separate session was held on risk assessment issues associated with new applications of biotechnologies such as precise genome modification in plants, use of RNAi in crop improvement, synthetic genomics, etc. In parallel, a series of workshops and training programmes were held on relevant topics like capacity building; support system for risk assessments; practical uncertainty analysis; best practices in biosafety research communication; GM mosquitoes, etc. These workshops, organized before and after the symposium, were designed to cover specific topics related to biosafety and GMOs in an informal and participatory manner. These were moderated by experts and allowed in depth discussions of the issues.

As coordinators of South Asia Biosafety Programme (SABP), an ongoing capacity building project in India and Bangladesh, Dr. Vibha Ahuja, General Manager Biotech Consortium India Limited, New Delhi and Prof. M. Imdadul Hoque, Department of Botany, University of Dhaka attended ISBGMO-11. As representatives from developing countries, participation in ISBGMO-11 was extremely useful as it provided insight into global advances in biosafety research. Discussions with leading experts in the field were very informative particularly in areas such as biofuels, RNAi technology, transgenic mosquitoes, etc. It is strongly felt that developing countries need to invest much more in biosafety research in order to keep up with global developments and to reap the benefits of modern biotechnology.

PRESENT STATUS OF AGRICULTURAL BIOTECHNOLOGY AND BIOSAFETY IN BANGLADESH

Muhammed Solaiman Haider, Deputy Director, Department of Environment (DoE) & Member Secretary, National Committee on Biosafety (NCB), Bangladesh

Bangladesh's economy is mainly based on agriculture. The area of Bangladesh is about 144,000 sq kilometers. The total arable land is about 14 million ha. The flood prone area is about 1.5 million ha, 5.05 million ha is drought prone and the salinity prone area is about 3.0 million ha. Bangladesh has been losing cultivable land at the rate of about less than one per cent every year due to river erosion, house building, road construction, etc.

At present the population of Bangladesh is about 160 million. The population is increasing at an alarming rate. Although Bangladesh is more or less self sufficient in food grain production there is a growing need to develop stress tolerant crop varieties to feed the ever increasing population with these limited resources. There is also the need to combat climate change induced disasters like flood, drought and intrusion of salinity. Improvement of fisheries and livestock; biodiversity conservation; biological and industrial waste management; health care systems; forestry and environment sectors also deserve attention. Biotechnology can play an important role to address the above issues.

The Government of Bangladesh has taken a number of initiatives to promote biotechnological research and infrastructure development in the country to enhance productivity, quality and value of products, stability of production systems and environmental conservation leading to sustained food security, poverty alleviation and livelihood security. Currently, several research organizations, public and private universities,

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Bangladesh - *continued from page 1*

private companies and NGOs are involved in biotechnology research in Bangladesh.

The National Committee on Biosafety (NCB) has already approved the application of confined field trials (CFT) of fruit and shoot borer (FSB) Bt-brinjal and late blight resistant potato being conducted by Bangladesh Agricultural Research Institute (BARI). BARI has successfully performed two cycles of confined field trials with both Bt-brinjal and late blight resistant potato. In case of Bt-brinjal during the first round, BARI performed CFT in three locations, namely, BARI headquarters at Joydebpur, BARI regional agricultural research stations at Jessore and Hathhazari, Chittagong. During the second round, trials were also performed at four other locations, namely, Jamalpur, Ishurdi, Rahmatpur and Bururhath.

In case of late blight resistant potato, the first round of confined field trials was performed in Joydebpur and Debigange. The second trials were performed in Joydebpur and Burirhath. BARI has been performing third round confined trials in the same locations in the case of both Bt-brinjal and late blight resistant potato.

The Bangladesh Rice Research Institute (BRRI) has been performing contained green house trials of the first generation of golden rice. The institute is also expecting to receive second generation golden rice soon.

The Government of Bangladesh has taken steps to develop various regulatory documents on biosafety to facilitate modern biotechnological research as well as contained and confined field trials of transgenic crops. The Biosafety Guidelines of Bangladesh was gazetted in 2008 by the Ministry of Environment and Forests (MOEF). Various committees, namely National Committee on Biosafety (NCB) headed by the Secretary, MOEF, Biosafety Core Committee (BCC) headed by the Director General and Department of Environment (DoE) have been formed in accordance with the Biosafety Guidleines. Most of the organizations performing genetic engineering research and field trials of transgenic plants, namely, BARI, BRRI, Dhaka University, Bangladesh Agricultural University have already formed the Institutional Biosafety Committees. NCB has formed Field Level Biosafety Committees (FBCs) to oversee the confined field trials of Bt-brinjal and late blight resistant transgenic potato.

Ministry of Environment and Forests developed the National Biosafety Framework (NBF) in 2007. In collaboration with Bangladesh Agricultural Research Council (BARC) and South Asia Biosafety Program (SABP), MOEF has developed the regulatory documents related to agricultural biotechnology and biosafety that are shown in the following table.

NAME OF REGULATORY DOCUMENT	*STATUS*
Biosafety Guidelines of Bangladesh	Gazetted in Janury 2008
National Biosafety Framework (NBF) of Bangladesh	Yet to be gazetted
Guidelines for confined field trials (CFT) of GE crops, Standard Operating Procedures (SOPs) and other related documents, namely, Inspectors' manual, data recording formats needed for confined field trials of GE crops	Yet to be gazetted as the Annexure of the Biosafety Guidelines of Bangladesh
The Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants	Yet to be gazetted as the Annexure of the Biosafety Guidelines of Bangladesh
Ministry of Environment has drafted the Biosafety Rules of Bangladesh and sent this document to the Ministry of Law & Parliamentary Affairs for their legal comments	Recently MOEF received comments from the Ministry of Law on the drafted Rule.

To promote biotechnology related research and development activities, Ministry of Science and Information & Communication Technology has been updating the National Biotechnology Policy of Bangladesh developed in 2005. Based on the decisions taken by the National Executive Committee on Biotechnology (NECB) headed by the Principal Secretary of the Prime Minister, the Ministry of Science & ICT has also established a biotechnology cell headed by the Joint Secretary of the Ministry.

The Ministry of Environment and Forests has also formed a biosafety cell in the Department of Environment headed by a Deputy Director to help the process of speedy implementation of biosafety related day-to-day activities.

SUPPORT FOR BT BRINJAL IN THE PHILIPPINES

Nature Biotechnology (2011) 29:9 doi:10.1038/nbt0111-9c

Filipino farmers clamoring for the adoption of genetically modified (GM) eggplants in October passed a resolution to support multi-location field trials of the biotech crop. GM crop farmers and agriculture representatives from across the country endorsed a set of resolutions to support the advancement of biotech crops in the country including the pest-resistant eggplant. "When we consulted them, [farmers] asked, 'Are the seeds available already? Why is it taking so long?'" says Reynaldo Cabanao, president of the Asian Farmers Regional Network (ASFARNET). The GM eggplant was developed by the Agricultural Biotechnology Support Project II (ABSPII), a global public-private collaboration based at Cornell University in Ithaca, New York. It was engineered with the Cry1Ac gene from the bacterium *Bacillus thuringiensis* (Bt) to fend off the fruit and shoot borer, which can destroy up to 50% of the region's number-one food crop.

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The Reading List

. . . new and notable articles

EXPLORING AND EXPLOITING EPIGENETIC VARIATION IN CROPS

King GJ, Amoah S, Kurup S.

This review addresses the mechanisms by which epigenetic variation modulates plant gene regulation and phenotype. In particular we explore the scope for harnessing such processes within the context of crop genetic improvement. We focus on the role of DNA methylation as an epigenetic mark that contributes to epiallelic diversity and modulation of gene regulation. We outline the prevalence and distribution of epigenetic marks in relation to eukaryote developmental processes, and in particular identify where this may be relevant to crop traits both in terms of specific developmental stages and in relation to physiological responses to environmental change. Recent whole genome surveys have identified specific characteristics of the distribution of DNA methylation within plant genomes. Together with greater understanding of the mode of action of different maintenance and de novo methyltransferases, this provides an opportunity to modulate DNA methylation status at specific loci as an intervention strategy in crop genetic improvement. We discuss alternative approaches that may be suitable for harnessing such induced epiallelic variation. Most of the discussion is associated with *Brassica* crops, which demonstrate considerable morphological plasticity, segmental chromosomal duplication, and polyploidy.

Genome (2010) Nov 53(11):856-68

PRODUCTION OF MARKER-FREE DISEASE-RESISTANT POTATO USING ISOPENTENYL TRANSFERASE GENE AS A POSITIVE SELECTION MARKER

Khan, R.S., Ntui, V.O., Chin, D.P., Nakamura, I. and Mii, M.

The use of antibiotic or herbicide resistant genes as selection markers for production of transgenic plants and their continuous presence in the final transgenics has been a serious problem for their public acceptance and commercialization. MAT (multi-auto-transformation) vector system has been one of the different strategies to excise the selection marker gene and produce marker-free transgenic plants. In the present study, ipt (isopentenyl transferase) gene was used as a selection marker gene. A chitinase gene, ChiC (isolated from *Streptomyces griseus* strain HUT 6037) was used as a gene of interest. ChiC gene was cloned from the binary vector, pEKH1 to an ipt-type MAT vector, pMAT21 by gateway cloning and transferred to *Agrobacterium tumefaciens* strain EHA105. The infected tuber discs of potato were cultured on hormone- and antibiotic-free MS medium. Seven of the 35 explants infected with the pMAT21/ChiC produced shoots. The same antibiotic- and hormones-free MS medium was used in subcultures of the shoots (ipt like and normal shoots). Molecular analyses of genomic DNA from transgenic plants confirmed the integration of gene of interest and excision of the selection marker in 3 of the 7 clones. Expression of ChiC gene was confirmed by Northern blot and western blot analyses. Disease-resistant assay of the marker-free transgenic, in vitro and greenhouse-grown plants exhibited enhanced resistance against *Alternaria solani* (early blight), *Botrytis cinerea* (gray mold) and *Fusarium oxysporum* (Fusarium wilt). From these results it could be concluded that ipt gene can be used as a selection marker to produce marker-free disease-resistant transgenic potato plants on PGR- and antibiotic-free MS medium.

Plant Cell Reporter (2010) Dec 24. [Epub ahead of print]

RECOMBINANT PROTEIN EXPRESSION IN *NICOTIANA*

Matoba, N., Davis, K.R., Palmer, K.E.

Recombinant protein pharmaceuticals are now widely used in treatment of chronic diseases, and several recombinant protein subunit vaccines are approved for human and veterinary use. With growing demand for complex protein pharmaceuticals, such as monoclonal antibodies, manufacturing capacity is becoming limited. There is increasing need for safe, scalable, and economical alternatives to mammalian cell culture-based manufacturing systems, which require substantial capital investment for new manufacturing facilities. Since a seminal paper reporting immunoglobulin expression in transgenic plants was published in 1989, there have been many technological advances in plant expression systems to the present time where production of proteins in leaf tissues of nonfood crops such as *Nicotiana* species is considered a viable alternative. In particular, transient expression systems derived from recombinant plant viral vectors offer opportunities for rapid expression screening, construct optimization, and expression scale-up. Extraction of recombinant proteins from *Nicotiana* leaf tissues can be achieved by collection of secreted protein fractions, or from a total protein extract after grinding the leaves with buffer. After separation from solids, the major purification challenge is contamination with elements of the photosynthetic complex, which can be solved by application of a variety of facile and proven strategies. In conclusion, the technologies required for safe, efficient, scalable manufacture of recombinant proteins in *Nicotiana* leaf tissues have matured to the point where several products have already been tested in phase I clinical trials and will soon be followed by a rich pipeline of recombinant vaccines, microbicides, and therapeutic proteins.

Methods in Molecular Biology (2011) 701:199-219

ENHANCER-PROMOTER INTERFERENCE AND ITS PREVENTION IN TRANSGENIC PLANTS.

Singer, S.D., Cox, K.D. and Liu, Z.

Biotechnology has several advantages over conventional breeding for the precise engineering of gene function and

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CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Agbio 2011: Global Summit on AgBio Innovations	Tamil Nadu Agricultural University and Maryland India Business Round Table Washington	January 31 – February 2, 2011	
ICPACC 2011: International Conference on Preparing Agriculture for Climate Change	Punjab Agricultural University	February 6 - 18, 2011 Ludhiana	http://www.pau.edu/int_conf/program.htm
3rd International Group Meeting on Wheat Productivity Enhancement Under Changing Climate	University of Agricultural Sciences, Dharwad and Directorate of Wheat Research, Karnal	February 9-12, 2011 UAS, Dharwad	http://www.uasd.edu/3rdIGM/wheatintmeet2.pdf
International Conference: Leveraging Agriculture for Improving Nutrition and Health	International Food Policy Research Institute (IFPRI)	February 10 - 12, 2011 New Delhi	http://www.ifpri.org/2020-agriculture-nutrition-health
Indian Seed Congress 2011	National Seed Association of India (NSAI)	February 22 - 23, 2011 Hyderabad	http://www.nsai.co.in/ISC_2011_Delegate.pdf
Bio Asia 2011: The Global Bio Business Forum	Government of Andhra Pradesh, Federation of Asian Biotech Associations, All India Biotech Association, University of Hyderabad	February 21-24, 2011, Hyderabad	http://www.bioasia.in/
8th International Safflower Conference: Safflower Research and Development in the World - Status and Strategies	Indian Society of Oilseeds Research and Indian Council of Agricultural Research	January 19 - 23, 2012 Hyderabad	http://www.dor-icar.org.in/downloads/Conference1.pdf
INTERNATIONAL			
South Africa – Argentina Joint Regional Biosafety Workshop and Seminar: Biosafety of GM Crops: Emerging Issues and Challenges Affecting Regulatory Decision Making	The International Centre for Genetic Engineering and Biotechnology in collaboration with the South African Department of Agriculture, Forestry and Fisheries & Argentinean Secretariat of Agriculture, Livestock and Fisheries (SAGyP)	March 7 - 11, 2011 Pretoria, South Africa	http://www.icgeb.org/tl_files/Meetings/2011/ICGEB%20Workshop%20SA%202011-%20Notification.pdf
First International Workshop on the Food and Environmental Safety Assessment of Genetically Modified Animals	Argentine Ministry of Agriculture, Livestock and Fisheries, (SAGyP, Biotechnology Directorate); ICGEB; United Nations University Biotechnology Programme for Latin America and the Caribbean (UNU-BIOLAC) and International Life Sciences Institute (ILSI Argentina)	September 5 - 9, 2011 Buenos Aires, Argentina	http://www.agrobiotecnologia.gov.ar/gmanimal2011/

Eggplant - *continued from page 2*

Farmers who have witnessed the success of Bt corn are eager for Bt eggplant to be available, says Desiree Hautea, ABSPII coordinator for South East Asia, at the University of the Philippines, Los Baños. The GM eggplant is currently undergoing confined field tests adhering to biosafety regulations set by the Philippines Department of Agriculture, Bureau of Plant Industry. Multiple-site trials will follow, though commercialization plans remain undefined.

Reading List - *continued from page 3*

provides a powerful tool for the genetic improvement of agronomically important traits in crops. In particular, it has been exploited for the improvement of multiple traits through the simultaneous introduction or stacking of several genes driven by distinct tissue-specific promoters. Since transcriptional enhancer elements have been shown to override the specificity of nearby promoters in a position- and orientation-independent manner, the co-existence of multiple enhancers/promoters within a single transgenic construct could be problematic as it has the potential to cause the mis-expression of transgene product(s). In order to develop strategies with, which to prevent such interference, a clear understanding of the mechanisms underlying enhancer-mediated activation of target promoters, as well as the identification of DNA sequences that function to block these interactions in plants, will be necessary. To date, little is known concerning enhancer function in plants and only a very limited number of enhancer-blocking insulators that operate in plant species have been identified. In this review, we discuss the current knowledge surrounding enhancer-promoter interactions, as well as possible means of minimizing such interference during plant transformation experiments.

Plant Cell Reporter (2010) Dec 19. [Epub ahead of print]

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