SOUTH ASIA
BIOSAFETY PROGRAM

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SABP

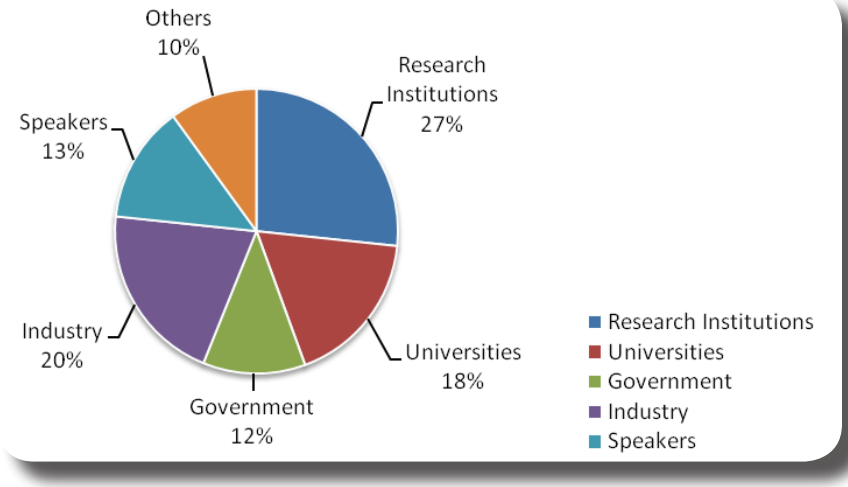
The South Asia Biosafety Program (SABP) is an international developmental program initiated with support from the United States Agency for International Development (USAID). The program is implemented in India and Bangladesh and aims to work with national governmental agencies to facilitate the implementation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

SOUTH ASIA CONFERENCE ON CURRENT APPROACHES TO THE ERA OF GE CROPS — IMPRESSIONS FROM THE PARTICIPANTS

The South Asia Conference on Current Approaches to the Environmental Risk Assessment (ERA) of GE Crops was held May 16 to 18, 2011 at New Delhi. The conference was attended by about 180 participants from various stakeholder groups such as members of regulatory bodies; policymakers; scientists from industry, research institutions and universities; students and other organizations. A categorical breakdown of the participants is shown in the infographic.



Subsequent to the conference, several responses were received from participants sharing their experiences. The overall response to the conference was very satisfactory as participants greatly appreciated the deliberations as well as other organizational aspects. Comments included:

> "The South Asia Conference on Current Approaches to the Environmental Risk Assessment of Genetically Engineered Crops held in New Delhi for three days organized by CERA and BCIL was an eye opener. I learnt about several important and interesting topics that need to be addressed before releasing any transgenic crop such as growing of transgenic crops in its centres of origin, escape of transgenes to wild relatives, emergence of herbicide resistant weeds, development of insect resistance to transgenes, etc. I felt the panel discussion on the last day on the topics of horizontal gene transfer, antibiotic resistance markers and herbicide tolerance management of GE crops was very interesting and thought provoking. It was interesting to know the various opinions and views regarding the ERA in different countries. From the conference I was able to infer that ERA should be science-based and assure confidence in the public."
>
> *— student*

> "I thank you for your excellent management of the South Asian Conference on Current Approaches to the ERA of GE Crops 16th to 18th May 2011. The conference has provided insights into the ERA of countries like Canada, Philippines, Mexico and others. It is an eye opener for us to deal with antibiotic and herbicide resistant markers. Some of the discussions were very useful. I thank CERA, BCIL and DBT for organizing the conference with such meticulous management."
>
> *— senior SAU scientist*

> "It was indeed a very pleasant experience to attend this meeting and sharing experience and expertise with delegates and speakers from different countries. We really benefitted from the quality of presentations and discussions. The meeting was well planned and executed. Kudos to the team for organizing this in very effective and flawless manner."
>
> *— industry representative*

A conference evaluation form was circulated electronically with a focus on receiving the feedback as well as suggestions for future meetings. There has been limited response to the questionnaire and all the participants have rated the conference good to excellent. Some of the important suggestions that have been emerged are:

- Risk assessment is a complex issue with different connotations to various sectors. More interaction between scientists with dissimilar views as well as non-scientific communities will help to fill the gaps in understanding different aspects of biosafety.
- Based on the earlier ERA results, recommendations should have been made as to the extent risks are real risks and how much the current mandatory essential tests can be done away with.

(continued on page 2 - see ERA)

ERA - *continued from page 1*

- Current biosafety guidelines should be revised as early as possible and should be more science-based as several new experiments have revealed some of the tests such as gene-flow studies or horizontal gene-transfer studies are no longer essential.
- There should be greater focus on case studies applicable to India and the South Asia region.
- With all necessary steps having been taken by the Indian government, current GM crop guidelines should be made to reach Indian students and researchers.
- The addition of a session with a case study using an actual biotech trait would be helpful in understanding the problem formulation approach to defining the data expectations of the regulators and how generated data is used by regulators to make decisions.

REGULATORY REGIME ON BIOSAFETY: NECESSITY OF BIOSAFETY RULES FOR BANGLADESH

Mohammed Solaiman Haider, Deputy Director, Department of Environment & Member Secretary, National Committee on Biosafety, Ministry of Environment and Forests, Bangladesh, Email: haider@doe-bd.org

A regulatory regime on biosafety is comprised of legal instruments that are relevant to the regulation of GMOs such as laws, acts, regulations, decrees, orders, guidelines, etc., including the institutional arrangements for implementing those regulations. A regulatory regime is needed to ensure an adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity, taking into account risks to human health.

As a party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Bangladesh is committed at a global level to implementing the obligations under the Protocol. To fulfill these obligations, the Government of Bangladesh developed Biosafety Rules that were drafted conducting extensive stakeholder consultations. To date, Bangladesh has had to implement its biosafety activities following the Biosafety Guidelines of Bangladesh, which have very little legal force. Therefore, it has been felt there is an urgent necessity to put in place the Biosafety Rules to administer the regulatory regime.

Justification of Biosafety Rules under Environment Conservation Act

A review of the existing laws reveals the followings facts.

- There is no separate law to deal comprehensively with the adverse impacts that might arise from the use, handling, transfer and transboundary movements of GMOs as required by the Protocol.
- Sectoral laws and regulations are mostly old, whereas the ideas of GMOs and their possible threat to biodiversity, environment and human health are relatively new.
- Sectoral laws and regulations have their own priorities; they were not adopted to address the potential risks of GMOs.
- Some of the provisions of the sectoral laws and regulations might be relevant, but the scope is limited. They do not provide a comprehensive regulatory regime for biosafety in Bangladesh. For example, the Destructive Insects and Pests Act, 1914 and the Destructive Insects and Pests Rules, 1966 regulate only the import, export and transit of plants and plant products. They do not regulate use, transfer, handling, contained use, direct release, etc., of plants and plant products, which could be GM plants or plant products.

There are three alternative means of implementing the obligations of the Protocol in Bangladesh:

- to amend the existing relevant sectoral laws and regulations;
- to amend one or two major laws highly relevant to the regulation of GMOs in potential areas, for example, seeds, plant and plant products; and
- to make a completely new comprehensive law on biosafety.

It is, however, suggested that making a new law with overriding force would be preferable to amending more than thirty existing relevant laws, administered by almost fifteen government ministries/departments.

Furthermore, amending one or two sectoral laws would implement the obligations of the Protocol partially, leaving considerable area unregulated. It is therefore recommended that a comprehensive law under the purview of the Environment Conservation Act 1995 covering the biosafety concerns arising from all sources of GMOs (GM plants, animals, insects, microbes, fish and their products such as GM food, feed and medicine, etc.) should be put in place in order to implement the obligations of the Protocol.

It is noteworthy that under the present constitutional arrangement in Bangladesh (Article 65 of the Constitution), an act or rules may be made by the relevant administrative organs of the government in exercise of the power of legislation delegated under an Act of Parliament. The Environment Conservation Act, 1995 is such an Act. Under section 20 of the Act, Parliament has delegated necessary rule-making power to the Ministry of Environment and Forest. Therefore, the draft rules on biosafety have been developed under section 20 of the 1995 Environment Conservation Act. Rule-making under an Act requires mandate. The purposes of the Environment Conservation Act (ECA, 1995) are wide enough to authorize rule-making on biosafety. The purpose of the ECA is 'to provide for the conservation, improvement of environmental standard and control and mitigation of the pollution of the environment'. The rule-making power under section 20 is also wide enough and provides that 'the Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.'

Thus in order to achieve the purposes of conservation of biodiversity, protection of human health and improvement of environmental standards, necessary rules may be made to regulate the use, handling, transfer, export, import, etc., of GMOs that might have adverse impacts on biodiversity and the environment. Furthermore, passing an Act of Parliament is a time consuming and complex task. Rules can be amended more easily than an Act of Parliament, which can only be amended by another amending Act of Parliament. Rules, on the other hand, can be amended by the relevant administrative organs with the approval of the higher authority of the Government. Finally, biosafety regulation requires a flexible mechanism so international decisions under the Protocol can be implemented as and when necessary. Rules could provide that flexibility in operation.

Considering the pros and cons, the Department of Environment under the Ministry of Environment and Forest has developed the draft Rules on Biosafety, in consultation with stakeholders, ensuring public participation in the law making process.

The Reading List

. . . new and notable articles

SELECTION FOR RESISTANCE TO MCRY3A - EXPRESSING TRANSGENIC CORN IN WESTERN CORN ROOTWORM

Meihls LN, Higdon ML, Ellersieck M, Hibbard BE

To investigate the development of resistance to mCry3A, a laboratory colony of the western corn rootworm, *Diabrotica virgifera virgifera* LeConte, was established from field survivors of mCry3A-expressing (MIR604) corn, *Zea mays* L. Feral adults emerging from MIR604 (selected) and isoline (control) field plots were collected and returned to the laboratory. Progeny of each colony was reared one generation on isoline corn and then crossed reciprocally with a nondiapausing colony. The resulting nondiapausing progeny were then reared on greenhouse corn in accordance with the wild type parent's origin (on MIR604 or isoline corn). After four, seven, and 10 total generations of selection, the resistance ratio of the selected colony was 0.5, 4.3, and 15.4 in terms of lethal concentration ($LC)_{50}$ values in toxicity assays, with the latter two LC50 values being significant. After seven generations of selection in total, selected and control colonies were screened on MIR604 and isoline corn under field conditions. There was a significant colony x corn pedigree interaction in terms of plant damage. There was no significant difference in damage between MIR604 and isoline corn, whereas this difference was significant for the control colony. After 14 generations of selection, a seedling bioassay was performed. Again, there was a significant colony x corn pedigree interaction, this time in terms of the number of larvae recovered. There was no significant difference in the number of larvae recovered from MIR604 and isoline corn for the selected colony, whereas this difference was significant for the control colony, although larval size was greater on isoline corn for both colonies. Resistance has developed in western corn rootworm laboratory colonies to all Bt proteins currently registered for corn rootworm management, which emphasizes the importance of adhering to resistance management plans for maintaining product efficacy.

Journal of economic entomology (2011) 104(3):1045-54.

MOLECULAR BASIS OF GLYPHOSATE RESISTANCE - DIFFERENT APPROACHES THROUGH PROTEIN ENGINEERING

Pollegioni L, Schonbrunn E, Siehl D

Glyphosate (N-phosphonomethyl-glycine) is the most widely used herbicide in the world: glyphosate-based formulations exhibit broad-spectrum herbicidal activity with minimal human and environmental toxicity. The extraordinary success of this simple, small molecule is mainly attributable to the high specificity of glyphosate for the plant enzyme enolpyruvyl shikimate-3-phosphate synthase in the shikimate pathway, leading to the biosynthesis of aromatic amino acids. Starting in 1996, transgenic glyphosate-resistant plants were introduced, thus allowing application of the herbicide to the crop (post-emergence) to remove emerged weeds without crop damage. This review focuses on mechanisms of resistance to glyphosate as obtained through natural diversity, the gene-shuffling approach to molecular evolution, and a rational, structure-based approach to protein engineering. In addition, we offer a rationale for the means by which the modifications made have had their intended effect.

The FEBS Journal (2011) Jun 11. doi: 10.1111/j.1742-4658.2011.08214.x. [Epub ahead of print]

KNOCKDOWN OF MIDGUT GENES BY DSRNA-TRANSGENIC PLANT-MEDIATED RNA INTERFERENCE IN THE HEMIPTERAN INSECT *NILAPARVATA LUGENS*

Zha W, Peng X, Chen R, Du B, Zhu L, He G

BACKGROUND: RNA interference (RNAi) is a powerful technique for functional genomics research in insects. Transgenic plants producing double-stranded RNA (dsRNA) directed against insect genes have been reported for lepidopteran and coleopteran insects, showing potential for field-level control of insect pests, but this has not been reported for other insect orders.

METHODOLOGY/PRINCIPAL FINDINGS: The Hemipteran insect brown planthopper (*Nilaparvata lugens* Stål) is a typical phloem sap feeder specific to rice (*Oryza sativa* L.). To analyze the potential of exploiting RNAi-mediated effects in this insect, we identified genes (Nlsid-1 and Nlaub) encoding proteins that might be involved in the RNAi pathway in *N. lugens*. Both genes are expressed ubiquitously in nymphs and adult insects. Three genes (the hexose transporter gene NlHT1, the carboxypeptidase gene Nlcar and the trypsin-like serine protease gene Nltry) that are highly expressed in the *N. lugens* midgut were isolated and used to develop dsRNA constructs for transforming rice. RNA blot analysis showed that the dsRNAs were transcribed and some of them were processed to siRNAs in the transgenic lines. When nymphs were fed on rice plants expressing dsRNA, levels of transcripts of the targeted genes in the midgut were reduced; however, lethal phenotypic effects after dsRNA feeding were not observed.

CONCLUSIONS: Our study shows that genes for the RNAi pathway (Nlsid-1 and Nlaub) are present in *N. lugens*. When insects were fed on rice plant materials expressing dsRNAs, RNA interference was triggered and the target genes transcript levels were suppressed. The gene knockdown technique described here may prove to be a valuable tool for further investigations in *N. lugens*. The results demonstrate the potential of dsRNA-mediated RNAi for field-level control of planthoppers, but appropriate target genes must be selected when designing the dsRNA-transgenic plants.

PLoS One. (2011) 6(5):e20504.

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
National Symposium Innovative and modern Technologies for Agricultural Productivity, Food Security and Environmental Management	Society for Applied Biotechnology	July 22 - 23, 2011 Mangalore, Karnataka	http://www.sabt.org.in/conferences.htm
TERI-ITEC Courses 2011-12 Course II - Applications of biotechnology and its regulation	The Energy and Resources Institute (TERI)	July 25–August 12, 2011 Gurgaon	http://www.teriin.org/index.php?option=com_events&task=details&sid=382
Consultative Workshop to Strengthen Compliance to BCH Requirements	Ministry of Environment and Forests and Biotech Consortium India Limited	August 17, 2011 New Delhi	
International Conference on Emerging Trends on Food and Health Security in Cold Deserts	Defence Institute of High Altitude Research (DIHAR), Defence Research and Development Organisation (DRDO)	September 23 - 25, 2011 LEH-Ladakh	
National Conference on Recent Advances in Plant Sciences	P.G. Department of Botany, Dharm Samaj College, Aligarh	October 15 - 16, 2011 Aligarh, Uttar Pradesh	https://docs.google.com/document/pub?id=1FJjEInqt_gMcnRtoxZnKc-SyR4AWfwaYJQ7lInfcC4lQ
World Cotton Research Conference	International Cotton Advisory Committee and Indian Society for Crop Improvement under the aegis of Indian Council of Agricultural Research	November 7 - 11, 2011 Mumbai	http://www.wcrc-5.com/WCRC5_Circular.pdf
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			
Biosafety, Biosecurity, & Biodefence (BioSSD) 2011 International Congress on Asia Pacific's Practices, Challenges, and Strategies	PROTEMP Conferences and beta congress (Germany) in collaboration with the Malaysian government agencies	July 18 – 20, 2011 Putra World Trade Center, Kuala Lumpur, Malaysia	http://www.biossdcongress.com/
Biosafety: An International Short Course in Environmental Aspects of Agricultural Biotechnology	Michigan State University Institute of International Agriculture in collaboration with the Plant Breeding and Genetics program	July 31 – August 5, 2011 Michigan, USA	http://worldtap.msu.edu/short-courses/biosafety/
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/
Biosafety Workshop on Problem Formulation: A Strategic Approach to Risk Assessment of GMOs	International Centre for Genetic Engineering and Biotechnology (Trieste)	September 19 - 23, 2011 Trieste, Italy	http://www.icgeb.org/tl_files/Meetings/2011/ICGEB%20TS%20BSF%2019_23%20September%202011.pdf
VII Brazilian Biosafety Congress	National Biosafety Association-ANBio	September 19 - 23, 2011 Joinville/SC, Brazil	http://www.anbio.org.br/
5th International Botanical Conference -- Climate Change and Biodiversity: Role of Plant Scientists	Bangladesh Botanical Society	December 09 – 11, 2011 Department of Botany, University of Dhaka, Bangladesh	www.bdbotsoc.org or http://www.dhakai.com/botany/Circular.pdf

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