



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.

DNA-BASED DIAGNOSTICS FOR GM CROPS: CHALLENGES AHEAD

Gurinder Jit Randhawa, Principal Scientist, National Research Centre on DNA Fingerprinting, National Bureau of Plant Genetic Resources, New Delhi

After successful adoption of *Bt* cotton, India is on the threshold of commercializing a wide range of genetically modified (GM) crops. Over the past decade the National Bureau of Plant Genetic Resources (NBPGR) has, upon technical clearance from the Review Committee on Genetic Manipulation (RCGM), issued 135 import permits for transgenic planting material for research purposes to public and private research institutions. For regulatory compliance, DNA-based diagnostics can be employed not only for developing risk assessment strategies and to assist in post-release monitoring, but also to ensure public confidence and to help solve legal disputes, if they arise.

The detection techniques for GM crops have developed at a faster pace in recent years. With more than 190 GM events in 24 crops already globally commercialized, the area under GM crops has also expanded dramatically during the past years. This, coupled with the number and complexity of new events targeting multiple traits involving a set of different genes/promoters/markers and more complex GM events with

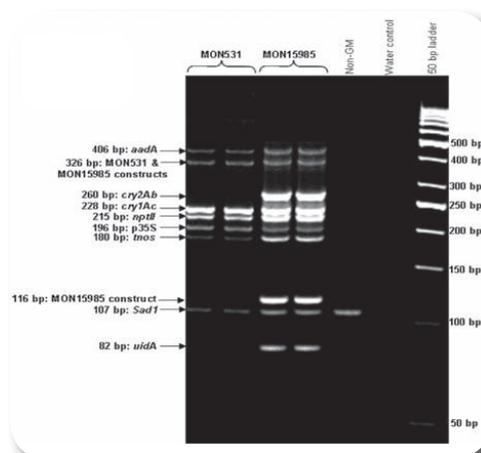
stacked/pyramided/multiple genes, could pose challenges in the area of GM diagnostics.

Among the different analytical methods for GM detection, a widely applied approach is polymerase chain reaction (PCR) targeting the recombinant DNA fragment. PCR-based assays are categorized as qualitative and quantitative. Among the qualitative PCR-based methods, event-specific is the most robust because it unambiguously distinguishes specific GM events. In quantitative real-time (RT) PCR-based methods, the RT multi target analytical system is rapid, cost effective and ready-to-use for simultaneous detection of multiple GM events in a single experiment. The system consists of pre-spotted plates containing lyophilized primers and probes using event-specific primers and probe combinations.

The expertise and capacity for PCR-based GM detection systems have been significantly strengthened and upgraded at NBPGR in the recent past. The research work in this area has been published in peer reviewed national and international journals. While one patent on an innovation in GM diagnostic methodology has already been granted, another two patent applications filed by NBPGR are under process. NBPGR has also participated in three rounds of successful cross validation studies for PCR-based detection with the Central Food and Technology Research Institute, Mysore and the Centre for DNA Fingerprinting and Diagnostics, Hyderabad. Internationally, the institute successfully qualified in proficiency testing organized during 2010 by the European Commission, Joint Research Centre, Italy, for testing unknown GM contents in the powdered samples of different transgenic maize events using RT PCR assays. Molecular testing of imported transgenic lines of two thousand eight hundred seventy nine (2879) has been undertaken to date. Three hands-on training sessions on living modified organism (LMO) detection and a brainstorming session on *GM Chip Technology: Development and Applications* were organized

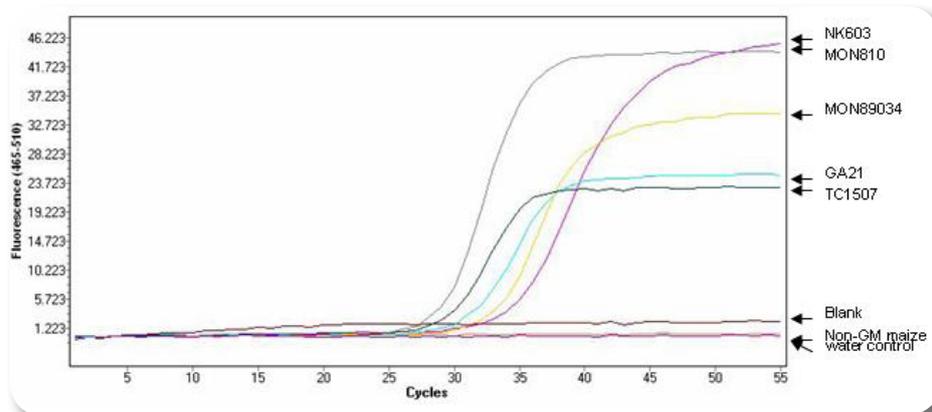
at NBPGR recently. As a step toward commercialization and widespread adoption of GM diagnostic technologies, NBPGR has signed a Memorandum of Understanding, on behalf of ICAR, with M/s Amar Immunodiagnostics, Hyderabad for transfer of PCR-based technology for ten GM crops on a non-

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exclusive basis. The research work on GM detection was undertaken in three ICAR-DBT sponsored projects and one ICAR/GEF-World Bank sponsored project coordinated by the Ministry of Environment and Forests, India. To further harness international experience and expertise to strengthen national capabilities in this priority area, NBPGR is also



executing a joint project on *Novel Cost Effective Methods for GMO Detection: Applications to the Indian-Slovenian Context* with the Department of Science and Technology, India and the Government of Slovenia, which involves exchange visits by scientists working on GM diagnostics at NBPGR with the National Institute of Biology, Ljubljana, Slovenia.

To minimize the time required as well as costs, testing laboratories need to develop a matrix and a sound decision tree to identify and quantify GMOs with the smallest number of PCRs possible. Future diagnostic methods need to be improved in multi-detection systems that enable a search for a high number of possible modifications in a single step. The key technical requirement in the authorization of GMOs is the provision of details of flanking sequences and an event-specific detection method by developers for the checking and monitoring of GM events. There is an urgent need to establish a close collaboration among various diagnostic laboratories and technology developers to work in tandem with the regulatory authorities in the shape of a formal national network on GM diagnostics in India. Such a network of referral GM detection laboratories with accreditation under ISO17025 by the National Accreditation Board for Calibration and Testing of Laboratories for quality assurance and global harmonisation is the need of the hour.

To discuss some of these issues in an interface, and to train a core group of researchers, NBPGR is organising an NAIP World Bank sponsored training programme on *Molecular Diagnostics for Risk Assessment of GM Crops* from November 8 to 21, 2011, where national and international experts will suggest suitable and latest approaches in the area of GM diagnostics.

ENHANCING RESEARCH AND CAPACITY DEVELOPMENT ON AGRICULTURAL BIOTECHNOLOGY: THE ROLE OF NATIONAL AGRICULTURAL TECHNOLOGY PROJECT

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Over the last four decades, the agricultural technology system in Bangladesh has made a significant contribution to increasing cereal production and agricultural productivity.

Rapid growth in food grain production has led to almost food grain self-sufficiency at the national level. However, there exists a huge shortfall in non-cereal agricultural produce, such as pulses, oilseeds, vegetables, spices and fruits. The output level of pulses and oilseeds has either remained static or declined in absolute terms. On the other hand, nearly one per cent of cultivable land is going out of agriculture every year due to population growth, urbanization, housing, industrial growth and expansion of unplanned infrastructures, which has led to shrinkage in the land resource base and has consequently pushed agriculture into marginal and vulnerable areas. The agricultural technology system today is facing new challenges such as the current global eco-political and trade environment; shrinkage of the natural resource base of land, water and biodiversity; increased salinity; water logging; climate change and input-output prices. All these will have long term consequences on the economy and livelihoods of the people. A well thought out and conspicuously designed intervention in research extension and supply chain development are therefore necessary to

meet upcoming challenges. National Agricultural Technology Project (NATP) has taken human resource development as a key strategy to drive research and development success.

To revitalize the agricultural technology system and increase agricultural productivity, the Government of Bangladesh (GoB) is implementing the National Agricultural Technology Project (NATP) with financial assistance from the World Bank and the International Fund for Agricultural Development (IFAD) as co-financier. The longer term overall objective of the NATP is to support GoB's strategy to improve national agricultural productivity and farm income, with particular focus on small and marginal farmers. The project is being implemented jointly by the Ministry of Agriculture (MoA) and the Ministry of Fisheries and Livestock (MoFL) with MoA as the lead ministry. The activities are being implemented by seven agencies under the MoA and MoFL.

To enhance the efficiency and effectiveness of the National Agricultural Research System (NARS), the project is financing:

- Sponsored Public Goods Research (SPGR);
- Competitive Grants Program (CGP); and
- Enhancement of Research Institutional Efficiency (ERIE)

of the NARS. Under the research components 149 sub-projects in different research thematic areas have been awarded to scientists of agricultural research institutes and universities, 14 of which are on biotechnology. Human resource development is critical in addressing emerging issues in agriculture. Under the project a long term human resource development plan has been prepared for the NARS institutes. In the plan, training and higher biotechnology studies has been given due importance. NATP is providing career growth options for high performing scientists.

Human resource development and farmer training are being implemented under the project in order to improve scholarly capacity; reduce the skill gap; enhance knowledge and ability to develop and implement research; extension; value chain and fiduciary management for researchers, extension providers, entrepreneurs, managers and farmers. NATP is following a multi-track approach for its human resource development and training program that includes higher studies, short term training, study visits, exposure visits,

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PROBLEM FORMULATION FOR THE ENVIRONMENTAL RISK ASSESSMENT OF RNAI PLANTS: CONFERENCE PROCEEDINGS NOW AVAILABLE

Genetically engineered crops approved for cultivation have been the subject of environmental risk assessments (ERAs) conducted by the regulatory agencies that are responsible for evaluating their safe use. Risk assessments of these crops systematically consider the potential adverse environmental impacts that may be associated with their cultivation and are a prerequisite to the commercial release of genetically engineered crops in all countries where they are currently cultivated. Although there are legislative and procedural differences between countries, and within agencies that produce environmental risk assessments, the assessments themselves are conducted based on a set of underlying principles and practices that are outlined in international consensus documents, national laws and regulations as well as agency guidance. Together, these constitute the current paradigm for ERA of genetically engineered crop plants.

The majority of approved genetically engineered crops have been transformed to express one or more novel proteins that confer useful agronomic traits such as insect resistance or herbicide tolerance. The classic approach for genetic engineering has been the introduction of a transgene from one organism to another. This transgene contains a promoter, an open reading frame and a terminator which allows the gene to be transcribed and translated by the host, producing a protein which confers a new trait. There are several emerging technologies in genetic engineering that build on these earlier approaches, and one of them is the use of RNA interference (RNAi).

The term RNAi has come to refer to the effect of a common set of eukaryotic mechanisms that result in post-transcriptional gene silencing. Observations of natural phenomena that are now known to be caused by RNAi mechanisms, including some forms of virus cross protection in plants,

have been known for decades, but it wasn't until the late 1990s that the molecular pathways responsible for these were discovered. Even before the molecular basis of RNAi was well understood, RNAi methods were adopted quickly by the research community because of the relative ease, specificity, and efficacy with which gene silencing could be accomplished.

The application of RNAi to produce genetically engineered crops with improved agronomic, nutritional, industrial and food-processing traits is becoming increasingly common. As new products approach commercialization, it is timely to consider whether the approach currently applied to the environmental risk assessment of genetically engineered crops expressing novel proteins remains appropriate for the ERA of genetically engineered plants utilizing RNAi approaches. This question was the subject of the conference "Problem Formulation for the Environmental Risk Assessment of RNAi Plants" convened by the Center for Environmental Risk Assessment (CERA), ILSI Research Foundation June 1-3, 2011. The objectives of the conference were:

1. To share information about current applications of RNAi for genetically engineered plants;
2. To use case studies to explore whether problem formulation for RNAi plants leads to new or additional risk hypotheses when compared with non-RNAi plants expressing similar traits, or if new risk assessment methodologies are necessary.

The proceedings of the conference, including presentations, case studies, a summary of discussions, and the points of consensus agreed by the participants can be downloaded from CERA's website: http://cera-gmc.org/docs/cera_publications/pub_08_2011.pdf.



The Reading List

. . . new and notable articles

ASSESSING THE ECOLOGICAL RISKS FROM THE PERSISTENCE AND SPREAD OF FERAL POPULATIONS OF INSECT-RESISTANT TRANSGENIC MAIZE

Raybould A, Higgins LS, Horak MJ, Layton RJ, Storer NP, De La Fuente JM, Herman RA.

One source of potential harm from the cultivation of transgenic crops is their dispersal, persistence and spread in non-agricultural land. Ecological damage may result from such spread if the abundance of valued species is reduced. The ability of a plant to spread in non-agricultural habitats is called its invasiveness potential. The risks posed by the invasiveness potential of transgenic crops are assessed by comparing in agronomic field trials the phenotypes of the crops with the phenotypes of genetically similar non-transgenic crops known to have low invasiveness potential. If the transgenic and non-transgenic crops are similar in traits believed to control invasiveness potential, it may be concluded

that the transgenic crop has low invasiveness potential and poses negligible ecological risk via persistence and spread in non-agricultural habitats. If the phenotype of the transgenic crop is outside the range of the non-transgenic comparators for the traits controlling invasiveness potential, or if the comparative approach is regarded as inadequate for reasons of risk perception or risk communication, experiments that simulate the dispersal of the crop into non-agricultural habitats may be necessary. We describe such an experiment for several commercial insect-resistant transgenic maize events in conditions similar to those found in maize-growing regions of Mexico. As expected from comparative risk assessments, the transgenic maize was found to behave similarly to non-transgenic maize and to be non-invasive. The value of this experiment in assessing and communicating the negligible ecological risk posed by the low invasiveness potential of insect-resistant transgenic maize in Mexico is discussed.

TRANSGENIC RESEARCH. (2011). [EPUB AHEAD OF PRINT]

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seminars and workshops. All these activities are contributing to technology adoption and quality output of research and development activities of the project.

Higher study in NATP comprises a post-graduate (Ph.D. and MS) degree program and post-doctoral research in different fields of agriculture including biotechnology and genetic engineering. Under Phase 1 of NATP, a total of 115 Ph.D. fellows (85 in-country and 30 foreign) have so far enrolled of which 6 Ph.D. scholars are directly working on biotechnology. Aside from those, there are 14 fellowships in plant breeding and

genetics, plant pathology and horticulture, many of whom have selected research topics in either biotechnology or related problems. This demonstrates that after completion of Ph.D. programs, several scientists will be equipped with the latest bio-technological knowledge and will be able to develop needs-based biotechnology programs.

The human resource development program of NATP is enhancing the capacity of NARS scientists and helping to build a research team in biotechnology that will lead to technological catch-up and will improve the research quality by adopting best science in technology system of Bangladesh.

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Workshop and Training Program on Sampling and Detection Methods Applied to Transgenic Crops	International Life Sciences Institute - India	November 17 - 19, 2011 Hyderabad	http://www.ilsa-india.org/
Stakeholder Consultation on Regulation of Transgenic Crops having Stacked Events/Genes	Department of Biotechnology and Biotech Consortium India Limited	November 23, 2011 New Delhi	
3rd Global Conference on Plant Pathology for Food Security	Indian Society of Mycology and Plant Pathology and Maharana Pratap University of Agriculture and Technology	January 10 - 13, 2012 Udaipur	http://isompp.org/3gc.html
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
Indian Seed Congress 2012	National Seed Association of India	February 10 - 11, 2012 Pune	http://www.indianseedcongress.com/default.htm
International Conference on Plant Biotechnology for Food Security: New Frontiers	Society for Plant Biochemistry and Biotechnology, National Research Centre on Plant Biotechnology	February 21 - 24, 2012 New Delhi	http://www.spbbindia.org/
INTERNATIONAL			
Workshop on Capacity-Building for Research and Information Exchange on Socio-economic Impacts of Living Modified Organisms under the Cartagena Protocol on Biosafety	Secretariat of the Convention on Biological Diversity and Ministry of Environment and Forests	November 14 - 16, 2011 New Delhi	http://bch.cbd.int/protocol/meetings/
The International Conference of GM Crops	Faculty of Agriculture, Cairo University	November 20 - 23, 2011 Cairo University, Egypt	http://www.icgmc2011.com/
Asia Sub-regional Training of Trainers' Workshop on the Identification and Documentation of Living Modified Organisms	Secretariat of the Convention on Biological Diversity and Ministry of Environment and Forests (MoEF)	November 21 - 25, 2011 New Delhi	http://bch.cbd.int/protocol/meetings/
Regional Workshop on Field Trials and Post-Release Monitoring of GMOs	Ministry of Culture	December 5 - 7, 2011 Zagreb, Croatia	http://www.icgeb.org/meetings-2011.html
5th International Botanical Conference -- Climate Change and Biodiversity: Role of Plant Scientists	Bangladesh Botanical Society	December 9 - 11, 2011 Department of Botany, University of Dhaka, Bangladesh	www.bdbotsoc.org or http://www.dhakai.com/botany/Circular.pdf

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