



SOUTH ASIA
BIOSAFETY PROGRAM

September 2011

Vol.7 No.9

NEWSLETTER

for private circulation only - not for sale

www.cera-gmc.org

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.

UPDATE ON GUIDANCE FOR INSTITUTIONAL BIOSAFETY COMMITTEES IN INDIA

Dr. K.K. Tripathi, Member Secretary, RCGM and Advisor, Department of Biotechnology, Government of India

According to Indian regulations, organizations handling genetically modified organisms (GMOs) and recombinant DNA (rDNA) materials for research or production must, with the approval of the Department of Biotechnology (DBT), Ministry of Science & Technology, constitute an Institutional Biosafety Committee (IBSC). In the regulatory framework for GMOs, the IBSC is one of the statutory committees that operates directly from the premises of the institution and is responsible for the proper implementation of biosafety rules, regulations and guidelines.

As part of capacity building activities, DBT has, from time to time, taken several initiatives to strengthen the function of the IBSCs (see box in right column). These include organizing consultations/training workshops, preparing guidelines, handbooks, etc. In 2004 DBT prepared a "Handbook for IBSC Members" for IBSC members and DBT nominees of IBSCs, which was widely circulated and well received by students, scientists, industry, institutions, universities, consultants and all those associated with rDNA technology research and development, handling of GMOs as well as the scientific fraternity of modern biology and biotechnology involving various areas of healthcare, agriculture, environment and industrial applications.

INITIATIVES BY DBT FOR REGULATORY COMPLIANCE BY ISBCs

Guidelines: DBT has formulated various biosafety guidelines for research involving GMOs that include recombinant DNA safety guidelines (1990, revised in 1994), guidelines for carrying out research in transgenic plants (1998) and guidelines for preclinical and clinical evaluation of rDNA vaccines, diagnostics and other biologicals.

Workshops (2004):

In 2004, DBT, in association with Biotech Consortium India Limited (BCIL), organized a series of six National Consultations on Biosafety Aspects Related to GMOs for ISBC members and nominees of DBT on IBSCs with an objective to interact with IBSC representatives in evaluating and monitoring recombinant DNA projects.

Handbook: DBT and BCIL prepared a handbook for IBSC members that was circulated nationally. The handbook explains in detail the roles and responsibilities of IBSC members, procedures for setting up an IBSC and evaluating project proposals including a checklist for same.

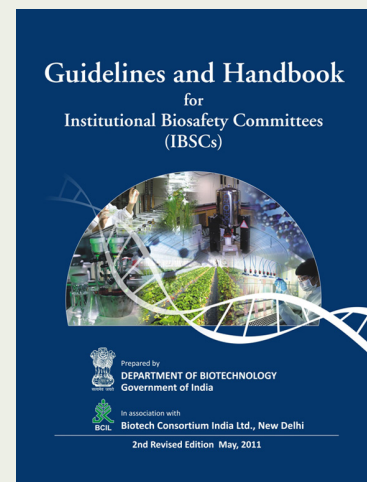
CD-ROM: DBT, in association with BCIL, prepared a CD-ROM compiling all guidelines, rules, regulations and protocols with various government notifications for the benefit of all the stakeholders.

Web: DBT operationalised a web-based database and two websites, <http://dbtbiosafety.nic.in> and <http://www.igmoris.nic.in>, to facilitate interaction with IBSCs and information compilation and dissemination on national rDNA activities.

Workshops (2009): Interaction with IBSCs was again undertaken by DBT and BCIL through a series of six workshops for DBT nominees and IBSC members to strengthen regulatory compliance by IBSCs. Participants were also apprised of compliance requirements with respect to online information exchange websites established by DBT.

In the past seven years since the Handbook was prepared, several new IBSCs have been constituted, which has resulted in the need to provide further guidance to strengthen regulatory compliance by increasing the number of IBSCs. Accordingly DBT has prepared a second revision of the

(continued on page - see DBT)



handbook, which has been restructured to include updated guidelines for IBSCs, a checklist for evaluating proposals and new formats for submissions to Review Committee on Genetic Manipulation (RCGM). A CD-ROM with electronic copies of the handbook and other relevant rules and regulations has also been prepared. It has three sections:

- **Guidelines:** Describes the constitution, composition, role and functions of IBSCs and provides information for compliance requirements by IBSCs and processes to be followed while dealing with genetically modified organisms (GMOs)/living modified organisms (LMOs) and rDNA materials in line with Rules, 1989 and guidelines issued by DBT from time to time.
- **Checklist:** An indicative checklist to assist IBSC members in reviewing the research proposals from investigators. Specific additions/deletions or modifications can be made to suit the requirements of each project on a case-by-case basis.
- **Guidance and formats for submission of applications to RCGM:** Forms for submission of applications to RCGM have been restructure and classified into various categories and numbered accordingly. Formats for issue of approvals have also been included. A section providing general guidance to applicants to facilitate compliance and timely processing of applications has also been included. Application forms have also been included with an option of electronic filling for the convenience of users/regulators.

BIOTECHNOLOGY RESEARCH AT BARI: ENTERING THE WORLD OF CUTTING-EDGE SCIENCE

M.A. Yousuf Akhond, Ph.D., Senior Scientific Officer,
Biotechnology Division, Bangladesh Agricultural Research
Institute (BARI), Email: a_akhond@hotmail.com

Bangladesh Agricultural Research Institute (BARI) is the largest research institute in Bangladesh. More than 700 scientists work at BARI under various disciplines, in different parts of the country, conducting research on more than a hundred crops. The application of research outputs at the field level has substantially increased production of wheat, potato, maize, pulses, oilseeds and different vegetable crops in Bangladesh.

Biotechnology research at BARI began in 1985 with the establishment of a tissue culture lab for potato seed production, which contributed significantly to the introduction of virus-free clean potato seed technology in Bangladesh. Another tissue culture laboratory, this one for micropropagation of horticultural crops, was established with Food and Agriculture Organization of the United Nations (FAO) assistance in 1993. This laboratory also had a pioneering role in developing micropropagation protocols of different horticultural crops and conducting farmers' field trials of tissue cultured plantlets, in particular, banana, jackfruit and pineapple, as well as others. As the productivity of various major crops in the country was reaching a ceiling and the demand for food was increasing, intervention with advanced biotechnological tools was seen as a way of supplementing conventional crop improvement techniques. In this context, the micropropagation laboratory was upgraded to a full-fledged research division in 1998 with the aim of establishing a centre of excellence in plant biotechnology research in Bangladesh. Eventually the Ministry of Agriculture came forward and, with government support, a state-of-the-art plant molecular genetics and

genetic engineering research laboratory was completed in 2009. This purpose-built laboratory is equipped with all the modern facilities needed to conduct research in advanced molecular biology and plant genetic engineering. There are separate units for molecular biology, microscopy, DNA sequencing and plant transformation. The facility also includes a modern, automated 'level II' greenhouse in which research on transgenic crops under contained conditions can be conducted. An isolated research field has also been set up for confined field trials of genetically engineered crops following biosafety regulations. At the same time existing laboratories of the other divisions and crop research centres of BARI have also been upgraded with modern facilities for molecular breeding, toxicology research, plant pathology, soil analysis and electron microscopy.

Meanwhile, since 2005, work has been underway in the Biotechnology Division to introduce bio-engineered fruit and shoot borer resistant 'Bt' eggplants (through marker-assisted backcrossing) and late blight resistant 'RB' potato in Bangladesh under ABSP II, a USAID supported project with the collaboration of Maharashtra Hybrid Seeds Company Limited in India and Cornell University in the United States. Nine locally adapted 'Bt' eggplant cultivars and two 'RB' potato varieties are being tested under confined field conditions at various locations in Bangladesh. The multi-location confined field trials of eggplants will be completed this year.

Soon after the establishment of the laboratory, scientists working in the biotechnology division initiated research on advanced molecular biology and genetic engineering techniques. Training of scientists in the area of advanced plant biotechnology is given emphasis and the research work is actively supported by Bangladesh Agricultural Research Council (BARC) with funding from the National Agricultural Technology Project (NATP) and the Krishi Gobeshona Foundation (KGF). Scientists of the institute also participated in various training programmes arranged by South Asia Biosafety Programme (SABP) on biosafety issues. An institutional biosafety committee was formed in line with the National Biosafety Guidelines of Bangladesh to oversee the on-going biotechnology research in the institute.

Research on biotechnology at BARI is based on national needs and problems faced by the farmers. Relevant information is fed back right from the farmers' fields through various channels like BARI's own on-farm research stations and through the Department of Agricultural Extension. Research priority is then set in consultation with BARC with special emphasis on developing biotic and abiotic stress tolerant crop varieties keeping the issues created by climate change in perspective. Despite a relatively recent start in the area of advanced plant biotechnology research and few available skilled personnel, biotechnology scientists at BARI have already demonstrated their abilities in the areas of GMO detection, marker-assisted breeding, DNA fingerprinting, recombinant-DNA technology and plant transformation. Plasmid vectors are being constructed and

DNA sequencing is being carried out in-house on a regular basis. Students from different public and private universities are routinely carrying out their research work using the advanced facilities of the biotechnology laboratory. This area of research is likely to expand in the coming years as the experiences of the scientists increases and with proper attention being paid to human resource development in the required fields.





The Reading List

... new and notable articles

TALE NUCLEASES AND NEXT GENERATION GM CROPS

Mahfouz MM, Li L

Site-specific and adaptable DNA binding domains are essential modules to develop genome engineering technologies for crop improvement. Transcription activator-like effectors (TALEs) proteins are used to provide a highly specific and adaptable DNA binding modules. TALE chimeric nucleases (TALENs) were used to generate site-specific double strand breaks (DSBs) *in vitro* and in yeast, *Caenorhabditis elegans*, mammalian and plant cells. The genomic DSBs can be generated at predefined and user-selected loci and repaired by either the non-homologous end joining (NHEJ) or homology dependent repair (HDR). Thus, TALENs can be used to achieve site-specific gene addition, stacking, deletion or inactivation. TALE-based genome engineering tools should be powerful to develop new agricultural biotechnology approaches for crop improvement. Here, we discuss the recent research and the potential applications of TALENs to accelerate the generation of genomic variants through targeted mutagenesis and to produce a non-transgenic GM crops with the desired phenotype.

GM CROP. 2011 APR 1;2(2) [EPUB AHEAD OF PRINT]

ENGINEERING THE PLANT GENOME: PROSPECTS OF SELECTION SYSTEMS USING NONANTIBIOTIC MARKER GENES

Penna S, Ganapathi T

In the past 2-3 decades, great progress has been achieved in the field of plant: genetic manipulation. This progress is based on fine-tuning of gene transfer methods, selection of transformed cells, and regulation of transgene expression. Transgenic: plant production requires selectable marker genes that enable the selection of: transformed cells, tissue and plants. The most used are those that exhibit resistance to: antibiotics or herbicides. Although this type of selection is routinely practiced, there are perceived risks in the deployment of transgenic plants containing these markers. A number of strategies have emerged on the development of alternate selection: systems referred to as positive selection and marker-free systems. Transgenes that: permit plant cells to utilize new carbon sources are being employed in transformation: research. Current research on marker-free transgenics is growing rapidly and its: application is being tested in different plant species.

GM CROP. 2010 MAY 1;1(3):128-36

GENE FLOW FROM TRANSGENIC COMMON BEANS EXPRESSING THE BAR GENE

Faria JC, Carneiro GE, Aragão FJ

Gene flow is a common phenomenon even in self-pollinated plant species. With the advent of genetically modified plants this subject has become of the utmost importance due to the need for controlling the spread of transgenes. This study was conducted to determine the occurrence and intensity of outcrossing in transgenic common beans. In order to evaluate the outcross rates, four experiments were conducted in Santo Antonio de Goiás (GO, Brazil) and one in Londrina (PR, Brazil), using transgenic cultivars resistant to the herbicide glufosinate ammonium and their conventional counterparts as recipients of the transgene. Experiments with cv. Olathe Pinto and the transgenic line Olathe M1/4 were conducted in a completely randomized design with ten replications for three years in one location, whereas the experiments with cv. Pérola and the transgenic line Pérola M1/4 were conducted at two locations for one year, with the transgenic cultivar surrounded on all sides by the conventional counterpart. The outcross occurred at a negligible rate of 0.00741% in cv. Pérola, while none was observed (0.0%) in cv. Olathe Pinto. The frequency of gene flow was cultivar dependent and most of the observed outcross was within 2.5 m from the edge of the pollen source.

GM CROP. 2010 MAR 1;1(2):94-98

TARGETING METABOLIC PATHWAYS FOR GENETIC ENGINEERING ABIOTIC STRESS-TOLERANCE IN CROPS

Reguera M, Peleg Z, Blumwald E

Abiotic stress conditions are the major limitations in modern agriculture. Although many genes associated with plant response(s) to abiotic stresses have been identified and used to generate stress tolerant plants, the success in producing stress-tolerant crops is limited. New technologies are providing opportunities to generate stress tolerant crops. Biotechnological approaches that emphasize the development of transgenic crops under conditions that mimic the field situation and focus on the plant reproductive stage will significantly improve the opportunities of producing stress tolerant crops. Here, we highlight recent advances and discuss the limitations that hinder the fast integration of transgenic crops into agriculture and suggest possible research directions.

BIOCHIM BIOPHYS CTA. 2011 AUG 16 [EPUB AHEAD OF PRINT]

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
National Symposium on Advances in Biotechnological Research in Agri-Horticultural Crops for Sustaining Productivity, Quality Improvement & Food Security	Sardar Vallabhbhai Patel University of Agriculture & Technology	September 14-16, 2011 Meerut, Uttar Pradesh	http://www.svbpmeerut.ac.in or http://www.svbpmeerut.ac.in/repos/SVPUAT%20Symposium.pdf
International Conference on Emerging Trends on Food and Health Security in Cold Deserts	Defence Institute of High Altitude Research, Defence Research and Development Organisation	September 23 - 25, 2011 LEH-Ladakh	
International Conference on Issues for Climate Change, Land Use Diversification and Biotechnological Tools for Livelihood Security 2011	Hi-Tech Horticultural Society and SVPUA&T	October 8 - 10, 2011 Meerut, Uttar Pradesh	http://www.svbpmeerut.ac.in or http://www.svbpmeerut.ac.in/pages/repos/confrence.pdf
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-SyR4AWfwaYJQ7IInfC4IQ
Winter School on Introduction Primary Goals of Plant Breeding with Agricultural Crops is Generally Aimed at Improved Yields, Nutritional Qualities and Pther Traits of Molecular Breeding and Marker Assisted Selection in Rice Improvement	Central Rice Research Institute	November 1 - 21, 2011 Cuttack	http://www.crri.nic.in/
World Cotton Research Conference 5	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
National Agricultural Innovation Project Sponsored Training Programme "Molecular Diagnostics for Risk Assessment and Management of Genetically Modified Crops"	National Bureau of Plant Genetic Resources	November 8 - 21, 2011 New Delhi	http://www.nbpg.ernet.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			
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/
The International Conference of GM Crops	Faculty of Agriculture, Cairo University, Egypt	November 20 - 23, 2011, Cairo University, Egypt	http://www.icgmc2011.com/
Regional Workshop on Field Trials and Post-Release Monitoring of GMOs	Ministry of Culture, Zagreb, Croatia	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 09 - 11, 2011 Department of Botany, University of Dhaka, Bangladesh	www.bdbotsoc.org or http://www.dhakai.com/botany/Circular.pdf

SABP CONTACTS

India

Dr. Vibha Ahuja
General Manager
Biotech Consortium India Limited
Anuvrat Bhawan, 5th Floor
210, Deendayal Upadhyaya Marg
New Delhi 110 002 India
Email: vibhaahuja@biotech.co.in

Bangladesh

Prof. Dr. M. Imdadul Hoque
Department of Botany
University of Dhaka
Dhaka - 1000
Bangladesh
Email: mimdadul07@yahoo.com

Others

Center for Environmental
Risk Assessment (CERA)
ILSI Research Foundation
1156 Fifteenth Street,
N.W., 2nd Floor
Washington D.C.
20005-1743 USA
Email: info@cera-gmc.org



To receive an electronic copy of this newsletter send your name, institutional information and e-mail address to: info@cera-gmc.org