SOUTH ASIA
BIOSAFETY PROGRAM

June 2008
Vol.4 No.6

NEWSLETTER

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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 the local governments to facilitate implementation of transparent, efficient and responsive regulatory frameworks that ensure the safety of new foods and feeds, and protect the environment.

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 address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

## INDIA'S NEWLY PROPOSED NATIONAL BIOTECHNOLOGY REGULATORY AUTHORITY

### Background

India's biotechnology regulatory system has experienced a number of changes since the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells 1989 (Rules, 1989) were first notified under the Environment (Protection) Act, 1986, including the elaboration of a series of guidance documents published by the Department of Biotechnology (DBT) in 1990, 1998, 1999 and most recently in 2008. The extraordinary growth of the Indian biotechnology sector has significant implications for policy in the area of regulation and this was the subject of two reports commissioned by the Ministry of Agriculture and the Ministry of Environment and Forests to evaluate the regulatory framework for products of agricultural biotechnology and recombinant pharmaceuticals, respectively.

The 2004 Report of the Task Force on the Application of Agricultural Biotechnology chaired by Prof. M.S. Swaminathan (the Swaminathan Report) recommended the establishment of an "autonomous, statutory and professionally-led National Biotechnology Regulatory Authority" that would have "two separate wings – one dealing with food and agricultural biotechnology, and the other with medical and pharmaceutical biotechnology. The Report declared that the "NBRA is essential for generating the necessary public, political, professional and commercial confidence in the science based regulatory mechanism in place in the country".

The 2005 Report of the Task Force on Recombinant Pharma chaired by Dr. R.A. Mashelkar (the Mashelkar Report) similarly supported the establishment of a National Biotechnology Regulatory Authority/Commission "providing a professionally managed single window mechanism for giving various clearances including biosafety issues". A model for the NBRA was proposed that "would comprise of four wings namely: a) Agricultural products/Transgenic Crops; b) Pharmaceutical/ Drugs and Industrial Products; c) Transgenic Foods/Feed; and, d) Transgenic Animals/Aquaculture" and that "alternate models of how a National Biotechnology Regulatory Authority can be created also needs to be examined." The Mashelkar Report additionally provided a series of recommendations to streamline the existing regulatory system for recombinant pharmaceuticals until the feasibility of establishing a NBRA could be evaluated.

In 2005, DBT published a draft National Biotechnology Development Strategy which elaborated a ten year vision for the future of biotechnology in India. The National Biotechnology Development Strategy was approved by the Government of India in November, 2007 after a two year consultation period with multiple stakeholders. As regards the regulation of biotechnology, the Strategy states that the NBRA will be established as an "independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes".

### The newly proposed National Biotechnology Regulatory Authority

As per the directive of Prime Minister's Office and the Committee of Secretaries, DBT has been entrusted with the responsibility of establishing the National Biotechnology Regulatory Authority (NBRA). To this end, DBT has prepared a Draft Establishment Plan for the National Biotechnology Regulatory Authority that describes the proposed structure of the NBRA as part of a new regulatory framework for products and processes of modern biotechnology.

As detailed in the Establishment Plan, the NBRA will be an independent, autonomous, statutory agency established by the Government of India with a mandate to safeguard the health and safety of the people of India and to protect the environment by identifying risks posed by, or as a result of, modern biotechnology, and managing those risks through regulating the safe development and deployment of biotechnology products and processes.

In order to establish and empower the NBRA, DBT has drafted new legislation, namely the National Biotechnology Regulatory Bill, 2008. Both the draft Establishment Plan for the National Biotechnology Regulatory Authority and the National Biotechnology Regulatory Bill, 2008 have been posted on the web for public comments (http://igmoris.nic.in/default1.asp and http://dbtbiosafety.nic.in/inner1.html). The comment period ends **June 22, 2008** and comments should be submitted to:

Mr. Sundeep Sarin, Joint Director
Department of Biotechnology, Ministry of Science & Technology
7th Floor, Block-II, CGO Complex, Lodhi Road New Delhi–110 003
-or-
Dr. Vibha Ahuja, Deputy General Manager
Biotech Consortium India Limited
Anuvrat Bhawan, 5th Floor, 210, Deen Dayal Upadhyaya Marg
New Delhi - 110 002
Fax: 011-23219063
-or-
Submit comments by e-mail to nbra.dbt@nic.in

CALENDAR

## CALENDAR OF EVENTS

| Event | Organization | Date | Place |
|---|---|---|---|
| **INDIA** | | | |
| Regional consultations on the proposed National Biotechnology Regulatory Authority (NBRA) | Department of Biotechnology (DBT) and Biotech Consortium India Limited (BCIL) | June 2008 | Mumbai/ Ahmedabad and Kolkata |
| Workshop on Guidelines for Conducting Confined Field Trials of GE Crops and Standard Operating Procedures (SOPs) | National Seed Association of India and BCIL | June and July, 2008 | Hyderabad and Aurangabad |
| SAU Workshops on Management and Monitoring of Field Trials of Genetically Modified Crops | Ministry of Environment and Forests, DBT and BCIL | June to August, 2008 | State Agricultural Universities in 12 States |
| GM Food Safety Assessment in India: Taking Stock and Planning for the Future | Indian Council of Medical Research, BCIL and SABP | July 8, 2008 | NIN, Hyderabad |
| **GLOBAL** | | | |
| First Global Conference on GMO Analysis | European Network of GMO Laboratories and the European Commission | June 24 to 27, 2008 | Villa Erba, Como, Italy |
| 10th International Symposium on the Biosafety of Genetically Modified Organisms | International Society for Biosafety Research (ISBR) | November 16 to 21, 2008 | Wellington, New Zealand |

## GM CONFINED FIELD TRIALS TRAINING WORKSHOP HELD IN BANGLADESH

The Bangladesh Agricultural Research Council (BARC) together with the South Asia Biosafety Program (SABP) organized a training workshop on the monitoring and inspection of confined field trials in Dhaka, Bangladesh on June 3 and 4, 2008. Participants were selected from the Central and Regional Agricultural Research Stations (RARS) of the Bangladesh Agricultural Research Institute (BARI) where the confined field trials of Bt-brinjal will be conducted. In addition, scientists from the Seed Certification agency (SCA) and the Department of Agricultural Extension in these regions also participated, together with delegates from BARC, the Department of Environment, Bangladesh Rice Research Insititute, Dhaka University and Bangladesh Agricultural University, Mymensingh.

Dr. Md. Abdur Razzaque, Executive Chairman, BARC, emphasized, in his opening address, that the upcoming trials with Bt-brinjal will be the first confined field trials with a trangenic crop in Bangaldesh. Therefore, the scientists as well as the monitoring officers must be trained properly to develop their confidence to conduct the confined field trial in a safe and sound manner. He also stressed the difference between 'nice to know' and 'need to know' with regard to the information required by the regulatory agencies. He suggested the participants focus on factors that are important for the safe conduct of field trials.

During the two-day workshop the participants covered different topics needed for conducting confined field trials of transgenic crops, focussing on the Guidelines for Confined Field Trial and a set of Standard Operating Procedures (SOPs) developed by BARC in conjunction with SABP. Other documents provided to participants included a Monitoring and Inspection Manual and checklists for performing inspections of confined field trials. Group exercises based on potential scenarios that could arise during confined field trials were used to familiarize participants with what to expect. The workshop will be followed up with visits to the field trials in the coming months.

## QUARANTINE AND TRANSBOUNDARY MOVEMENT OF TRANSGENICS

Dr. Ravi K. Khetarpal, Head, Plant Quarantine Division, National Bureau of Plant Genetic Resources, New Delhi

[This is the second and final half of an article that began in the May 2008 issue of the South Asia Biosafety Program newsletter. If you missed the first half, you can read it online at http://www.agbios.com/docroot/articles/08-142-001.pdf.]

The transboundary movement of any planting material poses the environmental risk of introducing exotic pests and diseases; moving transgenic planting material and crops has the added risk of introducing a new or unwanted transgene. Quarantine and trade related issues are country specific but also need to adhere to international norms. Unfortunately, few details are provided in the Convention on Biological Diversity on the methodology of quarantine processing and pertinent issues that are important during transboundary movement of transgenics.

Although it may appear to be a simple and routine job, the reality is very different. Issues that need to be addressed to ensure safe transboundary movement of transgenics include;

- A national regulatory system or framework must be explicit about the mandatory testing of transgenics in quarantine. It should provide for adequate manpower and funds to achieve it and ensure that a national mechanism for risk assessment of transgenics and pest risk analysis (PRA) are in place.
- Presently, quarantine stations located at various seaports, airports and land frontiers in most of the South Asian countries do not have the infrastructure and expertise to handle and test the bulk imports of genetically modified (GM) seeds to ensure proper testing for transgenes and pests.
- A methodology needs to be developed and standardized to detect the presence of transgenic/GM contamination (deliberate or inadvertent mixing of GM seed with non-GM seed) in samples not declared as transgenic during quarantine processing. This needs serious attention by the researchers at a global level as it may help in checking the transgenic samples that are being imported illegally as non transgenic.

(continued on page 4 - see Quarantine)

# CREAM 0F THE (WEB) CR0P

harvesting the best from the worldwide web

Between September 2007 and May 2008 we put a spotlight on websites that provide information on genetically modified organisms in the Indian context, which were developed by Department of Biotechnology in India.

This month we begin a new series highlighting international websites that feature material we hope our readers will find useful and informative. Our first focuses on the AGBIOS website Home page **(http://www.agbios.com/main.php)**. We will look at other pages at this extensive website in future newsletters. - Editor

## THIS M0NTH'S PICK:

*the*
***AGBIOS** website*
***Home page***
*http://www.agbios.com/main.php*

AGBIOS is a consultancy dedicated to providing public policy, regulatory, and risk assessment expertise to public and private sector stakeholders working in agricultural biotechnology. With offices in Canada and Argentina, AGBIOS works internationally with intergovernmental organizations and government departments and agencies on issues of policy and regulation pertaining to genetically modified and other novel foods, crops and forest tree species. The Company also provides experience and expertise to public sector research institutions and commercial enterprises seeking regulatory approval of biotechnology products, and to other public and private sector groups seeking clarification of issues associated with the development and utilization of biotechnology processes and products.

The AGBIOS website is a resource for constantly updated information on biosafety and transgenic crops. The site contains a complete database of approvals for transgenic crops around the world together with numerous references, background information and news items relevant to agricultural biotechnology. Case studies in the environmental and food safety risk assessment of specific transgenic crops are provided for self-instruction and workshop training.

The four main sections of the site are accessed from links on the main page as illustrated below. Each of these four sections will be covered separately in future editions of this newsletter.


- The 'Articles' section provides a database of papers on biosafety and regulation of agricultural biotechnology, referenced by keyword and author name;
- 'News' contains the archives of news stories posted on the site over the last nine years;
- The 'GM Database' provides information on all transgenic crop plant events that have been approved for food or feed use and commercial production around the world; and
- 'Briefings' contains case studies on the risk assessment of specific transgenic plants and some general information on regulation and risk assessment.

## Quarantine - *continued from page 2*

- Based on a country's requirement there is a need to develop a system for the certification of GM food and products and, eventually, their regulation.
- There is an urgent need, at the international level, to harmonize the Agreement on Application of Sanitary and Phytosanitary (SPS) Measures of the World Trade Organization (WTO) with the Cartagena Protocol (the Protocol) to ensure that bulk imports of transgenics are subjected to proper biosafety norms along with PRA, which is a mandatory requirement under the SPS.

Bear in mind that a tight biosafety regime on imports could raise fundamental questions about adherence to the core WTO obligation relating to 'national treatment'. Also, the WTO does not exactly share a comfortable relationship with international biosafety regulations that trace their foundation to the Protocol. To date, no internationally agreed upon standards related to risk assessment and risk management of GMOs/LMOs have been finalized; the stumbling block being the competing standards regarding the use of GMOs in the production, manufacture and export of commodities, including planting materials and food. In any case, while addressing biosafety issues in the regulatory set-up, a balance between economic development and environmental protection should be maintained.

In India, the National Bureau of Plant Genetic Resources (NBPGR) of the Indian Council of Agricultural Research is the nodal agency that issues import permits and undertakes the quarantine processing of imported transgenic planting materials. An import permit is issued after technical clearance for import has been given by the Review Committee on Genetic Manipulation of the Department of Biotechnology. National identity numbers (exotic collection numbers) are also allocated to each accession of imported transgenic material at NBPGR. NBPGR has established a National Containment/ Quarantine Facility that has been built so that no viable biological material/pollen/pathogen can enter or leave the containment. A methodology for the simultaneous testing of transgenics for pests as well as for transgene detection has been developed for the purpose. To date, about 8000 samples of transgenic crops (*Brassica*, soybean, cotton, maize, rice, wheat, tobacco and chickpea) have been processed for quarantine clearance during which they have been tested for associated exotic pests, if any, and to ensure the absence of terminator gene technology (embryogenesis deactivator gene), which are mandatory legislative requirements. In addition, primers have been designed for scorable/selectable markers, regulatory sequences and specific transgenes. These primers have been used in individual and multiplex PCR for simultaneous detection of two or more genes in the respective transgenic material. NBPGR has taken the lead at the national level to train human resources in the area of quarantine and biosafety since the year 2000. A 25-minute long audio-visual CD that covers the regulatory requirements, quarantine and transgene testing procedures carried out during the transboundary movement of transgenics into the country was brought out recently and is available on demand. Presently, NBPGR is engaged in developing diagnostic kits for certain transgenes and pests. It is also undertaking research on testing the transgenicity of samples not declared as transgenics.

As the variety of genes incorporated into GMOs increases, it will result in more ELISAs and PCR tests, higher costs and it will take more time. Technology based on gene-chips looks promising for high-throughput analysis, *i.e.*, screening multiple GMOs simultaneously, provided the relevant DNA sequence information is available and it will need to be exploited for quarantine purposes.

In view of the liberalization in trade among the South Asian countries and the South Asian Free Trade Agreement, there is a need to create a platform to harmonize the regulatory measures related to trade and exchange of transgenic material and to use the synergy of expertise and infrastructure to ensure biosafety in the region.

## TERI OFFERING 'BIOTECHNOLOGY APPLICATIONS AND REGULATION' TRAINING

Following the excellent response it received after giving its first training program on 'Applications of Biotechnology and its Regulation' in 2007, TERI University, sponsored by Indian Technical and Economic Cooperation (ITEC), Government of India, will be offering the same training program from August 19 to September 5, 2008. Details follow:

The programme will focus on agricultural biotechnology techniques and the status of acceptance of new technologies.

The faculty for this course will be drawn from TERI and experts from other institutions will be invited to ensure that all the subjects are taught by the leading subject experts.

Details about the program can be found at http://www.teriin.org/events/docs/itec_brochure_21may08.pdf.

All expenses related to participation will be borne by the Government of India and a moderate per diem will be provided to participants.

Candidates must apply to the Indian Embassy in their own country. Please send a copy of the application, marked "Application for ITEC", to the name and address noted below. To be considered, applications must be received by June 25, 2008. Candidates will apply to their respective institutions, following the routine approval process for attending international training programmes, in accordance with the institute's rules. The application form is downloadable from http://itec.nic.in/form.htm.

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