SOUTH ASIA
BIOSAFETY PROGRAM

December 2008
Vol.4 No.12

NEWSLETTER

for private circulation only - not for sale

www.agbios.com/sabp

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.

DEVELOPMENTS OF BIOSAFETY REGULATORY REGIME IN BANGLADESH

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The development of biotechnology has already been emphasized in the policy regime of the Government of Bangladesh. Harvesting the beneficial aspects of modern biotechnology is regarded as crucial for the overall development of a country like Bangladesh. The essence of the precautionary approach to mitigate, avoid or prevent the potential adverse or harmful effects of genetically modified organisms (GMOs) to the biodiversity, environment and human health must be taken into account while working with modern biotechnology.

During the past decade, substantial progress has been achieved worldwide in terms of research and development in biotechnology. Such achievements have been obvious in several areas including agriculture, industry, medicine and public health. Nevertheless, such progress and accomplishment has, at the same time, evoked tremendous concerns among researchers themselves as well as the public at large. Such concerns are centered on the release of transgenic organisms into the open environment; biosafety precautions and preventative measures; the apprehension that certain transgenic organisms may be harmful or become pathogenic to economic plants, animals and human beings; and the unanticipated virulence of manipulated genes or gene products that may disperse uncontrolled and freely into the nature. Keeping in mind, however, the potential risks in doing research with and development of GMOs, the regulatory regime of modern biotechnology has been evolved and named as biosafety.

Bangladesh has made a great deal of progress on the way towards establishing a biosafety regulatory regime. The task was initiated with the formulation of Biosafety Guidelines. The Ministry of Science and Technology of Bangladesh formulated Biosafety Guidelines for the first time in 1999. Bangladesh ratified the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity on February 5, 2004, which came into force in May 5, 2004. Being the National Focal Point (NFP) of the CPB, the Ministry of Environment and Forest took the lead of establishing biosafety regulatory regime. The Biosafety Guidelines of Bangladesh have subsequently been updated by the Ministry of Environment and Forests in conformity with the CPB and were published in the National Gazette in January 2008. Following the Biosafety Guidelines different Regulatory Committees have been formed, namely the National Committee on Biosafety (NCB), the Biosafety Core Committee (BCC) and Field Level Biosafety Committees for monitoring confined field trials of Bt eggplant and late blight resistant potato.

The Biosafety Guidelines of Bangladesh are basically intended to be a resource for information, guidelines, policies, and procedures that will enable and encourage those working in the laboratory environment to work safely and reduce or eliminate the potential for exposure to biological hazards. Biosafety Guidelines are important and extremely essential, not merely for researchers within the country, but also for various cooperative and collaborative ventures between national institutions and overseas research partners interested in laboratory testing or field trials of GMOs in Bangladesh.

Being a party to the CPB, Bangladesh ought to develop the capacity to handle biosafety issues associated with the trans-boundary movement and the subsequent uses of GMOs. In 2007, Bangladesh developed the National Biosafety Framework (NBF). The Biosafety Framework has been finalized through the process of multi-stakeholder consultation and it lays the foundation for establishing a regulatory regime to ensure safe transfer, handling, transit, trans-boundary movement, development, field trial and commercial release of GMOs. The NBF is complimentary to the national commitments towards implementation of a multilateral environmental agreement like the Cartagena Protocol on Biosafety. During the development of the NBF, Bangladesh published the following educational and awareness materials on biosafety:

- Biosafety booklet in native language Bangla.
- Biosafety leaflet in Bangla.
- Posters on biosafety.

Bangladesh established a web-based biosafety Information Exchange System or the Biosafety Clearing House (BCH) in 2008. The Bangladesh BCH is interconnected with the BCH central portal being operated and maintained by the Secretariat of the Convention on Biological Diversity.

Conducting research and development on GMOs calls for the institutes and research and development organizations to be compliant with the standard operating procedures (SOPs) and various monitoring data recording formats. The Ministry of Environment and Forests is in the process of finalizing SOPs and data recording formats for confined field trials of eggplant.

Under the aegis of the National Committee on Biosafety (NCB) of the Ministry of Environment and Forests, the Government of Bangladesh has so far endorsed the following research and development activities:

- Importing TPSP plasmid for developing salinity and drought resistant IR-64 (rice): Greenhouse experimentation to be conducted by Bangladesh Rice Research Institute (BRRI).
- Importing late blight resistant plasmid pCLD 04541: Research and development in lab and greenhouse

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CALENDAR OF EVENTS

Event	Organization	Date	Place
INDIA			
Series of Workshops on 'Management and Monitoring of Field Trials of Genetically Modified Crops'. Organized by Department of Biotechnology (DBT), Ministry of Environment & Forests (MoEF) and Biotech Consortium India Limited (BCIL).	Workshops are being held at the following SAUs: - Narendra Deva University of Agriculture & Technology, Faizabad, Uttar Pradesh **(December 20, 2008)** - Orissa University of Agriculture & Technology, Bhubaneswar, Orissa **(December 22, 2008)** - Punjab Agricultural University, Ludhiana, Punjab **(December 22, 2008)** - Acharya NG Ranga Agricultural University, Hyderabad, Andhra Pradesh **(December 17, 2008)** - Indira Gandhi Krishi Vishwavidyalaya, Raipur, Chhattisgarh **(December 24, 2008)** - Bidhan Chandra Krishi Viswavidyalaya, Nadia, West Bengal **(December 29, 2008)** - Rajendra Agricultural University, Samastipur, Bihar* - Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana* - Tamil Nadu Agricultural University, Coimbatore, Tamil Nadu* - Rajasthan Agricultural University, Bikaner* - Dr. Y.S. Parmar University of Horticulture and Forestry* * *Dates to be finalized.*		
National symposium on 'Bt-cotton: Opportunities and Emerging Threats'	CRDA, Central Institute for Cotton Research (CICR), DOCD	January 8 - 9, 2009	CICR, Nagpur
Winter School on 'Biosecurity and Biosafety: Policies, Procedures and Issues'	National Bureau of Plant Genetic Resources, New Delhi	January 14 - February 3, 2009	New Delhi
National Seminar on 'Genetically Modified Crops: Status, Issues and Awareness'	School of Life Sciences, North Maharashtra University	January 20 - 21, 2009	Jalgaon, Maharashtra
BioAsia 2009: The Global Bio Business Forum	Federation of Asian Biotech Associations, Government of Andhra Pradesh, University of Hyderabad and All India Biotech Association	February 2 - 4, 2009	Hyderabad
6th Global Knowledge Millennium Summit 'Bio-Nano: The Global War on Hunger' Opportunities- Indian Farmers	The Associated Chambers of Commerce and Industry of India (ASSOCHAM)	February 12 - 14, 2009	New Delhi
BANGLADESH			
4th International Botanical Conference.	Bangladesh Botanical Society	January 16 - 18, 2009	Botany Department, Dhaka University

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experimentation to be conducted by Bangladesh Agricultural Research Institute (BARI).

- Confined field trials of Bt eggplant at **three** BARI research stations.
- Confined field trials of late blight resistant potato at **two** BARI research stations (Joydevpur and Debiganj).

The Bangladesh government is now moving forward to develop a Biosafety Act or Biosafety Rules, taking the basic elements of NBF into consideration. Strengthening relevant government agencies such as border control (customs), quarantine and inspection facilities; setting-up data collection, management and storage facilities; development of reference or accredited laboratories for wider ranges of safety analysis and establishment of inter-institutional networks for risk analysis, management, reporting, communication; and as a whole, the full implementation of the NBF are some of the important challenges ahead for Bangladesh in establishing a full scale biosafety regulatory regime in the country.

BIOTECHNOLOGY SYPOSIUM HELD IN BANGLADESH

From December 3 to 5, 2008, an international symposium on Regulatory and Safety Issues in the Commercialization of Biotechnology Research in Developing Countries was held in Dhaka, Bangladesh. The symposium was hosted by the BRAC University and it was sponsored by, among others, the International Centre for Genetic Engineering and Biotechnology (ICGEB), Ministry of Science and Information and Communication Technology, Bangladesh Academy of Sciences, the Center for Intellectual Property Studies (CIP) Sweden and a number of other local organizations.

The main purpose of the symposium was to provide information relevant to biotechnologists, policymakers and other professionals in developing countries that would enable them to make informed decisions on applications of biotechnology. Areas covered included technology transfer, intellectual property and intellectual property rights, biosafety, bioethics and regulatory affairs as they relate to field trials, clinical trials and the commercialization of biotechnology research. Participants and speakers came from Bangladesh and abroad to share their experience, in particular with regard to international practices in these areas.

Closing the symposium was a panel discussion where the participants gave their opinions on the challenges and opportunities faced by developing countries in utilizing biotechnology. Focus on developing human and physical resources was regarded as key, with an emphasis on training and experience in regulatory affairs and intellectual property protection as these were seen as particularly lacking. The symposium closed with a call for greater cooperation between the participating countries from Cuba to Malaysia in the field of commercialization of biotech products.

A full report on the Symposium can be read at http://www.gnobb.org/symposiumlast.pdf.

CREAM OF THE (WEB) CROP

harvesting the best from the worldwide web

THIS MONTH'S PICK:

Office of the Gene Technology Regulator

website

http://www.ogtr.gov.au/

The Office of the Gene Technology Regulator (OGTR) was established within the Australian Government Department of Health and Ageing to provide administrative support to the Gene Technology Regulator (the Regulator) in the performance of her functions under the Gene Technology Act 2000 (the Act). The Regulator is responsible for administrating the Act, which introduced a national scheme for the regulation of genetically modified organisms (GMOs) in Australia, in order to protect the health and safety of Australians and the Australian environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

The OGTR website is divided into 12 sections:

- **About the OGTR:** An overview of the OGTR, the Act, the Regulator and her roles and functions, the National Gene Technology Regulatory System and the prohibitions and approvals required by the legislation.
- **What's New:** Postings of the latest licence applications, notifications on decisions to issue licences, invitations to comment, quarterly and annual reports of the OGTR, *etc*.
- **GMO Record:** Information on and an explanation of all GMO product dealings approved by or notified to the Regulator or specified in an Emergency Dealing Determination. This section also contains information on all genetically modified product approvals notified to the Regulator by other regulatory authorities. Case by case Risk Assessment and Risk Management Plans (RARMPs) produced in response to licence applications proposing Dealings Involving Intentional Release (DIR) of a GMO into the Australian environment are included here.
- **Classes of Dealings:** Contains definitions of the six different classes of dealings in relation to GMOs and the corresponding approval processes as set out in The Act and the Gene Technology Regulations 2001.
- **Licence Application & Assessment Process:** Includes an outline of the generalized steps involved in the licensing process, a definition of the types of licences that may be issued, a list of the status of licence applications, which includes links to relevant documents, definitions of the statutory conditions that may be included in a licence, and information on having a licence varied, surrendered, suspended or cancelled.
- **IBC & Accredited Orgs:** Contains general information for IBC and accredited organizations about gene technology regulation and any changes made to the regulation and a list and definitions of exempt or proposed dealings and any changes made to them and to the various guidelines. Also contains information about accreditation of an organization, links to OGTR operational policies, risk analysis framework and frequently asked questions.
- **Monitoring & Compliance:** Gives guidance and outlines protocols for monitoring and compliance activities, for reporting on non-compliance and requirements for importation.
- **Maps of Trial Sites:** Contains information about, status and location of all field trials involving the intentional release of GMOs and a web-based geographic information system that enables users to search by geographic region, specific GMO or by individual licence.
- **Forms & Guidelines:** Contains PDF and RTF copies of all the forms, guidelines and operational policies required under the Act.
- **Publications:** Provides access to a range of documents, such as quarterly and annual reports, fact sheets, documents associated with risk assessment and other relevant documents such as Australia's gene technology legislation and documents produced by the gene technology advisory committees.
- **Gene Technology Committees:** An overview of the relationship structure between the Gene Technology Advisory Committees.
- **Media Information:** Provides access to the OGTR media releases, dating back to 1999, under the new regulatory and previous voluntary systems.

POTENTIAL EFFECT OF BT PROTEINS EXPRESSING IN TRANSGENIC RICE LINES ON NON-TARGET AND PREDATORY INSECTS

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Transgenic crops resistant to insect pests are increasingly attracting interest as a component of pest management strategies. Most insect-resistant transgenic crops commercialized to date carry crystal protein genes (*cry*) from the bacterium *Bacillus thuringiensis* (*Bt*). Such *Bt* crops can promote increased yield and decreased insecticide use (Fernandez-Cornejo and McBride, 2000). Although the potential benefits of *Bt* crops are great, evolution of resistance by pests and awareness of possible effects of various *Bt* proteins on non-target insects, predators, and parasites are one of major risks limiting the commercialization of transgenic food. Rice, the staple food for half of the world's population, including India, has recently beceome the latest target crop to use the *Bt* technology. Several insect-resistant *Bt* rice lines for the control of yellow stem borer, striped stem borer, and leaf folder have been developed at the International Rice Research Institute (IRRI) in the Philippines by the introduction of various single or fusion *Bt* genes into the background of elite indica rice cultivars (Datta *et al*, 2002, 2003). Transgenic *Bt* IR72 rice lines showed a significantly higher level of resistance against four target insects (yellow stem borer, pink stem borer, striped stem borer and leaf folder) under both natural and artificial infestations in field conditions in China (Ye *et al*, 2001). Similarly, Tu *et al* (2000) have reported a 28 per cent yield advantage of a *Bt* hybrid rice over the non-*Bt* hybrid by protecting against two lepidopteran insects, yellow stem borer and leaf folder, in field conditions of China. In India limited scale field evaluation of transgenic *Bt* rice lines has been performed at Directorate of Rice Research, Hyderabad.

A rice field has a highly diverse and interlinked group of insect species including herbivores, predators, and parasitoids. This complex forms an essential component of biological control and is one of the fundamentals of insect management strategies in rice. For biological control to be effective in managing the balance of insect pest population in rice fields, it is essential to assess the effect of novel insecticides like *Bt* on non-target insects and their predators/parasitoids. Insight into the potential effect of the deployment of transgenic *Bt* rice on the population dynamics of other non-target insects and their predatory organisms can be gained by evaluating the effects of the Bt protein on life-history parameters of brown planthopper and mirid bug feeding on *Bt* rice and control non-*Bt* rice. Mirid bug, *Cyrtohinus lividipennis* (Hemiptera: Miridae) survives predaciously by feeding on brown planthopper, *Nilaparvata lugens* larvae and nymphs in the rice ecosystem.

A study was planned to assess the potential effect of Bt protein expressed in transgenic *Bt* rice on two non-target insect species, *N. lugens* and *C. lividipennis*. This is a major requirement of ICMR/DBT guidelines and protocols for the safety assessment of GM foods and mandatory for commercial release of the GM crops in India. The objective of the study was to assess the effect of Bt toxins on life-history parameters of brown planthopper, a non-target insect of rice, and its predator insect, mirid bug, to understand the secondary exposure of Bt proteins. *N. lugens* is a major pest of rice and is an important constituent of the population structure of the rice growing area of Asian countries. A transgenic *Bt* rice line expressing high amount (0.812 to 1.279 µg/g TSP) of Bt protein was used for this study. Our ELISA results clearly showed no detectable biologically active Bt protein in the body tissues of *N. lugens* after feeding on the transgenic rice lines expressing a high amount of Bt protein. The lack of any detectable level of toxic protein in the insect body could be due to (1) the absence of toxic protein in the xylem or phloem saps and therefore insects with a piercing and sucking type of feeding behavior are not exposed to it or (2) the degradation of toxin protein after ingestion by *N. lugens* adults.

Similarly, there was no indication of the activity of the biologically toxic protein on *C. lividipennis* feeding on *N. lugens* larvae/nymphs reared on transgenic *Bt* rice. In choice tests carried out on caged rice plants in a containment greenhouse at IRRI, the egg-laying capacity and hatchability of laid eggs of *N. lugens* insects on *Bt* rice and non-*Bt* rice control plants were similar. A deleterious effect of Bt toxins was not noticed on survival, weight, and development of larvae and nymphs, nor on adult fecundity and egg-laying capacity. Our study also indicated no negative effect of Bt proteins on predators and parasites of *N. lugens* by secondary exposure, as the differences in larval survival, developmental period, and male to female ratio of the predator insect *C. lividipennis* feeding periodically on *N. lugens* larvae reared on *Bt* rice and non-*Bt* rice lines were not significant. No change in growth fitness characteristics was observed among the insects of both species reared on *Bt* rice and non-*Bt* rice.

In summary, Bt toxin at the level expressed in the transgenic rice did not affect the development and reproduction of *N. lugens* and its predator insect *C. lividipennis* that fed on brown planthopper nymphs reared on *Bt* rice. The potential risks of secondary exposure to predators and parasitoids posed by other phytophagous insects, especially phloem feeders such as *N. lugens*, feeding on *Bt* transgenic crops are negligible. The finding provides data on the much-debated environmental risk of exposure to Bt protein, particularly with respect to non-target pests, including predators and parasites. However, further studies are need to substantiate such non-toxicity at a much higher dose of Bt protein.

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