SOUTH ASIA
BIOSAFETY PROGRAM

September 2008
Vol.4 No.9

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.

NORMAN E. BORLAUG INTERNATIONAL AGRICULTURAL SCIENCE AND TECHNOLOGY FELLOWS PROGRAM : MY EXPERIENCES

V.L. Maheshwari, Professor & Director, School of Life Sciences, North Maharashtra University, Jalgaon (MS) India

Risk assessment of genetically modified food was a relatively new area for me and I availed the opportunity under the Norman E. Borlaug International Agricultural Science and Technology Fellows Program of the United States Department of Agriculture (USDA) to get an in depth understanding of the risk analysis of genetically modified food with particular emphasis on molecular and biochemical characterization of the transgenic event and novel protein, respectively. Since I am a biochemist by training and have been working on isolation, purification, characterization and evaluation of biological activity of plant derived secondary metabolites involving their toxicity profile, I was eager to learn more about the toxicity and allergenicity components of risk analysis and use of bioinformatics as a tool in assessing the biosafety of genetically modified food.

When I arrived at Iowa State University (ISU), Ames, my mentor, Dr. Jeffrey Wolt, a professor of agronomy and an independent risk assessor, suggested that I review the framework/guidelines of risk analysis of different agencies, including the Indian regulatory agency, and literature on the topic from the past five years.

We visited Pioneer Hi-Bred in Johnston, Iowa, where I did a presentation on the work we have been doing in India. This was followed by a visit to their labs and greenhouses where I met with scientists involved in the regulatory affairs of transgenic crops.

Dr. Wolt arranged for me to spend time with Prof. Kan Wang, Director of the ISU Plant Transformation Facility, and Dr. Taner Sen, an expert in bioinformatics at ISU. I made full use of this opportunity and, by using different examples, came to comprehend the molecular characterization of the transgenic event. Dr. Sen taught me the basics of bioinformatics and how to interpret the results and I experienced hands-on training in bioinformatics with Dr. Sule Karaman, a scientist with Pioneer Hi-Bred and a part-time post doctoral fellow at ISU, using various aspects of the Golden Rice 2 case study developed by Prof. R.E. Goodman of the University of Nebraska - Lincoln.

My work and discussions with Dr. Wolt on toxicology assessment and theoretical models for predicting toxicity were supplemented with many different opportunities. Among these, I worked at length with Dr. Brian Delaney, Sr. Research Scientist (toxicology) at Pioneer Hi-Bred, Johnston, who provided me with detailed insight into the industry perspective and *modus operandi* as regards toxicity from the point

Prof. Maheshwari (from top) with Dr. Sule Karaman; with Prof. Kan Wang, at ISU, Ames, Iowa; and at Pioneer Hi-Bred headquarters at Johnston, Iowa, with his mentor, Prof. Jeff Wolt.

(continued on page 2 - see Experiences)

CALENDAR

CALENDAR OF EVENTS

Event	Organization	Date	Place
INDIA			
Sensitization workshop on 'Registration of Plant Varieties Under PPV & FR Act, 2001'	All India Crop Biotechnology Association, Biotech Consortium India Limited (BCIL) and PPV & FR Authority	September 26, 2008	Hyderabad
SAU workshops on 'Management and Monitoring of Field Trials of Genetically Modified Crops'	Ministry of Environment & Forests, Department of Biotechnology and BCIL	October - December, 2008	At SAUs in 16 States
BANGLADESH			
International Symposium on Regulatory and Safety Issues in the Commercialization of Biotechnology Research in the Developing World	International Centre for Genetic Engineering & Biotechnology (ICEGB) and BRAC University. For more information e-mail biotechsymp2008@yahoo.com	December 2 - 4, 2008	BRAC University, Dhaka
4th International Botanical Conference	Bangladesh Botanical Society	January 16 - 18, 2009	Botany Department, Dhaka University
INTERNATIONAL			
10th International Symposium on the Biosafety of Genetically Modified Organisms	International Society for Biosafety Research (ISBR)	November 16 to 21, 2008	Wellington, New Zealand

Experiences - *continued from page 1*

when the idea of a new transgenic event is conceived. I also learned about registration procedures at presentations given during a second trip to Pioneer, Dr. John Cunnick of ISU gave me a lengthy explanation of the advantages and limitations of various animal models in assessing the allergenicity of novel protein and I continued my bioinformatics exercises with different protein sequences provided by Prof. Wolt and Dr. Karaman.

Towards the end of week four, accompanied by Dr. Wolt, we went to Washington DC where I made a presentation at USDA. This was followed by meetings and some interaction with scientists at USAID and at the US Environmental Protection Agency. We also met with the Country Manager (South Asia) of the US Trade and Development Agency (USTDA), my sponsoring agency, and we visited DuPont Crop Genetics in Wilmington, Delaware where Dr. Greg Ladics gave a presentation on allergenicity assessment of novel proteins, which was followed by a long discussion session.

During my stay at ISU I was given the chance to interact with a few other professors on the campus, which helped me to find solutions to my queries and curiosity. To round out the experience, on the weekends I made a couple of visits to the Iowa state capitol, Des Moines, to sightsee and to attend a couple of social/family gatherings.

Overall, it was a thoroughly enjoyable learning experience. I am thankful to my program mentor, Prof. Jeff Wolt, for his instruction and for arranging my many visits and to USTDA for its financial assistance for the fellowship. This exposure has helped me to acquire a thorough understanding of the risk analysis of genetically modified food and the use of bioinformatics. The knowledge I have gained will be utilized for mass awareness/capacity building programs and to assist the regulatory agency in India. To this end, I have already delivered lectures on this topic at three Indian universities for the benefit of students and faculty and I have incorporated it into my ongoing research program.

For more information about the Borlaug Fellows Program go to http://www.fas.usda.gov/icd/borlaug/borlaug.htm

BARC / SABP CONFINED FIELD TRIAL WORKSHOP HELD IN BANGLADESH

The Bangladesh Agricultural Research Council (BARC), in collaboration with the South Asia Biosafety Program (SABP), organized a two-day workshop on the Regulation and Monitoring of Confined Field Trials of Genetically Modified Plants in Bangladesh at Dhaka on August 30 and 31, 2008. The workshop was attended by 46 participants involved in the development and regulation of genetically engineered plants in Bangladesh. They included representatives from the Bangladesh Agricultural Research Institute (BARI), the Department of Agricultural Extension, the Bangladesh Rice Research Institute, the Seed Certification Agency, the Department of Environment, Lal Teer Seeds, the NGO sector and universities.

The first day of the workshop was held at the Training Center of BARC. An overview of the structure and functions of the

BARC / SABP Confined Field Trial workshop participants and presenters at BARC Training Centre on August 30, 2008.

(continued on page 4 - see Workshop)

CREAM OF THE (WEB) CROP

harvesting the best from the worldwide web

THIS MONTH'S PICK:

U.S. Database of Completed Regulatory Agency Reviews website

http://usbiotechreg.nbii.gov/database_pub.asp

The United States Regulatory Agencies Unified Biotechnology (USRAUB) website, which focuses on agricultural products of modern biotechnology, has a searchable database that covers genetically engineered crop plants that have completed all recommended or required reviews for food, feed or planting use in the United States. The agencies responsible for oversight of the products of agricultural modern biotechnology are the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA). Depending on its characteristics, a transgenic plant may be subject to review by one or more of these agencies.

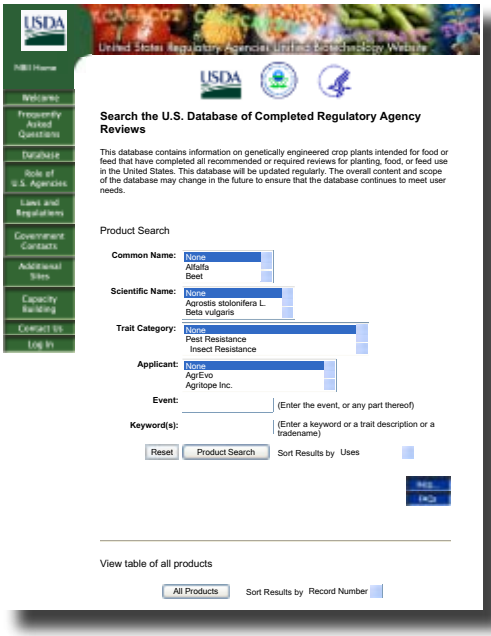
This database provides a one-stop access point to all the regulatory decisions on each genetically engineered plant product submitted for review in the United States. The product uses are differentiated in the database as: "food," "feed," or "planting". Each record in the Database of Completed Regulatory Agency Reviews (http://usbiotechreg.nbii.gov/database_pub.asp) includes information from the relevant regulatory agencies. The bulk of regulatory information for each product is housed by the regulatory agencies, and can be accessed through links on the database. The database is updated regularly.

The database can be searched by selecting from drop-down menus, or by entering more specific information into the "Event" or "Keyword" boxes. The user can call up a list of all products reviewed for a specific crop, or of all products that are modified for a specific trait. All products submitted by specific developers can also be listed. While the user can search for a product in the database by entering its tradename in the Keywords search box, the list of tradenames is not regularly maintained within this system, but rather included for information purposes on an "as available" basis. If a user cannot find a product by its tradename, that does not mean it is not in the database, rather that its tradename has not been associated with a U.S. regulatory agency action.

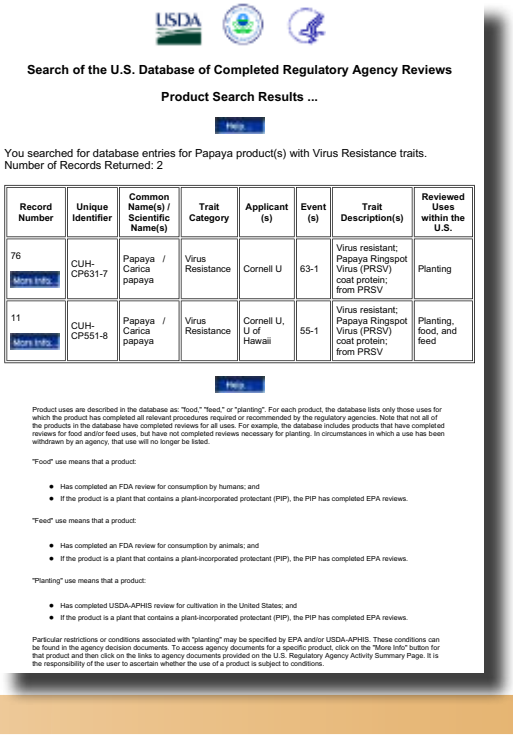
A search result contains basic information about the product(s) including the use(s) for which the product has completed all reviews required or recommended in the United States. A link takes the user to a detailed U.S. Regulatory Agency Activity Summary of the product that provides further links to regulatory agency documents for the product.

The products listed on the database are not limited to products that are currently used or produced for export in the United States. The database includes products that were never commercialized, or that are no longer being marketed for commercial or regulatory reasons (*e.g.*, voluntary cancellation of a pesticide registration). However, as a service to users, the USRAUB website provides a link to a non-governmental website that provides information on the commercial status of certain products of agricultural biotechnology.

DATABASE SEARCH PAGE



SEARCH RESULTS PAGE



Workshop - *continued from page 2*

various Bangladesh regulatory committees was given by Mr. Solaiman Haider, Secretary of the National Committee on Biosafety and Project Director of the National Biosafety Framework. Dr. O.P. Govila, Professor (Retd.), Indian Agricultural Research Institute, provided a description of his experiences as an Indian regulator and Dr. Robert Potter of AGBIOS explained the biosafety requirements and conditions needed to safely conduct confined field trials. The afternoon session focused on Standard Operating Procedures (SOPs) with an emphasis on the conditions to be met by trial managers and monitoring officers during confined field trials of transgenic plants and, more specifically, those required for genetically engineered eggplant.

The second day of the workshop was held at BARI and began with a presentation by Dr. Govila on the new structure for the regulation of confined field trials being implemented in India. Following a review of the procedures for the monitoring and inspection of confined field trials, the participants were escorted to the confined field trial site of genetically engineered eggplant at BARI in order to put the presentations into context. Dr. Govila conducted a training inspection of the site, accompanied by prospective regulatory officials to illustrate the process and procedures of such an inspection.

Dr. O.P. Govila conducting a training inspection of confined field trial site of genetically engineered eggplant at BARI, accompanied by prospective regulatory officials, on Day 2 of the BARC / SABP Confined Field Trial workshop.

BARI staff and other participants working towards conducting confined trials were provided with guidance on the in-season monitoring of trials with the emphasis on documentation of activities at the site itself. These visits were valuable in providing a hands-on demonstration of the procedures for monitoring and inspecting confined field trials, pointing out common mistakes that are often made and providing explanations of the corrective actions that should be taken. In a final session, procedures for handling potential breaches of compliance with the operating procedures were discussed, from the point of view of both the trial management and the regulatory authorities. Throughout the workshop, there were lively discussions of the regulatory issues surrounding genetically engineered crops in Bangladesh focusing in particular on the data that will be needed to perform an environmental risk assessment prior to a full release of such crops. Such discussion will deepen the understanding of genetic engineering and the role it can play in agricultural development in Bangladesh.

BT BRINJAL TO GO COMMERCIAL NEXT YEAR

Business Standard - September 10, 2008

After an overwhelming success of *Bacillus thurengiensis* (Bt) cotton, Bt brinjal is all set to go commercial from the next sowing season, with the completion of its trial runs. After the launch, Bt brinjal will become the first edible product in the country to be grown using genetically modified (GM) seeds.

According to R.K. Sinha, executive director, All India Crop Biotechnology Association, the Indian Council of Agricultural Research has been sowing GM seeds of Bt brinjal for the last four to five years and has found no harm in commercialising it with adequate approval from the authorities concerned. This year, ICAR covered between 15 and 18 acres under Bt brinjal across the country to test the viability of commercialisation before the final approval.

"Brinjal is a staple food for many poor people, which also has medicinal properties. Hence, commercialisation would not only benefit farmers, who can save their investment in pesticides, but may also boost their income by way of a higher production," Sinha said.

On December 10, 2007, the Supreme Court had refused to stay Mahyco's (Maharashtra Hybrid Seeds Company) trials of Bt brinjal in various parts of the country following a plea from social activists Aruna Rodrigues and P.V. Satheesh. A committee, under the union ministry of environment and forests, had given a clearances for the large-scale field trials in August 2007. According to a study by Mahyco, the technology supplier for Bt brinjal and a strong advocate of genetically-modified agricultural crops, farmers invest about Rs 100 per pesticide spray per acre for anywhere between 40-45 sprays of the 90-day brinjal crop.

To read the full article go to http://agbios.com/main.php?action=ShowNewsItem&id=9992

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