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.

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 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.

(continued on page 2 - see Experiences)
Barc / SABP Confined Field Trial workshop participants and presenters at BARC Training Centre on August 30, 2008.

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
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.

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