



SOUTH ASIA
BIOSAFETY PROGRAM

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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.

SABP CONFINED FIELD TRIAL TRAINING PROGRAM - JULY 2009

A REPORT FROM VARIOUS PERSPECTIVES

From June 7 to 13, 2009, a delegation of nine scientists from India took part in the South Asia Biosafety Program's Confinement Field Trial Training Program. In the course of the one-week program the scientists travelled from their home states in India to Washington, D.C.; Research Triangle Park, North Carolina; and Davis and Fresno, California. The following is a summary report written from the various perspectives of the participants in the Training Program, both delegate and host.

Dr. P.H. RAMANJINI GOWDA, Professor and Head, Department of Biotechnology, UAS, Bangalore

The SABP confined field trial program at USA was conducted from June 6 to 14, 2009 and included a group of seven participants from different Indian states along with Dr. Vibha Ahuja, General Manager, Biotech Consortium Ltd., New Delhi and Dr. O.P. Govila, Consultant for Biotechnology and former Head of the Department of Genetics & Plant Breeding, IARI, New Delhi.

The team visited USDA Biotechnology Regulatory Service in Washington D.C. where Drs. Andrew Roberts, Thomas Sim and Subray Hegde explained the regulatory system of growing genetically modified crops and containing the environmental risks. They also explained the role of the Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA).

The team then visited Syngenta Seeds, Research Triangle Park, North Carolina. Dr. David Guyer and Dr. Stacy Charlton explained the activities that Syngenta is involved in, which include gene discovery, protein designing, vector transformation, plant protein expression, plant analysis and immunology. Syngenta has recently developed VipCot transgenic

cotton, which can control a wide range of insect pests. The company has developed its own regulatory information management system. The team visited a Syngenta Bt cotton trial and evaluated the compliance of regulatory measures.

Finally, the team visited Arcadia Biosciences in Davis, California. Dr. Don Emlay, Director, Regulatory Affairs and Compliance explained the regulatory measures that had been adopted by Arcadia. The team then visited the company's field trials of transgenic nitrogen use efficient rice, salt tolerant rice and safflower that produces GLA.

The training program on confined field trial of transgenic crops was very useful for the team since all the members are either involved in developing or regulating transgenic crops or both.



UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT
Saharah Moon Chapotin - Biotechnology Advisor

From USAID's perspective, the meetings between the Indian visitors and the Syngenta and Arcadia Biosciences staff was a mutually beneficial exchange of information on the Indian regulatory system and the approach taken by U.S.-based product developers to manage confined field trials (CFTs). The visit to the actual field sites was additionally important in several respects. The training participants normally have two contrasting roles in their positions in India – they function as both regulators and product developers. The participants were invited to join the SABP training program because they serve on field trial monitoring committees and thus form part of the Indian government's biosafety regulatory system. In their regular positions at universities or research institutions, however, they are research scientists, where they lead projects to develop new bioengineered crops. The field trial visit was relevant from both these perspectives. It is important for those involved in developing or enforcing regulations to understand what the consequences of these regulations in the field are. The visitors saw firsthand the lengths to which Syngenta and Arcadia must go to ensure the integrity of their confined field trials and comply with the USDA regulations. Extensive regulatory requirements can also be quite off-putting to product developers as they approach the field trial stage. Seeing how the field trial

managers were able to conduct field research and evaluate new transgenic lines despite the strict controls imposed by, for example, the California Rice Commission on top of the USDA/APHIS regulations for Arcadia's rice trials, was an important reminder that daunting regulations are not necessarily insurmountable, and that with adequate planning, resources and effort, CFTs can be safely conducted, allowing product development to proceed.

"Each confined field trial (CFT) is considered as an 'environmental release' of GM crop and hence an article for regulation. Permission from USDA is strictly required for importation, interstate movement and environmental release of GM crops. Regulation of CFTs is done to minimize the risk of mixing transgenic crops with non-transgenic crops or wild species in the environment."
Dr. R.M. Sundaram

"The programme on confined field trials from June 8-12th 2009 was very useful. We learned about the biosafety regulations followed in USA and also learned judging the release of GM crops based on environmental risks. The private companies have also educated us about how they follow good standard operation procedures. Syngenta and Aracadia Biosciences have vast experience in research and field trails of GM crops. I learned about the meticulous planning of the experiments and how to carry out the experiments following stringent biosafety regulations."
Dr. P.H. Ramanjini Gowda

Host - USDA ANIMAL AND PLANT HEALTH INSPECTION SERVICE, BIOTECHNOLOGY REGULATORY SERVICES
Dr. Andrew Roberts, Communications and International Affairs Branch

On June 8th, SABP sponsored a visit by Indian scientists to USDA's Biotechnology Regulatory Services (BRS) in Riverdale, MD. The scientists are part of India's effort to develop and implement a compliance and monitoring program for confined field trails of genetically engineered plants and the visit to Riverdale was the first stop on a trip to the U.S. that included tours of field trials in North Carolina and California. In a three hour session, the U.S. regulators and the Indian scientists exchanged information and discussed fundamental issues related to oversight of field trials.

From BRS, Dr. Subray Hegde, a biotechnologist with the Environmental Risk Assessment Program, gave a presentation on how BRS sets confinement conditions for field trails related to the biology of the plant and the GE trait. Tom Sim, Director of the Regulatory Operations Division, presented on the compliance and enforcement programs at BRS. Highlights included how BRS works with applicants to help ensure compliance and how BRS deals with compliance incidents with the goal of helping field trial managers get back into compliance. Dr. O.P. Govila provided an overview of India's confined field trial guidelines, highlighting the many similarities with the U.S. system.

The conversation was very open and dynamic with a lot of interest from the visiting scientists about the U.S. regulatory process and how BRS makes decisions. The discussion of common challenges for compliance and monitoring for field trials was clearly appreciated by both sides, and there was a clear interest in exploring the options for addressing those challenges. Although the meeting was brief, it represents the first step in what BRS hopes will be a long and productive dialog on the joint U.S. and Indian interest in effective mechanisms for monitoring confined field trials.

"The strict but case specific nature of the biosafety regulations recommended by the Biotechnology Regulatory Services (BRS),

USDA portrays the practical nature of the functioning of the regulatory system." **Dr. L. Arul**

"The training started with the exposure to the federal regulatory procedures for genetically modified crops at USDA office in Washington D.C. The regulatory procedures for conducting confined field trials in U.S. was elaborated by the staff working exclusively for that purpose. The major objectives of regulating confined field trial was to check escape of transgenic material during the trial period. It was not linked with other conditions like LOD protocol, food safety data etc." **Dr. S.K. Chakrabarti**

Host - SYNGENTA BIOTECHNOLOGY - Research Triangle Park, NC
Stacy Charlton - Global Director, Regulatory Compliance
Dave Guyer - NAFTA Team Lead, Regulatory Compliance

On June 9th and 10th 2009, Syngenta had the pleasure of hosting a delegation from India as part of the South Asia Biosafety Program's Confined Field Trial (CFT) Training Workshop. The delegation was composed of distinguished Indian scientists charged with the responsibility of designing a system of inspection and over-sight for India's confined field trial activities.

Syngenta conducts confined field trials in several countries around the globe, including India, but the focus of the CFT Training workshop was the U.S. confined field trial program. The Syngenta U.S. CFT program includes hundreds of field trials annually across a number of crop types at both internal Syngenta sites and sites managed by third parties.

The successful management of such a diverse and broad trial program requires a robust regulatory compliance program that balances the regulatory requirements with the practical considerations of field activities. Additional important elements of the compliance program include training, communication, support from management, and dedicated field personnel. All of these elements were reviewed during the Syngenta CFT Training workshop.

The participants were very enthusiastic and engaged for the duration of the program, and it was clear that they were eager to learn. The morning of the first day was spent sharing information with presentations on Syngenta's quality management approach to compliance and recent developments in crop biotechnology in India including an informative overview of the plant biotech regulatory framework in India. It became apparent during the morning discussions that Syngenta's regulatory compliance procedures are quite similar to the proposed Indian CFT approach and the participants were very interested in the practical components (*i.e.*, challenges of implementation) of the program.

After lunch the entire group boarded a bus to embark on a field tour of a Syngenta confined Bt cotton trial. For the field trial visit, we were joined by a Syngenta third party trial inspector who shared his field experience and demonstrated the use of a portable rangefinder to determine isolation distances.

The Indian scientists eagerly and enthusiastically participated in a mock CFT inspection to determine adherence with Syngenta's regulatory compliance program and U.S. regulatory requirements.

On the morning of June 10th, the Indian scientists completed Syngenta's online CFT training program before departing on the next leg of their trip. The visiting scientists commented that an online program like Syngenta's has the potential to reach the wide range of scientists and field personnel who are expected to conduct CFTs in India.

We felt privileged that AGBIOS chose Syngenta to participate in this effort and compliment AGBIOS on a great job organizing the workshop, providing clear direction on the objectives and managing any operational and logistical issues that allowed us to focus on the CFT training part of the agenda. We are also indebted to our Indian guests for providing us with greater insight into the current state of biotechnology in India.

Overall impression, the Training Program was well organized and well tailored to the needs and objectives of the visiting Indian scientists.

“I was awfully impressed after visiting Syngenta Company: the laboratory setup, regulatory division and green house setup are well organized and maintained. Arcadia’s field trial of rice was very good and well maintained in all respects. Absolutely, the confined field trial workshop has improved our knowledge and understanding in the monitoring of regulated field trials of different crops in India.”

Dr. A.S. Jadhav

Host - **ARCADIA BIOSCIENCES** - Davis and Fresno, CA
Don Emlay - Director, Regulatory Affairs and Compliance

Arcadia Biosciences was recently fortunate to spend two days with a delegation representing India and the South Asia Biosafety Program to present and discuss our containment procedures and how we achieve and ensure compliance with these procedures during the conduct of field trials with regulated genetically engineered crops. With India being a significant adaptor of new agricultural technologies and Arcadia having business relationships with Maharashtra Hybrid Seed Company and Advanta Seeds, it was important for Arcadia to share ideas and approaches to containment and compliance during field testing with transgenic crops. While our objective was to share our approach to the application

of containment procedures through compliance with both regulatory agency and Arcadia’s internal requirements, the interactions over the two days of the visit provided significant insight for Arcadia into the thoroughness and quality of the procedures India is considering.

It was clear that delegation members are committed to the safe introduction of genetically engineered crops into Indian agriculture while recognizing the need for a scientific approach to the conduct of field trials that proves the safety and benefits of the new crop while protecting existing conventional crops and the environment. India has utilized the experiences of other countries with longer histories of regulating genetically engineered crops and combined these experiences and regulations into highly useful guidance for the conduct of field trials with transgenic crops. The Department of Biotechnology, Ministry of Science & Technology document, “Guidelines & Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants” is a terrific document that should be highly beneficial to any organization or researcher (in any country) involved in the development of genetically engineered plants. Having highly trained individuals monitoring field trials to ensure compliance with containment requirements will contribute significantly to public acceptance of these new and beneficial crops in advance of commercialization.

“This training has helped me in understanding the importance and updating myself on biosafety regulations. This will be used to sensitize different stakeholders in my state.” **Dr. P.P. Shastry**

“This training has provided deep understanding of CFT and real procedure to be followed for monitoring and conductance of CFT. The responsibility of companies and monitoring team are well understood in detail.” **Dr. A.R. Pathak**



CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Training Course -- Applications of Biotechnology and Its Regulations	The Energy and Resources Institute (TERI)	August 4 - 21, 2009 New Delhi	http://www.teriin.org/index.php?option=com_events&task=details&sid=225
International Conference -- Challenges in Biotechnology and Food Technology	Department of Technology, Annamalai University, Annamalai Nagar	August 26 - 28, 2009 Annamalai Nagar	http://annamalaiuniversity.ac.in/conference_tech_icbf2009.htm
National Seminar -- Bt Cotton: Opportunities and Prospects	Central Institute of Cotton Research	September 10 - 12, 2009 Nagpur	http://www.cicr.org.in/
National Seminar -- Nutritional Strategies for Improving Quality of Life	Department of Foods & Nutrition, College of Home Science, G.B. Pant University of Agriculture & Technology	September 11 - 12, 2009 Pantnagar	http://www.gbpuat.ac.in/news/National%20Seminar%20Notice.htm
National Seminar -- Spices Improving Productivity and Quality with Focus on Himalayan Spices	Sher-e-Kashmir University of Agricultural Sciences and Technology of Jammu	October 22 - 24, 2009 Jammu	http://skuastkashmir.ac.in/
Sixth Solanaceae Genome Workshop	School of Life Sciences, University of Hyderabad	November 9 - 13, 2009 New Delhi	http://202.71.128.145/sol2009.org/home.html
7th Pacific Rim Conference on the Biotechnology of <i>Bacillus thuringiensis</i> and its Environmental Impact	Indian Council of Agricultural Research, Department of Biotechnology, Calcutta University and All India Crop Biotechnology Association	November 25 - 28, 2009 New Delhi	http://7btconference.org/
INTERNATIONAL			
International Short Course -- Food Safety	Institute of International Agriculture, Michigan State University	July 26 - 31, 2009 Michigan State University	http://www.iaa.msu.edu/short-course-food.html
International Short Course -- Environmental Aspects of Agricultural Biotechnology	Institute of International Agriculture, Michigan State University	August 9 - 14, 2009 Michigan State University	http://msustatewide.msu.edu/resource.asp?ResourceID=2218
Theoretical and Practical Course -- Developments in Biosciences for Enhanced Food and Environmental Biosafety	Department of Molecular Biology and Biotechnology, Faculty of Science, University of Dar es Salaam, Dar es Salaam, Tanzania	August 18 - 30, 2009 Department of Molecular Biology and Biotechnology, Faculty of Science, University of Dar es Salaam	http://www.icgeb.org/meetings-2009.html
International Short Course -- Agricultural Biotechnology	Institute of International Agriculture, Michigan State University	September 13 - 25, 2009 Michigan State University	http://www.iaa.msu.edu/short-course-iab.html
ABIC 2009: Agricultural Biotechnology for Better Living and a Clean Environment	National Center for Genetic Engineering and Biotechnology (BIOTEC), National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology (MOST) and ABIC Foundation	September 22 - 25, 2009 Queen Sirikit National Convention Center, Bangkok, Thailand	http://www.abic.ca/abic2009/home/About.php
Measures of Hope and Promises Delivered: An International Conference on Socioeconomic and Environmental Impact Assessment of Biotech Crops	South Asian Regional Centre for Graduate Study and Research in Agriculture (SEARCA), International Service for the Acquisition of Agri-biotech Applications (ISAAA) and International Food Policy Research Institute (IFPRI)	September 29 - 30, 2009 Bangkok, Thailand	http://www.bic.searca.org/
International Conference -- Knowledge Management in Biotechnology Transfer and Adoption in Southeast Asia: Lessons Learned, Policy Issues and Directions	SEARCA	October 1 - 2, 2009 Bangkok, Thailand	http://www.bic.searca.org/
Biosafety Workshop -- Theoretical Approaches and Their Practical Application in the Risk Assessment for the Deliberate Release of Genetically Modified Plants	Wendy Craig (Biosafety Unit, ICGEB, Trieste, Italy)	October 12 - 16, 2009 ICGEB Conference and Meetings, Padriciano 99, I-34012 Trieste, Italy	http://www.icgeb.org/meetings-2009.html

South Asia

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