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South Asia Biosafety Program

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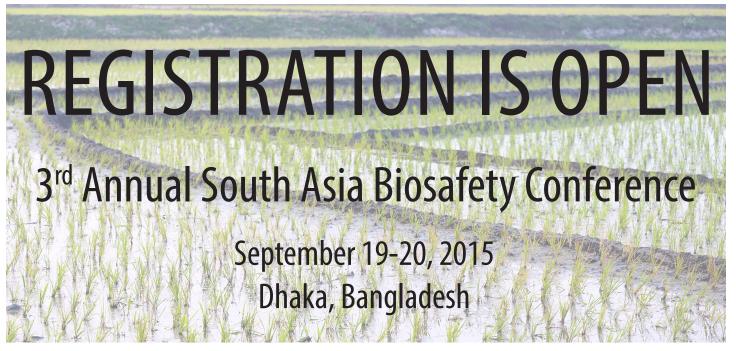
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Featuring Sessions on:

- Biotechnology Research in South Asia
- Considerations for International and Regional Harmonization
- **Nutritionally Enhanced Crops and their Safety Assessments**
 - Preparing a Regulatory Dossier
 - Regulation of Biotechnology in South Asia
- What Happens After Release: Stewardship and Monitoring

Show your work during the Poster Session!

The 3rd Annual South Asia Biosafety Conference Poster Program is a new opportunity for individuals to share their research, findings, and achievements with colleagues at the conference. Presenting a poster is a noteworthy way to share expertise or accomplishments, and poster presenters will have a dedicated time to present and discuss their work with the diverse group of attendees.

For more information, please see pages 7-8 or visit http://sabc.biotech.co.in/

Highlights from the Seminar on Golden Rice Research and Regulatory Issues



"The development

of pro-vitamin A

enriched Golden

Rice is a crop bio-

fortification approach

intended to help

address Vitamin A

Deficiency (VAD)."

The Bangladesh Agricultural Research Council (BARC) and the Bangladesh Rice Research Institute (BRRI) co-organized a technical briefing on the status of the Golden Rice Project and plans for upcoming regulatory submissions in Bangladesh and the Philippines. Dr. Donald MacKenzie, the newly appointed regulatory affairs and stewardship leader for the Golden Rice Project at the International Rice Research Institute (IRRI), delivered the seminar on June 23, 2015, at the BARC Training Building. Approximately 50 participants attended the seminar from various National Agricultural Research System (NARS) institutes, including the Bangladesh Agricultural Research Institute, BRRI, BARC, the Bangladesh Institute of Nuclear Agriculture, the Cotton Development Board, the Bangladesh Standards and Testing Institute, the South Asian

Regional Standards Organization, university faculty, and members of the Biosafety Core Committee (BCC) responsible for the safety assessment of new plant biotechnology products.

Following welcoming comments by Mr. Aminuzzaman, Director, Human Resource and Training Unit, BARC, the Chief Guest, Dr. Abul Kalam Azad, Executive Chairman of BARC, provided the inaugural address. Dr. Md. Ansar Ali, Director (Research), BRRI, chaired the seminar.

During his introduction, Dr. MacKenzie provided a brief recap of the significant health toll due to Vitamin A Deficiency (VAD), particularly in high-risk populations such as pre-school children and pregnant and lactating

women in a number of Asian countries. In Bangladesh, the incidence of VAD is about 22 percent in pre-school children and about 24 percent in pregnant women. By comparison, the corresponding statistics for India are 62 percent and 16 percent, respectively. Across South and Southeast Asia, it was noted that more than 90 million children suffer from VAD, resulting in 670,000 deaths per year and about 350,000 cases of blindness per year. Dr. MacKenzie emphasized that combating VAD requires a combination of interventions, including poverty alleviation

and diet diversification, the promotion of optimum infant feeding practices, such as breast feeding, the use of dietary supplements and food fortification, and crop bio-fortification.

The development of pro-vitamin A enriched Golden Rice is a crop bio-fortification approach intended to help address VAD. As noted by Dr. MacKenzie, the bio-fortification of rice can be a very effective means of increasing pro-vitamin A intake, particularly in Bangladesh where rice provides more than 70 percent of daily calories, on average.

Following a brief overview of the history of development of Golden Rice, Dr. MacKenzie discussed the breeding objectives of the project and some of the regulatory studies completed and in process. Golden Rice was developed through Agrobacterium-mediated transformation

> of a temperate japonica cultivar to express the phytoene synthase enzyme from maize and a phytoene (carotene) desaturase enzyme from a common soil bacterium (Erwinia uredovora). Expression of these two enzymes in the rice endosperm creates a functional biosynthetic pathway for β -carotene (pro-vitamin A). The other new enzyme expressed in Golden Rice is phosphomannose isomerase, from E. coli, which was used as a selectable marker for regenerating transformed plants on mannosecontaining media. The criteria for acceptability of Golden Rice varieties is that they must contain ≥ 5 ppm β-carotene in the grain (after two months storage), there should be no unintended effects resulting from the

genetic modification, and yield and agronomic performance must be equivalent to conventional varieties.

Previous work on the GR2-R event in different germplasm backgrounds demonstrated it did not meet all these criteria in that unintended effects on agronomic parameters were observed in certain circumstances and yield performance was inconsistent. The current focus is on event GR2-E, which has undergone five generations of

Continued on page 3

backcrossing into three indica rice cultivars, IR64, PSBRc82, and BRRI dhan 29, which is intended for cultivation in Bangladesh.

Dr. MacKenzie presented Southern blot data showing that the genetic construct in GR2-E had been stably inserted at a single site within the rice genome with no evidence of rearrangement. Furthermore, there was no interruption of any endogenous gene, or the potential to create new novel open reading frames, as verified by nucleotide sequence analysis. He also provided data showing that the phytoene synthase (Psy) and phytoene desaturase (CrtI) proteins were rapidly degraded by pepsin, and thus would be metabolized in the body like any other dietary protein, and that there were no significant amino acid sequence similarities with known protein toxins or allergens.

As noted by Dr. MacKenzie, additional work remains, including acute toxicity testing of the Crtl protein; examining expression levels of Crtl and Psy in rice grain to estimate potential dietary exposure; the analysis of key nutrients and anti-nutrients in grain and straw following recommendations in the OECD consensus document on new rice varieties; and agronomic and phenotypic characterization. Dr. MacKenzie highlighted the Project's commitment to openly engaging

with stakeholders in developing all the necessary safety data to the highest quality to meet regulatory requirements internationally, and sharing this information widely.

At the end of his presentation Dr. MacKenzie gave an outline of the overall research planning for GR2-E in the Philippines and Bangladesh. GR2-E (in PSBRc82 background) is undergoing two seasons of confined field trials in the Philippines during 2015/16 to generate material for compositional analysis. The goal is to submit an application for food/ feed safety review in multiple countries in the fall of 2016. Additional multi-location trials are anticipated in the Philippines during 2016/17 to generate agronomic and phenotypic data to support an application for environmental review. In Bangladesh, BRRI is planning for confined field trials during two seasons in 2016 to perform the agronomic assessment of GR2-E in BRRI dhan 29 and to collect the necessary biosafety data.

After the presentation, there was a lively discussion with the participants asking several questions and offering many suggestions. The Chair, Dr. Md. Ansar Ali, provided the closing comments and vote of thanks, expressing continued strong support for the project and prospects for the future.





NEW BOOK ON "GM CROPS: PERCEPTION VS REALITY" NOW AVAILABLE

Author: Dr. T. M. Manjunath, Consultant in Agri-biotechnology & Integrated Pest Management

An excerpt from the book: "Genetic Engineering (GE) or Genetic Modification (GM) of plants is a precise and well-researched area in life sciences and it has the potential to offer solutions to several biotic and abiotic challenges faced in agriculture, contributing to improved farming. When the GM crops were first approved for commercial cultivation in the USA followed by five other countries in 1996, the area occupied by them was only 1.7 million hectares. Since then, their adoption has increased significantly every single year and reached about 175 million hectares grown by 18 million farmers in 27 (19 developing, 8 industrial) countries by 2013 – an incredible 100-fold increase in the area in 18 years! These have substantially contributed to effective control of target pests and better weed management, resulting in increased crop production and steep reduction in use of chemical pesticides.

 $These \ benefits \ have \ percolated \ to \ improving \ the \ social \ and \ economic \ conditions \ of \ millions \ of farmers \ and \ also \ in \ reducing \ the \ environmental \ pollution$ across the globe. Such benefits have been derived in India also following the introduction of Bt cotton in 2002. This is reflected by the fact that as of 2013, about 7 million (70 lakh) Indian farmers have cultivated Bt cotton on 11 million hectares that comprised 95% of the total cotton acreage in our country. There is no credible scientific evidence to prove that GM crops have caused any ill effects on humans, animals or the environment anywhere in the world.

Despite such facts, the opponents have been projecting the GM technology and GM crops as controversial through unsubstantiated allegations, agitations and scaremongering stories regarding their safety and benefits. Their persistent and orchestrated misinformation has created a suspicion about this technology among the farmers and general public who ask endless questions such as "Is GM technology unnatural? Is it needed? Are GM crops safe? Do they affect biodiversity? Are they a threat to local varieties? Do they consume more water and fertilizers? Do they encourage new pests and diseases? Are they affordable? Are they beneficial? Were they responsible for farmers' suicides?" etc. Besides the deliberate negative propaganda, lack of adequate knowledge about this modern technology is also responsible for such doubts.

The objective of this publication, "GM Crops: Perception vs Reality" is to clarify some of the commonly held perceptions with the help of scientific facts drawn from authentic publications. It is hoped that it would help dispel doubts and enable the readers to understand and appreciate the value of GM technology and GM Crops."

To access the book: Please contact the publisher to receive hard copies, by emailing ram@ableindia.org.in and shivendra@ableindia.org.in

The Biosafety Research in Pakistan Grants Program: Project Updates



The Biosafety Research in Pakistan Grants Program (BRPGP) supports laboratory, field, and literature research that will significantly advance knowledge relevant to environmental risk assessment of genetically engineered plants in Pakistan.

The Biosafety Research in Pakistan Grants Program is managed by the ILSI Research Foundation Center for Environmental Risk Assessment (CERA) as part of the biosafety component of the Pakistan Strategy Support Program (PSSP). The PSSP is financially supported by the US Agency for International Development (USAID) through the International Food Policy Research Institute (IFPRI), which manages PSSP. The Biosafety Research in Pakistan Grants Program recognizes the need for biosafety research as part of a broader effort to support science-based decision-making and policy development and will fund research aimed at addressing the effects of agricultural biotechnology, particularly transgenic crops, on the environment and biodiversity in Pakistan.

Grantees come from agricultural or environmental research institutions and universities in Pakistan. All grantee's work must:

- Address the effects of genetically engineered (transgenic) crops on the environment.
- Be relevant to Pakistan and take place in Pakistan.
- Demonstrate applicability to environmental risk assessment of transgenic plants and regulatory decision-making in Pakistan.

BRPGP is well known in Pakistan and has succeeded in bringing together a community of practice that can serve as an important information resource for the Pakistan government. It has awarded a total of 16 grants since it began in 2012. In this month's SABP newsletter, we will be featuring project updates from Dr. Bushra Mirza, Dr. Fiaz Ahmad and Dr. Shaukat Ali.

GRANTEE: Dr. Bushra Mirza

JOB TITLE: Professor and Chairperson, Department of Biochemistry

ORGANIZATION: Quaid-i-Azam University

PROJECT TITLE: "Evaluation of Potential Gene Flow from Bt Cotton in

Pakistan"

PROJECT UPDATE: Agriculture plays a pivotal role in the economy of Pakistan. Expansion of genetically modified cotton in Pakistan started in 1997, but commercialization was delayed for another decade. Different survey reports show that Bt varieties were cultivated on about 60% of the cotton growing area in 2007; 50% in Punjab and 80% in Sindh. In Pakistan, it is still the only transgenic crop being cultivated. At least 16 Bt cotton varieties, including one Bt cotton hybrid, have been approved for cultivation in Pakistan so far.

Through the funding provided by the Biosafety Research in Pakistan Grant Program, a project is being executed to gather information about varieties of Bt cotton under cultivation in main cotton growing areas of Southern Punjab. Information is also being gathered about cultivation practices, neighboring crops and the presence of the pollinator(s) in the field. To assess any possible gene flow, evaluation of presence of transgene and its protein in the non-Bt plants identified and collected in proximity of the Bt cotton crops is also being conducted. Furthermore, ethnobotanical data of these cultivated or wild plants is also being studied.

During this project, extensive field work has been conducted and samples have been collected from six districts of Punjab, specifically Faisalabad, Khanewal, Vehari, Bahawalpur, Multan and Toba Tek Singh. These districts represent 80% of the cotton belt area of Pakistan.

To view all grant projects, visit the CERA website at:

http://cera-gmc.org/index.php/The_Biosafety_Research_in_Pakistan_Grants_Program



GRANTEE: Dr. Fiaz Ahmad

JOB TITLE: Head Scientific Officer, Physiology/Chemistry Section

ORGANIZATION: Central Cotton Research Institute Multan

PROJECT TITLE: "Effect of Bt cotton on chemistry, microbial community structure and enzymatic activity in the rhizosphere soil"

PROJECT UPDATE: Over the last decade, the cultivation of *Bt* cotton in Pakistan has increased significantly, reaching up to more than 90% of the cotton belt. Although, the presence of the Cry1Ac protein in Bt cotton can provide shelter against lepidopterous species, the Bt toxin may have non-target effects on microbial diversity and ecosystem services. This study was conducted to evaluate the effects of Bt cotton on microbial populations, enzymatic activities and nutrient dynamics in the rhizosphere in comparison with non-Bt cotton.

In the first part of the study, extensive field surveys were conducted in three districts, specifically Multan, Lodhran and Bahawalpur of Southern Punjab. During the second part of the study, replicated field trials were conducted at four selected sites of the above districts to verify the research findings of the survey. In the survey study, rhizosphere soil samples were collected from Bt and non-Bt cotton fields in the area and analyzed for different parameters. The results revealed that the microbial population and the activity of enzymes (including dehydrogenase and phosphatase) increased slightly in the Bt cotton rhizosphere. Similarly, the total soil carbohydrates (CHO), active-C, soil-N (total and nitrate nitrogen), soil-P (total and extractable), soil -K, -Zn and -Fe increased in the Bt cotton rhizospheres.

The replicated field trials verified the findings of the survey study. Although the trend of the findings from both the studies was similar, the replicated field trials yielded more pronounced results. The Bt cotton rhizospheres significantly improved the population (log10 CFU g-1 soil) and activity (CO2-C mg kg-1 day-1) of the microbes and dehydrogenase enzyme activity (µg TPF g-1 h-1) over non-Bt cotton rhizospheres. Moreover, the fertility related soil parameters such as OM, macro (N, P, K) and micro nutrients (Zn, Fe) were also higher in Bt cotton rhizospheres than the non-Bt cotton.

From these research findings, it is concluded that Bt cotton may be grown safely without having any adverse effects on soil microflora and fertility related soil parameters.

GRANTEE: Dr. Shaukat Ali

JOB TITLE: Principal Scientific Officer

ORGANIZATION: Natural Agriculture Research Centre, Pakistan

Agricultural Research Council

PROJECT TITLE: "Potential risk for cross resistance development in

cotton growing areas of Pakistan"

PROJECT UPDATE: The use of transgenic *Bt* cotton is tremendously dominating Pakistan's agriculture. The development of resistance to Bt toxins can be quite distinct, depending upon the species, selection regimen or geographical origin of the founder colony (Heckel, 1994). Information on resistance monitoring helps immensely in devising proactive resistance management strategies that can retard the rate of resistance development. A major threat to cotton farmers in Pakistan is the development of insect resistance that may be disastrous to 1.3 million cotton growers in Pakistan. Hence, regular bioassays to assess the susceptibility of the test insect to the Cry toxins will monitor the changes in the baseline that can be used in monitoring resistance that may occur due to selection pressure of the Cry1Ac toxin.

This project scrutinizes the changes in baseline toxicity, through detection of variability in the toxicity of Cry1Ac toxins to Helicoverpa armigera from different cotton growing regions of Pakistan during the 2013-2014 cropping season.

A research study was conducted to study growth and development of Helicoverpa armigera on transgenic cotton cultivars containing different levels of the Cry1Ac toxin and a non transgenic cotton cultivar. The larvae of H. armigera was collected from the chickpea fields of NARC and cotton fields of Vehari and Bakker. The insect culture was maintained and reared on an artificial diet.

Significant correlation was found between insects mortality rate and Cry1Ac toxin levels in leaves ($R^2 = 0.911$) at an exponential correlation (y = 1.72x + 74.26). The overall mortality rate of target pests (*H. armigera*) collected from three different regions (NARC, Vehari, Bakkar) of Pakistan ranged from 71.5-92.8% at 0.5-3.7 μg/g Cry1Ac toxins. The mortality rate of the NARC culture was found in the range of 79.5-90.0%, the Vehari culture was 71.5-88.0%, while the Bhakkar culture was 76.5-92.8%. In the case of the non-transformed control cotton cultivar, negligible larval mortality was noted. The *H. armigera* collected from the non-cotton area (NARC) and the cotton areas (Vehari and Bhakkar) showed sensitivity to a considerable level (~70%) even at 0.5 ug/g of fresh tissue weight. This reflects that *H. armigera* is still very much sensitive to Cry1Ac toxin which is currently prevailing in the Bt cotton of Pakistan. However, there is a need to extend the scale and spectrum of this study in the future, with other target insect pests. Continuous monitoring of field grown cotton regarding the efficacy of Bt toxins and the sensitivity of target insect pests will be extremely important to minimize the risk of resistance build up in the target insect pests.



EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
Media Workshops on Communicating Science and Biosafety	Indian Institute of Mass Communication (IIMC)	July 22-23, 2015 Ahmedabad July 28-29,2015 Chandigarh	www.iimc.nic.in
2 nd International Conference and Exhibition on Biotechnology	Bright International Conferences & Events Organization	August 3-4, 2015 Hyderabad	www.brightice.org/ biotechnology2015
National Symposium on Germplasm to Genes: Harnessing Biotechnology for Food Security and Health	Society for Plant Biochemistry and Biotechnology, National Research Centre on Plant Biotechnology, and Indian Agricultural Research Institute	August 9-11, 2015 New Delhi	www.nrcpb.org
Advanced Training Course on Recent Advances in Improvement of Vegetable Crops	Dr. YS Parmar University of Horticulture & Forestry	September 2-22, 2015 Nauni-Solan (HP)	www.yspuniversity.ac.in/ trainings/caft-2015.pdf
Summer Course on Novel Genomic Tools and Modern Breeding Approaches for Enhancing Productivity and Nutritional Quality of Pulse Crops	Indian Institute of Pulses Research, Indian Council of Agricultural Research	September 5-25, 2015 Kanpur	www.iipr.res.in/pdf/ school_200515.pdf
6 th World Congress on Biotechnology	OMICS International	October 5-7, 2015 New Delhi	www.biotechnologycongress. com/india/index.php
INTERNATIONAL			
7 th Asia Pacific Biotech Congress	OMICS International	July 13-15, 2015 Beijing, China	www.biotechnologycongress. com/asia-pacific
2015 International Symposium and Annual Meeting of the KSABC	Korean Society for Applied Biological Chemistry (KSABC)	August 17-19, 2015 Seoul National University, South Korea	www.ksabc.or.kr/english/ symposium/symposium_2015. htm
3 rd Annual South Asia Biosafety Conference	South Asia Biosafety Program (SABP)	September 19-20, 2015 Dhaka, Bangladesh	http://sabc.biotech.co.in
Biosafety Workshop 2015: Scientific and Technical Approaches in GMO Decision-Making	International Centre for Genetic Engineering and Biotechnology (ICGEB) Biosafety Unit	October 19-23, 2015 Trieste, Italy	www.icgeb.org/trieste-biosafety- workshop-2015.html



The South Asia Biosafety Program (SABP) is an international developmental program implemented in India, Bangladesh and Pakistan with support from the United States Agency for International Development. SABP aims to work with national governmental agencies and other public sector partners to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds, and environmental protection.





BANGLADESH

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To receive an electronic copy of this newsletter send your name, institutional information and e-mail address to: vibhaahuja.bcil@nic.in



Registration Form 3rd Annual South Asia Biosafety Conference



September 19-20, 2015 BRAC Centre Inn, Dhaka, Bangladesh

that cannot be accommodated will be added to a waitlist, and notified if space becomes available.					
Attach mailing label from brochure, or your business card.					
Complete the label is incorrec	_			ion on the mailing	
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Gender Title		Female Mrs.	Ms.	Dr.	
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Registration*

Category	Fee		
	INR	US\$	
Industry	Rs. 5,000/-	\$85	
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Students	Rs. 2,000/-	\$35	
BCIL Biotech Club Members	25% discount 25% discount No fee up to two nominations and Rs. 2,000/- each for additional nomination		
Additional delegates from same organization (except students)			
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*In case you face difficulty in online registration, please download the registration form and send it to us along with payment through bank transfer. The details for Bank Transfer are as follows:

Beneficiary Name: Biotech Consortium India Limited

Account Number: 00032320008527

IFSC Code: HDFC0000003 (HDFC Bank Limited)

Cancellation/Refund Policy

Registration cancellations must be made in writing and received by BCIL no later than September 1, 2015. Cancellations received by this date are subject to a 20% processing fee. Registration and ticketed event cancellations received after September 1, 2015, are NOT subject to a refund.

Registration forms should be sent to:

Dr. Vibha Ahuja, Chief General Manager

Biotech Consortium India Limited (BCIL)

Anuvrat Bhawan, 5th Floor

210, Deen Dayal Upadhyaya Marg

New Delhi - 110 002

Telephone Number +91-11-23219064-67 (Ext. 204; 205);

23219059(D)

Fax Number +91-11-23219063

 $Email: \ vibhaahuja@biotech.co.in; vibhaahuja.bcil@nic.in\\$

Poster Program Abstract Submission Form 3rd Annual South Asia Biosafety Conference

September 19-20, 2015 BRAC Centre Inn, Dhaka, Bangladesh

THE 3RD ANNUAL SOUTH ASIA BIOSAFETY CONFERENCE POSTER PROGRAM is a new opportunity for individuals to share their research, findings and achievements with colleagues at the conference. Presenting a poster is a noteworthy way to share expertise or accomplishment, and poster presenters will have a dedicated time to present and discuss their work with the diverse group of attendees.

All poster abstracts must convey relevance to biosafety research, risk assessment, or regulation of genetically modified organisms (including programs or activities to improve capacity and knowledge generation).

The following are some suggestions about poster abstracts that will contribute to ensuring the readability and quality of the submission. Abstracts of accepted posters will be included as part of the conference onsite program and will be published as submitted, without content editing.

- · Check for proper spelling and grammar.
- Use a standard typeface such as Times Roman with a font size of 12.
- Begin sentences with words (not numbers).
- Standard abbreviations may be used without definition, but nonstandard abbreviations/acronyms should be placed in parentheses after the first use of the terminology. It is important to keep nonstandard abbreviations/acronyms to a minimum, to allow for readability and understanding.
- Do not include tables, figures, or graphs in the abstract. Such content is appropriate for the poster.
- Limit the abstract to 300 words.
- Try to organize the abstract with the following headings where appropriate: purpose, methods, results, conclusions (e.g., for research projects) OR purpose, description, evaluation and outcomes (e.g., for capacity building projects).

Space is limited. Posters will be considered on a first come, first served basis, based on the relevance to the program.

ABSTRACT SUBMISSION FORM FOR POSTER PROGRAM

PLEASE COMPLETE THE FORM BELOW AND E-MAIL IT TO lwilliams@ilsi.org AND COPIED TO vibhaahuja.bcil@nic.in.

You will receive a return email acknowledging receipt of your abstract and subsequently a second email informing you if your poster has been accepted for the conference poster program.

l.	Lead Presenter
	First Name:
	Last Name:
	nstitution and Address:
	E-mail:
	Telephone Number:
	NOTE: Poster Presenters must register for the 3 rd Annual South Asia Biosafety Conference. If an abstract is received from a author who is not registered, the abstract will NOT be included in the review process).
II.	Poster Title:
	Poster Authors:
	NOTE: list all poster authors including their name, organization, address and e-mail. Separate authors with a semi-colon and please INCLUDE the lead presenter also).
III.	Poster Abstract (maximum 300 words)