SEPTEMBER 2015

South Asia Biosafety Program

NEWSLETTER for private circulation only – not for sale

Recommendations on Comparative Approaches to Safety Assessment of GM Plant Material now available PAGE 2 New paper published in Transgenic Research on Low-Level Presence in Seed

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We look forward to seeing you at the 3rd Annual South Asia Biosafety Conference September 19-20, 2015 in Dhaka, Bangladesh

INAUGURAL POSTER COMPETITION ANNOUNCED!

Winners receive cash prizes and two-year ISBR memberships

The South Asia Biosafety Program (SABP) is pleased to announce its inaugural Poster Competition which will take place during the South Asia Biosafety Conference, September 19-20, 2015.

All posters are eligible for the competition, and two prizes will be awarded. First prize consists of a two year membership for the <u>International Society of Biosafety Research</u>, a USD \$100 cash prize, and an award certificate. Second prize consists of a two year membership for the International Society of Biosafety Research, a USD \$50 cash prize, and an award certificate. The winners' names and abstracts will be posted on the South Asia Biosafety Program website, and highlighted in the South Asia Biosafety Program Newsletter. The posters will be judged September 19 and the winners will be announced on September 20 before the final plenary session of the conference.

Evaluation and Judging

Posters will be evaluated as follows:

- 1. Abstract (10%): Clarity and correlation with poster.
- 2. Scientific content (70%): Introduction and background with literature cited, objectives, materials and methods, results and discussion, and significance to field. The quality of the research presented will be judged on its scientific rigor and significance as conveyed by the poster. Each poster must be self-explanatory. Judges may discuss the poster with its presenter but this will not be considered in the evaluation of the display.
- 3. Poster Display (20%): Posters will be judged on organization, effective use of space, legibility, grammar and spelling, and graphics.

Each poster display is judged independently by three judges. Judges are encouraged to provide constructive comments for each poster, however comments may be very brief or absent because of the limited time available.



For more information, please visit the conference website at http://sabc.biotech.co.in/

www.cera-gmc.org

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RECOMMENDATIONS ON COMPARATIVE APPROACHES TO SAFETY ASSESSMENT OF GM PLANT MATERIALS NOW AVAILABLE THROUGH TAYLOR & FRANCIS

Title: "Recommendations from the workshop on Comparative Approaches to Safety Assessment of GM Plant Materials: A road toward harmonized criteria?"

Abstract: An international meeting of genetically modified (GM) food safety assessors from the main importing and exporting countries from Asia and the Americas was held in Buenos Aires, Argentina, between June 26th and 28th, 2013. Participants shared their evaluation approaches, identified similarities and challenges, and used their experience to propose areas for future work. Recommendations for improving risk assessment procedures and avenues for future collaboration were also discussed. The deliberations of the meeting were also supported by a survey of participants which canvassed risk assessment approaches across the regions from which participants came.

This project was initiated by Argentine Agri-Food Health and Quality National Service (SENASA, Ministry of Agriculture, Argentina), with the support of the International Life Sciences Institute (ILSI) and other partner institutions. The importance of making all possible efforts toward more integrated and harmonized regulatory oversight for GM organisms (GMOs) was strongly emphasized. This exercise showed that such harmonization is a feasible goal that would contribute to sustain a fluid trade of commodities and ultimately enhance food security. Before this can be achieved, key issues identified in this meeting will have to be addressed in the near future to enable regulatory collaboration or joint work. The authors propose that the recommendations coming out of the meeting should be used as a basis for continuing work, follow up discussions and concrete actions.

DOI: 10.1080/21645698.2015.1011886

Link to the publication: http://bit.ly/10sRqS9

Suggested citation: Bartholomaeus, A., Batista, J.C., Burachik, M., Parrott, W. (2015). Recommendations from the workshop on Comparative Approaches to Safety Assessment of GM Plant Materials: A road toward harmonized criteria? Taylor & Francis. 6 (2): 69-79.

NEW PAPER PUBLISHED IN TRANSGENIC RESEARCH ON LOW-LEVEL PRESENCE IN SEED

Title: "Proposed criteria for identifying GE crop plants that pose a low or negligible risk to the environment under conditions of low-level presence in seed"

Abstract: In addition to legal, financial and regulatory challenges, such LLP situations in seed may also require an environmental risk assessment by the country of import. Such assessments have typically been informed by the national framework established to support decisions related to wide scale cultivation, and frequently do not take into account the low environmental exposure and prior regulatory history of the GE plant. In addition, such assessment processes may not be well suited to the decision-making timeframe that is necessary when dealing with an LLP situation in imported seed. In order to facilitate regulatory decision making, this paper proposes a set of scientific criteria for identifying GE crop plants that are expected to pose a low or negligible risk to the environment under LLP conditions in seed. Regulatory decision makers in some importing countries may decide to use these criteria to assist in risk analysis associated with LLP situations they are experiencing or could experience in the future, and might choose to proactively apply the criteria to identify existing GE plants with regulatory approvals in other countries that would be expected to pose low risk under conditions of LLP in seed.

DOI: 10.1007/s11248-015-9899-z

Link to the publication: http://bit.ly/1LZTsLO

Suggested citation: Roberts, A., Finardi-Filho, F., Hegde, S., Kiekebusch, J., Klimpel, G., Krieger, M., Lema, M., Macdonald, P., Nari, C., Rubinstein, C., Slutsky, B., Vicien, C. (2015). Proposed criteria for identifying GE crop plants that pose a low or negligible risk to the environment under conditions of low-level presence in seed. *Transgenic Research* 10.1007/s11248-015-9899-z

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Proposed criteria for identifying	GE crop plants that pose
a low or negligible risk to the env	ironment under conditions
of low-level presence in seed	
Andrew Roberts - Flavio Finardi-Filho - Sabray He	gle - Juan Kiekebusch -
Gonzalo Klimpel · Mark Krieger · Martin A. Lema	Philip Macdenald -
Claudia Nari - Clara Rubinstein - Bernice Slutsky -	Carmen Vicien
Revenuel: 26 May 2015/ Accessed: 30 July 2015	
© The Anthorits 2003. This article is published with open access	s at Springerlink.com
Abstract The low-level presence (LLP) of geneti-	frequently do not take into account the low environ
cally engineered (GE) seeds that have been approved	mental exposure and prior regulatory history of the G
in the country of origin but not the country of import	plant. In addition, such assessment processes may no
presents challenges for regulators in both seed	be well suited to the decision-making timeframe that i
importing and exporting countries, as well as for the	necessary when dealing with an LLP situation i
international seed trade and the farmers who rely on it.	imported seed. In order to facilitate regulatory deci
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support decisions related to wide scale cultivation, and	decide to use these criteria to assist in risk analysi
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S. Heple	C. Nati - C. Rubinstein
Bioschoology Regulatory Services, Animal and Plant	Momanto Co., St. Louis, MO, USA
reason supervise survey, court, washington, DC, USA	C. Rubineria
J. Kickebuch	ILSI Argentina, Buenes Aires, Argentina
Associación de Semilleres Argentines, Buenes Aires, Associación	B Date
	American Seed Trade Association, Alexandria, VA, USA
G. Klimpel	Contraction of the contract of
DuPost Pioneer, Johnson, IA, USA	
M. Krieper	
Dow Agrificiences, Indianapolis, IN, USA	
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BANGLADESH

Highlights from the Meeting on Regulatory Process Guidance for the Bangladesh Biosafety Regulatory System



The Bangladesh Biosafety Regulatory System is defined by the Biosafety Rules of Bangladesh, promulgated under the Environment Conservation Act (ECA). These rules lay out basic regulatory requirements and refer to the Bangladesh Biosafety Guidelines, making those guidelines legally binding under the regulations. The Biosafety Guidelines describe a regulatory structure consisting of a policy and decision making National Committee on Biosafety (NCB), which may request technical support from a Biosafety Core Committee (BCC).

A Biosafety Core Committee (BCC) and stakeholder consultation meeting was held on August 10, 2015 at the Department of Environment (DoE). The purpose of the meeting was to review options and recommendations prepared by the South Asia Biosafety Program (SABP) to ensure that they align with the goals and practices of the government prior to further development and broader stakeholder outreach.

Participants included BCC members as well as representatives from Dhaka University, BRAC University, the Bangladesh Agricultural Research Institute (BARI), the Bangladesh Rice Research Institute (BRRI), the National Institute of Biotechnology (NIB), the Cotton Development Board, the Center for Medical Biotechnology and private seed companies.

The meeting began with the welcome address of Mr. Mohammed Solaiman Haider, Members Secretary, BCC. Mr. Q.S.I. Hashmi, Additional Director General, DoE, chaired during the opening session. Dr. Andrew F. Roberts, Director, Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, presented the drafted Regulatory Process Guidance documents. In his presentation, Dr. Roberts mentioned that



the regulatory processes are intended to ensure that regulated activities are able to proceed in compliance with the policies of the government. In the case of biosafety regulations, the purpose is to allow the use of biotechnology while ensuring adequate protection of the environment and human health. He also pointed out that the regulatory process is the set of procedures, timelines, forms and protocols that are necessary for an applicant to submit an application to the regulatory authority and receive a decision on that application.

It was mentioned that the main purpose of the regulatory process guidance is to provide applicants and other stakeholders with an understanding of how the regulatory process works and how long the process is expected to take. Dr. Roberts described that although the guidance itself is not a legally binding document, following the guidance can provide transparency and predictability to applicants and reduce the likelihood of delays, confusion and complaints. He compared the existing regulatory processes that are mandated by the Biosafety Guidelines and proposed recommendations on different regulatory processes including laboratory work with genetically modified organisms, field release which covers both trials and commercial release, and importation. Through flow charts, he suggested different regulatory processes and proposed timelines for specific activities. The participants actively took part in the discussion and gave various suggestions to incorporate in this guidance document.

Mr. Raisul Alam Mondal, the Director General, DoE, joined in the meeting and thanked Dr. Roberts for developing this important document which will be very useful for regulators as well as for the applicants working with genetically modified organisms. Mr. Mondal sought cooperation from the participating scientists to contribute for the improvement of the document.

The meeting concluded in agreement that Dr. Roberts will update the guidance document based on the comments of the BCC members and participating stakeholders. It will then be submitted to the DoE for broader consultation before its adoption by the regulatory body of Bangladesh.

Interested in contributing to the SABP Newsletter?

The SABP Newsletter, published monthly, is distributed to over 4000 regulators, scientists, policy makers and other stakeholders interested in agricultural biotechnology in South Asia. Each edition includes editorials, information about biosafety regulation and policy developments in India, Bangladesh and Pakistan, SABP and other capacity building activities in the region, and related science or news stories.

All contributions to the newsletter should have a clear connection to the mission of SABP, relate to South Asia and cannot be promotional. For more information or for your article to be considered, please email Libby Williams at Iwilliams@ilsi.org.

EVENT	ORGANIZED BY	DATE	WEBSITE		
INDIA					
ICAR – Winter School on Advances in Improvement of Vegetable Crops using Biotechnological Approaches	Indian Agricultural Research Institute	September 18- October 8, 2015 New Delhi	www.iari.res.in/files/Latest- News/Winter_School_ Color_VegSci-23052015.pdf		
ICAR – Winter School on Recent Advances in Groundnut Production Technology	Acharya N.G. Ranga Agricultural University	September 25- October 15, 2015 Tirupati	http://cbp.icar.gov.in/ Data/Coordinator/6805/ BROCHURE.pdf		
6 th World Congress on Biotechnology	OMICS International	October 5-7, 2015	www.		

New Delhi

CALENDAR OF EVENTS

		New Delhi	biotechnologycongress. com/india/index.php		
25 th Asian-Pacific Weed Science Society Conference (APWSS 2015)	Indian Society of Weed Science, Indian Council of Agricultural Research, Directorate of Weed Research and Prof. Jayashankar Telangana State Agricultural University	October 13-16, 2015 Hyderabad	www.isws.org.in/25intro. aspx		
ICAR - Winter School on Novel Genomics Tools and Modern Genetics and Breeding Approaches for Vegetable Crops Improvement	Indian Institute of Vegetable Research	November 7-27, 2015 Varanasi	www.iivr.org.in/sites/ default/files/imageblock/ IIVR%20Winter%20 School%20Brochure.pdf		
National Seminar on Plant Genomics and Biotechnology Challenges and Opportunities in 21 st Century	Department of Agricultural Biotechnology, College of Agriculture, and Orissa University of Agriculture & Technology	January 23-24, 2016 Bhubaneswar	www.ouat.ac.in/ ForthEvents.aspx		
INTERNATIONAL					
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		
3 rd International Conference on Agriculture and Biotechnology (ICABT 2015)	Asia-Pacific Chemical, Biological & Environmental Engineering Society (APCBEES)	November 9-10, 2015 Jinju, South Korea	www.icabt.org		



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.

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Center for

Environmental

Risk Assessment

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

SOUTH ASIA BIOSAFETY PROGRAM

BANGLADESH

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