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 national governmental agencies 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.

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 Bangladesh and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

GLIMPSES OF COP-MOP6

The sixth meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP 6) was held from October 1 to 5, 2012 in Hyderabad, India.

Governments from more than 150 countries got together to review the status of the implementation of the core elements of the Cartagena Protocol on Biosafety (the Protocol) and resolve some of the contentious issues at the meeting. Approximately 1300 participants representing parties to the Protocol and other governments, UN agencies, intergovernmental and non-governmental organizations, academia and industry attended the meeting. Speaking at the inauguration Ms. Jayanthi Natarajan, Minister of Environment & Forests for the Government of India, as the new president of the Convention (by virtue of its being the host country) urged member countries to work together to strengthen biosafety measures the world over. She also stressed the need for more cooperation and knowledge sharing among the member countries.

Several substantive issues were discussed at the meeting. COP-MOP6 also provided an opportunity to look at the challenges of implementing key provisions of the Protocol.

The meeting adopted 16 decisions on: compliance; the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (the Supplementary Protocol); subsidiary bodies; cooperation with other organizations, conventions and initiatives; the Biosafety Clearing-House (BCH); capacity building; the roster of experts; monitoring and reporting; assessment and review; notification requirements; handling, transport, packaging and identification (HTPI) of living modified organisms (LMOs) (Article 18); unintentional transboundary movements of LMOs (Article 17); financial mechanism and resources; socio-economic considerations; risk assessment and risk management; and the budget.

Agreement was reached on a number of complex issues. Regarding risk assessment, the parties agreed to test the "Guidance on risk assessment of LMOs" developed by an Ad Hoc Technical Expert Group (AHTEG) in actual cases of risk assessment and share their experiences. The delegates also agreed on an improved plan of action on capacity building to support the implementation of the Protocol and adopted further steps to strengthen the BCH, which is an online information exchange facility under the Protocol. To advance discussions on socio-economic considerations, the parties agreed to establish an AHTEG to develop clarity on these issues. The detailed report on the COP/MOP 6 will be available at the CBD website

Photos: IISD Reporting Services

ABOUT THE CARTAGENA PROTOCOL AND COP-MOP

1. The Cartagena Protocol on Biosafety is a supplementary agreement to the Convention on Biological Diversity. Its objective is to contribute to ensuring the safe transfer, handling and use of living modified organisms that may have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. The Protocol was adopted January 29, 2000 in Montreal, Canada and entered into force September 11, 2003. To date, 163 countries and the European Union have ratified or acceded to it.
3. The Protocol is named after the Colombian city of Cartagena where the final round of its negotiations was launched.
4. The governing body of the Protocol, known as the Conference of the Parties to Convention on Biological Diversity serving as the Meeting of the Parties to the Protocol (or COP-MOP, in short), has held five meetings: Kuala Lumpur, February 2004; Montreal, June 2005; Curitiba, March 2006; Bonn, May 2008; and Nagoya, October 2010.

WORKSHOP ON SAFETY ASSESSMENT OF GM CROPS: COMPOSITIONAL ANALYSIS

SEPTEMBER 13-15, 2012 -- WASHINGTON, DC

The International Life Sciences Institute (ILSI) International Food Biosafety Committee (IFBiC) organized a workshop on Safety Assessment of GM Crops: Compositional Analysis September 13 through 15, 2012. About 90 participants from 30 countries attended.

Its objectives were to:

- Review traditional breeding methods, effects on composition and compositional variability.
- Consider compositional analysis with a scientific, non-biased view.
- Discuss the science behind the current approach to compositional analysis in the framework of the safety assessment.
- Arrive at a consensus and make possible recommendations regarding the state of the current approach to compositional analysis.

The opening day keynote presentation was given by Dr. Sherry Flint-Garcia, USDA-ARS, who gave a detailed talk on the genetics and consequences of crop domestication. She described that genetic analysis and improvement of crops relies on variation in genes controlling traits of interest; how genetic variation has arisen naturally over millions of years and continues to arise in all plant species; how a proportion of this genetic variation contributes to phenotypic variation within the species; and how phenotypic variation has been manipulated by humans during the domestication of crop plants, which occurred primarily between 3,000 and 10,000 years ago in the various global centres of origin. Dr. Garcia used maize as a case study to demonstrate the relationship between genetic and phenotypic diversity in the domestic crop and its wild ancestors. She explained that the evaluation of nested association mapping (NAM) and maize-teosinte introgression lines allows us to understand the impact of domestication on trait variation and the reintroduction of valuable genetic variation into modern maize.

Divided into four scientific sessions and four round table discussions, the first session, Conventional Development of New Crop Varieties, was chaired by Dr. Wayne Parrot of the University of Georgia, USA. It consisted of four presentations: first, Dr. Flavio Bresegbello, EMBRAPA, Brazil, using rice case studies, spoke about traditional and modern plant breeding methods; next, Dr. John Finer, Ohio State University, spoke about genomic variation in plants recovered through plant cell and tissue culture; then, Dr. Matthew Blair, Universidad Nacional de Colombia, spoke about mineral biofortification strategies for major staples, using the common bean as an example; and lastly, a talk by Dr. Peter Shewry, Rothamsted Research, UK on natural variability in wheat grain composition.

The second session, Development of Crops Using Modern Biotechnology, consisted of three presentations. The first, by Dr. Rita Mumm of the University of Illinois, used maize as an example to describe the product development steps with genetically modified crops. Then Dr. Laura Privalle, BASF Plant Science, USA spoke about bringing a transgenic crop to market and where compositional analysis fits. She explained that in the process of developing a biotech product, thousands of genes and transformation events are evaluated to select the event that will be commercialized. Once selected, the commercial event is subjected to a rigorous safety evaluation. The assessment considers the safety of the gene, safety of the protein produced by the gene, plant performance, impact of the biotech crop on the environment, agronomic performance and equivalence of the crop/food to conventional crops/food, which she said is addressed by compositional analysis that is comprised of a comparison of the nutrient and anti-nutrient composition of the consumed portions of the crop between the event, its parental line and various conventional lines.

The session's final presentation, by Dr. Kazumi Kitta of the National Agriculture and Food Research Organization, Japan was about the availability and utility of crop composition data. She outlined that, for the efficient safety assessment of GM crops, an easily accessible wide compilation of crop composition data are required for use by researchers and regulatory agencies. To achieve this, they developed an internet accessible food composition database comprising macro-, micro- and anti-nutrients, endogenous toxicants and physiologically active substances of staple crops, such as rice and soybeans. She mentioned that ILSI has also been addressing the same matter and has provided a crop composition database.

The third session, Compositional Analysis Methods, saw three presentations. The first, by Dr. Kathleen Jones, US FDA, described the process for developing a composition consensus document for the safety assessment of novel foods and feeds especially for products of modern biotechnology. During the course of her talk she spoke about the Organization for Economic Co-operation and Development's (OECD) Task Force for the Safety of Novel Food's efforts to promote international harmonization of the safety assessment of biotech derived foods and feeds. The OECD Task Force has been able to develop the OECD Composition Consensus Document, which is available online.

The second paper, by Dr. Hilary Rogers of Eurofins, USA was about how compositon methods are developed and validated, addressed various approaches to method development and validation as well as the factors that determine method selection and how extensive the validation needs be. She pointed out that a number of organizations, namely, AOAC International and International Organization for Standardization (ISO) publish peer reviewed methods for cross-industry matrices, while others like American Oil Chemists' Society (AOCS) and American Association for Clinical Chemistry (AACC) are focused on specific industry segments, namely, fats/oils and cereal grains. She also said that development of a new method requires an understanding of the chemistry and properties of the analyte to be tested as well as various types of instrumentation currently available.

The session's final presentation, by Dr. Richard Goodman of University of Nebraska-Lincoln, addressed the evaluation of endogenous allergens for the safety evaluation of genetically engineered food crops, which was a review of methods and relevance. He cited maize, soybean and wheat examples. After giving a brief history of evaluation, Dr. Goodman said that current guidelines call for testing without qualification, without data demonstrating increased risk associated with altered expression and without guidance regarding the magnitude of change that would be unacceptable. He also described how, recently, European and Asian regulators have asked for tests using individual donors only by one and two-dimensional blots and direct ELISA. Some scientists have used proteomics tests rather than immunoassay. He noted that by 2012, the allergens of many foods are well characterized, but reactions are not ascribable to individual proteins and the natural variation in foods is relatively unknown but, evidence suggests, highly variable. It was discussed that both immunoassay and proteomics have significant limitations for measuring allergenicity. Based on these findings he said that

those with specific allergies should avoid consuming those allergens without regard to dose.

The final session, Interpretation of Composition Data, had four presentations. The first, by Dr. Wilna Jansen van Rijssen, retired from the South African Department of Health, was about the importance of composition in food safety. Stating that food safety is not inherent but is based on a history of safe human and animal use, Dr. Jansen van Rijssen stressed that compositional analysis is important because it is difficult to compare the safety of whole food.

Dr. David Lovell, University of London, UK, described the use of statistical ideas in the analysis of experiments related to the composition of crops and the genetic factors that underlie their composition. He described how statistical analysis of a database is dependent upon the experimental design and that no amount of statistical sophistication can rescue a badly designed study, pointing out that identifying statistical significance should not be the primary objective of a statistical analysis. Instead, more emphasis should be given to the estimation of effects and the precision of these experiments, which should also be linked to the identification of the size of the effects that are considered biologically important or relevant that can then be used in the design of experiments in terms of sample size and statistical power.

Dr. Lynne Underhill of Health Canada spoke about regulatory perspectives and how composition data are interpreted as regards food. She described how safety assessment of novel foods fits into the food mandate of Health Canada. She also described the regulatory framework for pre-market safety assessment of novel food in Canada including CODEX principles and other guidance. Covering different elements of the safety assessment process with special emphasis on the importance and purpose of compositional analysis, she highlighted some of the challenges faced by regulators, namely, how much data is needed, especially "what is nice to know" vs "what needs to be known", etc.

The session's final presentation was by Dr. Bill Price who spoke about regulatory perspectives on how composition data are interpreted as they relate to feed. He discussed the US's unified approach to the regulation of feed derived from bioengineered plants, why animal feeds are extremely important in the evaluation process and the history of regulation of bioengineered food and feed including how OECD and CODEX fit into it.

The workshop's round table discussions covered the following issues:

- How does transgenic methodology affect the resultant progeny compared to the methodology employed during traditional plant breeding? Is the likelihood of generating unintended effects inherently greater with one methodology compared to the other?
- How does the inherent variability of crop components affect data interpretation and subsequent safety evaluation? What role does inherent variability play in evaluating the safety consequences of any unintended effects?
- What is the appropriate comparator to use in a compositional analysis study to support the safety assessment? What defines history of safe use/safe consumption?
- What factors are to be considered when determining what tissues and what components should be included in the analysis? Are current OECD guidelines adequate?, etc.

During the wrap up session, Dr. Angela Hendrickson Culler, co-chair, ILSI-IFBiC Crop Composition Issues Task Force, reviewed the outcome of the three-day long workshop including reports from the round table discussions. The following outcomes were achieved through the workshop's deliberations and discussions:

- It is possible to arrive at a better understanding of the role compositional analysis plays in the overall safety assessment of genetically modified crops.
- It is possible to develop comprehension of the science behind compositional analysis studies and interpretation of the resultant data.
- It was stressed that messages should be shared.

The Reading List

. . . new and notable articles

CROP GENOME PLASTICITY AND ITS RELEVANCE TO FOOD AND FEED SAFETY OF GENETICALLY ENGINEERED BREEDING STACKS

Weber N, Halpin C, Hannah LC, Jez JM, Kough J, Parrott W

TGenetically engineered (GE) stacks (also known as stacked or combined events) are produced by combining two or more single transgenic events in a plant through conventional breeding. Although generating varieties with combined traits is fundamental in conventional breeding, GE stacks are sometimes viewed differently from conventionally bred non-GE crops with respect to risk and safety assessment. Two fundamental questions regarding safety assessment of GE stacks are: (1) Does the presence of more than one event increase genomic instability, and could such instability be hazardous, and (2) can interactions between the products of the transgenes impact safety? This paper focuses on the first question. Plant genomes are inherently plastic and prone to genetic changes from diverse phenomena, including movement of various mobile elements, recombination, and other mutations. Furthermore, these genetic changes that occur in conventionally-bred non-GE crops with a long history of safe use have given rise to new proteins and, in turn, enhanced biochemical diversity. Because the transgenic insertions of safety-assessed events are fully integrated into the genome, there is no indication that stacked events pose greater risk of genetic instability compared to other conventional gene stacks. Therefore, taking into account the inherent genomic plasticity in plants and the lack of a biological mechanism through which transgenes increase genetic instability to a measurable extent, evaluating transgenic insertion stability in GE stacks does not contribute to a safety assessment. Evaluation should therefore focus on the presence of possible interactions.*PLANT PLANT PHYSIOLOGY (2012) OCT 11. [EPUB AHEAD OF PRINT].* *http://www.plantphysiol.org/content/early/2012/10/11/pp.112.204271.abstract?sid=a8d026c1-5605-4e53-ade7-269d7e9901c3*

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Practical Course in Plant Biotechnology	Barwale Foundation	November - December, 2012	http://www.barwalefoundation.org/html/announcement-2.htm
National Seminar on Improving Cane Productivity and Sugar Recovery to Sustain Sugar Industries	Sugarcane Research Institute, Rajendra Agricultural University	November 27 - 29, 2012 Pusa (Samastipur), Bihar	http://www.pusavarsity.org.in/Brochure.pdf
Conference on AgriBiotechnology: Industrial Relevance in Geonomics and Nanobiotechnology	Confederation of Indian Industry and The TERI-Deakin Nanobiotechnology Centre, The Energy and Resources Institute	November 27, 2012 New Delhi	http://www.teriin.org/index.php?option=com_events&task=details&sid=545
Winter School on Molecular Breeding Approaches for Genetic Enhancement in Oilseed Crops	Directorate of Oilseeds Research	December 1 - 21, 2012 Hyderabad	http://dor-icar.org.in/media/docs/winter-school-dec-2012.pdf
Winter School on Breeding for Higher Productivity and Industry Suitable Food Colorants and Bioactive Health Compounds in Vegetable Crop Plants: Conventional and Hi-Tech Cutting Edge Approaches	Division of Vegetable Science, Indian Agricultural Research Institute	December 4 - 24, 2012 New Delhi	http://www.iari.res.in/files/Winter_school-Circular-30072012.pdf
International Symposium on Food Security Dilemma: Plant Health and Climate Change Issues	Bidhan Chandra Krishi Viswavidyalaya	December 7 - 9, 2012 Kalyani, West Bengal	http://www.bckv.edu.in/userfiles/file/Final_Circlr_%20Int_Symp_AAPP.pdf
AgTech Global Summit – 2012	Bejo Sheetal Bio-Science Foundation and Maryland India Business Round Table	December 9 - 13, 2012 Aurangabad	
BIOFEST 2012 International Conference and Exhibition on Life Sciences	Bright International Conferences & Events Organization	December 12 - 13, 2012 Hyderabad	http://www.isaaa.org/kc/events/details.asp?ID=431
2nd Jammu and Kashmir Agricultural Science Congress	Sher-e-Kashmir University of Agricultural Sciences and Technology of Jammu	December 15 - 17, 2012 Jammu	http://www.skuast.org/new/science-congress/brochure-science.pdf
North Zone Meeting of Indian Society of Mycology and Plant Pathology and National Symposium on Emerging Trends in Plant Pathology	Sher-e-Kashmir University of Agricultural Sciences and Technology of Jammu	December 19 - 20 2012 Jammu	http://www.skuast.org/new/training/sympo-plantpathology.pdf
National Training Workshop on Applications of Genomics in Crop Improvement	G.B. Pant University of Agriculture & Technology	December 27 – January 16, 2013, Pantnagar	http://www.gbpuat.ac.in/
National Convention on India Cotton: Gearing Up for Global Leadership	The Gujarat Association for Agricultural Sciences, Navsari; Indian Society For Cotton Improvement, Mumbai; Navsari Agricultural University, Surat; and Central Institute for Cotton Research, Nagpur	January 6 - 8, 2013 Surat	http://www.nau.in/announce.php?id=686
INTERNATIONAL			
1st International Conference for GM Crops and Food	Faculty of Agriculture, Cairo University	November 27 – 29, 2012 Cairo, Egypt	http://www.icgmc.com/
International Scientific Workshop on Non-target Organisms and GM Crops: Assessing the Effects of Bt Proteins	European Food Safety Authority (EFSA) and the Netherlands Commission on Genetic Modification (COGEM)	November 29 - 30, 2012, Amsterdam, The Netherlands	http://www.cogem.net/index.cfm/en/symposium/

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