SOUTH ASIA
BIOSAFETY PROGRAM

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NEWSLETTER

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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.

Over the next three years, SABP will work 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.

Harmonization of environmental risk assessment principles and processes is an important goal for stakeholders interested in the safe introduction, cultivation and international trade of genetically modified crops. Many useful and appropriate models for the science-based risk assessment have been developed (NRC, 1987; Tiedje *et al*., 1989; OECD, 1993, EFSA, 2004) that are consistent with international treaties (CBD and IPPC). In addition to developing an appropriate science-based assessment, countries face the challenge of how to address the societal interests (including micro and macro economic interests) in decision-making and risk management. No single model exists to do this.

Internationally, the standards and practice of environmental risk assessment of GM crops are generally consistent with respect to the safety concerns that must be addressed. It is accepted broadly that the potential hazards posed by the introduction of a new organism or production practice should be evaluated relative to an existing product or practice, and should consider the characteristics of the introduced trait, the phenotypic expression of the new trait and the interaction of the modified plant and the receiving environment. The quality of pre-market environmental risk assessment is realistically limited by our knowledge of existing ecosystems and by our understanding of the biology of the unmodified host organism, including its potential interactions within ecosystems. In this context, there is a need for increased public sector research to increase our understanding of both natural and managed ecosystems, both to strengthen pre-market risk assessment and to provide baseline data to support systematic hypothesis-driven post-market monitoring. However, the new molecular and "omics" technologies currently being examined have more uncertainty associated with them since they have not been validated yet for use in mainstream risk assessment. It is equally important to recognize that delays in adopting some technologies while waiting for new knowledge is not without risk.

Experience from over ten years of producing GM crops has increased our familiarity with certain products from the perspective of field testing, importation and production. It is reasonable to use this experience in a retrospective analysis and differentiate among risks. Trait and crop combinations with multiple years of safe production should be viewed differently from experimental GM materials. Likewise, the risks associated with importation of LMO FFPs should be evaluated in an appropriate manner based on the level of exposure; while for field trials should be on adequate risk management (confinement). Lastly, post-market monitoring/surveillance can be a valuable and appropriate exercise when based on the results of the risk assessment. Poorly defined goals and criteria for monitoring could lead to a mischaracterization of the risk or false sense of security.

Perhaps the greatest uncertainty regarding the future of regulatory decision making for GM crops can be seen when contrasting the environmental risk assessment standards under OECD, the Cartagena Protocol, and the IPPC. Specifically, there are distinct differences in how other considerations are handled. Under OECD recommendations, these are not dealt with within the risk assessment process *per se* although they are presumed to play some role in ultimate decision-making. The Cartagena Protocol formally introduces the notion of socio-economic concerns being an important consideration, but to date has not provided specific guidance on how and to what extent they may be incorporated in biosafety decisions. Finally, under the IPPC we see a more formalized incorporation of economic (not social) analysis as an integral part of the pest risk analysis.

As evidenced by the public debate in Europe, rigorous science-based risk assessment is a necessary but not sufficient condition for gaining social acceptance of agricultural biotechnology. In Canada and the U.S., there are differences between the two regulatory systems that have been developed for the new products of biotechnology. Neither system, however, requires a consideration of economic impacts as part of the environmental risk assessment like those described by the EU regulations and directives. In decision making processes, socio-economic concerns may be an important consideration in the public's acceptance that affects regulatory decision-making. As such, a challenge for governments is how best to address them within the legal and regulatory framework while also meeting their obligations under other international agreements. Any movement towards a more complete cost-benefit risk assessment for the introduction of GM crops will take time and require additional research on defining and using relevant economic indicators of environmental impact. In addition, as noted by the NRC Committee on Environmental Impacts

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CALENDAR OF EVENTS (INDIA)			
Event	**Organization**	**Date**	**Place**
Second Asian Graduate Course on Production and Use of Food Composition Data in Nutrition	National Institute of Nutrition (ICMR) and International Nutrition Foundation. For more information go to ftp://ftp.fao.org/ag/agn/infoods/asia_food_comp06.pdf	November 5-25, 2006	National Institute of Nutrition, Hyderabad, India
Cartagena Protocol on Biosafety: from decisions to diagnostics	National Bureau of Plant Genetic Resources (NBPGR), New Delhi. For more information contact: director@nbpgr.ernet.in gurinder.randhawa@rediffmail.com	November 23-30, 2006	National Bureau of Plant Genetic Resources , New Delhi

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Associated with Commercialization of Transgenic Plants, building public confidence in the regulatory system will require a more systematic and public effort to acknowledge diverse societal values and the evaluation of socio-economic impacts along with environmental risks. While such efforts may prove helpful in the overall assessment of the impact of GM crops, it may add little to the key objectives of a physical and biological science-based environmental safety evaluation which focuses on the nature of the plant, the introduced trait, the likely receiving environment and the interactions among these. Finally, if one is to include the potential socio-economic impacts as part of the environmental risk assessment, then intellectual honesty would require one to consider equally the potentially positive and negative impacts.

From:
Environmental Risk Assessment of Genetically Modified Plants: International Harmonization and Related Issues by D.J. MacKenzie, T.E. Nickson, M.A. McLean and J.P. Purcell.

GM FOOD SAFETY WORKSHOPS

The Indian Council of Medical Research (ICMR), in association with AGBIOS Inc. and Biotech Consortium India Limited (BCIL), and under the South Asia Biosafety Program, hosted two workshops on the Safety Assessment of Foods Derived from Genetically Modified Crops. The workshops were held at the National Institute of Nutrition, Hyderabad (18-22 September 2006) and the Industrial Toxicology Research Centre, Lucknow (25-29 September 2006).

Over 40 scientists participated in the week long programs which coupled discussions about the concepts and principles that are used to frame the safety assessment of genetically modified (GM) foods with practical exercises where the participants were tasked with taking on the role of a risk assessor to evaluate information and data for a number of experimental and commercialized GM foods. The workshops focused on the interdisciplinary nature of GM food safety assessment and the participants, working in teams that included allergists, toxicologists, plant breeders and nutritionists, were very engaged. As one workshop participant stated "It was a wonderful experience attending the workshop. It helped me to realize as to what aspects are important for approving GM foods."

Two more workshops are planned for 2007: January 22-26, 2007 in Pune and January 29-February 2, 2007 in Kolkata, and the summary agenda is provided here. For more information, please contact Dr. Vibha Ahuja or submit the registration form, which can be found on on page 4 of this newsletter.

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SUMMARY AGENDA FOR WORKSHOPS

Topics
DAY 1
Concepts and Principles of GM Food Safety Assessment Regulating GM Foods Starting the Safety Assessment Host and Donor Organisms Molecular Characterization An Introduction to Protein Expression Introduction to the Case Study Case Study review
DAY 2
Overview of Allergenicity Assessment and Introduction to Specific Steps Introductory Bioinformatics FASTA BLASTP Limitations to short amino acid searches Transitioning from Sequence Searches to Serum Screening Bioinformatics report writing Case Study review: allergenicity
DAY 3
Human Serum Testing Animal models for assessing potential allergenicity Pepsin digestion Heat stability and abundance Assessing potential toxicity of novel proteins Assays Case Study review: toxicity
DAY 4
Compositional Analysis Livestock feeding trials Case study review: nutritional assessment
DAY 5
Case Study review & preparation of decision letter Case Study and decision letter presentations GM Food Safety Assessment: the Road Ahead in India

(continued on page 4 - see Workshops)

MOEF CONFERENCE - NOV 20-22, 2006

The Ministry of Environment and Forests (MoEF), Government of India, is implementing a GEF/World Bank funded project on Capacity Building on Biosafety in context of Cartagena Protocol on Biosafety. The project covers the assessment, management and long term monitoring and documentation of the risks to the sustainable use of biodiversity and to human health potentially posed by the introduction of Living Modified Organisms (LMOs). As part this MoEF will be convening an International Conference on Biosafety in New Delhi, November 20,22, 2006. The conference will address a number of topics pertinent to the Cartagena Protocol on Biosafety.

A copy of the registration form can be downloaded from http://envfor.nic.in/divisions/csurv/biosafety/newsletter/Int_Conf.pdf.

For more information, please contact Dr. Manoranjan Hota, Additional Director, MoEF, Telefax +91 11 24367663, e-mail: hota@nic.in.

DRAFT AGENDA FOR
INTERNATIONAL CONFERENCE ON THE IMPLICATIONS OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Organised by: Ministry of Environment and Forests, Government of India
In association with: Biotech Consortium India Limited, and ITDC New Delhi
Venue: The Ashoka Hotel, Diplomatic Enclave, 50-B, Chanakyapuri, New Delhi – 110 021 Dates: November 20 – 22, 2006

DAY 1: NOVEMBER 20, 2006	
INAUGURAL SESSION	Shri Bir Singh Parsheera, Additional Secretary, Ministry of Environment & Forests and Chairman, GEAC; Dr. Ahmed Djoghlaf, Executive Secretary, Convention on Biological Diversity; Dr. Prodipto Ghosh, Secretary, Ministry of Environment & Forests; Shri A. Raja, Hon. Union Minister of Environment & Forests, Government of India; Shri Desh Deepak Verma, Outgoing Project Director & Joint Secretary, Ministry of Environment & Forests.
TECHNICAL SESSION-I: International Efforts to Support the Implementation of the Cartegena Protocol on Biosafety	CHAIR: Dr. Ahmed Djoghlaf, CBD Secretariat. SPEAKERS: Dr. Eija Pehu,Agriculture and Rural Development Department, World Bank; Dr. Larry Paulson, USAID; Dr. Nizar Mohamed – UNEP-GEF; Representative from UNDP Country Office.
TECHNICAL SESSION-II: National Arrangements to Implement the Cartagena Protocol on Biosafety	CHAIR: Mr. Bir Singh Parsheera, Additional Secretary, Ministry of Environment & Forests and Chairman, GEAC. SPEAKERS: Dr. Manoranjan Hota, Additional Director, Ministry of Environment & Forests, Government of India; Dr. Elizabeth Hodson, Colombia; Dr. Augustin Lopez, Mexico; Dr. Desmond Mahon, Canada.
TECHNICAL SESSION-III: Capacity Building: Needs and Challenges	CHAIR: Dr. Desmond Mahon (Chair, CBD Liaison Group on Capacity-Building for Biosafety). SPEAKERS: Dr. Mark Tepfer, ICGEB; Dr. Ranjana Sharma, (Canada); Dr. Yanqing Wang (China); Dr. P.K. Ghosh, Senior Vice President, Cadila Pharmaceuticals.
DAY 2: NOVEMBER 21, 2006	
TECHNICAL SESSION-IV Living Modified Organisms for Food, Feed and Processing: The Challenges of Handling, Transporting and Packaging LMOs	CHAIR: Dr. C.D. Mayee, Chairman Agricultural Scientists Recruitment Board (ASRB) and Co-Chair GEAC, India. SPEAKERS: Dr. Ranjini Warrier, Additional Director, Ministry of Environment & Forests, Government of India; Dr. Biswajit Dhar, Professor and Head, Centre for WTO Studies, Indian Institute of Foreign Trade; Dr. Raju Barwale, Managing Director, Maharashtra Hybrid Seeds Company Ltd.; Mr. Sanjay Kumar, Ministry of Commerce.
TECHNICAL SESSION-V: Labeling of LMOs	CHAIR: Dr. Eija Pehu, The World Bank. SPEAKERS: Dr. S.R. Rao, Director, Department of Biotechnology, Ministry of Science & Technology, Government of India. Labelling & trisibility of LMOs impact in depending contacts; Mr. R.K. Sinha, Executive Director, All India Crop Biotechnology Association (AICBA); Dr. D. Chattopadhyay – Ministry of Health, Government of India, Labelling GM Food: India's view point; Dr. V. S. Reddy, ICGEB.
TECHNICAL SESSION-VI: Risk Assessment of LMOs for Deliberate Release into the Environment	CHAIR: Mr. Desh Deepak Verma, Outgoing Project Director & Joint Secretary, Ministry of Environment & Forests. SPEAKERS: Dr. Morven A. McLean, AGBIOS, Canada and Dr. Vibha Ahuja, BCIL, India; Dr. B. Sesikeran, Director, National Institute of Nutrition (NIN); Dr. Wendy Craig (ICGEB); Dr. T.V. Ramanaiah; Dr. Flerida A. Cariño, Institute of Environmental Science and Meteorology, University of the Philippines; Dr. K.R. Koundal, Project Director, National Research Centre on Plant Biotechnology, Indian Agricultural Research Institute; Dr. Ravi Khetrapal, NBPGR.
DAY 3: NOVEMBER 22, 2006	
TECHNICAL SESSION VII: Detection of LMOs	CHAIR: Dr. K.K. Tripathi, Advisor, Department of Biotechnology, Ministry of Science & Technology, Government of India. SPEAKERS: Dr. Gurinder Jit Randhawa, Senior Scientist, National Research Centre on DNA Fingerprinting, National Bureau of Plant Genetic Resources; Dr. Lalitha R. Gowda, Scientist, Dept. of Protein Chemistry and Technology, Central Food Technological Research Institute; Dr. Anil Gupta, G. B. Pant University of Agriculture & Technology.
TECHNICAL SESSION VIII: Information Sharing and the BCH	CHAIR: Dr. Mark Tepfer, ICGEB. SPEAKERS: Dr. Alex Owusu-Biney, Ghana; Mr. Bhagirath Choudhary, International Service for the Acquisition of Agri-Biotech Applications (ISAAA); Dr. Ajai Parida, Programme Director – Biotechnology, M.S. Swaminathan Research Foundation; Dr. Gamini Gamage, Sri Lanka; T.R. Sharma, Crop data base.
TECHNICAL SESSION IX: The Challenges Ahead for Implementing the Cartegena Protocol in Developing Countries	CHAIR: Mr. Sudhir Mittal, Joint Secretary & GEF Focal Point in India. SPEAKERS: Dr. Ruth Mackenzie (UK); Dr. Nizar Mohamed, UNEP-GEF; Mr. Desh Deepak Verma, Outgoing Project Director & Joint Secretary, Ministry of Environment & Forests; Dr. Balakrishna Pishupati (UNU, Japan); Dr. J. L. Karihaloo, Coordinator, Asia-Pacific Consortium on Agricultural Biotechnology.
CONCLUDING SESSION	Shri Bir Singh Parsheera, Additional Secretary; Shri Namao Narain Meena, Hon'ble Minister of State, Ministry of Environment & Forests, Government of India; Dr. Manoranjan Hota, Addl. Director & Project Coordinator.

Workshops - *continued from page 2*

WORKSHOPS ON SAFETY ASSESSMENT OF GENETICALLY MODIFIED (GM) FOODS JANUARY 22 - 26, 2007, PUNE, AND JANUARY 29 - FEBRUARY 2, 2007, KOLKATA

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REGISTRATION FORM

PLEASE USE BLOCK LETTERS

Name: _____ **Position:** _____

Employer/Institution/Company: _____

Address: _____

_____

Telephone: _____ **Fax:** _____ **E-mail:** _____

Relevant areas of expertise to GM food safety assessment: _____

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We welcome reader comments or suggestions. E-mail your letters to: nringma@agbios.com **Mail your letters to:** The Editor, SABP Newsletter, P.O. Box 475, Merrickville, Ontario, K0G 1N0 Canada

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