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 processes, socio-economic concerns may be an important consideration in the public’s 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 "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 FPPs should be evaluated in an appropriate manner based on the level of exposure; while for field trials should be on adequate risk management (confine). 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 (continued on page 2 - see Risk Assessment)
Risk Assessment - continued from page 1

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.


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
Transiting 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

DAY 1: NOVEMBER 20, 2006
INAUGURAL SESSION
CHAIR: Shri Bir Singh Parsheera, Additional Secretary, Ministry of Environment & Forests and Chairman, GEAC; Dr. Ahmed Djoghlaf, Executive Secretary, Convention on Biological Diversity; Dr. Pradip 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 Cartagena 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, ICGB.

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 (ICGB); Dr. T.V. Ramanalal; Dr. Florida A. Carinio, 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, NBPR.

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. Gurinderjit 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, ICGB. SPEAKERS: Dr. Alex Owusu-Binye, Ghana; Mr. Bhagirath Choudhary, International Service for the Acquisition of Agri-Biotech Applications (ISAAA); Ajay Parida, Programme Director – Biotechnology, M.S. Swaminathan Research Foundation; Dr. Gaminji Gamge, Sri Lanka; T.R. Sharma, Crop data base.

TECHNICAL SESSION IX:
The Challenges Ahead for Implementing the Cartagena 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. Karihaloo, Coordinator, Asia-Pacific Consortium on Agricultural Biotechnology.

CONCLUDING SESSION
CHAIR: 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 ON SAFETY ASSESSMENT OF GENETICALLY MODIFIED (GM) FOODS

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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