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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.

SABP CONFERENCE ON ERA OF GE CROPS

Dr. Vibha Ahuja, General Manager, Biotech Consortium India Limited and Dr. Andrew Roberts, Center for Environmental Risk Assessment, ILSI Research Foundation

OVERVIEW

The South Asia Conference on Current Approaches to Environmental Risk Assessment of Genetically Engineered Crops was held in New Delhi, May 16 to 18, 2011. It brought together scientists and professionals from India and abroad to share their experiences and knowledge of the science and practice of environmental risk assessment (ERA) as well as closely related, scientific issues. Presentations from Indian and international speakers served as the basis for the discussions at the conference and sessions focused on the accumulated international experience in ERA, the development and use of organized and rational methods for determining information needs related to ERA, standards and best practices for collecting and interpreting data for use in ERA as well as scientific issues related to the oversight of GE plants following risk assessment. On the final day of the conference, panel discussions allowed expert panellists to share their experience with attendees regarding several issues which, although not necessarily directly related to ERA, continue to capture attention surrounding the introduction of GE plants into the environment.

This report provides a brief description of each session of the conference, including a few summary points arising from the presentations themselves and subsequent question and answer sessions. Finally, the authors believe that some useful observations can be distilled from the discussions at the conference and are also presented.

SESSION I: INTERNATIONAL EXPERIENCE IN ENVIRONMENTAL RISK ASSESSMENT OF GE PLANTS

The presentations in this session provided an overview of past and current experience in the conduct of ERA, as well as efforts to harmonize ERA of GE plants internationally. The work of the OECD in providing a forum for harmonization of ERA, beginning in the 1980s and continuing to the present was considered, along with the individual country experiences of Australia, the Philippines and India in this regard. There emerged several points of concurrence regarding the experience of countries in conducting ERA for GE plants.

ERA conference guest speakers, from left, Dr. Ranjini Warrier, Ministry of Environment and Forests, India; Dr. Sally McCammon USDA Biotechnology Regulatory Services, United States; Dr. Joe Smith, Office of the Gene Technology Regulator, Australia; Dr. Flerida Cariño, University of the Philippines.

SUMMARY POINTS

- Although countries have differences in their laws and regulations, as well as their socio-political circumstances, the scientific considerations for ERA remain largely the same.
- The experiences of the countries presented here, as well as the harmonization efforts undertaken in OECD, show that science that informs ERA can be broadly agreed and that it is useful to separate the scientific aspects of ERA from policy or political considerations.

SESSION II: PROBLEM FORMULATION FOR ENVIRONMENTAL RISK ASSESSMENT

Problem formulation is a process for identifying the information that is necessary to complete an ERA under a particular circumstance. It provides a rational basis to answer the very simple but important question; "What do you need to know?" This session provided an overview of both the process and

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ERA - *continued from page 1*

methodology for problem formulation as well as a discussion of how it can contribute to ERA and to regulatory frameworks.

SUMMARY POINTS

- Problem formulation, as a methodology for identifying the information that is necessary to conduct ERA, is incredibly useful and can support transparency and consistency in the ERA process.
- There is ample experience and research in biosafety, and a sufficient body of knowledge related to ERA of GE plants, to serve as the basis for conducting problem formulation.
- Problem formulation can be useful in India (and in other countries) in the development of research plans to support future risk assessments, and is likely to be useful in the development of guidance for ERA.

Problem formulation workshop.

SESSION III: **SELECTED TOPICS IN ERA**

The focus of this session was the collection and interpretation of data that is useful to ERA. Presentations introduced considerations for laboratory, semi-field and field experiments as well as the collection and interpretation of data from regulatory or variety improvement field trials. Attention was given to the topic of gene flow to wild and weedy relatives and in centers of origin in order to provide the necessary foundation for developing the information to address this in ERA.

SUMMARY POINTS

- The collection of data for use in ERA should be based on a rational plan of analysis and the appropriate experimental methods.
- Data can be derived from many different sources, but it should be carefully considered for utility and to avoid the unnecessary collection of data that will not be ultimately useful for ERA.
- Regarding the potential for gene flow, there is experience in addressing the issue in ERA which can form the basis for a rational plan for the collection of information.

SESSION IV: **ADDITIONAL SCIENCE FOR THE OVERSIGHT OF GE PLANTS**

In many instances the ERA will lead to either the management of identified risks, or the further collection of information that may be used to assess the adequacy of the ERA and risk management practices. Presentations discussed international experiences with post-release environmental monitoring as a method of risk management. Post-release environmental monitoring can be divided into two types: (1) hypothesis driven, case specific monitoring; and (2) "general surveillance" or nonhypothesis driven monitoring. The best known example of hypothesis driven monitoring is the development of schemes and models for managing the development of target insect resistance after the deployment of insect-resistant GE plants.

SUMMARY POINTS

- Case specific, hypothesis driven monitoring can be a useful tool for risk management.
- Care should be given to the design of case specific monitoring schemes in order to ensure that the information being collected is useful for its intended purpose.
- Although general surveillance may be useful in some forms, the purpose for such a monitoring scheme needs to be carefully considered, in order to avoid the escalation of costs and proliferation of monitoring data, which has not been useful in the assessment or management of risks.

PANEL DISCUSSIONS: **RECURRING ISSUES FOR ERA OF GM PLANTS**

For the final session of the program, panellists were asked to consider three recurring issues for ERA and how these have been addressed: horizontal gene transfer; the use of antibiotic resistance markers; and the management of herbicide tolerance when cultivating herbicide-tolerant, GE crops. In the discussions of horizontal gene transfer and the use of antibiotic resistance markers, there was general agreement among the speakers that these issues have been adequately addressed by scientists and regulators in the past. There was a consensus among the panellists that these issues did not present a significant environmental risk and that additional scientific study was unlikely to be useful. However, the communication of these conclusions with stakeholders, the public and regulatory officials is necessary to provide confidence in the results of ERA. For the discussion of herbicide tolerance management it was agreed among panellists that the issue was not unique to GE plants, and that the management of herbicide tolerance was primarily an issue of good agronomic practices related to the use of herbicides. Panellists did agree that herbicide tolerance management was an important issue and that efforts to encourage practices that prolong the utility of available herbicides are worthwhile, whether or not those efforts were directly related to ERA for GE plants.

Release of crop specific biology documents on rice, okra, cotton and maize.

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Panel - *continued from page 2*

SUMMARY POINTS

- Regarding the issues of horizontal gene transfer and the use of antibiotic resistant markers, the collection of additional data is unlikely to be useful for ERA of GE plants.
- International experience in addressing these issues in ERA provides a basis for the conclusion that neither horizontal gene transfer nor the use of the most common antibiotic resistance markers, e.g., nptII poses any significant risk to the environment.
- Herbicide tolerance management is an important stewardship activity and, although herbicide tolerance is not unique to the cultivation of GE, herbicide tolerant plants, it can be a consideration for subsequent use of GE plants.
- For all three topics discussed by the panellists, communication about the science of risks and the science behind them is important for assuring confidence in ERA.

Problem formulation workshop.

OBSERVATIONS FROM THE CONFERENCE

In light of the information presented and discussed at the conference, and in view of the need for further development of ERA in the context of India, the authors of this report offer the following observations.

- Considering the wealth of experience that is available with ERA of GE plants, the methods that are available for identifying necessary information, and the need for a clear and transparent ERA process, India should proceed with the development of ERA guidance to help foster the collection of data for ERA, the transparency and predictability of the ERA process, and the confidence of the public in the results of ERA.
- Effective communication strategies should be further pursued to improve the transparency and public confidence in the results of ERA as well as to prevent the unnecessary escalation of data requirements that do not contribute to the risk assessment.
- Efforts to build technical capacity in environmental risk assessment, as well as in accessing and interpreting baseline information and experimental methods for data collection relevant to ERA, should be given high priority.

REPORT FROM THE SABP CONFERENCE ON ERA OF GE CROPS: A BANGLADESH PERSPECTIVE

Prof. Dr. Naiyyum Choudhury, former Chairman, Bangladesh Atomic Energy Commission and member, Biosafety Core Committee (BCC)

The Center for Environmental Risk Assessment (CERA) of ILSI Research Foundation, in collaboration with Department of Biotechnology of the Government of India and Biotech Consortium India Ltd. (BCIL) organized, under the South Asia Biosafety Program (SABP), the South Asia Conference on Current Approaches to the Environmental Risk Assessment (ERA) of Genetically Engineered Crops. The conference was held at New Delhi from May 16 to 18, 2011. The approximately 160 participants included scientists, policymakers, businessmen and students. Along with five other Biosafety Core Committee (BCC) members, I was invited to attend by the conference organizers.

There were five main scientific sessions and a concluding event. The conference was inaugurated with speeches from invited dignitaries including Dr. M.K. Bhan, Secretary, Department of Biotechnology; Shri M.F. Farooqui, Additional Secretary, Ministry of Environment and Forests; and Dr. S.K. Datta, Deputy Director General, ICAR. The keynote address was given by Dr. C.D. Mayee, Chairman, Agricultural Scientists Recruitment Board; Dr. K.K. Tripathi, Advisor, Department of Biotechnology gave an introductory remark; Dr. Vibha Ahuja, General Manager, Biotech Consortium India Limited gave the welcome address and Dr. Andrew Roberts, Deputy Director, CERA offered a vote of thanks.

Bringing together scientists and professionals from India and abroad to share experiences and knowledge of the science and practice of ERA, the conference focused on accumulated international experience, development and use of organized

Special guests at opening of conference.

and rational methods for determining information needs, standards and best practices for collecting and interpreting data and scientific issues related to the oversight of transgenic plants following risk assessment. Individual country experiences in Australia, the Philippines and India were highlighted along with OECD work from 1980 to 2009. The individual country experiences of Australia, the Philippines and India were also highlighted in the scientific sessions.

An interesting and useful session on problem formulation (PF) for ERA provided an overview of both the process and

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Bangladesh - *continued from page 3*

methodology for PF and how it can contribute to ERA and to regulatory frameworks. PF research experience related to the biosafety of GE plants by the EU for over three decades and the methodology of problem formulation used in India helped to organize and explain data collection for the ERA of transgenic plants. It demonstrated that the PF approach to ERA provides a rational basis for addressing the common components like hazard identification, exposure assessment and consequence assessment. The planned development of a conceptual model that encompasses problem definition, risk hypothesis and analysis linking transgenic crops and assessment endpoints will allow characterization of risk.

A scientific session on the oversight of transgenic plants detailed international experiences with hypothesis-driven and case-specific monitoring, also termed as "general surveillance" or non-hypothesis driven monitoring, risk management. While both can be useful, it was generally agreed that hypothesis-driven monitoring is much more amenable to rational examination and provides a much clearer picture of the necessary information and collection methods. Although there was the suggestion general surveillance may be useful there were some reservations regarding its requirements. Current international experience suggests the cost and scope of surveillance can far surpass its utility, however, case-specific monitoring schemes should be carefully designed to ensure information being collected is useful for its intended purpose.

The final session of the program concentrated on three recurring ERA issues and how they have been addressed:

- horizontal gene transfer;
- use of antibiotic resistance markers; and
- management of herbicide tolerance when using transgenic crops.

Conference audience participation.

There was general agreement among the speakers that these issues have been adequately addressed by scientists and regulators in the past and do not present a significant environmental risk associated with transgenic plants. However, the communication of these conclusions with stakeholders, the public and regulatory officials would be necessary to provide confidence in the ERA results. It was agreed the management of herbicide tolerance was primarily an issue of good agronomic management related to the use of herbicides.

Dr. Joe Smith, Office of Gene Technology Regulator, Austrialia, speaking on ERA of GE Crops in Australia.

The South Asia Biosafety Program's very effective capacity building program in risk assessment and biosafety in developing countries has provided an excellent opportunity for scientists in the South Asia region to connect with world-class experts on biosafety, biodiversity, risk assessment and, to a lesser extent, risk communication and exposure to more recent approaches to the ERA of GM technology. The hope is the experience gained through the exchange of ideas and interaction among scientists of developed and developing countries will be effectively utilized by the participants in their respective countries in risk assessment strategies for transgenic crops.

It is worth mentioning that the Bangladesh National Committee on Biosafety has already approved confined field trial of Bt-brinjal and Late Blight Resistant potato in different locations of Bangladesh. The Biosafety Core Committee (BCC), as the technical committee, has been playing an active role in the decision-making process for contained, confined and future open field trials of genetically engineered plants. Most of the BCC members attended the conference and gained instruction on different aspects of ERA in the decision-making process on the field release of GE crops in Bangladesh.

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