

Panel VI Summary

International Harmonization of Safety Issues (Report)

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This symposium is the fourth in a series of unique collaborative meetings entitled, The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms.

These collaborative meetings bring together researchers, private industry, academia, and officers from throughout the world to present the latest biosafety data from field trials and development of genetically modified plants and microorganisms. The symposium uniqueness stems from not only the presentations and scientific issues on biosafety but also updates field tests toward commercialization, international new developments, and international harmonization.

As the moderators of Panel VI, we were pleased to have a distinguished panel of internationally recognized experts from Africa, Asia, Europe, North America, and South America. We were honored to have Dr. Joseph Gopo, Biotechnology Research Institute, Scientific and Industrial Research and Development Center, Harare, Zimbabwe; Dr. Zhangliang Chen, The National Laboratory of Protein Engineering and Plant Genetic Engineering, College of Life Sciences, Peking University, Beijing, China; Dr. Helen K. Marquard, Biotechnology Unit, Department of the Environment, London, United Kingdom; Ms. Carmen Vicien, National Advisory Committee on Agricultural Biosafety Secretariat of Agriculture, Fisheries and Food, Buenos Aires, Argentina; and Mr. Simon Barber, Plant Biotechnology Office, Agriculture and Agri-Food Canada, Nepean, Ontario, Canada.

The panel members shared information on national, subregional, regional, and international activities in the area of cooperation in the development of biosafety frameworks for products of biotechnology. This report offers the moderators' views on a central focus critical to the panel members' presentation - necessary components of an approach to achieving international harmonization in biosafety evaluations.

The need for international harmonization

Dr. Chen gave us the ultimate need when he indicated that as population increases at a rapid rate and arable land decreases dramatically in China, the demand for yield increase in agriculture has become one of the first priorities. He anticipated that many more transgenic crops will reach the stage of farmer release within 3-5 years.

Dr. Marquard stated that the need for harmonized approach to biosafety at the international level is urgent as genetically modified organism (GMO) products are starting to be traded internationally. She went on to suggest that the recent United Na-

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tions Environmental Program's (UNEP) International Technical Guidelines for Safety in Biotechnology represent a major step forward in establishing an international biosafety framework.

Dr. Gopo stressed the need for effective mechanisms on biosafety evaluation of GMOs. He stated that although countries in his region had been approached by multinational organizations to test GMOs, in his opinion there were no adequate mechanisms to make effective decisions.

Ms. Vicien commented that evaluation of safe utilization of GMOs shows unequal development in the countries of the region. She further noted that the importance of harmonizing policies regarding agricultural biosafety in the region was highlighted.

Mr. Barber stated that, in Canada, a fundamental consideration in developing the Canadian regulatory approach has been, where possible, to use existing agricultural statutes and expertise and not to duplicate regulatory efforts under different legislation. We could easily substitute "different national authorities" for "different" legislation. Obviously, all of us are faced with expanding needs and demands and limited resources.

An approach to achieving international harmonization

International harmonization can occur through compatible regulatory systems that allow reciprocity of evaluation of safety. Such an international harmonization approach envisions that "equivalent" approaches are used in different countries. In this context, equivalent should mean "equal", not "the same". Therefore, such a coordinated system for biosafety review that facilitates international harmonization should focus on

- (1) assurance that scientific principles are used for evaluation of organisms;
- (2) integration of compatible national approaches; and
- (3) coordination of national approaches.

Ensuring that our policies for reviewing genetically engineered crops and organisms are based on scientific principles is also critical. We have worked under the auspices of the Organization for Economic Cooperation and Development (OECD)--to reach a consensus on a number of these principles--first, those pertaining to the safe field testing of new varieties, then those allowing the scale-up of field testing for agronomic evaluation, as well as for the evaluation of new foods produced through biotechnology. We are moving toward consensus on other scientific principles relevant to whole classes of new crop varieties.

Integration of compatible approaches means working with other countries to identify commonalities in our respective biosafety systems so that we can build confidence in each other's review processes. International agreement on consistent and compatible approaches for biosafety review must focus on the scientific question and the most efficient way of doing the biosafety review.

Lastly, to secure coordination of national approaches, we can continue to utilize in

ternational symposia; national, regional, sub-regional meetings; and bilateral and multi-lateral conferences. Such symposia, meetings, and conferences are an effective means to exchange information about the biosafety review process and identification of relevant biosafety issues. Coordination of national approaches can also be achieved through several internationations and regional organizations (OECD), United National Organizations, North American Plant Protection Organization (NAPPO), to name a few.

On behalf of Panel VI, we wish to thank the Organizing Committee and the Japan International Research Center for Agricultural Sciences for hosting this symposium.