

Regulating GMOs

Farmers and agribusiness operators worldwide are struggling with issues of productivity, health and safety, environmental degradation, and diverse nutritional needs. Genetically modified (GM) food crops originally appeared to offer opportunities for increased agricultural output with fewer inputs. However, approval of GM food crops has been slow and regulatory, biosafety, trade, and political concerns over GM crops are growing. The APO held the seminar on "Prospects and Regulatory Framework of Biotechnology, with Special Focus on Genetically Modified Crops," 3–11 November, in Japan, to discuss those opportunities and concerns.

The seminar, which was attended by 20 participants from 17 APO member countries, was timed to allow attendance at the World Rice Research Conference and associated field visits sponsored by the International Rice Research Institute, Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF), and APO, 4–7 November. The four resource papers presented at the APO seminar are summarized below.

Senior Research Fellow Joel I. Cohen of the International Food Policy Research Institute spoke on "World trends in regulation and control of genetically modified crops for food safety and environmental protection," focusing on the Cartagena Protocol on Biosafety (CPB). Now ratified by 110 countries, among which 11 are APO members, the protocol is intended to ensure that countries have mechanisms to determine the environmental safety of living modified organisms (LMOs) proposed for import. The advance informed consent element gives time to review each LMO. If not satisfied with scientific evidence of safety, the imports can be refused. Information can be shared among countries in the review process, as in the EU, but Cohen pointed out that in the developing world in many cases no regulatory systems are in place and exchange of information is rare.

Consumer anxieties about GM food have put the brakes on testing events. Public GM crop research integrating biotechnology with agricultural research may hold the key to allaying public fears. Cohen noted that Asia has the most countries engaged in public GM crop research and the highest percentages of events in testing.

Cohen concluded that functional national biosafety systems under the framework of the CPB will require working externally to address political, trade, and environmental concerns and internally to determine policy and implementation issues. In Asia, regional trading patterns, emerging population needs, water and land use, and distance from seed suppliers are special considerations.

GMO Committee member Ken-ichi Hayashi, MAFF, Japan, gave an overview of "Impact assessment on biodiversity of GM crops in Japan." Japan has a long history of international cooperation in biotechnology-related forums and is a signatory to the CPB. After CPB ratification, a country must meet three domestic conditions: 1) integrate the CPB into national law; 2) establish a national biosafety clearinghouse; and 3) formulate guidelines/regulations to supplement the laws. Only Japan and Switzerland have so far completed all three national conditions.

Japan's Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of LMOs and supplementary regulations and guidelines came into force in February 2004. All steps in the GMO development process from laboratory to greenhouse to isolated field to ordinary field are covered under the legal provisions. Events approved under pre-



GMO seminar participants on a field visit

vious MAFF guidelines must be reapproved by the new interministerial Committee for Impact Assessment on Biological Diversity. As of September 2004, 29 applications had been received, of which 10 had been approved including four for unconfined release. A broad consensus on field trials of GM crops is important in Japan, and strictly adhered to MAFF guidelines governing these were drafted to address public concerns. Hayashi concluded that while biotechnology applications can help to meet the increasing food demand and preserve biological resources, scientific assessments of GM crop safety based on international frameworks such as the CPB are critical.

The GM food safety assessment process under the Food Safety Basic Law (May 2003) was explained in layperson's terms by Japanese Food Safety Commission (FSC) Secretariat member Kenji Isshiki in his presentation "Safety assessment of foods derived from recombinant DNA techniques." The FSC has a three-fold mission: conducting risk assessment of food; communicating risks to consumers, food-related business operators, farmers, etc.; and responding to food-borne emergencies. The FSC, which adopts Codex Alimentarius standards, acknowledges that humans have always eaten food with accepted risks, i.e., some that are only safe after cooking or other processing, and have not examined each component for safety. With information on the type of modification introduced into GM food, it is possible to make a scientific assessment of the safety of the change in comparison with the natural food and the likely effects on human health and nutrition.

In its risk communication efforts, public disclosure and transparency are watchwords, said Isshiki. The FSC holds public meetings; updates its Web site with the minutes of weekly meetings, which are open to the public and media; and operates telephone hotlines.

Nobuyuki Kabaki of the FAO Regional Office for Asia and the Pacific spoke on the project for "Capacity building in biosafety of GM crops in Asia."

(Continued on page 6)

Regulating GMOs (Continued from page 5)

Biotechnology, specifically gene manipulation, offers opportunities to achieve food security with the creation of four GM crop groups. The first group raises pest tolerance, alleviating environmental burdens. The second endows tolerance to drought, salinity, and extreme temperatures, enabling increased production in unfavorable regions. The third raises yields and quality, increasing production and reducing malnutrition. The fourth adds value and diversifies crop uses, raising farmers' incomes and forming new agribusinesses.

Kabaki pointed out that, in addition to potential human and animal health risks and environmental consequences, another problem is the gap between users and suppliers. This can be seen as a north-south problem, in which patent holders in developed countries sell to poorer countries that are disadvantaged in applications. The tropical monsoon climate of Asia might also affect GM crops differently than the temperate zone.

With the ultimate aim of regional harmonization in biosafety, the FAO initiated the Capacity Building in Biosafety of GM Crops in Asia project in 2002 with Japan as a donor and 10 participating countries (all of which are APO members except for China). The specific objectives are to strengthen national capacities for ensuring GM crop biosafety, establish an Asian Network on Biotechnology, and promote R&D on GM crops. Kabaki stressed that strengthening of human resources for establishing and implementing regulatory mechanisms on biosafety should be a priority in each country. 