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Agenda Item: XI.2

Fourth Session of the APEC High Level Policy Dialogue on Agricultural Biotechnology 2005 – Final Report and Recommendations

Purpose: Consideration
Submitted by: Steering Committee, APEC High Level Policy Dialogue on
Agricultural Biotechnology



Senior Officials' Meeting II
Jeju, Korea
30-31 May 2005

EXECUTIVE SUMMARY

APEC High Level Policy Dialogue on Agricultural Biotechnology

The 4th Meeting of the APEC High Level Policy Dialogue on Agricultural Biotechnology was held March 2-3 in Seoul. Main issues for discussion included implementation of the Cartagena Protocol on Biosafety, Intellectual Property Rights and Technology Transfer, and Bioinformatics.

With regard to the Cartagena Protocol on Biosafety, participants discussed the benefits of intra-governmental coordination and showed considerable interest in the examination of costs/benefits and trade implications of implementation of the Protocol.

Following presentations and discussions, the participants endorsed the following public policy development activities: continued farmer-to-farmer activities; recommendations developed at the Investment Seminar held in Malaysia in December 2004; and a project proposal for a Biosafety workshop in APEC (this has since been approved by the BMC).

Recommendations

It is recommended that the Senior Officials:

1. Endorse the final report and recommendations of the 2005 High Level Policy Dialogue on Agricultural Biotechnology.

“Fourth Session of High Level Policy Dialogue on Agricultural Biotechnology”
Seoul, Korea
March 2-3, 2005

1. The Steering Committee of the High Level Policy Dialogue on Agricultural Biotechnology presents to Senior Officials the final report of the Fourth Session of APEC High Level Policy Dialogue on Agricultural Biotechnology, March 2-3, 2005. As directed by the APEC Leaders in Santiago in 2004, the APEC High Level Policy Dialogue on Agricultural Biotechnology was hosted by Korea in Seoul, Korea, and was attended by 17 of the 21 APEC economies (Australia; Canada; Chile; China; Indonesia; Japan; Korea; Malaysia; Mexico; New Zealand; Peru; the Philippines; Russia; Chinese Taipei; Thailand; the United States; and Vietnam). Representatives from the APEC Agricultural Technical Cooperation Working Group’s Subgroup on the Research, Development and Extension of Agricultural Biotechnology, the APEC Intellectual Property Experts’ Group, and the Convention on Biological Diversity also participated.
2. Mr. Lee Myung Soo, Vice Minister from the Ministry of Agriculture and Forestry in Korea delivered opening remarks to the Dialogue, highlighting the benefits agricultural biotechnology can provide with respect to fostering increased production, cultivating crops in traditionally unfavorable conditions, and contributing to the reduction of pesticide use. Vice Minister Lee noted that, unfortunately, some groups inflate concerns surrounding the technology and, in so doing, threaten its development. This situation, as Vice Minister Lee described, draws economies together and encourages cooperation. Vice Minister Lee viewed this international cooperation as an opportunity, stating that the enhancement of efforts and further development of agricultural biotechnology rests on the need for the sharing of information and benefiting from each other’s experiences. Vice Minister Lee noted that Korea is currently not a large agricultural biotechnology developer, but stated that Korea seeks to expand in this area. In closing, Vice Minister Lee reiterated the need for Korea and all APEC Economies interested in further developing this technology to employ the Policy Dialogue as a means to share information, learn from each others’ experiences, and discuss policy issues and potential cooperation.
3. Dr. Chuck Lambert, Deputy Undersecretary from the United States Department of Agriculture, provided a brief overview of the history of the Policy Dialogue, highlighted recent successes of the forum, and called on participants to actively engage in the discussions and consider policy recommendations in the context of the Policy Dialogue Workplan. Dr. Lambert noted the value of the Policy Dialogue as a unique forum for policymakers to address common challenges and concerns in efforts to realize the benefits of agricultural biotechnology and its potential to empower people and societies to participate more fully in the global economy. Dr. Lambert highlighted public policy development activities presented in support of priorities identified in the Policy Dialogue and the ways in which the private sector played a role. Dr. Lambert also highlighted the Dialogue’s success in effectively raising awareness of biotechnology within APEC, noting the 2004 Joint Ministerial Statement in which APEC Ministers acknowledged the importance of biotechnology and instructed Senior Officials to continue work of the Policy Dialogue to advance discussions in the areas of policy and information exchange, intellectual property rights and technology transfer, economic and human resource investment, and agricultural biotechnology public policy development. Dr. Lambert acknowledged the approval of the 2004-2006 Policy Dialogue Workplan and, within that

context, encouraged participants to consider recommendations for future work and how APEC can advance policy considerations of interest to all economies.

4. The morning session focused on the implementation of the Cartagena Protocol on Biosafety (CPB). In advance of the second Meeting of the Parties to the Cartagena Protocol at the end of May, which was preceded by a meeting of technical experts in mid March, this year's Policy Dialogue addressed the issue of implementation of the Cartagena Protocol on Biosafety. With the entry into force of this important international agreement, this year's Policy Dialogue meeting served as an ideal opportunity for APEC economies to discuss policy issues that should be considered when decisions are being made with regard to implementation of the Protocol. This session provided participants with an understanding of the current issues being discussed in the CPB Meeting of the Parties in order for agricultural biotechnology policy makers to play a more active and informed role in their respective inter-agency/ministerial decision making process regarding the CPB.

5. Ms. Wang Xueman of the Convention on Biological Diversity opened the session with an expert presentation on the "Implementation of the Cartagena Protocol on Biosafety." In her presentation, Wang provided some basic facts and objectives of the Protocol noting its importance as an international environmental agreement with the purpose of protecting biodiversity and human health. Wang provided a description of the decision making process for the import of Living Modified Organisms (LMOs). While acknowledging that the guidelines were purposefully ambiguous, Wang explained that LMO import decisions in the Protocol should be based on the following three elements: risk assessment, precautionary approach and socio-economic considerations. Wang noted that a Technical Experts Group (TEG) was examining the format and information of documentation, the thresholds for adventitious presence of LMOs, and detection techniques that would be guided by the Protocol. Wang also shared an overview of the basic supporting mechanisms for the Protocol. Acknowledging the international debate on countries' concerns with meeting the obligations to the Protocol and to other international agreements, Wang discussed briefly the Protocol and the World Trade Organization, noting the relationship as one of 'mutual supportiveness'. Canada's

6. Mr. Robert Carberry of the Canadian Food Inspection Agency provided a presentation on the "Approach to Regulation of LMO Agriculture Commodities" based on Canada's experience in participating in Protocol discussions and in trading with Parties to the Protocol. Mr. Carberry began the presentation with an overview of Canada's regulatory framework. This is built on existing regulation and regulatory institutions; ensures that regulatory policies are based on science, are transparent, and involve consultation, and; provides flexibility to meet new regulatory challenges as new products are developed. Building on the introduction to Canada's system, Mr. Carberry noted the measures Canada uses in the import of LMOs to ensure Canada's environmental biosafety is not compromised, the primary point being that advance approval and science-based risk assessments are required for product import. Mr. Carberry highlighted the importance of risk assessment capacity, regulatory tools, and simple and efficient implementation policies and procedures. He also noted that testing and detection should be done with a clear objective for biosafety and that testing should be science-based, transparent, simple,

and reliable. Mr. Carberry also offered that technical market access arrangements can be used to avoid problems and ensure both countries achieve biosafety objectives.

7. Blair Coomber, representing Agriculture and Agri-Food Canada (AAFC), shared “Canada’s Economic Assessment of Article 18.2a Documentation Requirements.” Mr. Coomber noted that Canada supports the environmental objective of the Protocol but seeks clear and uniform provisions to ensure consistent, predictable, and practical implementation by all Parties. Mr. Coomber shared results of a third party economic assessment commissioned by AAFC in which potential costs incurred as a result of the implementation of the Protocol were outlined. Segregation activities and capabilities, testing costs, and management levels were identified as cost factors. Documentation costs and the level to which these would enhance costs based on the guidelines adopted in the CPB were also identified. It was unclear, however, where in the supply chain these added costs would be passed on (e.g. the exporter, the importer, or the farmer). Further, the study noted that the impacts of the implementation and costs incurred could ‘echo’ across the entire grain and oilseed system resulting in: less product development due to the increased cost of LMO development reflected in the price of seeds; decreasing number of new crop varieties as seed companies and growers reduce R&D efforts; and higher costs in grain handling. Mr. Coomber closed the presentation by noting that documentation is a tool within the broader regulatory system and suggested that countries focus on the broader regulatory, risk assessment, and management system. He added that documentation will have an impact on how food commodities are traded and that countries need to consider the broader economic and food security implication of onerous documentation requirements.

8. The moderator opened the floor for comments and policy recommendations on the topic of “Biosafety Protocol Implementation.” Many economies shared reports on their existing national approaches to the Biosafety Protocol and cited particular areas of interest. Participants discussed the benefits of intra-governmental coordination and the examination of costs/benefits and trade implications of implementation, particularly in relation to agricultural biotechnology. Economies present in the Policy Dialogue included both Parties and non-Parties to the Protocol, as well as exporters and importers, which provided valuable viewpoints in this regard.

General and specific recommendations are listed as follows.

General Recommendations:

- The Policy Dialogue will continue to promote the sharing of experiences among member economies with respect to the implementation of the Cartagena Protocol on Biosafety. Through these exchanges, member economies may learn from others’ experiences regarding the development of effective national biotechnology policies that meet both the objectives of the Protocol and other international treaty obligations.
- The Policy Dialogue will encourage intra-governmental dialogue as member economies consider the development and implementation of agricultural biotechnology policies that are closely tied to policies for economic development, food security, and environmental preservation, such as the implementation of the Cartagena Protocol on Biosafety.

- There is a need to better understand the cost implications of the implementation of the Cartagena Protocol on Biosafety. The Policy Dialogue will encourage the examination of the costs/benefits and trade implications of implementation of the Protocol for both importers and exporters.

Specific Recommendations:

- The Policy Dialogue agreed to support the presentation of a policy workshop that will examine cross-sectoral issues and policy options that member economies may consider as they develop biosafety policies.
- The Policy Dialogue will consider opportunities for highlighting economic considerations, and the practical, science-based implementation of the Cartagena Protocol on Biosafety consistent with other international treaty obligations.

9. George Fuller of Crop Life Asia made a presentation about the Private Sector Day. Some economies commented that it is important to provide accurate information on biotechnology to consumers and, in turn, improve consumer's confidence in the safety of biotechnology products.

More information on the Private Sector Day can be found on the APEC website at: <http://www.apecseg.org>

Following is the direct link to the presentations made at the 2005 Private Sector Day: http://www.apec.org/content/apec/documents_reports/apec_high_level_policy/2005.html

10. During the Luncheon, Doheon Lee of Kaist University in Korea provided Policy Dialogue participants with a basic introduction to bioinformatics. Dr. Lee described bioinformatics as the use of information science, such as computing and database organization, to manage large amounts of biological data to develop new understandings and perspectives for biological questions. Dr. Lee provided examples of ways in which scientists have used bioinformatics to better understand organisms holistically, including how networks of genes can act in concert to respond to disease or drought stresses. Dr. Lee also described how bioinformatics can be used as a tool for discovery, and how it can help simplify and improve conventional breeding techniques. As economies attempt to strengthen their own research efforts in agricultural biotechnology, this presentation provided some context for policy makers to consider the role that policy may play in encouraging the use of bioinformatics, including intellectual property policies that might encourage the sharing of scientific information among laboratories, and the establishment of policies encouraging the generation of bioinformatics data to further the biotechnological development of species for practical agricultural applications.

11. The afternoon agenda focused on intellectual property rights (IPR) and its role in the effective transfer of technology. The session aimed to provide information and updates to participants on Intellectual Property (IP) issues that may impact agricultural biotechnology. Specifically, the session focused on both the domestic and international dimensions of IPR and the manner by which IP can be utilized to promote technology transfer domestically and across

borders. The session also provided an overview of the issues under discussion in other fora on access and benefit sharing (ABS) of genetic resources.

12. In response to last year's Policy Dialogue recommendation that the Policy Dialogue contact the APEC Intellectual Property Experts' Group to seek information on the ways in which IPR is addressed in IPEG and in other international fora, Michung Ahn, Chair of the IPEG, provided a brief report to the Policy Dialogue participants. Ms. Ahn described the new international environment for IPR, the role of IPEG, and the activities in which IPEG is involved. In addition to deepening the APEC dialogue on Intellectual Property Policy, IPEG works to survey and exchange information on the current status of IPR protection and administration systems, studies measures for the effective enforcement of IPR, and facilitates technical cooperation to implement the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS). Ms. Ahn shared ways in which IPEG has raised awareness and promoted IP asset management in APEC economies.

13. Wichar Thitipasert of Thailand's Department of Agriculture provided an expert presentation on the "Protection of Plant Varieties: IPR, Access and Benefit Sharing." Mr. Wichar discussed TRIPS, systems for plant patenting, and the treatment of access to genetic resources as articulated in Article 15 of the Convention on Biological Diversity. Using Thailand's law for Plant Variety Protection as a basis, Mr. Wichart also described Thailand's experience in providing effective IPR protection for plant varieties and the importance of providing an effective access regime for plant varieties in order to promote and ensure benefit sharing resulting from the use of that genetic resource.

14. June Blalock of the United States Department of Agriculture provided an expert presentation on "Facilitating Technology Transfer Through Public-Private Partnerships." Ms. Blalock discussed the benefit of IPR in promoting public/private research and development (R&D) and the practicalities of how IPR can be used to transfer R&D for further development and commercialization. Ms. Blalock shared ways in which the U.S. government has instituted federal policies to promote the transfer of technology, and described a model of public-private technology transfer partnership. Ms. Blalock also briefly addressed the intersection of IPR and ABS regimes, specifically as they relate to agricultural products.

15. The moderator for the afternoon session opened the floor for economies to comment on "Intellectual Property Rights and Technology Transfer." Member Economies shared knowledge and experiences with respect to IPR and Technology Transfer and discussed ways in which the Policy Dialogue can assist in promoting technology transfer and capacity building for agriculture without duplicating efforts currently being discussed in other fora. Also, some members noted the importance of breeder's right protection which promotes the development of new varieties in agriculture production.

General and specific recommendations are listed as follows:

General Recommendations:

- The Policy Dialogue will encourage member economies to consider the development of policies that enable the ownership of innovations, in order to encourage the development of new technologies, facilitate public-private partnerships, collaborative research, and foster economic development.
- The Policy Dialogue will promote the presentation of policy-related activities in areas of shared knowledge, technology transfer, and formation of innovative collaborative research and development in the region.
- The Policy Dialogue will continue to provide mechanisms for private sector engagement in order to encourage the development of innovative public-private partnerships that will support technology transfer.
- APEC members supported that there is a desire to exchange information on economies' systems to promote access and benefit sharing of genetic resources. Members also supported a consideration for the protection of traditional knowledge.

Specific Recommendations:

- The Policy Dialogue endorsed the recommendations developed in the APEC Seminar "Creating a Positive Environment for the Investment in Agricultural Biotechnology", particularly those related to IPR, and agreed to support future, related work.
- Recognizing that APEC's Intellectual Property Experts' Group (IPEG) is the primary APEC fora for addressing IPR issues, the Policy Dialogue will maintain contact with IPEG in order to keep apprised of general IPR discussions and share developments that are relevant to agricultural biotechnology for policy discussion and consideration in Policy Dialogue meetings.

16. Mr. Robert Carberry, representing Canada as lead Shepherd, provided a summary of activities of the APEC Sub-Group on Research, Development and Extension of Agricultural Biotechnology (RDEAB) that reports under the APEC Agricultural Technical Working Group. The presentation included an overview of the background and objectives of the RDEAB, a summary of the 8th RDEAB Workshop that was held in Korea in November 2004, and an outline of the group's activities in 2005. The Workshop in Korea focused on the following four themes: science-based assessment of products of biotechnology, technical cooperation, transparency and information exchange, capacity building. In 2005, the RDEAB will continue implementing action items from the RDEAB implementation plan, will transfer the role of Lead Shepherd to the successor member economy, report to the ATCWG meeting, and hold its 9th RDEAB Workshop in Santiago, Chile in November 2005.

17. As a new item on this year's Policy Dialogue agenda, participants at the 4th Session of the Policy Dialogue heard reports of public policy development activities that have been presented in response to key interests of APEC economies. These activities included farmer-to-farmer workshops as a means to provide farmers and community leaders with the tools and training necessary to become an informed and effective voice for the technology. In recognizing the

critical role that investment plays in the development of agricultural biotechnology, the Policy Dialogue also supported the presentation of a seminar entitled: ‘Creating a Positive Environment for the Investment of Agricultural Biotechnology’. The seminar provided an opportunity for participants to explore the benefits and business opportunities that agricultural biotechnology presents, as well as to examine public and private sector strategies that have facilitated successful investment in the technology. Reports from these public policy development activities were presented to the Policy Dialogue.

18. Agusdin Pulungan of Asian Farmers Regional Network (ASFARNET) Indonesia provided a report of the “ASFARNET Workshop on Technology Promotion and Exchange on Agricultural Biotechnology” that was held in Indonesia in December 2004. Fifty-six farmers and farm leaders from Indonesia representing the provinces of North Sumatra, Lampung, West Java, Central Java, East Java, and South Sulawesi participated. In addition to ASFARNET representatives, officials from the Food and Agricultural Organization (FAO) and the International Service for the Acquisition of the Agribiotechnology Applications (ISAAA) attended. Participants shared information about the technology, discussed current issues facing its development, and considered ways in which farmers could play an informed and effective role in the debate. At the conclusion of the workshop, participants developed a statement, a Plan of Action, and a Workplan to carry out further activities. In a subsequent meeting with the Minister of Agriculture, the Director of ASFARNET Indonesia shared these results and called on the Indonesian government to move forward with the development of biotechnology in Indonesia for the benefit of its people.

19. Mr. Wee Beng Ee, representing Malaysia’s Ministry of Agriculture, provided a report and presented official recommendations from the APEC “Creating a Positive Environment for the Investment in Agricultural Biotechnology” Seminar that was held in Malaysia in December 2004. Participants in the seminar included both public and private sector representatives. The seminar enabled participants to examine policy and economic factors that impact the agricultural biotechnology investment framework, and to generate recommendations about priority goals and critical tools for APEC economies to encourage investments in agricultural biotechnology. Though circumstances and priorities vary among APEC members, the report noted that all economies face similar issues that are fundamental to successfully attract investment in biotechnology. Mr. Wee closed his report noting the recommendations from the Seminar that included a proposal to further develop the recommendations into ‘strategic toolbox’ for APEC Economies interested in attracting or increasing investments in agricultural biotechnology.

20. Josette Lewis of the United States Agency for International Development provided a short summary of the proposal on “Biosafety Policy Options for APEC Economies.” Ms. Lewis described the goal of the seminar as exploring the breadth of policy dimensions that are both incorporated into, and impacted by biosafety regulations. The seminar is expected to take place in December 2005. The 4th Session of the Policy Dialogue approved the project for APEC TILF funding.

21. Following a discussion session in which nearly all economies intervened with comments of support, participants overwhelmingly endorsed continued public policy development activities. These included: continued farmer to farmer activities, the endorsement of ‘investment seminar’

recommendations for further development into a strategic toolbox, and support for the presentation of a Biosafety Policy Options seminar. The session moderator called for volunteers to form a steering committee to begin work on the investment seminar activity. Volunteers included: Canada, Malaysia, and the United States. Other economies showed an interest and offered to confirm participation in the Steering Committee following consultation with officials in their respective governments.

22. APEC economies expressed their appreciation to the Korean government for hosting the fourth session of HLPDAB.