Stakeholders' Dialogue on Biosafety Regulations in the Asia-Pacific Region

PROCEEDINGS AND RECOMMENDATIONS

Royal Princess Hotel, Larn Luang, Bangkok
April 16-17, 2013

Organized by

Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB)
Asia-Pacific Association of Agricultural Research Institutions (APAARI)

Supported by

Global Forum on Agricultural Research (GFAR)

Stakeholders' Dialogue on Biosafety Regulations in the Asia-Pacific Region

Royal Princess Hotel, Larn Luang, Bangkok
April 16-17, 2013

Edited by

Kavita Gupta, National Bureau of Plant Genetic Resources,
New Delhi, India

J.L. Karihaloo, Asia-Pacific Consortium on Agricultural Biotechnology,
New Delhi, India

Organized by:

Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB)
NASC Complex, Dev Prakash Shastri Marg, Pusa, New Delhi-110012, India

Asia-Pacific Association of Agricultural Research Institutions (APAARI)
FAO-RAP Annex Building, 202/1 Larn Luang Road, Bangkok 10110, Thailand

Supported by:

Global Forum on Agricultural Research (GFAR)

About the Organizers

The **Asia-Pacific Association of Agricultural Research Institutions** (APAARI) is a regional association that aims to promote the development of National Agricultural Research Systems (NARS) in the Asia-Pacific region through inter-regional and inter-institutional cooperation. The overall objectives of the Association are to foster the development of agricultural research in the Asia-Pacific region so as to promote the exchange of scientific and technical information, encourage collaborative research, promote human resource development, build organizational and management capabilities of member institutions and strengthen cross-linkages and networking among diverse stakeholders. To meet these needs, the Association: i) convenes General Assembly once in two years, holds regular Executive Committee meetings twice a year and organizes consultations, workshops, trainings, etc., ii) collects, collates and disseminates research findings, iii) maintains links with other fora in the region and outside through meetings, participation and information exchange, and iv) promotes need based collaboration in research projects among member institutions, analyzing priorities and focusing on regional agricultural development. For details, please visit: *www.apaari.org*

The **Asia-Pacific Consortium on Agricultural Biotechnology** (APCoAB) was established in 2003 under the umbrella of APAARI. APCoAB has the mission to, "Harness the benefits of agricultural biotechnology for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific Region". APCoAB's main thrusts are to (i) serve as a neutral forum for the key partners engaged in research, development, commercialization and education/learning of agricultural biotechnology as well as environmental safety in the Asia-Pacific region; (ii) facilitate and promote the process of greater public awareness and understanding relating to important issues of IPR, *sui generis* systems, biosafety, risk assessment, harmonization of regulatory procedures, and benefit sharing in order to address various concerns relating to adoption of agricultural biotechnology; and (iii) facilitate human resource development for meaningful application of agricultural biotechnology to enhance sustainable agricultural productivity, as well as product quality, for the welfare of both farmers and consumers. To know more about APCoAB, please visit: *www.apcoab.org*

Contents

Foreword

GM crops are now being grown over 170 million hectares by about 17 million farmers in 28 countries. Half of this acreage is in developing countries, including Brazil, Argentina, India, South Africa, China, the Philippines etc. Most of these farmers have benefitted through increased yields, less use of pesticides and better weed management resulting in higher production and income as well as improved livelihoods. In Asia, GM crops are under commercial cultivation in China, India, Pakistan, the Philippines and Myanmar. Japan, Korea, the Philippines, Thailand and Chinese Taipei have also approved GM crops for food and livestock feed. Biosafety regulatory systems are operational in several other countries, including Indonesia, Iran, Malaysia, Myanmar and Vietnam.

India has experienced large scale adoption of Bt cotton by both small and large farmers; covering an area of 10.8 million hectares (ha) in 2012 which constitutes nearly 90 per cent of the total cotton area. In Pakistan, Bt cotton covers 2.8 million ha. In the Philippines, GM corn covers around 45 per cent of the total corn area comprising 1.2 million ha. Nearly 94 per cent of this area is sown with stacked Bt and herbicide-tolerant corn. High adoption of herbicide tolerance trait in the Philippines is ascribed to rapidly rising costs of manual weeding. Hence, such crops would possibly have similar acceptance in other developing countries.

Despite these gains, voices of opposition to GM crops have been raised from time to time on account of unfounded biosafety risks (environmental and health), cost of technology and economic benefits to the farmers. In fact, these concerns have been well addressed through extensive experimental studies, regulatory reviews, economic surveys and nearly 20 years of safe use of GM crops. In spite of this, there has been such a strong opposition that commercialization of eggplant was put under moratorium in India even after clearance by the regulatory and review committees.

In order to further dispel above concerns relating to biosafety, it is necessary that GM products are tested with the highest prescribed standards. Such an approach would help in building much needed confidence among technology users including farmers, consumers and the general public. It is in this context, APAARI has been organizing regularly over last one decade, stakeholders' meetings on different aspects of agricultural biotechnology and biosafety. In view of the continuing need, a "Stakeholders' Dialogue on Biosafety Regulations in Asia-Pacific Region", was held on 16-17 April, 2013 in Bangkok, Thailand with the support of Global Forum for Agricultural Research (GFAR) involving experts from different countries in the region as well as experts from international organizations. I am sure that the recommendations of the meeting included in this publication will help policy makers and national regulatory bodies to take appropriate decisions regarding safe application and commercialization of GM technology for the benefit of farmers and consumers in the region.

Raj Paroda
Executive Secretary
APAARI

Acronyms and Abbreviations

ACIAR	Australian Council for International Agricultural Research
AFS	Asia Food Solutions
APAARI	Asia-Pacific Association of Agricultural Research Institutions
APCoAB	Asia-Pacific Consortium on Agricultural Biotechnology
APHIS	Animal and Plant Health Inspection Service
ASEAN	Association of Southeast Asian Nations
AVRDC	AVRDC -The World Vegetable Center
BARC	Bangladesh Agricultural Research Council
BCH	Biosafety Clearing House
BGIAGMM	Biosafety Guidelines of Industrial Application of Genetically Modified Microorganisms
BIRC	Biosafety Information Resource Center
BRAI	Biotechnology Regulatory Authority of India
Bt	*Bacillus thuringenesis*
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CGIAR	Consultative Group of International Agricultural Research
CIMMYT	International Maize and Wheat Improvement Center
COA	Council of Agriculture
CPB	Cartagena Protocol on Biosafety
DBT	Department of Biotechnology
DNA	Deoxyribonucleic Acid
DOH	Department of Health
DPIAB	Development Program for Industrialization of Agricultural Biotechnology
EPA	Environmental Protection Agency
EPL	Environmental Protection Law
FAO-RAP	Food and Agriculture Organization of the United Nations –Regional Office for Asia and the Pacific

FBG	Food Biosafety Guidelines
FDA	Food and Drug Administration
FFP	Food and Feed Products
GEAC	Genetic Engineering Appraisal Committee
GEF	Global Environment Facility
GM	Genetically Modified
GOI	Government of India
HRD	Human Resource Development
IARI	Indian Agricultural Research Institute
IBC	Institutional Biosafety Committee
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICRISAT	International Crop Research Institute for Semi-Arid Tropics
IPPC	International Plant Protection Convention
IPR	Intellectual Property Rights
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri Bio-tech Applications
ISPM	International Standards for Phytosanitary Measures
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
JIRCAS	Japan International Research Centre for Agricultural Sciences
LMO	Living Modified Organisms
MARDI	Malaysian Agricultural Research and Development Institute
MDG	Millennium Development Goals
Mha	Million hectares
NBB	National Biosafety Board
NBC	National Biosafety Center
NBCRC	National Biological Control Research Center
NBDS	National Biotechnology Development Strategy
NBF	National Biosafety Framework
NBG	National Biosafety Guidelines
NBP	National Biosafety Projects
NBPGR	National Bureau of Plant Genetic Resources

NSC	National Science Council
OECD	Organization for Economic Cooperation and Development
OIE	World Organization for Animal Health
ONEP	Office of the Natural Resources and Conventional Policy and Planning
PARC	Pakistan Agricultural Research Council
PTTC	Platform for Translational Research on Transgenic Crops
RASM	Risk Assessment Search Mechanism
RCGM	Review Committee on Genetic Modification
SAARC	South Asian Association for Regional Cooperation
TAC	Technical Advisory Committee
UNEP	United Nations Environment Program
USDA	United States Department of Agriculture
VAAS	Vietnam Academy of Agricultural Sciences
WTO	World Trade Organization

Stakeholders' Dialogue on Biosafety Regulations in the Asia-Pacific Region

Background

The last few years have seen a slow-down of growth in agricultural production in several Asia-Pacific countries leading to food shortages and spiraling food prices. The poor and vulnerable sections have been especially hard hit causing a surge in hungry and undernourished people. Under the prevailing conditions, most of the developing countries of the region would not be able to meet the Millennium Development Goals (MDGs) of halving poverty and hunger by 2015. Providing sufficient quality and quantity of food has technical, but also social, political and economic dimensions that require immediate attention. One of the means of addressing the need for increased productivity is the use of new biological options including biotechnology.

Most countries recognize the significant role of biotechnology in meeting the challenges of food and nutritional security. Among the vast array of biotechnological tools currently under use, GM technology has the potential to increase productivity, profitability and sustainability of farm production systems, including small farm holdings. Since the first farm level cultivation of GM crops in 1996, the global area under these reached 170 million hectares (mha) in 2012 spread across 28 countries. In India, just 8 years since its first release, Bt cotton area has increased to a staggering 10.8 mha comprising over 90 per cent of the total 11 mha under cotton cultivation. Bt maize in the Philippines, grown for the first time in 2002, covered an area of 0.5 mha in 2010. In China, GM cotton, papaya, tomato, sweet pepper and poplar are being grown over 3.5 mha, while approval to GM rice and maize was granted in 2009. Several studies made on the performance and impact of GM crops have shown that farmers, irrespective of their farm size, have benefited through increased yield and reduced pesticide use which converted into higher profits and household incomes as well as increased aggregate employment.

While this potential of GM technology is well recognized, strong concerns exist over its likely risks to human health and environment and the extent to which these technologies offer accessible and effective solutions for resource-poor smallholder farmers. It is agreed that application of GM technology must be accompanied by systematic assessment of potential impacts on food and feed safety and safety of environment, including the diversity of flora and fauna and consideration of mechanisms enabling its access without increasing the debt burden and economic risks to farmers. Moreover, GM is not the only pathway available and for which awareness of genomic technologies is required. Countries clearly require skills in these areas and wider awareness of the implications of different technologies to be able to obtain full value from crop molecular genomics.

The Convention on Biological Diversity (CBD) while acknowledging the potential of biotechnology in meeting critical needs for food, agriculture and health, seeks to ensure the development of appropriate procedures to enhance the safety of biotechnological processes and products. The Cartagena Protocol on Biosafety to the CBD, to which most of the Asia-Pacific countries are parties, is a legally binding agreement to ensure adequate levels of protection for safe transfer,

handling and use of Living Modified Organisms (LMO) resulting from modern biotechnology that may have adverse effect on human health, and conservation and sustainable use of biological diversity.

A number of other international instruments contribute to biosafety with respect to GM technology. The General Agreement on Trade and Tariffs of the World Trade Organization (WTO) allows governments to regulate trade in order to protect human, animal and plant life or health. Three standard-setting bodies recognized under the WTO's Agreement on Application of Sanitary and Phytosanitary Measures (WTO-SPS Agreement), namely, the International Plant Protection Convention (IPPC), the Codex Alimentarius Commission (CAC) and the World Organization for Animal Health (OIE) address different aspects of biosafety, including environmental and food safety.

There are also legitimate concerns regarding Intellectual Property Rights (IPR) and equitable access. Conventions, agreements and their associated instruments have been designed to sustain the public goods dimensions of these innovations, including for example the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), but there are also underlying practical and communication issues regarding informed access to new technologies for resource-poor farmers in objective ways whereby they can have clear understanding of the relative advantages and disadvantages of alternative ways to address their challenges.

In conformity with their national and international obligations, several Asia-Pacific countries have put in place legislative measures to manage the potential risks associated with GM technology. The regulatory systems vary across countries; some have developed entirely new GM specific biosafety systems while others have modified existing regulations to address biosafety issues. The legal instruments used for the purpose have been new or modified laws, acts, decrees, guidelines and rules. Alongside, administrative systems and infrastructure have been developed to operationalize the legal instruments. Adopting one or the other approach, a number of countries have currently in place regulations on development, contained use, environmental release, commercialization and import of GM crops and products. Several other countries have their biosafety regulations at draft or implementation stages. However, there is little conformity among national regulations or consistency among national capabilities to implement them, which becomes an impediment to rapid diffusion of useful technologies.

Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), a program of the Asia-Pacific Association of Agricultural Research Institutions (APAARI) has been promoting appropriate use of agricultural biotechnologies to increase agricultural productivity and income of farmers in the Asia-Pacific region. It serves as a forum for stakeholders to address common issues of research, development and commercialization of agricultural biotechnology in the region. In 2006, APCoAB organized a "Workshop on Biosafety Regulations and the need for Harmonizing them in the Asia-Pacific Region" in which CBD Biosafety National Focal Points of 12 countries of the region and other technical experts participated. The objective was to identify areas of regulatory harmonization so as to facilitate sharing of benefits of the technology by farmers across the region. A unanimous recommendation of the workshop was to collate information on biosafety regulations, which would help in taking informed decisions regarding specific areas and modalities of harmonization. Accordingly, a publication entitled "Biosafety Regulations of Asia-Pacific Countries" was brought out by APCoAB in 2008 with the support of FAO which detailed biosafety regulations existing in 39 countries of Asia and the Pacific. The publication is available at www.apcoab.org. Since the publication of this compilation, new developments have

taken place in a number of Asia-Pacific countries with respect to framing and implementation of biosafety regulations. Besides, new scientific knowledge and tools have been developed that address some of the safety concerns related to GM products.

Keeping in view the above mentioned needs, a Stakeholders' Dialogue on Biosafety Regulations in the Asia-Pacific Region was organized by APCoAB-APAARI in Bangkok, Thailand on 16-17 April 2013 which brought together twenty five national biotechnology and biosafety planners, managers and researchers; international experts on biotechnology and biosafety and other stakeholders to deliberate on the issues with particular reference to developing countries of the Asia-Pacific region.

Objectives of the Stakeholders' Dialogue

- To share information on new developments in biotechnology and national and international biosafety regulations among diverse stakeholders for a wider sharing of their implications, the decision making processes in the light of their various perspectives and concerns and drawing on the learning from each others' experiences.
- To share knowledge on the scientific advances in the field of biotechnology and biosafety regulations and the human, environmental and economic risks and benefits of GM technologies, including the determination of who and by what mechanisms biosafety guidelines have been shared with, how effectively they have reached and impacted different stakeholders, especially farmers and civil society and the extent to which they have been shared and used inter-regionally.
- To deliberate on priority areas for regional and sub-regional cooperation in biosafety in order to accelerate the safe use and equitable accessibility of GM technologies for the benefit of small holder farmers, including new capacities required, which can be addressed through commitments from national stakeholders.

Inaugural Session

The Session was chaired by Dr. Hiroyuki Konuma, ADG, FAO-RAP, Bangkok. Dr. Raj Paroda, Executive Secretary, APAARI and Dr. Simon Hearn, Chairman APAARI made remarks as organizers of the meeting.

While welcoming the participants, Dr. Raj Paroda recalled that GM crops have been in farmers' fields since 1996 and now occupy nearly 170 million hectares throughout the world. Farmers in US, Brazil, Argentina, China, India, the Philippines, and 23 other countries have harnessed the benefits of GM technology by way of increased yields, less use of pesticides, and better weed management. However, there have been growing voices of concern, particularly about their possible environmental and health impacts. Unfortunately, these concerns are being raised despite overwhelming scientific evidence about the safety of GM technology and the benefits it has brought. Hence, there is a need for further discussion and outreach efforts so as to convince the society on the basis of factual information and to address genuine concerns. In the past, APAARI organized a number of expert consultations on agricultural biotechnology which also covered biosafety issues. Besides, a workshop, "Harmonization of Biosafety Regulations in Asia-Pacific Countries" was held in 2006 followed by a publication, "Biosafety Regulations of Asia-Pacific Countries" in 2008.

Dr. Simon Hearn, in his capacity as Chairman, APAARI welcomed Dr Konuma and other participants. He highlighted the efforts of APAARI towards agricultural policy advocacy, research prioritization, capacity development and communication. APAARI had also played an important role as facilitator of agricultural research and development in the Asia-Pacific region. In this regard, the meetings held on biotechnology and biosafety issues are significant since the countries in this region are still grappling with these while searching for tools to enhance agricultural productivity and market access to feed their growing population. Consumers are also demanding higher standards at all levels in the food chain. Dr. Hearn also highlighted some of the concerns expressed about GM safety and the need for a robust regulatory management of GM crops and products. He especially emphasized on the environmental impact of GM crops which needed to be addressed. Although the details may differ, the science and principles of risk management are common across countries. He hoped that the Stakeholders' Dialogue would result in identification of priority areas requiring attention at the national level as well as areas of cooperation at the regional level to enhance adoption of biosafety policies and regulatory systems that are mutually beneficial.

The Chief Guest, Dr. Hiroyuki Konuma released three APAARI publications entitled, "Improving Wheat Productivity in Asia", "Stakeholders' Interface on GM crops - Proceedings and Recommendations" and "APAARI Brochure". During his address, Dr. Konuma recalled that world is still home to 868 million chronically hungry people and Asia and the Pacific Region shared nearly two-thirds of the total chronically hungry population. The vast majority of such people live in developing countries and they are becoming increasingly vulnerable to food price hike and external shocks. In addition, micronutrient malnutrition, or so-called "hidden hunger" is also affecting additional two billion people worldwide causing serious public health problems, especially for children in developing countries. Food production systems in many parts of the world are not stable. World population would reach 9.2 billion by 2050 and according to FAO estimates, by the year 2050 the world has to increase food production by 60 per cent and by 77 per cent in developing countries alone to meet the needs of the increasing population. This has to be achieved from the available arable land, which has very little potential for future expansion and declining water resources.

Dr. Konuma gave details of the efforts made by FAO towards eradicating hunger. He opined that biotechnology offers a potential solution to meet the future demands of the rising population. Also, there is a need to address several critical challenges such as decline in agricultural investment, stagnation of agricultural productivity growth, high post-harvest losses and food waste, negative impacts of climate changes and natural disasters, and increasing competition between food production and bio-energy production. There is an increased interest and funding for biotechnology, including GM crops, across the world as they are seen to offer a possible solution to the impending food crisis. On the other hand, biotechnology has its own challenges and issues which need to be addressed. He emphasized that such regional meetings provide a platform to the policy makers to discuss and work towards solutions. He hoped the publication on biosafety regulations brought out jointly with APAARI and FAO would be revised soon as it has been serving a very important source of information for the region. He hoped that the Stakeholders' Dialogue would be able to achieve its objective of creating consensus and greater collaboration on biotechnology and biosafety application in the region.

Dr. J.L. Karihaloo, Coordinator, APCoAB proposed the vote of thanks to conclude the opening session.

Session I: Status of Agricultural Biotechnology and Biosafety Regulations in Asia-Pacific

This session was chaired by Dr. Simon Hearn, ACIAR and co-chaired by Dr. Umi Kalsom Abu Bakar, MARDI. Dr. K.V. Prabhu, IARI was the rapporteur for this session.

Overview of Agricultural Biotechnology and Biosafety in Asia-Pacific and Facilitation Role of APAARI

Dr. J.L. Karihaloo, Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), APAARI, New Delhi, India.

The presentation covered the overall status of biotechnology and biosafety regulations in the Asia-Pacific countries. Most countries of the region recognize research as an important tool for enhancing productivity, quality and profitability of agriculture and some countries invest substantially in agricultural R&D. Several countries also consider biotechnology as a powerful tool for crop and animal improvement and operate public funded programs in areas like tissue culture, marker assisted selection, genomics, genetic modification and animal reproductive technologies. In 2012, GM crops were grown on farmers' fields in Australia (0.7 mha), China (4.0 mha), India (10.8 mha), Myanmar (0.3 mha), Pakistan (0.2 mha) and the Philippines (0.8 mha) comprising crops like cotton, maize, canola, papaya, poplar, tomato and sweet pepper. China, Japan, Korea, Malaysia, the Philippines, Chinese Taipei and Thailand have approved some GM crops for food and feed, though not all for cultivation. Most of the Asia-Pacific countries are parties to the Cartagena Protocol on Biosafety and subscribe to its precautionary approach of biosafety management. A number of well-established biosafety frameworks with appropriate laws, rules, regulations, guidelines and standard operating procedures are in place in some countries. Procedures for public participation in decision making have been introduced in a number of national regulatory systems. Biosafety systems in several other countries are still in development phase and some are being supported by international agencies for establishment of biosafety framework. Dr. Karihaloo also identified some priority areas of regional and sub-regional cooperation in biosafety management in order to accelerate the safe use and equitable accessibility of GM technologies in the region.

Status of Biotechnology and Biosafety Regulatory System of India

Dr. Kavita Gupta, National Bureau of Plant Genetic Resources (NBPGR), New Delhi, India.

The presentation focused on the growth and application of biotechnology in India. Steps had been taken relatively early to promote transgenic research with emphasis on pest and disease resistance in crops; nutritional quality; silk-worm genome analysis; molecular biology of human genetic disorders; plant genome research; development, validation and commercialization of diagnostic kits and vaccines for communicable diseases; food biotechnology, etc. The impact of biotechnology related developments became visible with new products and processes coming into the market. The cultivation of Bt cotton in India since 2002 has been an important development in the adoption of GM crops in the country. The Indian biosafety regulatory system adopts a precautionary approach for the biosafety assessment of GM crops and their products. GM research, its commercialization and import are governed by the Environmental Protection Act (EPA) of 1986 and the Rules for the Manufacture, Use/Import/Export and

Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989. Six competent authorities under four ministries have been identified under the Rules for their effective implementation. A number of guidelines and protocols have been formulated on safety implementation and assessment at various stages of GM product development. In 2007, the Government of India (GOI) introduced a National Biotechnology Development Strategy to provide a single window mechanism for biosafety clearance of GM products. The Department of Biotechnology, GOI has the responsibility to establish and operationalize the newly prepared Biotechnology Regulatory Authority of India (BRAI), the bill which has been submitted for parliamentary approval.

Biotechnology Adoption and Biosafety Regulation in Malaysia

Dr. Umi Kalsom Abu Bakar, Malaysian Agricultural Research and Development Institute (MARDI), Kuala Lumpur, Malaysia.

The paper covered the new challenges for authorities and policymakers with regard to GM technology who have to consider impacts on human health and the environment. As GMO technology is relatively new in Malaysia, the governance systems in terms of biosafety are also in their infancy and the authorities are responding to these challenges in stages. In the year 2000, Malaysia signed the Cartagena Protocol on Biosafety and only seven years later, in 2007 the Biosafety Bill was passed in the Parliament. Consequently, the Biosafety Regulations were drafted and the Biosafety Act enforced in 2009.

The year 2010 was pivotal for biosafety implementation in Malaysia as in this year the National Biosafety Board (NBB) and the Department of Biosafety (JBK) were established. Consequent to this, the "Guidelines for Contained Use Activity of LMO" was published and the biosafety regulations were enforced. To date JBK has evaluated and approved for release a total of ten GM events for food, feed and processing; two events as product of LMOs and one for field trial. The GM events approved for food, feed and processing include GM soybean and maize resistant against insects and herbicide, GM maize resistant against corn-borer and rootworm. At the regional level, being an ASEAN member, Malaysia is building its testing capabilities to detect agricultural GMOs through the establishment of the ASEAN GM Food Testing Network, to assist ASEAN member countries better utilize existing national resources on genetic modification and food safety, as well as gain better access to information on developing GM testing capabilities for food. With the regulatory frameworks in place, higher public acceptance and confidence on modern biotechnology is anticipated. This in turn would further facilitate stronger support for research, development and commercialization for rapid adoption and market entry of biotechnology products in Malaysia.

Biotechnology and Biosafety in Papua New Guinea

Dr. Toshiro Shigaki, National Agricultural Research Institute (NARI), Papua New Guinea.

The presentation highlighted the geographical constraints in the implementation of biosafety measures for the Pacific island nations as they have small area and low population. Also, there are numerous islands scattered and far apart from each other. Papua New Guinea (PNG) ratified the Cartagena Protocol on Biosafety on October 14, 2005, and it entered into force on January 12, 2006. PNG drafted Biosafety and Biotechnology Bill under the UNEP-GEF

project which was endorsed by the Minister for Environment and Conservation. However, the Bill is still in the process of being endorsed by the Cabinet (March, 2013). Until the law enters into force, existing laws are being used to address cases concerning biosafety in PNG. The lack of specific laws that regulate the movement and use of LMOs pose serious concerns due to the possibility of unregulated and unchecked inflow of LMOs and their products. In fact, anecdotal evidence of intentional and unintentional introduction of GMOs/LMOs in PNG has been reported in the second regular national report on the 'Implementation of the Cartagena Protocol on Biosafety'. At the same time, the lack of clear procedures to handle GMOs/LMOs prevents the country to reap the benefits from improved crops and livestock that are proven safe elsewhere. However, despite these minor problems, the draft Bill is thought to adequately address the issues concerning the research and commerce of LMOs in PNG. PNG also needs to have linkages with other developing countries, especially with those in the Asia-Pacific region. This would curtail unnecessary cost for the implementation of the Protocol and allow the PNG stakeholders to learn from the successes and mistakes of other countries in the region.

Biosafety Regulations in Bangladesh

Dr. Wais Kabir, Bangladesh Agricultural Research Council (BARC), Bangladesh. (Presented by Dr J.L. Karihaloo).

The presentation highlighted the rapid progress in biotechnology research in agriculture and medicine made by Bangladesh in the recent past. Recognizing the potential benefits of modern biotechnology, Bangladesh has given priority to introduce biotechnology research and development activities especially in the field of agriculture, which can provide opportunities to increase sustainable food production. Safe use of modern biotechnology requires adequate legislation and controls for their testing, release, use and cross border movement to protect human health and environment. Bangladesh as signatory of CBD and Cartagena Protocol on Biosafety, has approved Biosafety Guidelines, Biosafety Framework and Biosafety Rules, including formation of regulatory committee for biotechnological research and testing of transgenic products. The Department of Environment under Ministry of Environment and Forests is the responsible agency for releasing GMO products. Bangladesh has been developing its national capacity to manage biosafety through confined field experiments on Bt brinjal, potato and golden rice through a collaborative research program. Bangladesh is developing its risk assessment capacity to handle transgenic crops.

Discussion

- Regarding current position with respect to GM crops in Thailand, it was clarified that a moratorium has been placed in Thailand on all field trials. From June 1994, no GM crop can be officially imported into Thailand for field release. Only a few crops are being imported as FFPs as they require different regulations. Presently, Thailand has stopped all import for field release except for research purposes.
- The issue of harmonization of the definition of "GM Crop" was raised. Most of the participants opined that a crop developed through inclusion of foreign DNA should be regarded as GM crop, and crop developed through mutageneisis were excluded. But if mutation was introduced transgenically, it would be considered as a GM crop.

- Further, it was clarified that a hybrid seed developed through molecular techniques such as marker assisted breeding and not containing a foreign gene is not regulated as GM crop in India.
- Dr. Paroda clarified that Cartagena Protocol needed to be understood in proper perspective, especially the 'Precautionary Principle'. Systems need to be in place to enable a scientific assessment of risks posed by a GM crop/event, after which commercial release can be undertaken. Placing a moratorium is not a solution to take care of risks since it will not allow proper assessment of the risks. Also, the regulatory systems need to be robust and implemented on the basis of clear scientific concepts. Countries like USA, Australia and Argentina are not signatories to Cartagena Protocol, but have robust testing and regulatory regimes for safe release of GM crops.
- With regard to GM commercialization in Malaysia, it was clarified that GM rice was still at the R&D stage and GM carnations were being imported into the country. MARDI has a strong HRD component under which personnel are regularly trained on various aspects of GM safety, including GM detection in food.

Session II: Status of Agricultural Biotechnology and Biosafety Regulations in Asia-Pacific

This session was chaired by Dr. Iftikhar Ahmad, PARC and co-chaired by Dr. Etienne Duveiller, CIMMYT. Dr. Kavita Gupta, NBPGR was the rapporteur for this session.

Status of Agriculture Biotechnology Adoption and Biosafety Regulations in Pakistan

Dr. Iftikhar Ahmad, Pakistan Agricultural Research Council (PARC), Islamabad, Pakistan

The presentation highlighted the development of agricultural biotechnology network in Pakistan since the country started working in this area in 1985. Currently, there are 36 biotech centers/ institutes in the country. However, only a few centers have appropriate physical facilities and well trained manpower to develop GM crops. Most of the activities are focused on cotton as the major GM crop. Biotic (virus, bacterial, insect) and abiotic (salt, drought, cold) resistance genes have already been incorporated in some crop plants. Despite acquiring capacity to produce transgenic plants, no GM crops except cotton, either produced locally or imported, have been released commercially in the country. GM cotton has been granted approval for commercial release in 2010 and Pakistan has the 8th largest area under GM crops in the world. Concerted and coordinated efforts based on biotechnology are being undertaken for improvement in the livestock sector as well. Pakistan is a signatory to the World Trade Organization (WTO), the Convention on Biological Diversity and the Cartagena Protocol. The country has ratified both CBD and CPB. Several legislations under the Agreement on Trade Related Aspects of Intellectual Property Rights have been promulgated in the country. The National Biosafety Guidelines were promulgated in April 2005 under which a three body regulatory system (IBC, TAC and NBC) has been established. National Biosafety Centre has been set for the implementation of National Biosafety Guidelines. The Plant Breeders Rights Act is currently under discussion, evaluation, and analysis. Shortage of trained human resource for biosafety studies, monitoring and evaluation are some of the constraints being faced after the release of GM cotton in the country.

Biotechnology Adoption and Biosafety Regulations in Chinese Taipei

Ms. Hung-Hsi Lee, Department of Science & Technology, Council of Agriculture (COA), Chinese Taipei.

The presentation covered the biotechnology research programs being conducted under the Council of Agriculture (COA), Chinese Taipei in the areas of plant seeds and seedlings, aquaculture, livestock, food, bio-fertilizers, bio-pesticides, animal vaccines, and testing and diagnostic technologies. These include, promotion of quality agricultural products, production of ornamental GMOs like fluorescent fish, development of model animals for biomedical research, and use of bioreactor technology for producing medicinal proteins including vaccines, growth factors and coagulation factors. In 2009, the Executive Yuan of Chinese Taipei approved the "Development Program for Industrialization of Agricultural Biotechnology" for a five year period (2009-2013). The program included six development strategies, namely, setting up an intergovernmental task force for promotion, forming demand-oriented science and technology policy, linking industry-academia R&D system, building a commercialization platform, training for business talents, and speeding up agricultural transformation. On the basis of Chinese Taipei's current agricultural advantages and future development opportunities, the COA proposed a strategic framework for industrialization by integrating the up-, mid- and downstream R&D capacities of the agricultural biotechnology industry. Chinese Taipei has established science-based assessment system to evaluate the characteristics of GMOs, their effect and stability in the environment, and for determining other unintended effects resulting from the GM technology. For the management of GMOs, Chinese Taipei has established regulatory system to ensure biosafety and biosecurity. The National Science Council (NSC) regulates R&D activities on the use of GM technology based on Laboratory Guidelines. At the level of field testing, the COA has established relevant laws and regulations for GM crops, livestock, aquaculture and feeds, bio-pesticides, bio-fertilizers and veterinary drugs; the Environmental Protection Agency (EPA) is in charge of testing items for microbial preparations used as environmental pest control agents. Accordingly, the COA and the EPA also have the regulations for approving marketing/sales and import/export of the items mentioned above. As for GM food, the Department of Health (DOH) is the agency in charge of GM food safety.

A Status Report on Biotechnology and Biosafety Regulations in Thailand

Dr. Nipon Iamsupasit, Biotechnology Alliance Association, Bangkok, Thailand.

The presentation highlighted the biotechnology R&D in Thailand on important crops such as chili, tomato and papaya for virus resistance; cotton and yard-long bean for major pests' resistance, and rice for stunt virus and salinity resistance. Department of Agriculture, Ministry of Agriculture and Cooperatives and Mahidol University developed GM papaya for papaya ring spot virus resistance, Kasetsart University developed GM orchids for color presentations and Rajamangala University of Technology, Srivijaya developed pineapple for herbicide tolerance. Moreover, the first introduction and field testing of genetically modified plants in Thailand was Flavr Savr tomato conducted in 1994. Additional field trials were also permitted for other GM crops such as GM cotton with toxin gene from *Bacillus thuringenesis* (Bt) in 1995 and 1996 and Bt corn in 1997. However, due to mounting pressure from NGOs, the Cabinet on April 3, 2001 decided to suspend all field testing of GM crops in Thailand. Therefore, all trials conducted for research purposes can only be implemented in laboratories or greenhouse settings. Later in

2007, the cabinet lifted ban on GM field trial with the following conditions: field trial must be approved by the Cabinet on case-by-case basis, after the technical clearance by the Department of Agriculture and a public hearing is conducted. For biosafety regulation, Thailand adopted the National Biosafety Guidelines for laboratory work, field testing and planned release in 1992 initiated by BIOTEC. Later, Institutional Biosafety Committees (IBCs) were established by various research and academic institutes. Moreover, the national framework regarding biosafety in Thailand had been developed by the Office of the Natural Resources and Environmental Policy and Planning (ONEP). Three Biosafety Guidelines had been developed, Biosafety Guidelines for Research and Development, Food Biosafety Guidelines and Biosafety Guidelines for Industrial Application of Genetically Modified Microorganisms. The other existing biosafety related laws are Plant Quarantine Act B.E. 2507 (1964), Plant Variety Protection B.E. 2542 (1999) and Food Act B.E. 2522 (1979). Draft Biosafety Law was also approved by the Cabinet on 22 January 2008 and it has been under review of the Council of State since June 2009.

Biotechnology Adoption and Biosafety Regulations in Vietnam

Dr. Pham Van Toan, Vietnam Academy of Agricultural Sciences (VAAS), Hanoi, Vietnam.

The presentation covered the Vietnam government policy to develop biotechnology as a priority for economic development. At present, Vietnam has no GM crops growing in the field. Some research projects on GM crops (corn, sweet potato, forestry trees and golden rice) and GM microorganisms are still in progress. Since 2010, Vietnam allowed field testing of GM corn for risk assessment on the environment and biodiversity. Every year, Vietnam imports a large amount of corn, soybean, wheat and their products for food and feed purposes which may contain GM products. Until now, Vietnam has no separate law regulating GMOs, but GMOs and GMO products are covered under the Environment Protection Law (1993) modified in 2006. Biodiversity Law (2008) which includes biosafety of LMO and genetic material from LMO, and Food Safety Law (2010) covers the food safety of GM food. Regarding the biosafety of GMOs and GM products, Vietnam government promulgated the Decree No 69/2010/ND-CP on June 21, 2010 which was modified as Decree No 108/2011/ND-CP on November 30, 2011. It regulates research and development of GMOs, risk assessment, environment biosafety, food and feed safety assessment and certification, production, commercialization, import, export, transportation and preservation/storage of GMOs, GM products and public information about the GMOs and GM products. Expanding the government decree, the Ministry of Agriculture and Rural Development promulgated the Regulation on the Trials of GM Crops used as Plant Variety, GM Feed/Food Safety Assessment and Certification; the Ministry of Natural Resources and Environment promulgated the Regulation on the Information Exchange and Biosafety Certification of LMOs on the Environment; the Ministry of Science and Technology promulgated the Regulation on the Research and Development of GMO, GM Products in Vietnam.

Recent Issues on GM Crops Needs and Regulations in India

Dr. K.V. Prabhu, Indian Agricultural Research Institute (IARI), New Delhi, India.

The presentation highlighted how the GM technologies have revolutionized the process of breeding new varieties of plants and animals worldwide. In doing so, the perceived risks are being assessed and managed before, during and after commercialization. The unprecedented success of Bt-cotton hybrids in India is a case that has shown a concrete path to be pursued

to tackle a serious problem effectively through transgenic route. Since the transgenic plant developed through genetic engineering could lead to a different plant constitution or a yet not experienced behavior in a native/wild type of a crop, it is perceived as a possible risk to human or animal health, and environment if released for cultivation without appropriate assessment. The Environment Protection Act of 1986 and India's conformity to the Cartagena Protocol on Biosafety require every transgenic crop to be released into the environment after it is assessed for its biosafety to humans, animals and environment through a series of tests and protocols as required by different regulatory bodies involving multiple administrative Ministries of the Government. The latter include, Institutional Biosafety Committee (IBSC) functional at each institution involved in research on transgenic crops. Review Committee on Genetic Modification (RCGM) and Genetic Engineering Appraisal Committee (GEAC) carry out the risk analysis and evaluate the products before their release in the environment. The procedures and protocols that are in place through different rules within the Act have been in operation for an event-based biosafety regulation. These are being dynamically upgraded and reformed to meet the ultimate objective of providing a safe technology as a potent tool to meet India's food and nutritional security as well as render agriculture profitable in a small farm based agrarian population. The regulatory system is constantly changing towards a consensus based risk analysis to ensure safe use of transgenic technology in India

Discussion

- Dr. Iftikhar Ahmad was of the opinion that most of the countries in the region officially support biotechnology. However, it is the non-science based arguments which hamper technology development and progress. He also highlighted that to take care of the biosafety issues, robust procedures need to be in place and safe technology should be offered to the public to build their confidence in GM crops. Besides, the technology should also be profitable to the farmers and beneficial to the consumers.
- Dr. Raj Paroda made the following important points:
    - Decisions regarding outscaling of technology need to be taken on the basis of nation's needs and the gaps in production system. Experiences of other countries should also be taken into account while prioritizing production needs.
    - There is a need to promote inter-ministerial coordination and cooperation, as biosafety issues in most of the countries of the region are being handled across several ministries, Ministry of Environment for environmental release, Ministry of Agriculture for field testing and Ministry of Food for food safety issues.
    - There is a need for building confidence of policy makers by science managers through good scientific arguments. Proper methodology for monitoring and evaluation should be in place. Building public confidence should form a part of the implementation process of any GM technology.
    - The efforts by Pakistan in developing nine Bt cotton varieties through public system are appreciable.
- Dr. K.K. Sharma pointed out that GM science and technology was moving faster than the improvements being made in the regulatory frameworks, especially in Asian countries.

- Dr. K.V. Prabhu sought opinions from Vietnam, Thailand, Pakistan, Malaysia whether there was concern regarding genetic contamination of biodiversity in crops for which the countries are centers of origin/diversity. Dr. Iftikhar Ahmad informed that no such concern existed in Pakistan. However, to protect its basmati export, Pakistan is not working on GM rice. Malaysia is a center of diversity of rice and it is presently working on GM rice. Its release is expected to be more stringently monitored. Vietnam, also a center of diversity for rice, is working on GM rice and diversity contamination is not an issue in the country. Dr. Paroda felt that options need to be adopted in a strategic manner and case-by-case, and decisions need to be taken country-by-country considering all relevant factors.
- Dr. Masa Iwanaga opined that the public perception was that scientists were acting like God by creating GM crops. Adoption of GM crops on a large scale would lead to monoculture and control of world agri-business and food production by a few large transnational companies. There is a urgent need to change this perception and influence policy makers by highlighting the success stories.
- Dr. Simon Hearn felt that response of decision makers to public concerns about risk, whether in case of biosecurity or biosafety, needs to be on the basis of scientific evidence. Public needs to be informed and educated in well understood language, who in turn would influence the policy makers.
- Dr. Paroda felt that there is a predominance of multi-nationals in GM crop development and the public system needs to be strengthened to deliver, which it had failed to do despite full government support, especially in India. Building partnerships between public and private sectors is the need of the hour and national systems have the responsibility to deliver sound technologies.
- Dr. Karihaloo felt that in cases of GM events approved for both food and feed, it would be difficult to assess whether these were being used exclusively for either of the purposes. Dr. Fuller reminded about Star-Link maize, a classical example of release of a crop for feed and not for food, which was ultimately detected in the food chain and taken off the market. The same mistake should not be repeated.
- The Chairman in his concluding remarks noted that four major issues had come up during discussions- how to bring change in mindset, how to build confidence of the public, how to advocate with policy makers and how to strengthen the public sector to deliver and build public-private sector partnerships to avoid being monopolized by the multi-nationals.

Session III: Key Note Lectures

This session comprised five key note lectures and was chaired by Dr. Masa Iwanaga, JIRCAS and co-chaired by Ms. Hung Hsi Lee, COA. Dr. Kavita Gupta, NBPGR was the rapporteur for this session.

Genetically Modified Vegetable Crops in Smallholder Farming Systems: Current Situation and Future Developments

Dr. Roland Schafleitner, Asian Vegetable Research and Development Center (AVRDC) - The World Vegetable Center, Chinese Taipei.

The growing demand for food can be met through a combination of technologies that increase crop yields and aid sustainable production. Much of the expected yield gains will have to be achieved in smallholder farming systems, where actual productivity levels are low. Genetic modifications of crops contribute to increased yields and enhanced sustainability of crop production, even in smallholder farming systems. However, smallholder farmers' uptake of this technology is low. Most GM crops were developed for large-scale commercial farming and some varieties are not suitable for smallholder farmers. Only a few GM horticultural crops are currently on the market, and the dissemination of GM eggplant in India has been stopped by the authorities. Insufficient national research capacity in developing countries, lack of farmer's knowledge on GM practices, and an absence of GM regulations and policies can restrict access to GM crops by smallholder farmers. Current GM biosafety measures are designed to suit large-scale commercial farming; compliance may be difficult in smallholder faming systems. Smallholder farmers need stronger support through government agricultural advisory services to profit from GM crops and to comply with biosafety regulations. They require more general knowledge on GM crops to make informed choices about what kind of crop to plant and must be able to understand regulations related to different types of seed. Biosafety regulations, such as monitoring requirements, might need reassessment and should be adapted to smallholder farming systems without lowering safety standards. Today's biotechnology research offers a diversity of opportunities beyond GM crops. DNA sequence technologies facilitate crop improvement through marker-assisted or genomic selection, mutation breeding and genome editing. These methods may replace or at least complement current GM technologies in the near future. Vegetable crops derived from these processes might not need GM regulation and thus would be cheaper to develop, and easier to adopt and handle in smallholder farming systems.

Asia-Pacific Regional Cooperation in Biosafety Regulations

Dr. Banpot Napompeth, National Biological Control Research Center (NBCRC), Bangkok, Thailand.

The presentation covered the biosafety-related issues under the Cartagena Protocol on Biosafety (CPB), the Convention on Biological Diversity (CBD) and the WTO-SPS Agreement on the Application of Sanitary and Phytosanitary Measures; the International Plant Protection Convention (IPPC) and its International Standards for Phytosanitary Measures (ISPMs); the Codex Alimentarius Commission (CAC) and its international standards on food safety and labeling; and the World Organization for Animal Health (OIC). Cooperation is one of the basic principles under the IPPC-ISPM No. 1. The Asia-Pacific region is divided into four sub-regions. ISAAA has classified India, China, Pakistan, the Philippines, Australia, and Myanmar as biotech crop mega-countries, each growing 50,000 ha or more of GM crops. Cooperation in biotechnology and biosafety could be at the national, regional or international level. Both GMOs and GMOs-FFP, and labeling should be subject to regulations. Some enabling instruments supporting Asia-Pacific biosafety regional cooperation are already evident, for example, under the UNEP-GEF National Biosafety Frameworks (NBF) projects, and various technical and regional conferences, training workshops, etc. organized by regional projects under FAO, FAO-RAP, ADB-GMS, and ASEAN. The development of the national biosafety frameworks (consisting of biosafety policy; regulatory regime; system to handle requests (administrative, risk assessment and management, decision-making); follow-up action (monitoring, inspection, and enforcement); and public awareness and participation) is fundamental to the formulation of

regional cooperation. Dr. Napompeth gave example of the U.S. regulation of plant agricultural biotechnology which involves three lead federal agencies (USDA-APHIS, FDA, and EPA) with five regulatory procedures that come into play from the time a developer plans to develop a potentially marketable GM plant product to when the product finally ends in the local food market (consisting of pre-submission discussion; field trials approvals; petitioning USDA-APHIS for "non-regulated status"; EPA regulation of crops with pest control properties; and FDA review of food and feed safety). It was concluded that Asia-Pacific being highly diversified in terms of R&D, human resources development, basic infrastructure, facilities, etc., a regional capacity building mechanism is urgently needed. There is also a need for alignment among the existing policies under different national competent authorities in each Asia-Pacific country; and where appropriate, harmonize biotechnology/biosafety regulations within the region, also taking into account similar attempts being made under sub-regional forums like ASEAN.

Biosafety Information Resources

Dr. Keng Yeang Lum, CABI South East Asia, Selangor, Malaysia.

The presentation highlighted the information resources on biosafety including several websites which offer useful entry points to this diversity of biosafety data. With a view to offer themselves as "one-stop shops", these sites contain huge listings of relevant information, tools and further links to other sites, providing an exhaustive range of biosafety-related information. These include the central portal of the Biosafety Clearing House (BCH), hosted by the CBD Secretariat, which describes itself as "an information exchange mechanism to assist Parties to implement its provisions and to facilitate sharing of information on, and experience with, LMOs". The Biosafety Information Resource Centre (BIRC) page facilitates search for electronic catalogues of biosafety-related publications and information resources including: news services; e-mail list servers; online databases and search engines; reports and case studies; journals, newsletters and teaching materials (manuals, toolkits and presentations). Under the guidance of the United Nations Environment Program (UNEP), around 120 countries have undertaken development of their National Biosafety Projects. The wealth of in-country experience in building capacity for biosafety generated by these projects is documented in the drafts of national biosafety frameworks available online. The FAO, together with sister organizations responsible for international standard setting in sanitary and phytosanitary matters, has developed the International Portal on Food Safety, Animal and Plant Health to provide a unified access point for authorized official international and national information across food safety, animal and plant health. ICGEB web pages offer information on biosafety and risk assessment for the environmental release of GMOs. Useful resources include a biosafety bibliographic database, the Risk Assessment Search Mechanism (RASM), BioSafRes database of research projects, and collection of biosafety reviews. OECD's BioTrack Online focuses on the regulatory oversight of modern biotechnology products in OECD member countries, as well as field trials. ISAAA provides a combination of science-based information and appropriate technology to those who need to make informed decisions about their acceptance and use. In addition, CABI's AGBiotechNet is an online agricultural biotechnology information service that covers transgenics and tissue culture of plants and animals, featuring immediate desktop access to worldwide in-depth news, specially commissioned scientific reviews, informative resource links and over 319,000 scientific abstracts. It joins many others in offering a rich array of biotechnology and biosafety information.

Communication Strategies for Agricultural Biotechnology and Biosafety

Dr. George B. Fuller, Asia Food Solutions (AFS), Bangkok, Thailand.

The presentation explained and gave an example of use of risk communication science, combined with insights from recent polling in Asia by the Asian Food Information Centre as a basis for exploring the communication strategies adopted by various groups. Based on the insights, strategies that might be effective to bring the public to a more neutral or even favorable point of view were suggested. Key elements of this strategy are confidence in international and national biosafety frameworks; illustrations of successful public sector technologies; illustrations of competition in the private sector; personal success stories of farmers who have benefitted from agricultural biotechnology; and highly credible proponents.

Biosafety Compliance–Support being provided by ICRISAT

Dr. K.K. Sharma, International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru, Andhra Pradesh, India.

The presentation highlighted the importance gained by transgenic technology in recent years due to the increasing demand for efficient agricultural production to provide sufficient food for the growing population. While conventional breeding is limited to exchanges between the same or very closely related species, the transgenic technology enables combining in one plant useful genes from a wide range of living sources within a relatively shorter time. Agricultural biotechnology has the potential to reduce crop losses from pests and diseases; improve the nutrient efficiency of food and animal feeds; extend the post-harvest life of fruits and vegetables; and to increase the stress tolerance of crop plants allowing them to tolerate various environmental extremes. In developing countries in particular, biotechnology has the potential to revitalize the agricultural sector and increase the profitability of farming. Biotechnological solutions to improve crop productivity can empower the rural sector by boosting food production, enhance income of small farmers, and improve nutritional security. As with every new emerging technology, GM crop technology needs utmost compliance in terms of biosafety regulations, intellectual property regime etc. that must be kept in view while developing transgenic crops. With this in view, an entity – Platform for Translational Research on Transgenic Crops (PTTC) – affiliated with ICRISAT and funded by the Department of Biotechnology, Government of India, has been established that serves to evaluate potential new genetic engineering options with utmost global compliance. Governed by the CGIAR policies, the transgenic research at ICRISAT adheres to the highest international standards, follows stringent regulations and conducts research in a socially responsible way. PTTC facilitates a collaborative and coordinated approach for the translation of existing genetic engineering technologies to the development of transgenic crop varieties, which can be efficiently taken through product development to commercialization. The conceptual framework of PTTC and the opportunities for the public and private sector organizations for product development including regulatory compliance were presented.

Session IV: Discussion on Key Issues

Discussions on three key issues: i) biotechnology R&D priorities especially aimed at small holders; ii) enhancing communication for public awareness; and iii) regional cooperation for biosafety management, were held.

i) Biotechnology R&D Priorities Especially Aimed at Smallholders

Dr. Roland Schafleitner, AVRDC, Chinese Taipei (Facilitator)

Dr. Schafleitner made introductory remarks following which the participants expressed their views.

- Dr. K.V. Prabhu opined that farm-holding size should not be a factor to decide whether GM technology should be adopted since the technology has proved to be scale-neutral in India. He mentioned that even herbicide tolerance is an appropriate technology for smallholder farmers, since the farm labor costs have escalated substantially. Any crop technology that gives an added profit over the previous technology is welcomed by the farmer. Researchers would prefer to take up crops being cultivated over large areas, even though by small farmers. As regards the traits to be addressed on priority, Dr. Prabhu suggested that wherever the desired trait cannot be transferred by conventional breeding methods, GM technology should be used.
- Dr. Iftikhar Ahmad felt that treating every technology as scale-neutral may not be a practical solution. GM route should be adopted where the sources of desired traits are not available in near relatives. Genetic engineering and conventional breeding need to work hand-in-glove to improve crops. Another priority would be to provide choices to the farmers in not just improved crops, but also in animal products, microorganisms and biopesticides. Therefore, there is a need to take a holistic view of the needs and available solutions. Opportunities exist to benefit both small and large farmers, it is just about the choices being offered to them.
- Dr. George Fuller was of the opinion that the priorities vary from country to country and cited the example of Thailand which needed GM technologies for coconut and papaya while these may not be priority crops for other countries. Thus, priorities need to be formulated at national level also keeping in view suitability to respective agro-ecologies.
- Dr. K.K. Sharma highlighted that public sector needed to focus on unmet needs of the smallholder farmers including crops like groundnut that are not being taken up by the private sector.
- Dr. Masa Iwanaga emphasized that prioritization should be based on target products, whether these are the resources for the small or large scale farmers. If the purpose is to address poverty and malnutrition, which are symptoms of a resources poor farmer, the traits as well as crops should be specific.
- Dr. Subash Dasgupta opined that definition of small farmers varied from country to country, but it was important to address food security crops for small farmers and research should focus on these areas. Countries in the region also need to develop biosafety policy along with the biosafety frameworks.
- Dr. Umi Kalsom Abu Bakar opined that researchers should search for options to procure technologies from other sources and build upon them instead of trying to reinvent the wheel. Such approach would not only shorten the period of product development but also reduce the required development cost.

ii) Enhancing Communication for Public Awareness

Dr. George B. Fuller, AFS, Thailand (Facilitator)

- Dr. Fuller emphasized the need to adopt better communication strategies for agricultural biotechnology and biosafety since public acceptance is an offshoot of public confidence. Scientists need to convince all the stakeholders, including policy makers and farmer, about the benefits of their products using factual and scientific information.
- Dr. Iftikhar Ahmad cited the example of Pakistan, where there is direct interaction between the farmers and scientists who work closely together with the farmers actually practicing the technology and realizing the benefits demonstrated to them. This approach was followed for Bt cotton release in Pakistan. Along with, policy makers need to be apprised of the technology, its benefits as also the safety issues and how these are being addressed.
- Dr. K.K. Sharma felt that there is a need for effective communication strategy to convince the farmers as well as the media. Media likes to sensationalize the negative impacts, however, they need to be approached tactfully and convinced scientifically.
- Dr. K.V. Prabhu expressed the need for professional communication chains to work closely with product development chains to effectively convey the message to farmers and media.
- Dr. Simon Hearn opined that regulatory decisions needed to be taken on the basis of scientific evaluation of risks and their acceptable levels. The latter could vary based on perception of the stakeholders where communication played an important part. Science would only define and evaluate the level of risk, but communication gives a reassurance of safety.
- Dr. Raj Paroda suggested that the national systems while allocating funds for biotechnology research should also earmark funds for public awareness to communicate effectively and strategically on the issues and opinions.

iii) Regional Cooperation for Biosafety Management

Dr. Banpot Napompeth, NBCRC, Thailand (Facilitator)

- Dr. Napompeth explained that cooperation in biosafety management should start with basic and practical national cooperation before expanding into sub-regional and regional cooperation. The lack of appropriate science-based and cost effective regulatory systems continues to be the major constraint to adoption of modern biotechnology. Rigorous but not onerous regulation management is needed for small and low income developing Asia-Pacific countries. These countries are highly diversified in terms of R&D, human resources development, basic infrastructure, and capacity building mechanism, all of which are urgently needed in the entire region. Different Asia-Pacific countries are also at different stages of biotechnology adoption. Cooperation, collaboration, linkages and networking in modern biotechnology and biosafety among the Asia-Pacific countries needs to be initiated, implemented and strengthened.
- Dr. Raj Paroda felt that there was a need to develop a mechanism for continued regional cooperation so that the key players deliberate, exchange ideas and come to a common understanding on a long-term basis. Cooperation would require commitment and development of an institutional mechanism for regular interaction.

- Dr. K.V. Prabhu put forth the view that the main hurdle to progress of biotechnology product development in developing countries of Asia-Pacific is the prohibitive costs of regulatory data generation. There is a case for cooperation in regulatory management of crops and traits of common interest. Therefore, regional cooperation for data generation on items such as toxicity, animal feeding and allergenicity would not only reduce the cost of regulatory compliance, but also lead to use of uniform data across the region. A mechanism could be developed for authentication of the data generated which could be used by other countries in the region without further verification. An example of sub-regional cooperation is the Ug99 resistance breeding in wheat being operated in the framework of SAARC mechanism.
- Dr. Iftikhar Ahmad proposed that APCoAB would be an appropriate forum to take forward the task of regional cooperation.

Concluding Session

This session comprised presentation of recommendations by the Facilitators of the previous session and was chaired by Dr. Raj Paroda, APAARI and co-chaired by Dr. Simon Hearn, APAARI. The rapporteur for the session was Dr. K.K. Sharma, ICRISAT.

Recommendations

Biotechnology R&D Priorities Especially Aimed at Smallholders

- Countries need to prioritize the use of GM technology based on their own crop/animal and trait priorities and specific agro-ecologies.
- Focus of GM R&D should be on food security crops grown by vast majority of small farmers and which usually are not the priority of private sector.
- Priority should be given to such traits that minimize the use of external inputs.
- With the advancement in technology, there is also a need to enhance the knowledge base of technology user, the farmer.
- Keeping in view the high cost of technology development and transfer, ways need to be explored to lower the biosafety compliance costs, including assisting poor countries in implementing the regulations through collaboration in data development.

Enhancing Communication for Public Awareness

- Enlist farmer support and inputs at the GM field trial stage itself rather than later when all the tests have been completed. To gain their acceptance, it is important to partner farmers right from the product development stage.
- Separate resources need to be allocated by research institutes/ technology developers for enlisting professional communicators to develop and carry out appropriate communication strategies.
- Make use of farmer champions post-introduction of GM crops for spreading the good word about the usefulness of technology.

Regional Cooperation for Biosafety Management

- There is a need for cooperation on the alignment and synergies of the existing policies on biosafety under different national component authorities in each Asia-Pacific country, and among sub-regional or regional economic/political associations.
- There exists an acceptable resolution on the co-existence issues among conventional agriculture, organic farming and GM crop cultivation. A settlement is urgently needed in each and among Asia Pacific countries concerned.
- In order to accomplish these aims and make them sustainable, there is a need of an effective financial mechanism and assistance such as that under GEF.

Concluding Remarks

In his concluding remarks, the Co-chair Dr. Simon Hearn observed that although there was a marked difference in agro-ecology across countries in the Asia-Pacific region, there was a remarkable similarity in the thinking on various aspects of biosafety. GM was just one application of biotechnology application for crop improvement. He highlighted the importance of effective communication and emphasized that th e next generation of scientists need to be better communicators. The technology developers need to involve the farmers and consumers at all stages of technology development and commercialization to ensure that they are convinced about the products and would be willing to adopt it. Citing the example of the quarantine system in Australia, he mentioned that its success has been due to involvement of the public and making them feel responsible through the motto "Quarantine is your responsibility". A similar approach needs to be adopted in biotechnology. There is a need to build public confidence in science and regulators who in turn should be completely convinced about it.

The Chairman, Dr. Raj Paroda in his concluding remarks opined that although the regulatory requirements of different countries are different, there is always scope for re-alignment and learning from others. APAARI had been providing a neutral platform for the countries in the region and organizing dialogues to facilitate development of a regional network. He emphasized that GM food offered a viable solution for both food security and food safety. However, the mechanism for safety assessment needs to be fool-proof to ensure public confidence.

While speaking on the cross-cutting issues being dealt by various ministries, he noted that there would be a lot of convergence/coordination required for the same. It would be better to have a single window system for biosafety clearance as is being envisaged by India. Also, he felt that while flagging the national strategy for biotechnology, countries need to highlight the socio-economic relevance of the technology. Dr. Paroda also expressed concern that public system had not been able to commercialize GM crops in the way private sector had done. He called for effective partnership between public and private sectors and also suggested that private sector should share some of the social responsibility to ensure food security. He offered that APCoAB would play a supportive role in policy advocacy and as a co-associate assist in developing regional linkages. At the end, he recommended that a network of biotechnologists from Asia-Pacific should meet every year to deliberate on all relevant issues and build effective linkages within the region.

Stakeholders' Dialogue on "Biosafety Regulations in the Asia–Pacific Region"

Royal Princess Hotel, Larn Laung, Bangkok
(16-17 April 2013)

Program

16 April 2013

08:00-08:30	**Registration**	
09:30-10:25	**Inaugural Session**	
09:30- 09:45	Welcome Address	*Dr. Raj Paroda*, Executive Secretary, APAARI
09:45-10:00	Opening Remarks	*Dr. Simon Hearn*, Chairman, APAARI
10:00-10:20	Release of Publication & Inaugural Address	*Dr. Hiroyuki Konuma*, ADG, FAO-RAP
10:20-10:25	Vote of Thanks	*Dr. J.L. Karihaloo*, Coordinator, APCoAB-APAARI
10:25-11:00	**Group Photograph & Tea/Coffee Break**	

Session I:
Status of Agricultural Biotechnology and Biosafety Regulations in Asia-Pacific
Chair: *Dr. Simon Hearn*, ACIAR
Co-Chair: *Dr. Umi Kalsom Abu Bakar*, MARDI
Rapporteur: *Dr. K.V. Prabhu*, IARI

11:00-11:30	Overview of agricultural biotechnology and biosafety in Asia-Pacific and facilitation role of APAARI	*Dr. J.L. Karihaloo*, Coordinator, APCoAB-APAARI
11:30-11:50	Status of biotechnology and biosafety regulatory system of India	*Dr. Kavita Gupta*, NBPGR
11:50-12:10	Biotechnology adoption and biosafety regulation in Malaysia	*Dr. Umi Kalsom Abu Bakar*, MARDI
12:10-12:30	Biotechnology and biosafety in Papua New Guinea	*Dr. Toshiro Shigaki*, NARI
12:30-12:50	Biosafety regulations in Bangladesh	*Dr. Wais Kabir*, BARC (Presented by Dr. J. L. Karihaloo)
12:50-13:15	Discussion	
13:15-14:15	**Lunch Break**	

Session II:		
Status of Agricultural Biotechnology and Biosafety Regulations in Asia-Pacific		
Chair: *Dr. Iftikhar Ahmad*, PARC		
Co-Chair: *Dr. Etienne Duveiller*, CIMMYT		
Rapporteur: *Dr. Kavita Gupta*, NBPGR		
14:15-14:35	Status of agriculture biotechnology adoption and biosafety regulations in Pakistan	*Dr. Iftikhar Ahmad*, PARC
14:35-14:55	Biotechnology adoption and biosafety regulations in Chinese Taipei	*Ms. Hung Hsi Lee*, COA
14:55-15:15	A status report on biotechnology and biosafety regulations in Thailand	*Dr. Nipon Iamsupasit*, BAA
15:15-15:45	Tea/Coffee Break	
15:45-16:05	Biotechnology adoption and biosafety regulations in Vietnam	*Dr. Pham Van Toan*, VAAS
16:05-16:25	Recent issues on GM crops needs and regulations in India	*Dr. K.V. Prabhu*, IARI
16:25-17:00	Discussion	
18:30	**Dinner hosted by APAARI**	

17 April 2013

Session III:		
Key Note Lectures		
Chair: *Dr. Masa Iwanaga*, JIRCAS		
Co-Chair: *Ms. Hung Hsi Lee*, COA		
Rapporteur: *Dr. Kavita Gupta*, NBPGR		
09:00-09:25	Genetically modified vegetable crops in small holder farming systems: current situation and future developments	*Dr. Roland Schafleitner*, AVRDC
09:25-09:50	Asia-Pacific regional cooperation in biosafety regulations	*Dr. Banpot Napompeth*, NBCRC
09:50-10:15	Biosafety information resources	*Dr. Keng Yeang Lum*, CABI
10:15-10:45	**Tea/Coffee Break**	
10:45-11:10	Communication strategies for agricultural biotechnology and biosafety	*Dr. George B. Fuller*, AFS

11:10-11:35	Biosafety compliance - support being provided by ICRISAT	*Dr. K.K. Sharma*, ICRISAT
11:35-12:00	Discussion	
12:00-13:00	**Lunch**	

Session IV: Discussion on Key Issues		
13:00-13:30	Biotechnology R&D priorities especially aimed at small holders	*Dr. Roland Schafleitner*, AVRDC
13:30-14:00	Enhancing communication for public awareness	*Dr. George B. Fuller*, AFS
14:00-14:30	Regional cooperation for biosafety management	*Dr. Banpot Napompeth*, NBCRC
14:30-15:00	Tea/Coffee Break	
15:00-16:00	**Concluding Session**	
	Chair: *Dr. Raj Paroda*, APAARI	
	Co-Chair: *Dr. Simon Hearn*, APAARI	
	Rapporteur: *Dr. K.K. Sharma*, ICRISAT	

Presentation of recommendations by Facilitators, discussion and closing remarks by Chair and Co-Chair

List of Participants

ALONGKORN KORNTONG (DR.)
Director
Department of Agriculture
Paholyothin
Bangkok
Thailand
Email: akorntong@yahoo.com

BANPOT NAPOMPETH (DR.)
Founder & Advisor
National Biological Control Research Center and Member, Compliance Committee
Kasetsart University
Bangkok
Thailand
Email: agrban@nontri.ku.ac.th

CHANIKA IAMSUPASIT (MRS.)
General Manager
Biotechnology Alliance Association
Bangkok
Thailand

ETIENNE DUVEILLER (DR.)
Director of Research for South Asia
International Maize and Wheat Improvement Center
Email: E.Duveiller@cgiar.org

GEORGE B. FULLER (DR.)
Founder & Managing Director
Asia Food Solutions
Bangkok
Thailand
Email: georgef@asiafoodsolutions.com

HATHAIRAT URAIRONG (MS.)
Deputy Director
Office of Biotechnology Research and Development
Department of Agriculture
Paholyothin
Bangkok
Thailand
Email: fongppt@yahoo.com

HIROYUKI KONUMA (DR.)
ADG and Regional Representative
FAO Regional Office for Asia and the Pacific
Phra Atit Road
Bangkok
Thailand
Email: Hiroyuki.Konuma@fao.org

HUNG-HSI LEE (MS.)
Deputy Director General
Department of Science and Technology
Council of Agriculture
37, Nan-Hai Road
Chinese Taipei
Email: hhlee@mail.coa.gov.tw

IFTIKHAR AHMAD (DR.)
Chairman
Pakistan Agricultural Research Council
Plot No. 20, G-5/1, P.O.Box 1031
Islamabad
Pakistan
Email: iftahmad@gmail.com

JAWAHIR LAL KARIHALOO (DR.)
Coordinator, APCoAB
Asia-Pacific Consortium on Agricultural Biotechnology
NASC Complex, DPS Marg
New Delhi
India
Email: j.karihaloo@cgiar.org

K. K. SHARMA (DR.)
Principal Scientist (Cell Biology) and
Director (PTTC)
International Crops Research Institute
for the Semi-Arid Tropics
Patancheru 502 324
Andhra Pradesh
India
Email: k.sharma@cgiar.org

K. V. PRABHU (DR.)
Head, Division of Genetics
Indian Agricultural Research Institute
New Delhi 110 012
India
Email: kvinodprabhu@rediffmail.com

KAVITA GUPTA (DR.)
Principal Scientist
Division of Plant Quarantine
National Bureau of Plant Genetic Resources
New Delhi-110012
Email: kavita6864@gmail.com ;
kavita@nbpgr.ernet.in

KENG YEANG LUM (DR.)
Chief Scientist
CABI South East Asia,
Bldg A19, Glasshouse Complex
C/o MARDI, 43400 Serdang
Selangor
Malaysia
Email: ky.lum@cabi.org

MASA IWANAGA (DR.)
President
Japan International Research Centre for Agricultural Sciences
Ministry of Agriculture Forestry & Fisheries
1-1 Ohwashi Tsukuba
Ibasraki 305 8686
Japan
Email: miwanaga@affrc.go.jp

NIPON IAMSUPASIT (DR.)
President
Biotechnology Alliance Association
Bangkok
Thailand
Email: niponiamsupasit@yahoo.com

PHAM VAN TOAN (DR.)
Director of Post Graduate School of VAAS
Vietnam Academy of Agricultural Sciences
Ministry of Agriculture and Rural Development
No. 2 Ngoc Ha Street, Ba Dinh
Hanoi
Vietnam
Email: toanvaas@gmail.com

RAJ PARODA (DR.)
Executive Secretary
Asia-Pacific Association of Agricultural Research Institutions
C/o TAAS
IARI, Pusa Campus
New Delhi-110012
India
Email: raj.paroda@gmail.com

ROLAND SCHAFLEITNER (DR.)
Head of Molecular Genetics
AVRDC - The World Vegetable Center
Shanhua Tainan 74199
Taiwan
Email: roland.schafleitner@worldveg.org

SAMAPORN SAENGYOT (DR.)
Maejo University
Chiang Mai
Bangkok
Thailand
Email: samaporn@mju.ac.th

SIMON HEARN (DR.)
Principal Advisor
Australian Centre for International Agricultural Research
PO Box 1571 Canberra ACT 2601
Australia
Email: Simon.Hearn@aciar.gov.au

SIRIYA THAMMACHAT (DR.)
Coordinator
Registration and Regulatory Affairs
Pioneer Hi-Bred (Thailand) Co. Ltd
Thailand
Email: siriya.thammachat@pioneer.com

SUBASH DASGUPTA (DR.)
Senior Plant Production Officer
(Horticultural and Field Food Crops)
FAO Regional Office for Asia and the Pacific
Phra Atit Road
Bangkok
Thailand
Email: Subash.Dasgupta@fao.org

SYED GHAZANFAR ABBAS (DR.)
Technical Staff Officer
Pakistan Agricultural Research Council
Sector G-5/1 Atta Turk Road
Islamabad
Pakistan
Email: guzniabbas@gmail.com

TOSHIRO SHIGAKI (DR.)
Principal Scientist- Biotechnology
Papua New Guinea National Agricultural Research Institute
Bubia, P.O. Box 1639, Lae
Morobe Province 411
Papua New Guinea
Email: toshiro.shigaki@nari.org.pg

UMI KALSOM ABU BAKAR (DR.)
Director- Biotechnology Research Center
Malaysian Agricultural Research and Development Institute
P.O.Box No. 12301
Kuala Lumpur 50774
Malaysia
Email: uab@mardi.gov.my


TIONS IN THE ASIA-PACIFIC REG
2013