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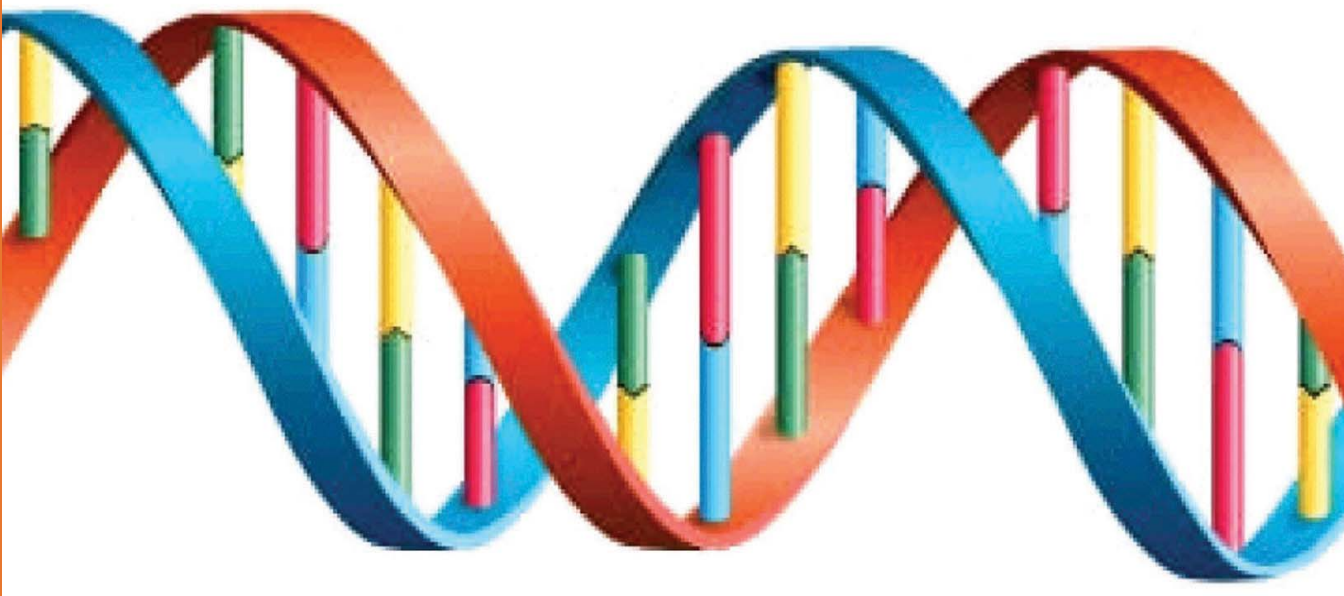
Report of the Regional Workshop on Strengthening Regional Cooperation and National Capacity Building on Biosafety in Asia



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Compiled by
Subash Dasgupta

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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Foreword

The advent of modern biotechnologies that allow overcoming natural reproductive barriers across plant species and genera created unprecedented opportunities for developing plant varieties with novel characteristics and for increasing efficiency of plant breeding with improved targeting of genes and gene combinations for manipulation. In order for nations to be able to adopt these technologies and expand their use, it is important that they invest in national capacity building in key areas of research, education, technology development and a framework of coherent national policies and regulations guiding biotechnology R&D, with a focus on rapidly expanding, but controversial, applications of recombinant DNA technology widely known as genetic modification. This regulatory framework must be robust and technically sound to encompass all aspects of design, handling, transboundary movement, testing and environmental release of living modified organisms (LMOs) resulting from modern biotechnology so as to ensure they pose no hazard to human health and biological diversity. In short, effective biosafety measures must be in place before contemplating commercial cultivation of GM crops.

With the signing of the international agreement – Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) – in 2000 and its entry into force in 2003, concerted efforts were focused on mobilizing international assistance to help developing nations build their institutional capacities in biosafety and meeting their obligations under the treaty. Technical assistance in this area is being provided through UNEP-GEF, FAO, and other agencies. FAO's regional office for Asia and the Pacific, in cooperation with the Government of Thailand, has launched "Asian BioNet," a regional initiative on capacity building in biosafety of GM crops in Asia. This workshop was the second held under the auspices of Asian BioNet aimed at strengthening regional cooperation in national capacity building on biosafety.

This document represents the outcome of the second workshop held from 17 to 20 June 2013 under the auspices of Asian BioNet aimed at strengthening regional cooperation in national capacity building on biosafety. The workshop was attended by representatives from eleven member countries as well as experts from FAO headquarters, APAARI, and CropLife Asia, an association of biotech industry organizations. It was also attended by resource speakers from India, Japan and the Philippines. The document provides up-to-date information on the existing status of national policies, guidelines, regulations, and administration of biosafety, and the challenges the countries in the Asian region are facing in strengthening capacity for expanding the scope of biotechnology research and development in their respective countries.

Hiroyuki Konuma
Assistant Director-General and Regional Representative
for Asia and the Pacific
Food and Agriculture Organization of the United Nations

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Abbreviations and Acronyms

AIA	Advance Informed Agreement
AO	Administrative Order
APAARI	Asia-Pacific Association of Agricultural Research Institutions
ASEAN	Association of South East Asian Nations
BARI	Bangladesh Agricultural Research Institute
BC	Biosafety Committee
BCH	Biosafety Clearing House
BEI	Biotechnology and Ecology Institute (Lao PDR)
BRAI	Biotechnology Regulatory Authority of India
BRL I	Biosafety Research Level I
BRL II	Biosafety Research Level II
BRRI	Bangladesh Rice Research Institute
BSO	Biological Safety Officer (Bangladesh)
BTT	Biosafety Technical Team (Indonesia)
CARDI	Cambodian Agricultural Research and Development Institute
CBD	Convention on Biological Diversity
CDC	Council for the Development of Cambodia
CFT	Confined Field Trial
CICR	Central Institute of Cotton Research (India)
CLI	CropLife International
CoM	Council of Ministers (Cambodia)
COP	Conference of Parties
CPB	Cartagena Protocol on Biosafety
DA	Department of Agriculture (Philippines)
DBT	Department of Biotechnology (India)
DENR	Department of Environment and Natural Resources (Philippines)
DLC	District Level Committee (India)
DNA	deoxyribonucleic acid
DOA	Department of Agriculture (Thailand)
DOB	Department of Biosafety (Malaysia)
DOF	Department of Fisheries (Thailand)
DOH	Department of Health (Philippines)
DOLD	Department of Livestock Development
DOST	Department of Science and Technology (Philippines)
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunosorbent assay
ERA	Environmental Risk Assessment
ESFB	Eggplant shoot and fruit borer
EU	European Union
FAO RAP	Food and Agriculture Organization Regional Office for Asia and the Pacific

FBC	Field-level Biosafety Committee (Bangladesh)
FFP	food, feed and processing
FTP	Foreign Trade Policy (India)
GAABT	Global Alliance for Ag Biotech Trade
GDA	General Directorate of Agriculture (Cambodia)
GE	Genetically Engineered
GEAC	Genetic Engineering Appraisal Committee (India)
GEF	Global Environment Facility
GMA	Grocery Manufacturers Association
GMAC	Genetic Modification Advisory Committee (Malaysia)
GMO	Genetically Modified Organism
HRD	Human Resource Department
IBC	Institutional Biosafety Committee
ICABIOGRAD	Indonesian Centre for Agricultural Biotechnology and Genetic Resources Research and Development
IGCT	International Grain Trade Coalition
IIS	Indonesian Institute of Sciences
ISF	International Seed Federation
ISTA	International Seed Testing Association
IVEGRI	Indonesian Vegetables Research Institute
J-BCH	Japan Biosafety Clearing House
KBCH	Korea Biosafety Clearing House
KCDC	Korea Centers for Disease Control and Prevention (Republic of Korea)
KFDA	Korea Food and Drug Administration
LLP	low-level presence
LMO	Living Modified Organism
MAFF	Ministry of Agriculture, Forestry and Fisheries (Cambodia)
MAFRA	Ministry of Agriculture, Food and Rural Affairs (Republic of Korea)
MARD	Ministry of Agriculture and Rural Development (Viet Nam)
MAS	marker-assisted selection
MEF	Ministry of Economy and Finance (Cambodia)
METI	Ministry of Economy, Trade and Industry (Japan)
MEXT	Ministry of Education, Culture, Sports, Science and Technology (Japan)
MFDS	Ministry of Food and Drug Safety (Republic of Korea)
MIME	Ministry of Industry, Mine and Energy (Cambodia)
MND	Ministry of National Defence (India)
MOA	Ministry of Agriculture
MOAC	Ministry of Agriculture and Cooperatives
MOC	Ministry of Commerce (India)
MoC&I	Ministry of Commerce and Industries (India)
MOE	Ministry of Environment
MOEF	Ministry of Environment and Forests
MOEYS	Ministry of Education, Youth and Sports (Cambodia)
MOF	Ministry of Finance (Japan)

MOF	Ministry of Oceans and Fisheries (Republic of Korea)
MoH&FW	Ministry of Health and Family Welfare (India)
MOHW	Ministry of Health and Welfare (Republic of Korea)
MOI	Ministry of Interior (India)
MOLIT	Ministry of Land, Infrastructure and Transport (Republic of Korea)
MONRE	Ministry of Natural Resources and Environment (Viet Nam)
MOP	Ministry of Planning (Cambodia)
MOST	Ministry of Science and Technology (Lao PDR)
MOT	Ministry of Tourism
MOTIE	Ministry of Trade, Industry and Energy (Republic of Korea)
MOWRAM	Ministry of Water Resources and Meteorology (Cambodia)
MPWT	Ministry of Public Works and Transport (Cambodia)
MRD	Ministry of Rural Development (Cambodia)
MSIP	Ministry of Science, ICT and Future Planning (Republic of Korea)
NAFDC	National Agency for Food and Drug Control (Indonesia)
NAPBB	National Action Plan on Biosafety and Modern Biotechnology (Cambodia)
NBB	National Biosafety Board (Malaysia)
NBF	National Biosafety Framework
NBPGR	National Bureau of Plant Genetic Resources (India)
NCB	National Committee on Biosafety (Bangladesh)
NECB	National Executive Committee on Biotechnology (Bangladesh)
NFRD	National Fisheries Research and Development Institute (Republic of Korea)
NIER	National Institute of Environmental Research (Republic of Korea)
NSCB	National Steering Committee for Biosafety (Cambodia)
NTBB	National Taskforce on Biotechnology of Bangladesh
NTCs	National Technical Committees
OECD	Organisation for Economic Cooperation and Development
PCR	polymerase chain reaction
RCGM	Review Committee on Genetic Manipulation (India)
RDAC	Recombinant DNA Advisory Committee (India)
RGC	Royal Government of Cambodia
RUA	Royal University of Agriculture (Cambodia)
SAT	Scientific Advisory Team (Cambodia)
SBCC	State Biotechnology Coordination Committee (India)
SOP	Standard Operating Procedure
SSA	Seed Association of the Americas
STRP	Scientific and Technical Review Panel (Philippines)
TPSP	trehalose-6-phosphate synthase/phosphatase
UNEP	United Nations Environment Programme

Executive Summary

Most Asian countries today confront the challenge of improving productivity of key food crops at a much faster pace in the face of rising consumer demand and shrinking natural resources, supporting agricultural production amid myriad of difficulties posed by global climate change to Asian farming systems and farmers' livelihoods. Scientific breeding remains on the top of the options for developing novel technologies aimed at making rapid improvement on yield frontiers.

While the conventional breeding tools and methods were adequate to produce the high-yielding *miracle* varieties since the latter half of the twentieth century, they are proving increasingly inadequate to breed varieties with dramatic improvements in yield potential and tolerance to a range of yield-limiting biotic and abiotic stress factors. This is mainly because of the narrowing of the diversity in the gene pool available for exploitation.

The advent of the tools of modern biotechnology not only opened unprecedented opportunities for widening the gene pool but also contributed to improving the efficiency and cost-effectiveness of conventional breeding. While the benefits of the use of the tools of modern biotechnology in crop breeding seem obvious, their use also triggered controversies on the ground of perceived risks food and feed products of such technologies may pose to human health and environmental safety. The advanced industrialized countries that allowed commercial cultivation of biotech crops (also known as GMO crops), particularly those derived from the use of recombinant DNA[1] technologies, put in place stringent regulatory measures for risk assessment and approval.

In Asia, countries remain at different levels in their preparedness to adoption of modern biotechnology for crop improvement and also meeting their obligations under relevant international treaties and protocols that regulate safe use and transboundary movement of living modified organisms (LMOs). The Food and Agriculture Organization of the United Nations (FAO) remains actively engaged in providing technical assistance to developing countries in Asia in their efforts to build and strengthen institutional capacity for enactment and enforcement of biosafety rules and regulations and fostering regional collaboration on biosafety through Asian BioNet. As part of this effort, the FAO Regional Office for Asia and the Pacific held a workshop in Bangkok, Thailand from 17 to 20 June 2013 to explore opportunities for strengthening regional collaboration on biosafety.

A broad range of stakeholders including representatives from the FAO headquarters, national agricultural research systems and the private sector attended the workshop. Invited experts gave an overview of the global and regional status of the biosafety regulatory framework vis-à-vis adoption of GMO (genetically modified organism)

[1] *deoxyribonucleic acid*

technology, while invited resource speakers focused on scientific and technical aspects of risk assessment, risk management, testing, monitoring and detection of LMOs in food, feed, and processed production.

The national focal points representing member countries provided an overview of the existing status of biosafety framework in their respective countries, particularly with regard to national policies on biosafety, biosafety laws and regulations, biosafety administration systems, procedures for granting approval to GMO applications, current status on research, development and use of GMOs with a focus on challenges and key areas for institutional capacity building in biosafety. It was revealed from the presentations that all 11 countries represented in the workshop had in place their respective biosafety frameworks, laws and guidelines for handling GMOs, although there were considerable variations in the status of their implementation. Most countries have ongoing biotechnology research in the laboratory and greenhouse. Only a few countries processed applications for either environmental release and transboundary movement of LMO FFP (food, feed and processing). Capacity building/development is very much needed in all aspects of risk analysis (assessment, management and communications) and decision-making processes.

The workshop adopted a number of recommendations to streamline national efforts on biotechnology research and development. It called on participating countries to prioritize the traits and crops where biotechnological interventions are required so that capacity building can be effectively focused on technology development, risk analysis and containment requirements, including the biosafety compliant laboratory needs in the region. For effective information sharing on agri-biotechnology and biosafety, the activities of Asian BioNet as a regional coordinating mechanism will be revitalized with administrative support provided by Thailand's Department of Agriculture.

It was recommended that member countries send all available country-level information to the Secretariat of Asian BioNet twice a year for uploading on the Asian BioNet website, to be designed with FAO's support. The workshop also proposed developing a database of laboratories equipped with facilities for GM detection for each country with nodal persons for contact, coordination and information sharing. Other recommendations included organizing capacity building activities to harmonize/standardize processes, protocols, means and mechanisms of GM detection and sampling strategies vis-à-vis trans-boundary movement and domestic research and development (R&D)-based commercialized products as well as developing a regional project on fostering cooperation in biosafety among Asian countries.

Conclusion

The workshop achieved its objective and was ended successfully with renewed commitments from the participating countries to reactive Asian BioNet within shortest possible time. The member countries agreed to send country information on regular basis to the Secretariat for posting in the webpage of Asian BioNet. The workshop participants came from 11 countries: 7 SE Asia (Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Thailand and Viet Nam), 3 South Asia (Bangladesh, India and Sri Lanka) and 1 Near-East

(South Korea) to discuss and share experiences in the implementation of biosafety regulation in their own country. The participants were mixed – consisting of regulators from some countries and scientists particularly from countries with no/minimal experience in implementing biosafety regulations in their countries. The scientist participants appeared to have very limited knowledge and experience in biosafety regulation.

All participating countries have national biosafety framework, laws and guidelines for handling GMOs, although the status of its implementation varies considerably among the countries. Most countries have ongoing biotechnology research in the lab and greenhouse. Only a few countries have not received/processed applications for either environmental release (Article 15) or transboundary movement of LMO-FFP (Article 11). Capacity building/development is very much needed in all aspects of risk analysis (assessment, management and communications) and decision-making process. The country presentations were very useful in providing the background on the status of biosafety implementation and activities in the participating countries.

It was unanimously agreed that DOA will remain as Secretariat of "Asian BioNet" and will provide necessary administrative and logistic supports to keep Asian BioNet updated. The member countries will send all available information at country level to the Secretariat of Asian BioNet twice a year to post in the website of Asian BioNet. Decision was taken to redesign getup of Asian BioNet in cooperation with FAO.

The topics covered by the resource persons in the workshop were: overview of risk assessment and LMOs; problem formulation on environmental risk assessment (ERA); ERA for cultivation; AIA and ERA for commodity; risk management; risk communication, and detection of LMOs, which covered important aspects of biosafety.

There is an uneven status of implementation and capacities on biosafety regulation among the participating countries. Participants' feedback from both plenary and sideline discussions indicated the priority need for capacity development in risk assessment for LMO-FFP particularly on food safety assessment and effective risk communications. With regard to the conduct of the workshop, they congratulate FAO RAP/DOA for organizing the workshop. However, for future workshops, a pre-evaluation of the participants and post-evaluation of the workshop based on the assessment to be provided by the participants are highly recommended. The countries in the region should continue to collaborate to strengthen capacity within each country in all areas of biosafety implementation. This is very important in light of the forthcoming implementation of regional economic integration that will expand to zero tariffs almost all goods by 2015.

Recommendations

1. It is recommended that participating countries prioritize the traits and crops that require biotechnological interventions so that the capacity building can be focused on technology development, risk analysis and containment requirements, including the biosafety compliant laboratory needs in the region. (Action: All countries)

2. Operations of Asian BioNet should be revitalized for effective information sharing on agri-biotechnology and biosafety. The Department of Agriculture (DOA), Thailand will continue to act as Secretariat of Asian BioNet. They will provide all administrative and logistic supports to keep Asian BioNet updated.
3. Develop a database of laboratories working in GM detection in each country with nodal persons for contact, coordination and information sharing. (Action: DOA)
4. Organize capacity building courses and workshops to harmonize/standardize processes, protocols, means and mechanisms of GM detection and sampling strategies vis-à-vis transboundary movement and domestic R&D based commercialized products. (Action: India, FAO)
5. Coordination among various national agencies involved in the regulation of GMOs should be strengthened. (Action: All countries)
6. Countries are also urged to strengthen documentation and sharing of experiences in risk assessment and risk management. (Action: All countries)
7. With assistance of FAO, participating countries in cooperation with other regional and international agencies should strengthen their efforts to improve and harmonize at national and regional levels GMO risk assessment and risk management methods. (Action: FAO, all countries)
8. FAO, in cooperation with other agencies may organize regional workshops to address emerging issues, and effective communication of risk assessment and risk management decisions. (Action: FAO)
9. The net-work meetings should be organized every two years with rotation of host countries. (DOA, FAO, all countries)
10. FAO should bring out a status report on capacity development related to biosafety in Asia. (FAO)
11. A regional project on fostering cooperation in biosafety among Asian countries should be developed. (FAO)

1 Introduction

Knowledge and applications generated through biotechnological research are contributing to technological advancement in many countries of Asia and the Pacific region. Agricultural biotechnologies represent a broad range of technologies used for genetic improvement of plant varieties and animal populations, characterization and conservation of genetic resources, diagnosis of plant or animal diseases and other purposes. It is quite natural that different countries of the region are at different stages of development of their national biotechnology policy and of large-scale application of agricultural biotechnologies.

When it comes to application of recombinant DNA-based biotechnologies, also known as genetic engineering or genetic modification, many countries are yet to develop adequate capacities, including a robust framework of laws and regulations on biosafety for safe transfer, handling and use of the living modified organisms and their derivatives, taking into account their possible adverse effects on biodiversity, human health and transboundary movements.

An increasing number of countries in this region consider the potential of agricultural biotechnologies in general, and of agricultural genetic engineering in particular, to open up new opportunities for increasing agricultural production and productivity. While some countries strengthened their research on biotechnology, they lag behind in putting in place a regulatory biosafety framework necessary to transfer living modified organisms (LMOs)-FFP (food, feed and processing) to farmers' fields as well as to establish an integrated system for the importation of LMOs-FFP into the territory for commodity uses. The ongoing efforts in this direction are insufficient and yet to produce desired results. This will invariably impact on adoption of modern biotechnology products, although quite a good number of technologies are already available for transfer to clients.

Governments' stand and public policy on this issue are also important. Some countries of the region are quite advanced in this field. For example, China, Malaysia and India embraced these technologies for a long time and China is moving fast in this direction. Of late, Indonesia and the Philippines have taken a number of policy decisions to promote technologies developed through modern biotechnology including LMOs. If this trend continues in future, there may be technological divide among the countries of this region that would negatively impact on efforts for achieving food security and eradicating hunger in countries that lag behind.

The lack of dynamism in undertaking concerted efforts toward evaluation of modern biotechnology products in agriculture is due to bottlenecks at the decision-making levels in the public agricultural administrative systems. One bottleneck is the ambiguity in the decision-making processes to deal with the new technology products. Another is the lack of relevant experience in risk analysis of the new technology products, which is viewed as

a new cumbersome challenge and a negative perception that has little to do with scientific precaution but more to do with imaginary concerns. In addition, inadequate technical knowledge of public officials responsible for handling regulatory affairs controlling modern biotechnology, frequent changes of national focal points due to retirement or transfer to other jobs, lack of political commitment and negative attitudes toward modern biotechnology among a section of government functionaries, politicians as well as the public also contribute to dithering when the moment arrives for granting approval to GMOs after exhaustion of all regulatory requirements.

In short, a strong political commitment and decisive leadership is conspicuously absent for undertaking concrete steps for a science- and a reasoned policy-based approach toward modern biotechnology in agriculture. In many countries biosafety is treated as a cross-cutting issue and it appears on *ad hoc* basis in many sectoral policy documents without any follow-up concrete actions and as a result, it loses importance.

Some advancement was made in developing each member country's "National Biosafety Framework" (NBF) with support from development partners, mainly FAO, the United Nations Environment Programme – Global Environment Facility (UNEP – GEF) and the World Bank, to meet obligations of governments to moving forward the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Although most countries had already developed their own NBF, some have not approved it yet, thus blocking further progress on biosafety in these countries. Some countries are ambivalent about what to do next after NBF and how to implement the NBF. Some countries are taking steps without a clear direction about which components of NBF need further development in the form of approved documents. Some are moving to develop their respective regulatory frameworks in the form of laws, acts, and guidelines; however, very few have plans to develop biosafety policies.

Although biosafety measures are country-specific, it seems that lack of political commitment, poor technical knowledge and weak institutional facilities are responsible for the current state of uncertainty. Lack of regional coordination is another serious factor aggravating the current stalemate. But the prospect that the applications of modern biotechnology would play a significant role in the future in increasing food production and reduction of food insecurity should be carefully taken into consideration. Countries that have advanced biotechnology programmes are expected to be better placed to reap the benefits than those that currently lag behind in developing their capacities in modern biotechnology. The technological divide thus created will lead to an uneven playing field when trade in biotechnology products will grow in volume and countries negotiate the terms of trade. To avoid the situation of having to confront an uneven playing field in trade and investment in modern biotechnology, each country needs to develop its own biotechnology policies and biosafety regulatory systems.

FAO's technical assistance to member countries initiated just after the adoption of Cartagena Protocol was designed to support their efforts to put in place national biosafety rules and regulations so that the regulatory framework is robust and transparent facilitating rapid adoption of modern biotech products in agricultural development. Substantial

support was provided through the project entitled "Capacity Building in Biosafety of GM Crops in Asia (GCP/RAS/185/JPN)", which was implemented by FAO Regional Office for Asia and the Pacific, Bangkok, Thailand from 2002 to 2005. One of the major outcomes of this project was the establishment of an Asian network, dubbed as "Asian BioNet". To review the outcomes and impacts of the project, FAO and the Department of Agriculture (DOA) of Thailand organized a week-long regional workshop on biosafety in Bangkok from 30 November to 4 December 2009. FAO's support to the efforts is continuing through Asian BioNet.

From the outputs generated through this mechanism as well as feedback received from FAO country offices, it is clear that these countries need further support in the acquisition of knowledge and capacity development in biotechnology, development of national biosafety policies as well as further strengthening of biosafety network and functioning of the Secretariat established under the DOA (Thailand). This has set the stage for the FAO Regional Office for Asia and the Pacific (RAP) to plan a regional consultation cum training workshop with the objective of assisting member countries in developing required policy documents along with regulatory frameworks and other associated documents related to biosafety evaluation of biotech crops before recommending them for cultivation.

2 Opening Session

Mr Vili Fuavao, Deputy Regional Representative, FAO Regional Office for Asia and the Pacific, delivered the welcome address on behalf of **Mr Hiroyuki Konuma, Assistant Director-General and Regional Representative for Asia and the Pacific**. He greeted the participants and thanked the Royal Thai Government for its support and cooperation in undertaking activities on "Biosafety of GMO Crops in Asia." He stated that the purpose of the workshop is to assist member countries develop required policy documents including regulatory frameworks and other associated documentation related to biosafety evaluation of biotech crops before recommending them for cultivation. Specifically, the workshop would focus on the promotion of technical capacity of member countries on various issues of biosafety and LMOs associated with food and agriculture, supporting development of related policies and biosafety regulatory frameworks and further strengthening regional cooperation on biosafety and LMOs associated with food and agriculture including operationalization of the Asian BioNet.

Mr Fuavao acknowledged that the understanding on biosafety varies from country to country and that these countries are at different stages of developing their respective biosafety frameworks. Thus, the process initiated by DOA and FAO should continue in the future in order to enhance the countries' capacity on and understanding of biosafety. A significant aspect of the workshop was the attendance of all members of ASEAN+3 countries except Brunei Darussalam. He emphasized that the timing of the workshop was aptly designed to move forward in issues relating to biosafety and hoped that the workshop would succeed in achieving the expected outputs. Mr Fuavao thanked again the Department of Agriculture, Government of Thailand, for its excellent cooperation in arranging the workshop. He also expressed thanks to Mr Andrea Sonnino from FAO headquarters and Dr Jawahir Karihaloo from the APAARI for their attendance in the workshop.

Mr Alongkorn Korntong, Director of Biotechnology Research and Development Office, Department of Agriculture (DOA), Government of Thailand, delivered the inaugural address on behalf of **Mr Dumrong Jirasutas, Director-General of DOA**. He welcomed the participants and thanked the Biosafety team of FAO, the Biotechnology Research and Development Office of the Department of Agriculture, and all other relevant biosafety agencies from the members of the Association of South East Asian Nations (ASEAN) and countries all over Asia and the Pacific Region for their efforts and cooperation in holding this workshop. He highlighted the workshop's objectives of promoting technical capacity on biosafety, supporting policies and regulatory frameworks and further strengthening of the regional cooperation on biosafety through Asian BioNet. He expressed his conviction that all distinguished participants would contribute their expertise to attaining these vital and crucial objectives for building the capacity on biosafety in Asia.

Mr Korntong focused on the role of Asian BioNet as a platform for the acquisition of knowledge and capacity development in biotechnology, development of national biosafety policy, and further strengthening of biosafety network. He said that Thailand, through the Biotechnology Research and Development Office of the Department of Agriculture, is ready to serve as Asian BioNet Secretariat. He solicited support of the participants to his proposal for Thailand to become the Asian BioNet Secretariat and sought their commitment and active participation in this regional forum.

Subash Dasgupta, FAO RAP Senior Plant Production Officer, delivered the vote of thanks.

3 Technical Session: Invited Expert Presentations

Three expert presentations were made during this session. In the first expert presentation, **Dr Andrea Sonnino, Senior Agricultural Research Officer, FAO headquarters, Rome,** focused on the topic, "Agricultural Biotechnology: A global perspective and regional collaboration". He presented an overview of the global food and nutrition scenario, the state of the natural resources in the context of climate change and the role modern biotechnologies could play in increasing agricultural productivity and production.

Dr Sonnino stressed that the application of agricultural biotechnologies remains shrouded in controversy. The debate is heavily skewed toward GMOs. There are no significant signs of abating of the debate, although it began more than 20 years ago. The opposite positions are firmly entrenched in what has been called a 'global war of rhetoric'. According to him, the excessive attention paid to GMOs and the polarized debate caused significant damage to the prospects of non-GMO biotechnologies. He listed a number of non-GMO biotechnologies that benefitted smallholders: eradication of rinderpest, New Rice for Africa (NERICA), marker-assisted selection (MAS) (rice and pearl millet), artificial insemination and embryo transfer (cattle), disease-free propagation materials (banana and plantain, root and tubers) and prophylaxis for aquatic organisms.

Dr Sonnino summarized the existing state of GMO cultivation as follows:

- There was success with 170 million ha (10 percent of cultivated land) brought under GMO cultivation.
- It is limited however to a few crop plants and traits.
- Few private companies dominate the sector.
- It is difficult to evaluate the impact on smallholders because of low quality data, uneven approaches, lack of social studies and non-uniform results.
- The regulation on GMO cultivation is complicated and expensive.
- There is low acceptance of GMO in some countries.

Highlighting FAO's role, Dr Sonnino mentioned that the FAO international technical conference on "*Agricultural biotechnologies in developing countries: Options and opportunities in crops, forestry, livestock, fisheries and agro-industry to face the challenges of food insecurity and climate change*"[2] laid emphasis on the following:

- Agricultural biotechnologies have not sufficiently benefited smallholder farmers in developing countries.
- Biotech research and development (R&D) should be focused on the needs of smallholder farmers.

[2] Referred to as ABDC-10.

- Effective communication strategies are needed to promote public participation in decision-making;
- Partnerships among countries will facilitate the biotech development and use.
- Enabling national biotechnology policies and science-based regulatory frameworks are needed.

In conclusion Dr Sonnino envisioned the role of biotechnologies in sustainable increase of agricultural production as follows:

- Food availability should increase 60 percent by 2050 (2.2 percent per year) to meet the increasing food demand and face climate change, while improving the natural resources base.
- This target can be achieved mainly by introducing sustainable practices to increase productivity.
- Smallholders and family farmers play a critical role in the achievement of food security.
- Sustained investments and capacity development in agricultural innovation are crucial to development.
- Biotechnologies are an important source of innovation that has not sufficiently benefited small and family farmers.
- GMOs can help but have limitations.

Mr Jawahir Karihaloo, Coordinator, APAARI and Mr Kavita Gupta from National Bureau of Plant Genetic Resources (NBPGR), India, made a presentation on "Biosafety Regulations of Asian Countries". They provided a picture of the current state of GM crops that were approved and have been under cultivation (since 2012) in Asian countries as follows:

- GM crops are under commercial cultivation in China, India, Pakistan, the Philippines, and Myanmar.
- China, Japan, Republic of Korea, the Philippines, and Thailand have approved GM crops for food and livestock feed.
- In India, the area under Bt cotton reached 10.8 million hectares (mha) in 2012, constituting 90 percent of the total cotton area of the country.
- In Pakistan, Bt cotton area covers 2.8 mha.
- In the Philippines, GM corn covers 4.5 percent of 1.2 mha potential yellow corn area.

The presentation focused on expansion of Bt cotton cultivation in India as a success story with GM crops showing yield increase by 40 percent, pesticide spray reduction from 4.2 kg/acre to 2.6 kg/acre, farmers' net cost savings of USD 20-24/ha and raw cotton export increase from USD 16.5 million in 2002-2003 to USD 2.6 billion in 2009-2010. The authors also provided a chronology of milestones in the development of biosafety regulations in the Asian region:

- **India** – 1990 (Recombinant DNA Safety Guidelines); 1998; 1999; 2008
- **the Philippines** – 1991 (Biosafety Guidelines on Genetic Engineering); 1998; 2002; 2004
- **Thailand** – 1992 (Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work and for Field Work and Planned Release)
- **Malaysia** – 1997 (National Guidelines for the release of GMOs); 2007; 2010
- **China** – 2001 (Regulation on Administration of Agricultural Transgenic Biosafety); 2002; 2007
- **Japan** – 2003 (Law on Conservation and Sustainable use of LMOs); 2011
- **Bangladesh** – 2005 (Biosafety Guidelines); 2010
- **Pakistan** – 2005 (Biosafety Rules)
- **Cambodia** – 2008 (Law on Biosafety)
- **Iran (Islamic Rep. of)** – 2009 (National Biosafety Act)
- **Viet Nam** – 2010 (Decree on biosafety management of GMOs)
- **Indonesia** – 2011 (Decree No. 61/2011 on evaluating release of GM crops); 2012

The speakers summarized the status of regulatory preparedness in Asia as follows:

- **Countries that have enforced biosafety regulations:** Bangladesh, China, India, Indonesia, Iran (Islamic Rep. of), Japan, Malaysia, Myanmar, Pakistan, the Philippines, Republic of Korea, Thailand, Viet Nam
- **Countries that have Biosafety Regulations at various stages of development:** Bhutan, Cambodia, DPR Korea, Lao PDR, Nepal
- **Almost all the countries in Asia and the Pacific region have become Parties to the Protocol, except Singapore.** But, becoming Parties to the Protocol does not necessarily reflect preparedness.

The speakers likewise mentioned that the provisions for risk assessment and risk management under the Regulations were as follows:

- **China** – Risk assessment is called "safety assessment system, risk management system "safety system" with clear-cut implementation bodies.
- **Indonesia** – Mechanism is outlined in GM regulation and defines risk assessment on environment, human, and animal health.
- **Republic of Korea** – Two separate systems for obtaining food safety approvals and for conducting environmental risk assessment for biotech crops.
- **Bangladesh, India, Pakistan, and the Philippines** – The risk assessment is done on a case-by-case basis depending on the level of risk and end use with several ministries/committees being involved.
- **Japan** – Two separate systems exist for obtaining food safety approvals and for conducting environmental risk assessment on biotech crops but under a joint

commission. All status information is available at the website of Japan Biosafety Clearing House (J-BCH).

- **Thailand** – Risk assessment of GMO is categorized as work bearing no risk, work bearing low risk, and work bearing high risk.

The Monitoring and Inspection Systems under the biosafety regulations were:

- **China –** Regulations stipulate authorities, coordination mechanisms, emergency handling system for monitoring of GMOs.
- **India, the Philippines –** Monitoring systems with specific committees are defined under various ministries for effective monitoring and inspection.
- **Thailand, Pakistan –** Institutional arrangements for monitoring and control are similar to India, with several organizations involved.
- **Indonesia –** Biosafety Commission monitors the biosafety testing and assessment. Results are publicized by mass for 60 days.
- **Republic of Korea –** No crops using biotechnology have been commercialized to date.
- **Bangladesh –** Only reporting mechanism has been spelt out.
- **Japan –** Regulation is silent on mechanism for monitoring and inspection.

Summarizing the discussion on biosafety regulations, Dr Karihaloo and Dr Gupta explained the components of a National Biosafety Framework in Asian countries developed with United Nations Environment Programme – Global Environment Facility (UNEP – GEF) fund. They also presented the model of Regional Collaboration in Regulatory Management, a one-door-one-key approach developed by the European Food Safety Authority (EFSA). Reflecting on the suitability of the European Union (EU) setup for the Asian region, the authors suggested that regional and sub-regional efforts may be initiated with mutual understanding of regulatory systems, sharing of information including risk assessment dossiers as well as capacity strengthening for risk assessment, management, handling, and detection of LMO's and communication systems.

The speakers concluded their presentation by recommending the following:

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

- Collaboration among countries can be harnessed by resource sharing (technical, material, and expertise), experience sharing (methodologies and materials), information sharing and regional capacity building (regional centres of excellence).

Ms Sonny Tababa, Biotechnology Affairs Director, CropLife Asia, presented industry perspectives on biosafety capacity building. CropLife Asia[3] is currently implementing a number of programmes in biosafety capacity building. She also presented the Technology Access Initiatives Framework that support continued global adoption of biotech crops.

Ms Tababa explained that biotech product developers comply at each stage of product development with safety assessment according to the UN: codex guidelines/OECD principles as well as other regulations. Outreach for informed decision making in the form of information sharing/educational outreach towards science-based regulations constitutes an important aspect of Technology Access Initiatives. In this endeavor, CropLife supports media outreach, the Pan-Asia Farmer Exchange, multi-media publications and new social media. Started in August 2007, the programme is now on its seventh year and includes 356 participants from Asia: China, India, Indonesia, Japan, Pakistan, the Philippines, Republic of Korea, Taiwan Province of China, Thailand and Viet Nam. It is a platform for knowledge sharing and exchange on agri-biotech with emphasis on biotech crops. It likewise brings together key stakeholders to learn about plant biotechnology through first-hand experience.

Ms Tababa focused on information sharing as part of technology access initiative to encourage value chain support. The approach entails continuous discussions with the value chain actors at local, regional and international levels to ensure acceptance of plant biotechnology. It also includes dialogue with the value chain actors to identify concerns that may exist about the technology and its impact on stakeholder groups or trade as well as enabling work towards mutually agreeable solutions.

In her presentation, Ms Tababa drew attention to the Global Alliance for Ag Biotech Trade (GAABT)- "Farm to Fork" industry coalition as an approach for working together across the agricultural/food chain to encourage national solutions to avoid trade disruption due to low-level presence. The alliance includes the following partners:

- **Grain/feed**
  - ➢ International Grain Trade Coalition (IGTC)
- **Producer Groups**
  - ➢ American Soybean Association/US Soybean Export Council
  - ➢ National Cotton Council
  - ➢ National Corn Growers Association
  - ➢ US Grains Council
  - ➢ US Wheat Associates

[3] CropLife Asia is an industry network that incorporates eight member companies (BASF, Bayer CropScience, Dow AgroSciences, Monsanto, DuPont, Syngenta, FMC and Sumitomo Chemical), two associate companies and 15 national associations in Asia.

- **Food**
  - ➢ Grocery Manufacturers Association (GMA)
- **Seed**
  - ➢ International Seed Federation (ISF)
  - ➢ Regional Seed Trade Associations (e.g. Seed Association of the Americas (SAA)
  - ➢ National Seed Trade Associations (e.g. American Seed Trade Association, Canadian Seed Trade Association)
- **Technology Providers**
  - ➢ CropLife International (CLI)
  - ➢ CLI Global Network of Regional and National Trade Associations (e.g. AgroBio Colombia, EuropaBio, CropLife Korea)

Ms Tababa stressed the importance of partnership and collaboration as vital to progress in science and innovation and the latter's adoption, no matter what technology. Partnerships come in a wide variety of forms: teaching/training researchers, information sharing about technology platforms, negotiations around access to patent-protected technology and funding. She put forward the following recommendations for biosafety capacity building: encouraging harmonized regulatory processes, conducting joint safety reviews, mutually accepting safety assessment, mutually accepting approval — at least concerning the food/feed aspect and developing a regional framework rather than separate country systems.

In their presentation, **Subash Dasgupta and Dr Hathairat Urairong, Senior Expert on Biotechnology, Department of Agriculture, Thailand**, reviewed the progress of Asian BioNet since 2009. They provided an update of activities undertaken by Asian BioNet, an initiative of the FAO Regional Office for Asia and the Pacific on Capacity Building in Biosafety of GM Crops in Asia. They informed that the Asian BioNet was established to assist countries in the region in safely harnessing the benefits of biotechnology in accordance with relevant global agreements on the subject.

The initiative focuses on the development and harmonization of an appropriate regulatory framework to deal with biosafety concerns relating to GM crops as well as the collection, analysis, dissemination and exchange of information on biotechnology and GM-related biosafety standards through inventories, databases, and decision support systems. They familiarized the participants with the output of key activities implemented by Asian BioNet.

4 Technical Session: Highlights of Country Reports

The information and data contained in the country presentations were reorganized and presented under the following relevant headings in order to focus discussion on inter-country variations in the state of institutional capacity for biosafety in Asian countries. The list of presenters is shown in Annex V.

4.1 National Policy Framework on Biotechnology

Bangladesh

The National Biotechnology Policy 2012 was approved by the Government in November 2012. The policy stipulates that "in order to keep pace with the fast advancing field of modern biotechnology, achieve world class competence in different areas of biotechnology and create enabling environment for modern biotechnology research, development extension and commercialization, appropriate measures will be taken for infrastructure and human resource development and creation of centres of excellence in identified priority areas of biotechnology based on national needs. Emphasis will be given on intellectual property rights, indigenous community knowledge, biosafety, biodiversity and other related issues in order to ensure safe and judicious use of this technology".

High-level institutional mechanisms such as the National Taskforce on Biotechnology of Bangladesh (NTBB) and the National Executive Committee on Biotechnology (NECB) have been established for effective monitoring and implementation of the policy. The National Authority on Biotechnology will act as an umbrella of the other regulatory authorities in the respective ministries. Under the NECB, National Technical Committees (NTCs) have been formed with separate terms of references for biodiversity, biosafety, crop biotechnology, animal and fish biotechnology, industrial biotechnology and medical biotechnology.

India

The National Biotechnology Development Strategy formulated by the Department of Biotechnology stipulates that "the strategy will lay a strong foundation for discovery and innovation, effectively utilizing novel technology platform with potential to contribute to long-term benefits in agriculture, animal productivity, human health, environmental security and sustainable industrial growth"[4].

[4] Karihaloo, J.L. and Kavita Gupta. 2013. *Biosafety Regulations of Asian Countries.* Presented at FAO Regional Workshop on Strengthening Regional Collaboration and National Capacity Building on Biosafety in Asia, Bangkok, 17-20 June 2013.

Viet Nam

The Government policies encompass strong support for application of biotechnology in agriculture, support for national programmes for biotech R&D in agriculture, aquaculture, and processing as well as capacity building in biotech R&D and capacity building in biosafety.

The overall objectives of the key national programme on development and application of biotechnology in agriculture and rural development up to the year 2020 are the followings:

- To develop plant varieties, domestic animals, microorganisms, bioproducts with high yield, good quality and economical efficiency and better serve the needs of economic restructuring in agriculture and rural development.
- To improve the quality and competitiveness of agricultural products, increase the rate of growth of agricultural, forestry and aquatic products so as to serve consumer demand and exports.

To achieve these objectives, ongoing efforts are focused on basic and applied research: through implementing research projects in crop plants, forest plants, microbiology, livestock husbandry, agro-bioindustry for agro-production and markets. These also include capacity building, manpower improvement-education programmes for Master and PhD study in different countries, infrastructure building, modernization of machinery and equipment, and strengthening international cooperation.

Lao PDR

The Biotechnology and Ecology Institute (BEI) of the Ministry of Science and Technology (MOST) formulated the following research and development strategies up to the years 2020-2030: "… Make intention to strengthen capacity of the scientific research, human resource development, infrastructure establishment and international cooperation for the purpose of establishing the Institute as Center of Excellence on Education, Research, Development, Applying and Public Service in the fields of biotechnology and ecology, to be within the regional level by the year 2020 and the international level by the year 2030; by using diversity of the genetic resources for:

- meeting the challenge of conservation and sustainable development;
- suitable, harmonization and focusing on the problem solution of related sectors;
- socio-economic development; and
- national poverty reduction and prosperity purpose."

Sri Lanka

The country has a National Biotechnology Policy in place. The key aspects of the policy are:

- Government commitment for research, development and commercialization of biotechnology;
- promotion of public awareness and position of biotechnology in society;
- development of human resources as part of capacity building;
- sustainable use of biodiversity for biotechnology;
- enhancing opportunities for biotech-related industries, and entrepreneurship in agriculture, health, industry, energy and environment; and
- establishment of centres of excellence and biotech parks.

Thailand

A key policy statement with regard to modern biotechnology is "Do not allow growing GM crops commercially unless they have been proven as safe for the environment and human health". The GM seed has to be regulated by DOA under the Plant Quarantine Act and is allowed only for research purpose which can be conducted only in laboratories and under confinement in greenhouses. Imports of transgenic soybeans and corn for FFP uses are allowed.

4.2 National Biosafety Framework

Bangladesh

The National Biosafety Framework (NBF) has been developed following an extensive assessment of biotechnology and biosafety in Bangladesh. The Framework provides the basis for future regulation of the management of GMOs in Bangladesh. The NBF consists of the following elements: National Policy and Guidelines on Biosafety, Legal Regime, Administrative Systems, Monitoring and Enforcement Systems, and Public Participation, Education and Awareness Procedures.

India

The National Biosafety Framework (NBF) of India consists of the following elements:

- Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms (HMO)/Genetically Engineered Organisms or Cells (1989) under the EPA (1986) known as 'Rules 1989' by the Ministry of Environment and Forests (MOEF);
- The Biological Diversity Act (2002), by the Ministry of Environment and Forests (MOEF);

- Plant Quarantine (Regulation of Import into India) Order (2003) by the Department of Agriculture and Cooperation empowering the National Bureau of Plant Genetic Resources under the Ministry of Agriculture (MOA) to deal with exchange of GM crops;
- National Seed Policy (2002) by MOA;
- DGFT Notification Relating to Inclusion of GM Policy in Foreign Trade Policy (2006-2009) by the Ministry of Commerce and Industries (MoC&I);
- Food Standards and Safety Act (2006) by the Ministry of Health and Family Welfare (MoH&FW);

Lao PDR

The Lao National Biosafety Framework is a comprehensive document that consists of the following elements: the Government policy on biosafety, the regulatory regime for biosafety, administrative systems for biosafety, mechanisms for public education awareness, capacity building programme to implement the Cartagena Protocol on Biosafety and project priorities to implement the Lao National Biosafety Framework.

Sri Lanka

The country's National Biosafety Framework includes five sections: Government policy on biosafety, regulatory regime, system to handle notifications or requests for authorizations, mechanisms for public awareness, education and participation, and system of monitoring and enforcement.

Thailand

The National Biosafety Framework adopted in 2007 entails a combination of policy, legal, administrative and technical instruments as well as mechanisms that are set in place to address safety for the environment and human health in the field of modern biotechnology. It consists of five elements: biosafety policy, regulatory regime, system to handle requests (administrative, risk assessment and management, decision making), follow-up actions (monitoring, inspection, and enforcement), and public awareness, education, and participation.

4.3 National Policies on Biosafety

Bangladesh

- Biosafety Guidelines of Bangladesh

The document was formulated by the Ministry of Science and Technology in 1999. Following the ratification by Bangladesh of the Cartagena Protocol on Biosafety in 2004, the document was updated in 2008 by the Ministry of Environment and Forests.

Biosafety guidelines are applicable to all research and development activities of modern biotechnology conducted in the laboratories of the government research institutes, state enterprises, universities, international organizations located in Bangladesh, private companies and non-governmental organizations. It applies to laboratory and field trial, transboundary movement, transit, handling and use of all GMOs/LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

- Guidelines for the Safety Assessment of Foods derived from Genetically Engineered (GE) Plants
- National Biotechnology Policy
- Crop Biotechnology Policy Guidelines
- Crop-wise Standard Operating Procedures (SOPs) for Confined Field Trials (CFTs)
- Inspector Manuals for confined field trials of GE plants
- Crop-wise data recording formats for CFT

India

- Recombinant DNA Safety Guidelines, 1990
- Revised Biosafety Guidelines, 1994
- Revised Guidelines for Research in Transgenic Plants, 1998
- Guidelines for Generating Pre-clinical and Clinical Data for rDNA Vaccines, Diagnostics and other Biologicals, 1999
- Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants In India and Standard Operating Procedures (SOPs), 2008
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants in India, 2008
- Protocols for Safety Assessment of Genetically Engineered Plants, 2008

The Philippines

In 1991, the Philippines became the first country in Southeast Asia to put in place its national biosafety guidelines. The Department of Agriculture formulated the following policy recommendations to enhance the adoption process of biotech crops and to enjoy fully the benefits of modern biotechnology while safeguarding the health of humans and animals and safety of the environment:

- Food safety assessment in situations of low-level presence of recombinant-DNA plant materials in food and feed
- New directive on insect resistance management for Bt Corn
- Guidelines on intermediate stacks
- Measures required when planting yellow corn seeds in sloping areas

Lao PDR

- Biosafety Guidelines on Biotechnology and Genetic Engineering (For field work and planned release), 2004
- Biosafety Guidelines on Risk Assessment and Management to LMO Foods, 2004
- Biosafety Guidelines on Biotechnology and Genetic Engineering (For laboratory work, 2004)

Cambodia

- The National Action Plan on Biosafety and Modern Biotechnology (NAPBB)

The National Action Plan on Biosafety and Modern Biotechnology (2010-2014) was developed to chart a roadmap for sound environmental management of LMO/GMO application in Cambodia. Emphasis is given to institutional capacity development at all levels in both public and private sectors for the development, management and safe use of modern biotechnology, which presently are virtually non-existent. The NAPBB clearly underscores the important roles modern biotechnology can play in enhancing competiveness of the agriculture sector – the backbone of the country's economy, food security, and social well-being while protecting both human health and environmental stewardship. Specific objectives of the plan are to:

- establish moral, ethical and biosafety guidelines for the appropriate use of biotechnology;
- ensure better management, conservation and use of genetic resource and biodiversity through the use of biotechnological tools;
- promote strengthening of national biotechnology R&D capacity;
- promote capacity building in biotechnology and biosafety in terms of knowledge generation and development as well as public perception;
- support commercialization of biotechnology products and processes; and
- increase public awareness of the potential of biotechnology.

Sri Lanka

- National Biosafety Policy

The country's National Biosafety Policy got Cabinet approval in the year 2005. The regulatory regime has identified some provisions in existing laws that could be used to control, check and even ban introduction of certain GMOs. It suggested drafting and enacting a new biosafety law that would consider all the weaknesses in the existing legal framework in complying with biosafety policy and regulatory framework.

Thailand

- 2004 Biosafety Guidelines for Work Related to Modern Biotechnology or Genetic Engineering

The guidelines classify transgenic research into the following four categories:

- ➢ Category 1: Safe experiment;
- ➢ Category 2: Low-risk hazard to laboratory staff, community and environment;
- ➢ Category 3: Medium-risk hazard to the researcher, the community, or involving the treatment of patients using rDNA technology as well as projects with undefined risks; and
- ➢ Category 4: High-risk hazard or considered immoral in principle and thus strictly prohibited.

- Biosafety Guidelines for Industrial Applications of Genetically Modified Organisms

The guidelines specify good industrial large-scale practice (GILSP) safe work. The following three categories have been identified:

- ➢ Category 1 – Safe work but not within the criteria of GILSP;
- ➢ Category 2 – Low-risk hazard work; and
- ➢ Category3 – Medium-risk hazard work.

4.4 National Biosafety Laws and Regulations

Bangladesh

- Biosafety Rules of Bangladesh, 2012

It is the key legal document that regulates the development, import, export, use and movement of all GMO products. The Law provides for punitive measures against misuse of GMO products. The Biosafety Guidelines of Bangladesh is legally binding under the Biosafety Rules. The Ministry of Environment and Forests is the national authority to enforce the Biosafety Rules.

India

India ratified the Cartagena Protocol on Biosafety in January 2003. It has signed the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress in October 2011. The key national regulations are:

- Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms (HMO)/Genetically Engineered Organisms or Cells, 1989 under the EPA (1986) known as "Rules 1989" by MOEF.

This document covers all activities involving research and development of products containing GMOs including transgenic crops, pharma products, industrial products, food and foodstuffs, field trials/clinical trials, deliberate/unintentional release, and import/export/manufacture.

- The Biological Diversity Act, 2002 by MOEF
- Plant Quarantine (Regulation of Import into India) Order, 2003 by the Department of Agriculture under the MOA
- DGFT Notification Relating to Inclusion of GM Policy in Foreign Trade Policy (2006-2009) by the Ministry of Commerce and Industry (MoC&I).
- Food Standards and Safety Act, 2006 by MoH&FW.

Indonesia

- Law No. 7 on Food, 1996
- Decree of Minister of Agriculture on Biosafety of GEP, 1997
- Joint Decree of Four Ministes on Biosafety and Food Safety of GEP, 1999
- Law No. 21 on Ratification of Cartagena Protocol on Biosafety, 2004
- Government Regulation No. 28 on Safety, Quality and Nutrition of Food, 2004
- Government Regulation No. 21 on Biosafety of GEP, 2005
- Law No. 32 on Protection and Management of Environment, 2009
- Presidential Decree No. 21, 2005
  - ➢ R&D of GEAP (containment and field test);
  - ➢ Obligation of risk assessment (environment and food safety of GMO for environmental release and direct use for food and processing;
  - ➢ Mitigation and monitoring; and
  - ➢ Regulatory Bodies (BC, BCH, BTT).

The Regulations cover the following activities:

- Risk assessment of environment safety (biotech crops)
  - ➢ Biosafety containment tests
  - ➢ Confined field trial
- Monitoring of confined field trials
- Risk assessment of food safety
- Risk assessment of feed safety
- Variety release for commercialization

Viet Nam

Viet Nam became an official Party of the Cartagena Protocol on Biosafety since 19 April 2004. The key national legislations are:

- Law on Biodiversity: This law, enforced since July 2009, provides for biodiversity conservation and sustainable development; rights and obligations of organizations, households and individuals in the biodiversity conservation and sustainable development.
- Circular No. 69/2009/TT-BNNPTNT: This circular stipulates on the regulation of field trials of Genetically Modified Crops (GMC) to biodiversity and environment in Viet Nam.
- Decree No. 69/2010/ND-CP: This decree stipulates the biosafety management of the related activities on genetically modified organisms, genetic specimen, and products originating from genetically modified organisms.
- Law on Food Safety: This law, enforced since July 2011, provides for rights and obligations of organizations and individuals in assuring food safety: conditions for assuring safety of foods and food production, trading, import and export; food advertisement and labeling; food testing; food safety risk analysis: prevention, stopping and remedying of food safety incidents; food safety information, education and communication; and responsibilities for state management of food safety.
- Decree No. 108/2011/ND-CP: It amends some articles of the Decree No. 69/2010/ND-CP dated June 6th, 2010 of the Government on Biosafety of Genetically Modified Organisms, Genetic Specimen and Products Derived from Genetically Modified Organisms.
- Decree 38/2012/ND-CP: It stipulates implementation of the Food Safety Law.
- Circular No. 09/2012/TT-BTNMT: It regulates the provision and exchange of information and data on genetically modified organisms.
- Circular 08/2013/TT-BTNMT: It stipulates the procedures for granting and revoking biosafety certificates for genetically modified crops.
- *Thông tư số 21/2012/TT-BKHCN:* It regulates biosafety in research, technology development of genetically modified organisms.
- *Thông tư số 20/2012/TT-BKHCN:* It provides guidance on conditions, order and procedures for recognizing laboratory studies on genetically modified organisms.

The following two legal documents are being prepared:

- *Circular:* Regulation on order and procedures for granting and revoking certificates for genetically modified plant to be used as food/feed; and
- *Circular:* Regulation on labeling of foods derived from GMO

The Philippines

The Philippines has a ten-year track record of a functional regulatory system.

- Biosafety Regulations:

One of the core elements of biosafety regulations in the Philippines is a rigorous risk assessment and management process which is used effectively by both technology developers and regulators. These regulations are in compliance with the Cartagena Protocol on Biosafety and pertinent principles and guidelines of the Codex *Alimentarius* Commission.

Lao PDR

The following four draft legislations are proposed for consideration by the Lao National Assembly during 2013-2014.

- Biosafety Law 2014: The objectives of this Law are (i) to ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, (ii) to provide a transparent and predictable process for review and decision-making on such LMOs and related activities and (iii) to implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
- The Biosafety (Contained Use) Regulations 2014: The objectives of these Regulations are to ensure that (i) potential adverse effects of LMOs are addressed and to protect human health and the environment when conducting contained use, and (ii) contained use activities are conducted in a safe manner so as not to escape into the environment.
- The Biosafety (Environmental Release) Regulations 2014: The objectives of these Regulations is to ensure that: (i) LMOs intended for release into the environment are released in a safe, transparent and scientifically sound manner and (ii) potential adverse effects of LMOs are addressed prior to their release into the environment, with a view to protecting human health and the environment.
- The Biosafety (Food and Feed Safety) Regulations 2014: The objectives of these Regulations are (i) to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to living modified food and feed, whilst ensuring the effective functioning of the internal market, (ii) lay down procedures for the approval and supervision of living modified food and feed and (iii) lay down provisions for the labeling of living modified food and feed.

Cambodia

- Law on Biosafety

Promulgated in 2008, the Law has 45 articles and 11 chapters: (i) General Regulations, (ii) Government Institutions, (iii) Import of LMOs, (iv) Export of LMOs, (v) Assessment of LMOs, (vi) Documentation for LMOs, (vii) Confidential Information, (viii) Review of Decision, (ix) Public Information, Awareness and Participation, (x) Penalties and (xi) Final Provisions.

The main objective of the Law is the implementation of biosafety based on precautionary principles and sound management of LMOs with respect to transportation, handling, storage and use in order to prevent any negative impact on biodiversity conservation, human health, and to ensure effectiveness of conservation and exploitation of biodiversities in a sustainable manner. The main scope of this Law is addressing the application of import-export, contained use, the deliberate release of LMOs into the environment, and/or direct use of LMOs for food or feed or for processing, which may affect conservation and sustainable use of biodiversities as well as human health.

Exceptions provided for in the law are as follows:

- ➢ LMOs used as pharmaceutical medicines covered by international agreement(s);
- ➢ LMOs subject to transit purpose that are not intended for use in Cambodia;
- ➢ Other LMOs that have been exempted by competent authorities; and
- ➢ Non-living LMOs products or substances of abiotic genetic LMOs.

A related regulation, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, was passed by Senate on 22 May 2013. The Law on Safety and Quality of Agricultural Products is in the preparation process by MAFF.

- Sub-decree on Mechanisms and Procedures for Implementing the Law on Biosafety

This Sub-decree was amended in 2010 to provide specific mechanisms and procedures deemed necessary for effective implementation of the Biosafety Law in order to (i) curb adverse effects on conservation of biodiversity, environment and human health, (ii) ensure effectiveness of conservation and sustainable use of biological diversity and (iii) promote awareness on modern biotechnology and prevent risks arising from the use of LMOs. The scope of this Sub-decree covers all activities pertinent to Article 3 of the Law on Biosafety which defines the conditions as to which groups of LMOs this Law shall and shall not be applied to in respect to import and export, contained use, deliberate release to the environment and direct use as food or feed or for processing.

The Sub-decree consists of 66 articles and 13 chapters: (i) General Provisions, (ii) National Steering Committee for Biosafety, (iii) Scientific Advisory Team, (iv) Procedures for Import

of Living Modified Organisms, (v) Risk Assessment, (vi) Exports of LMOs, (vii) Confidential Information, (viii) Risk Assessment Management, (ix) Public Information, Awareness-raising and Participation, (x) Resources, (xi) Penalties, (xii) Transitory Provisions and (xiii) Final Provisions.

Republic of Korea

The Republic of Korea effectuated the Convention on Biological Diversity (CBD) in December 1993, and then the Cartagena Protocol on Biosafety (CPB) in 2003 to observe the CBD protocol. The Act on Transboundary Movements of LMO and other related matters (LMO Act) was effectuated in January 2008 to implement CPB.

Currently, the Republic of Korea's main acts for food and feed regulations are:

- Food Sanitation Act

The Act regulates human health safety assessment and review of GMOs used as food ingredients.

- *Feed Management Act*
- *Agricultural Products Quality Management Act*

Both of these acts regulate GM feed safety management and labeling. Overall, everything related to GMOs is being regulated by the *LMO Act* since 2008.

Sri Lanka

Sri Lanka has a broad range of laws on biosafety:

- Science and Technology Development Act, No. 11 (1994) enforced by the Ministry of Science and Technology;
- Animals Act, No. 29 (1958) by the Department of Animal Production and Health;
- Animal Feed Act, No. 15 (1986) by the Department of Animal Production and Health;
- Animal Diseases Act, No. 59 (1992) by the Department of Animal Production and Health;
- Fisheries and Aquatic Resources Act, No. 2 (1996) by the Department of Fisheries;
- National Heritage Wilderness Areas Act, No. 3 (1988) by the Forest Department;
- Fauna and Flora Protection (Amendment) Act, No. 49 (1993) by the Department of Wildlife Conservation;
- Quarantine and Prevention of Diseases Ordinance No. 3 (1897) by the Department of Agriculture and Department of Animal Production and Health;
- Consumer Affairs Authority Act, No. 9 (2003) by the Ministry of Commerce and Consumer Affairs;
- Water Hyacinth Ordinance No. 9 (1909) by the Department of Agriculture;

- Plant Protection Act, No. 35 (1999) by the Department of Agriculture;
- Forests, Chapter 283 (1907) by the Forest Department;
- Forest (Amendment) (1995) by the Forest Department;
- Food Act, No.26 (1980) by Food Commissioner's Department;
- National Environmental Act, No. 47 (1980) by the Central Environmental Authority;
- Control of Pesticides Act, No. 33 (1980) by the Department of Agriculture;
- State Lands Ordinance (Chapter 286) (1947) by the Land Commissioner's Department;
- Food Regulations 2006: This legislation that directly deals with biosafety came into effect from January 2007. The Ministry of Healthcare and Nutrition developed these regulations under the Food Act of 1980. Food which contains or has genetically modified organisms less than 0.5 percent is exempted from the provisions of these regulations. The Act stipulates that no person shall import, store, transport, distribute, sell or offer for sale any GMO as food for human consumption, any food containing GMOs or any food produced from ingredients produced from GMOs without the approval of the Chief Food Authority;
- Draft Biosafety Act.

Under the Draft Biosafety Act, six Sectoral Competent Authorities are appointed.

- ➢ Department of Agriculture: agricultural and non-agricultural (e.g. forest species, ornamentals plants and planting material, microorganisms, and animals)
- ➢ Department of Animal Production and Health: domestic animals including fish, birds and bees, and any other domesticated or wild animals kept in captivity and animal feed
- ➢ Department of Health: food
- ➢ Department of Fisheries and Aquatic Resources: all aquatic animals and aquatic plants from zooplankton and phytoplankton to higher forms
- ➢ Department of Wildlife Conservation: all animals except listed tropical aquarium fish and domestic animals
- ➢ Ministry of Industries: industrial products

The Draft Biosafety Act is presented in the diagram below:

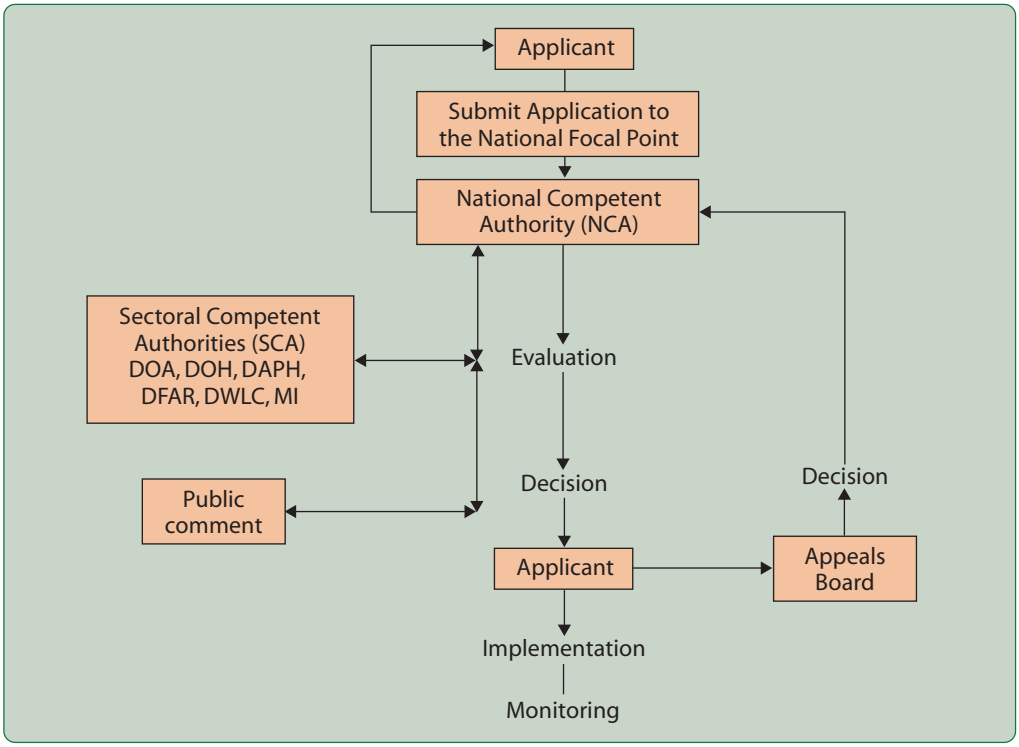

Diagram 1. Draft Biosafety Act, Procedure for Approval of Application

A dialogue with scientists was organized by the National Science Foundation (NSF) with the participation of scientists, academicians, ministry representatives and private sector representatives to elicit their views, comments and perception on the draft Biosafety Act with the aim of making necessary amendments.

The participants consisted of a cross section of the academicians, scientists, related to agriculture and medicine and also industry personnel.

In the first meeting held at the Hotel Cinnamon Grand, Colombo, Sri Lanka on 3 July 2012, presentations were made by resource persons from India and Sri Lanka prior to discussions. Presentations were followed by breakout sessions arranged in groups related to Agriculture, Medicine and Industry. A process of deliberation was expected among the participants and resource personnel to elicit diverse ideas.

Malaysia

- Biosafety Act, 2007 (enforced since 2009)

The objective of the Act is to protect human, plant and animal health, the environment and biological diversity through regulating the release, importation, exportation and contained use of Living Modified Organisms (LMOs) and products of LMOs.

The scope of the Act is limited to modern biotechnology as defined in the Cartagena Protocol on Biosafety as "*in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles, and fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection". The Act regulates import, import for contained use, export, contained use, import for release, and release of LMOs and products of LMOs.

Japan

- Food Sanitation Act (enforced by the Ministry of Health, Labour and Welfare (MHLW)
- Act on Safety Assurance and Quality Improvement of Feed (enforced by the MAFF)
- Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of LMOs
- Labeling based on Food Sanitation Act and Act on Standardization and Proper Labeling of Agricultural and Forestry Products

Thailand

Thailand acceded to the Cartagena Protocol on Biosafety to become a Party on 8 February 2006. As a non-party to the CPB until 2006, the government emphasized undertaking relevant actions to put in place a regulatory framework that meets the country's obligations and requirements under the international agreement.

- Plant Quarantine Act B.E. 2507 (1964), amended 1999, 2008

This Act prohibits 89 GM plant species from all sources except for R&D granted by the Director General of the Department of Agriculture (DOA) in compliance with DOA biosafety guidelines on import and transit of prohibited material declared. This act is applied for the control of importation of GMOs into Thailand in order to prevent any harmful effects to the environment and agriculture. However, GM soybean and GM corn as grain and LMOs-FFP are exempted as well as all food derived from all those prohibited plant species.

- Plant Variety Protection Act B.E. 2542 (1999)

Under this Act, *new plant species* and the holder of plant variety right are protected. GM plant which is registered under this Act is required to be assessed for potential risks.

- Food Act B.E. 2522 (1979)

The Act stipulates that soybean, corn and their products (22 items) derived from GM must be labelled. It may be mentioned that Thailand imported 1.8 million tons of soybeans mostly from Brazil, followed by the US, Argentina and Cambodia.

- Biosafety Act

There are only two existing legislations and three notifications that refer to GMO regulation in Thailand. There has been no specific and a full coverage on GMOs for all purposes in Thailand. The Cabinet decision on 31 August 2002 addressed the need to put in place a legislative framework for the country. Such legislation should allow Thailand to regulate and promote modern biotechnology at a faster pace than in the past.

The Biosafety Act has been approved by the Cabinet on 22 January 2008 and is currently under consideration by the Office of the Council of State. The draft Act is composed of nine chapters each dealing with (i) National Biosafety Committee, (ii) National Competent Authority, (iii) Control over GMO-related Activities (iv) Public Participation and Access to Information, (v) Biosafety Fund, (vi) Officials, (vii) Appeal, (viii) Liability and Redress, and (ix) Penalty.

4.5 Biosafety Administration Systems

Bangladesh

The country has the following biosafety committees: National Committee on Biosafety (NCB), Institutional Biosafety Committee (IBC), Field-level Biosafety Committee (FBC) and Biological Safety Officer(s) (BSO).

The NCB is affiliated with the Ministry of Environment and Forests (MOEF), which is the national focal point and national coordinating authority in the implementation of biosafety regulations. The NCB coordinates activities of biosafety committees at sub-national levels: IBC, FBC, and BSO. The NCB performs the following functions in discharging its responsibility:

- conduct regulation and monitoring of GMOs;
- formulate and review policies, guidelines, acts, rules, standards, and manuals on biosafety; supervise risk assessment, risk management and implementation of activities;
- review all existing bilateral and multilateral projects, all research undertaken by NGO/private/public organizations;
- review, monitor and recommend measures to minimize potential risks that may result from import, contained use, field trial and release or introduction of new species, strains or varieties of GMOs;

- assist institutes/faculties/companies working with GMOs to obtain necessary permission/clearance in favour of their activities;
- examine applications on case-by-case basis;
- notify the decision to the applicant through MOEF;
- instruct the respective authority to ensure implementation of biosafety measures at all steps: on-site (field), laboratory, transboundary movement, use, handling and release in the market;
- prepare different forms for permission to undertake laboratory work; field trial and for commercial release of GMOs including format for monitoring;
- hold public consultation on proposed national policies, guidelines and on the comparative ecological, economic and social impacts of alternative approaches to attain the purposes/objectives of the proposed genetic modification products and/or services;
- review the appointment of the members of the IBC;
- assess and identify priorities in Human Resource Department (HRD) capacity building requirements; and
- coordinate the activities of IBCs and FBCs.

India

The following are the concerned agencies:

- Ministry of Environment and Forests: It is primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of LMOs.
- Department of Biotechnology (DBT) (Ministry of Science & Technology): It promotes biotechnology and provides services in areas of research, infrastructure development, and training of human resources.
- Ministry of Agriculture: It formulates and implements policies aimed at agriculture agricultural growth. The Indian Council of Agricultural Research (ICAR) is responsible for monitoring agronomic benefits of GM technology, and post-release performance of GM crops.
- Ministry of Health and Family Welfare: It implements policies aimed at protecting and monitoring human health.
- Ministry of Commerce and Industries D/o Customs**:** It enhances trade with other countries through export/import policies. Enforcement is done at point of entry.

The statutory bodies include the following:

- The Recombinant DNA Advisory Committee (RDAC) under DBT: Advisory role
- Institutional Biosafety Committee
- Review Committee on Genetic Manipulation (RCGM) under DBT:

- Genetic Engineering Appraisal Committee (GEAC) under MOEF
- State Biotechnology Coordination Committee (SBCC) – State government
- District Level Committee (DLC) – State government

All GMOs are regulated products in India. Regulations are governed by Rules 1989, PQO, 2003 & FTP (2004-2009). The enforcement of regulations depends on the intended use (GMOs for the purpose of research in contained use and GMOs for intentional release). Import of GMOs for research purpose requires the following: import clearance from RCGM, import permit from NBPGR, phytosanitary certificate from the country of origin, declaration that the product contains GMOs (FTP) and documentations as per the Cartagena Protocol on Biosafety.

For intentional release (cultivation or food feed or processing) the following documents are required: import clearance from GEAC, phytosanitary certificate from the country of origin, declaration that the product contains GMOs (FTP) and documentations as per the Cartagena Protocol on Biosafety.

The Union Cabinet of India has approved the introduction of a Bill, namely, the Biotechnology Regulatory Authority of India (BRAI) Bill, 2010 that provides for establishment of the Biotechnology Regulatory Authority of India to promote the safe and responsible use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures.

The BRAI will function as the single window, competent national authority for biotechnology regulation to ensure safeguarding the health and safety of the people of India and to protect the environment. It will subsume the functions of existing multiple competent bodies under "Rules for Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989" notified under the Environment (Protection) Act, 1986 so as to keep pace in regulatory measures with the rapid technology advancement in the field of biotechnology.

Indonesia

According to the Government Regulation No. 21, Year 2005, on Biosafety Regulation of Genetically Engineered Products, biosafety encompasses the following: environment safety food safety and feed safety.

The regulatory bodies are:

- Ministry of Agriculture, Ministry of Environment, Biosafety Committee (BC), and Biosafety Technical Team (BTT): For environment assessment
- National Agency for Food and Drug Control (NAFDC)/Ministry of Agriculture, Biosafety Committee (BC), and Biosafety Technical Team (BTT): For food/feed assessment
- New Biosafety Committee (GR21/2005): This committee was formed by Presidential Decree No. 39, 2010 and came into effect on 15 June 2010.

The NBC is composed as follows:

- Biosafety Committee Chair
  - Vice Chair for Environment Safety (Ministry of Environment)
  - Vice Chair for Food Safety (NAFDC)
  - Vice Chair for Feed Safety (Ministry of Agriculture)
- Member of Biosafety Committee
  - Ex officio
  - Representative of Professional Association
  - Representative of NGO
- New Biosafety Technical Team (Chair of BC No. 01/2011)
  - Coordinator & Vice Coordinator for Environment Safety
    - Chair for Plant Group
    - Chair for Animal Group
    - Chair for Fish Group
    - Chair for Microorganism Group
    - Member (Senior Scientists)
  - Coordinator & Vice Coordinator for Food Safety
    - Member (Senior Scientists)
  - Coordinator & Vice Coordinator for Feed Safety
    - Member (Senior Scientists)

Viet Nam

- Ministry of Agriculture and Rural Development: Biosafety Committees

These are inter-ministerial committees constituted with officials representing the Ministry of Agriculture and Rural Development (MARD), the Ministry of Science and Technology (MOST), the Ministry of Natural Resources and Environment (MONRE), the Ministry of Health (MOH), and the Ministry of International Trade. It also includes experts, scientists, and independent reviewers on case-by-case basis.

Republic of Korea

- Biosafety Committee: This is a national-level committee chaired by the Prime Minister.

Other Ministries represented in this committee have the following roles:

- Ministry of Science, ICT and Future Planning (MSIP): for research and development use
- Ministry of Agriculture, Food and Rural Affairs (MAFRA): for agricultural, fishery and forestry use
- Ministry of Trade, Industry and Energy (MOTIE): for industrial use
- Ministry of Health and Welfare (MOHW): for human health and food use
- Ministry of Land, Infrastructure and Transport (MOLIT): for bioremediation
- Ministry of Oceans and Fisheries (MOF): for marine products use.

All GM plants used as food or food ingredients, feed, fibre, and fuel must undergo a rigorous review of their safety as part of the authorization procedure before they can be available in the market. In the Republic of Korea, this assessment is conducted by the Korea Food and Drug Administration (KFDA) for food and by the Rural Development Administration (RDA) for feed, whose panel of independent scientific experts cooperates closely with national authorities on food and feed safety. Only GM products that have been deemed safe are allowed to reach the market.

Lao PDR

The Biotechnology and Ecology Institute (BEI) under the Ministry of Science and Technology (MOST) has the following functions in relation to biotechnology:

- Biotechnology Division
    - ➢ study, experiment, test and use agriculture biotechnology to increase product quantity, quality and conduct research to develop testing kits for plant and animal diseases (Agriculture Biotechnology Unit);
    - ➢ develop and apply biomedical research to build up medical product and predict diseases (Medical Biotechnology Unit);
    - ➢ conduct research, develop and use biotechnology as tool to ensure food security including that of value added commercial products and control nutrient value and examine food and feed that contains living modified organism (Food and Feed Biotechnology Unit); and
    - ➢ study, research, experiment, test and use biotechnology as the tool of environment quality control and risk assessment from the use of living modified organism and its products by informing the Biosafety Clearing House (Environment Biotechnology Unit).

- Genetic Resource Division
    - ➢ identify, classify and certify species of microorganism, plant, animal and human by genome basic science (Genetic Identification Unit);
    - ➢ study, research, develop, experiment, control and select international advanced technology, which include the use of radio nucleic material and modern biotechnology, to improve genetic material of microorganism, plant and animal for the purpose of environmental adaptation, diseases resistance, high product quality, suitability to the market demand and environment friendliness (Genetic Improvement Unit);
    - ➢ study, research and develop extraction technology and structure identification of bioactive compound to build up modern biotechnology innovation (Bioactive Compound Extraction Unit); and
    - ➢ establish and develop data information in a genetic bank as the basic indicator of living organism, to access the *ex-situ* conservation and sustainable development (Genetic Bank Unit);

Cambodia

The following institutional mechanisms at different levels were created in October 2011 for implementing the Law on Biosafety:

- National Steering Committee for Biosafety (NSCB)

This is a nationally representative high-level inter-ministerial committee composed of 16 senior officials representing almost all the line ministries and agencies of the Royal Government of Cambodia (RGC). These are: (i) the Ministry of Environment (MOE), (ii) Ministry of Agriculture, Forestry and Fisheries (MAFF), (iii) Council of Ministers (CoM), (iv) Ministry of Interior (MOI), (v) Ministry of National Defence (MND), (vi) Ministry of Commerce (MOC), (vii) Ministry of Health, (viii) Ministry of Economy and Finance (MEF), (ix) Ministry of Industry, Mine and Energy (MIME), (x) Ministry of Education, Youth and Sports (MOEYS), (xi) Ministry of Rural Development (MRD), (xii) Ministry of Planning (MOP), (xiii) Ministry of Water Resources and Meteorology (MOWRAM), (xiv) Ministry of Tourism (MOT), (xv) Ministry of Public Works and Transport (MPWT) and (xvi) Council for the Development of Cambodia (CDC).

As the top-level governing body, the NSCB is responsible for formulating policies, biosafety and biotechnology action plan, monitoring and controlling the implementation of the plan, and more importantly promoting mainstreaming of biosafety and biotechnology policy in related national sectors.

- The Scientific Advisory Team (SAT)

Based at and headed by MAFF, it is a multidisciplinary team of nine representatives from line ministries such as: MOE, MOC, MIME, MOH, MOEYS and academic institutions including the Royal Academy, universities and laboratory institutions. There is provision for expanding the size of the team as deemed necessary, to involve related expertise such as ecology, seed science, environmental toxicology, animal and plant breeding, genetics, virology, microbiology, molecular biology, biotechnology, physiology, etc. One of the key responsibilities of SAT is reviewing and providing recommendations for risk assessment reports prior to granting approval for LMO import/export permits.

- The Ministry of Environment (MOE)

The MOE is the lead executing body of the Law. Article 4 of the Law stipulates that any legal or natural person who wishes to conduct any activity or operation involving contained use, deliberate release into the environment, and/or direct use as food or feed or for processing of LMOs in the Kingdom of Cambodia shall be subject to approval by the MOE prior to authorization by the concerned competent authorities. The MOE is responsible for issuing regulations, rules, orders and guidelines for implementing this Law, especially provision stipulated under Articles 6 and 15 (institutional arrangements), Article 17 (export of LMOs), Article 20 (risk assessment), Article 22 (documentation of LMOs), Article 25 (confidential information) and Article 31 (review of decisions) of this Law.

The Philippines

In the Philippines, biosafety review is conducted at various levels:

- The Institutional Biosafety Committee (IBC);
- The Department of Science and Technology (DOST) Biosafety Committee;
- Scientific and Technical Review Panel (STRP); and
- The Department of Agriculture (DA) regulatory agencies.

Malaysia

- National Biosafety Board (NBB)

The functions of the NBB are to make decisions on all applications under the Act, monitor activities relating to living modified organisms, promote research, development, education and training activities as well as establish mechanisms to facilitate the collection, storage and dissemination of data relating to LMOs and products of such organisms. The NBB is composed of members representing the following ministries:

- ➢ Ministry of Agriculture and Agro-Based Industry;
- ➢ Ministry of Natural Resources and Environment;
- ➢ Ministry of Health;
- ➢ Ministry of Plantation Industries and Commodities;
- ➢ Ministry of Domestic Trade and Consumer Affairs;
- ➢ Ministry of International Trade and Industry; and
- ➢ Ministry of Science, Technology and Innovation.

- Department of Biosafety (DOB)

The DOB is the implementing agency and operational arm of the NBB. Its functions are to:

- ➢ implement and enforce the Biosafety Act 2007;
- ➢ act as the Secretariat of the Genetic Modification Advisory Committee (GMAC) and committees/sub-committees established under the NBB and GMAC;
- ➢ monitor all activities relating to living modified organisms (LMOs) and products of such organisms;
- ➢ provide a platform for consultation with various parties in order to formulate and update policies, laws and guidelines related to biosafety;
- ➢ coordinate and integrate the efforts taken by the Federal Government agencies and the State, NGOs and the modern biotechnology industries related to biosafety issues;
- ➢ build strategic partnerships with relevant agencies within and outside the country in the field of biosafety;
- ➢ establish mechanisms to facilitate the collection, storage and dissemination of data related to biosafety;
- ➢ help the Government to formulate the country's stand on the issues of biosafety at international forums; and
- ➢ increase public awareness on biosafety.

Thailand

- National Biosafety Committee (NBC) (1993-2005)

The NBC was appointed continuously from 1993 until 2005. It ceased to operate and was no longer functional since November 2005, pending an enactment of the Biosafety Act.

- Institutional Biosafety Committee (IBC)

The IBC has been established within academic and research institutes to supervise the internal research in laboratory and green house. Currently, there are 36 IBCs scattered across the four main regions of Thailand. The IBC network consists of 4 authorities, 25 universities, 4 research institutes and 3 private companies. The IBC performs activities such as annual meetings, training and conducting roadshows.

- Office of Natural Resources and Environmental Policy and Planning

The Office (ONEP), being the National Focal Point, was established in collaboration with Department of Agriculture (DOA), Department of Livestock Development (DOLD), and the Department of Fisheries (DOF). It is designated as the Competent National Authority (CNA).

4.6. Procedures for Considering and Granting Approval to GMOs Applications

Bangladesh

The procedures are illustrated in the flow diagram as shown below:

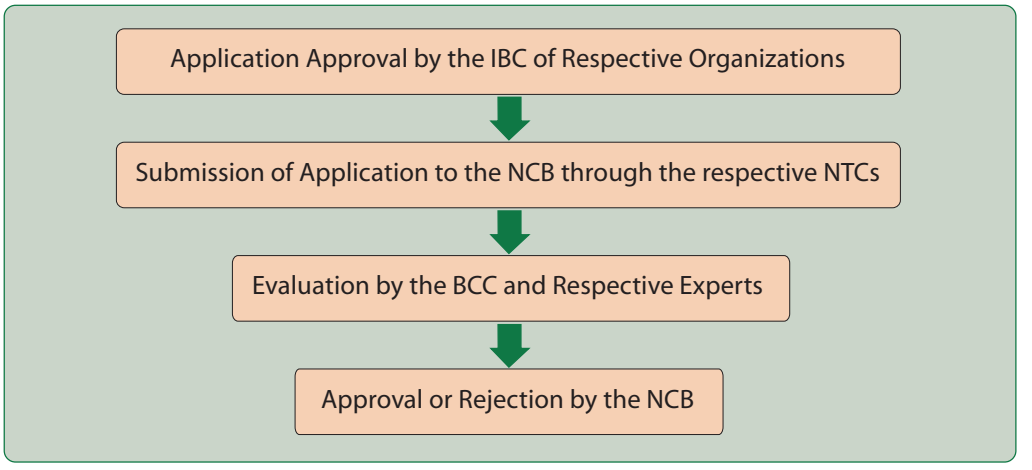

Diagram 2. Procedure for granting approval of GMOs, Bangladesh

India

- Assessment of an Application

  - ➢ The initial assessment of an application for confined field trial begins at the institutional level itself.
  - ➢ Based on information generated by the applicant in lab/greenhouse and on preliminary phenotypic evaluation of event selection, an application is made to IBC for one to a few events for further evaluation.
  - ➢ If recommended by IBC, the applicant may submit an application to RCGM for biosafety assessment of the event along with necessary requirements.
  - ➢ RCGM is the regulatory authority for Biosafety Research Level I (BRL I) trials. These trials are limited to no more than one acre per trial site location.
  - ➢ GEAC is the regulatory authority for Biosafety Research Level II-(BRL II) trials. Size and number of trials will depend on case-by-case basis.

- Grant of Approvals

  - ➢ GEAC approvals are valid for 4 years.
  - ➢ All renewals are valid for 2 years.
  - ➢ Approvals are subject to certain conditions.
  - ➢ GEAC has the authority to revoke approvals on the following grounds:
    - submission of wrong information
    - evidence of harmful effects
    - negligence

- Penalties

  - ➢ To prevent any damage to environment, nature or health, the SBCC or DLCs may take measures and necessary steps without issuing any order or notice at the expense of the person responsible for the damage.
  - ➢ SBCC/DLCs may ask for assistance from any other Government authority to carry out its instructions.

Indonesia

The focal point for assessment of food safety is the National Agency for Food and Drug Control (NAFDC). The output is recommendation of food safety from Biosafety Committee and certificate of food safety from the NAFDC.

The focal point for assessment of feed safety is the Ministry of Agriculture. The output is recommendation of feed safety from Biosafety Committee, and certificate of feed safety from the Ministry of Agriculture.

The focal point for environmental safety assessment is the Ministry of Environment. The output is recommendation of environmental safety from Biosafety Committee, and certificate of environmental safety from the Ministry of Environment.

Viet Nam

- Approval for GM crop trial

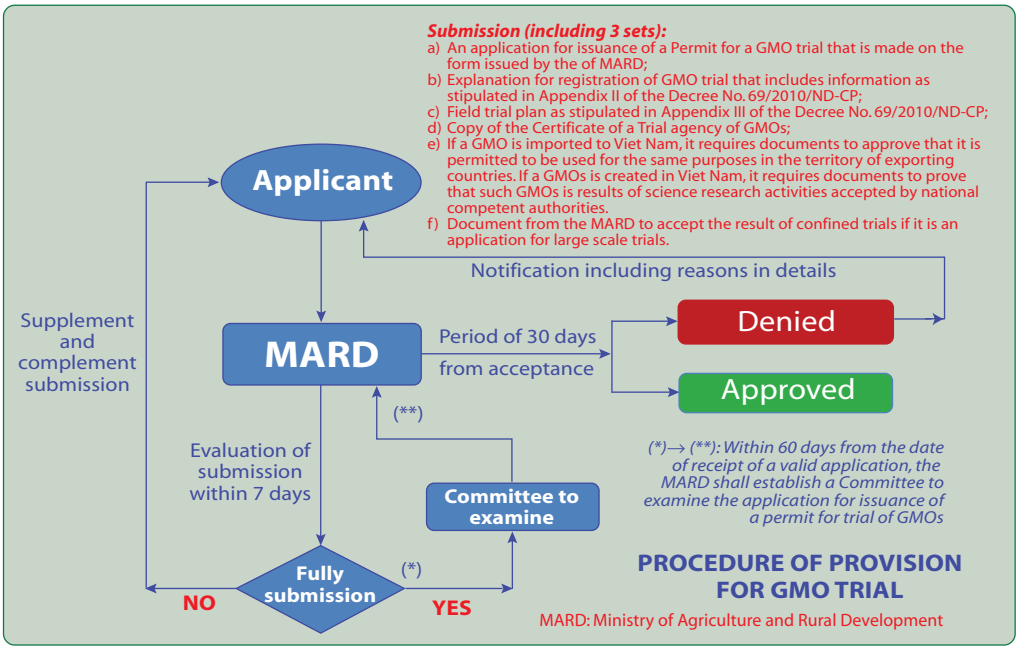

Diagram 3. Procedure for approval of GMO trial, Viet Nam

- Biosafety Certificate for GMOs

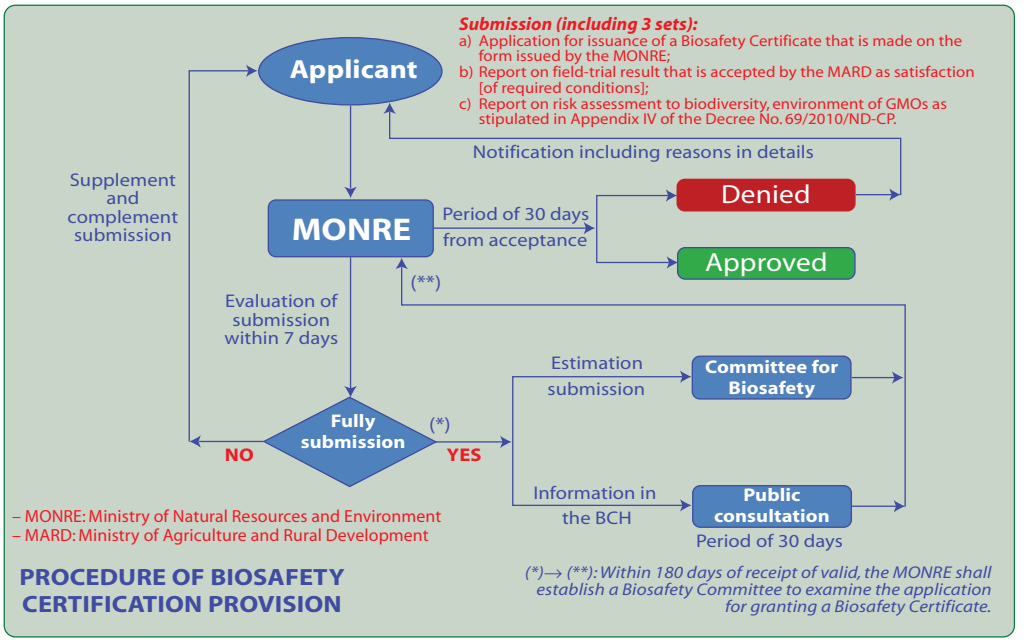

Diagram 4. Procedure for provision of biosafety certification, Viet Nam

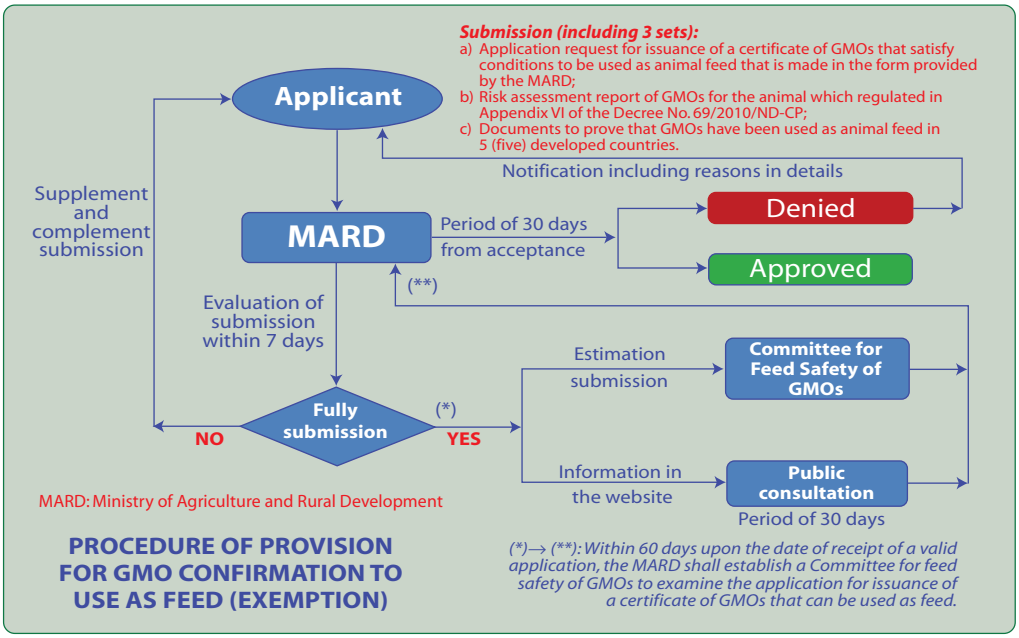

Diagram 5. Procedure for provision for GMO confirmation to use as feed (Exemption), Viet Nam

- GMO events to be used as feed

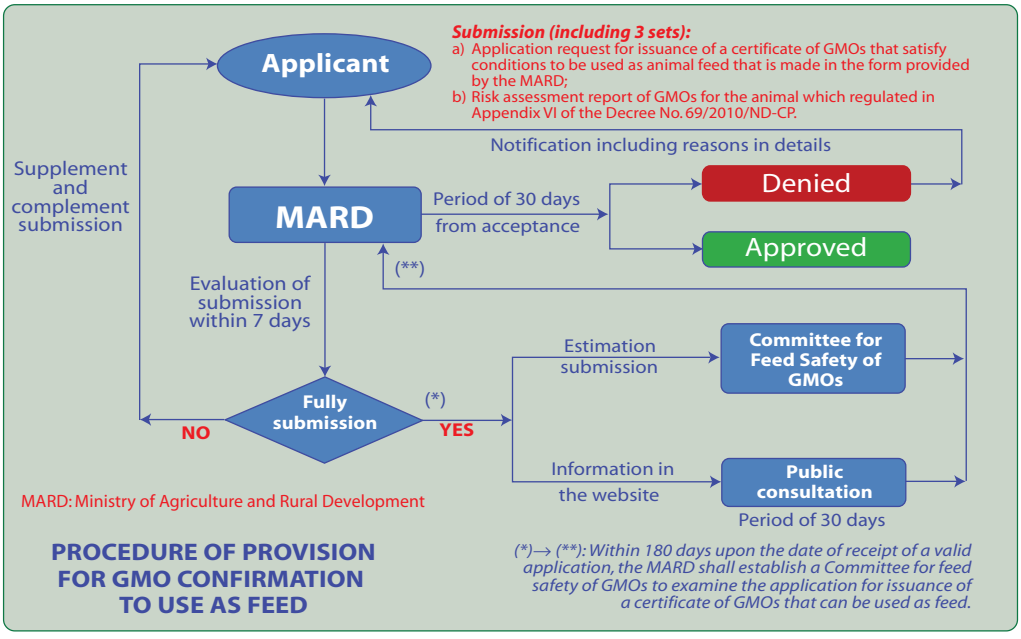

Diagram 6. Procedure for provision for GMO confirmation to use as feed, Viet Nam

As evident from these flow diagrams. Viet Nam has developed detailed standard operating procedures for approval of GMOs that are intended to be used as food and feed (including exemptions and biosafety certificate provision.

Cambodia

- Application notifications

Imports of LMO products for field trials, release into environment and for food, feed and processing shall be made via written request to competent authorities. The MOE, as a designated lead agency in safe and sound management of LMOs, is the national body for receiving and responding to all LMO applications.

- Application processes

Importers or users of LMOs in Cambodia shall submit an application to and get approval from the MOE prior to carrying out their activities. The MOE will review the application and provide a written reply to the applicant(s) within 90 days by indicating the status of application, whether further information is needed. Failure to supply requested information required for risk assessment will result in rejection of the application. However, if the information in the application is considered to be complete, then risk assessment can proceed.

- Risk assessment and advice

After acceptance of the application, the scientific advisory group will conduct a risk assessment based on the dossier provided by the applicant(s). In case of insufficient information for a risk assessment, the scientific advisory group has the right to request for further information. The MOE shall inform in writing the applicant and mass media about their decision within 270 days after receiving applications.

- Approval

The approval for using LMO products shall be made on case-by-case basis. This means approval for field trial is different from approval for releasing LMO into the environment. Similarly, the approval for field trial in containment area and approval for field trial in open environment is also different. The flow diagram below illustrates the steps in submission and approval of LMOs.

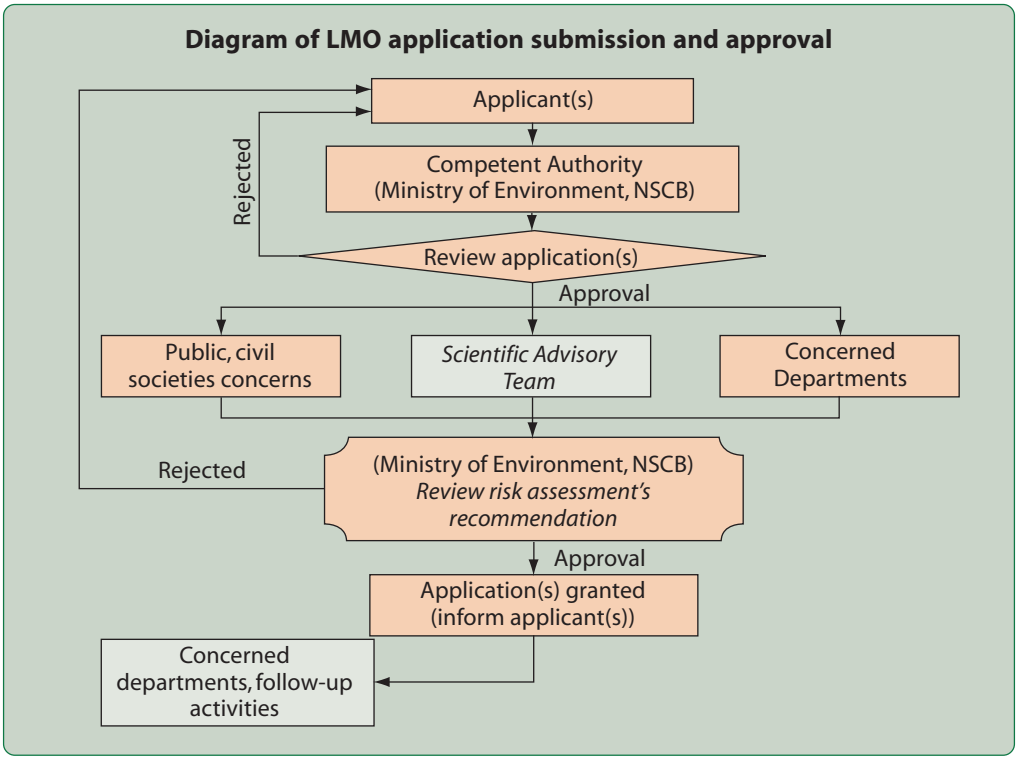

Diagram 7. Submission and approval of LMO application, Cambodia

The Philippines

- Biosafety Procedure

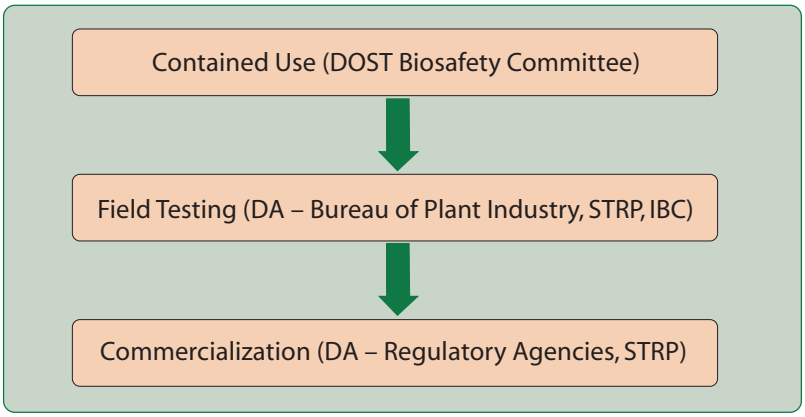

Diagram 8. Biosafety procedure, the Philippines

Republic of Korea

Low-risk level facilities (levels 1 and 2) are required to submit a statement procedure to MSIP, and high-risk level facilities (levels 3 and 4) must submit a permission procedure on environmental risk facilities to MSIP and on human health risk facilities to MOHW. During the import stage, the GMO importer must obtain import approval from the head of related ministries before the GMO can be used. In addition, the GMO product stage is managed by the ministries mentioned above.

However, until now, in the Republic of Korea, there has been no case of domestic cultivation approval. For the risk review and consultation procedure on GMOs, first, the developer, producer, and importer of GMOs must apply for a risk review to the following related agencies: Rural Development Administration (RDA) for feed and Ministry of Food and Drug Safety (MFDS) for food. After this, RDA and MFDS will perform a consultation with the following related agencies: Korea Centers for Disease Control and Prevention (KCDC), National Institute of Environmental Research (NIER) and National Fisheries Research and Development Institute (NFRD).

For the marketing, transport and storage of GMOs, operators should observe the GMO handling and management standards. In addition, the related ministries must regularly inspect facilities, manufacturers, moving routes, etc. to prevent unintended environmental release of GMOs.

Japan

- Safety as food

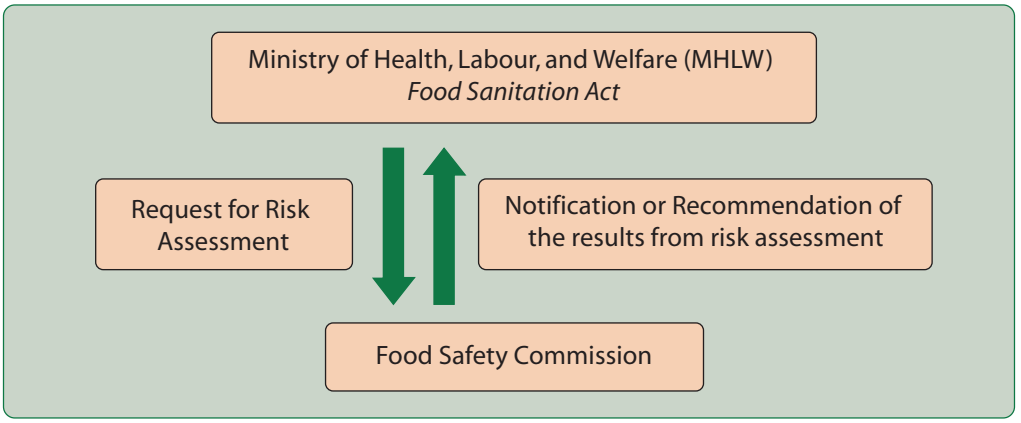

Diagram 9. Procedure on recommendation on food safety, Japan

- Safety as feed

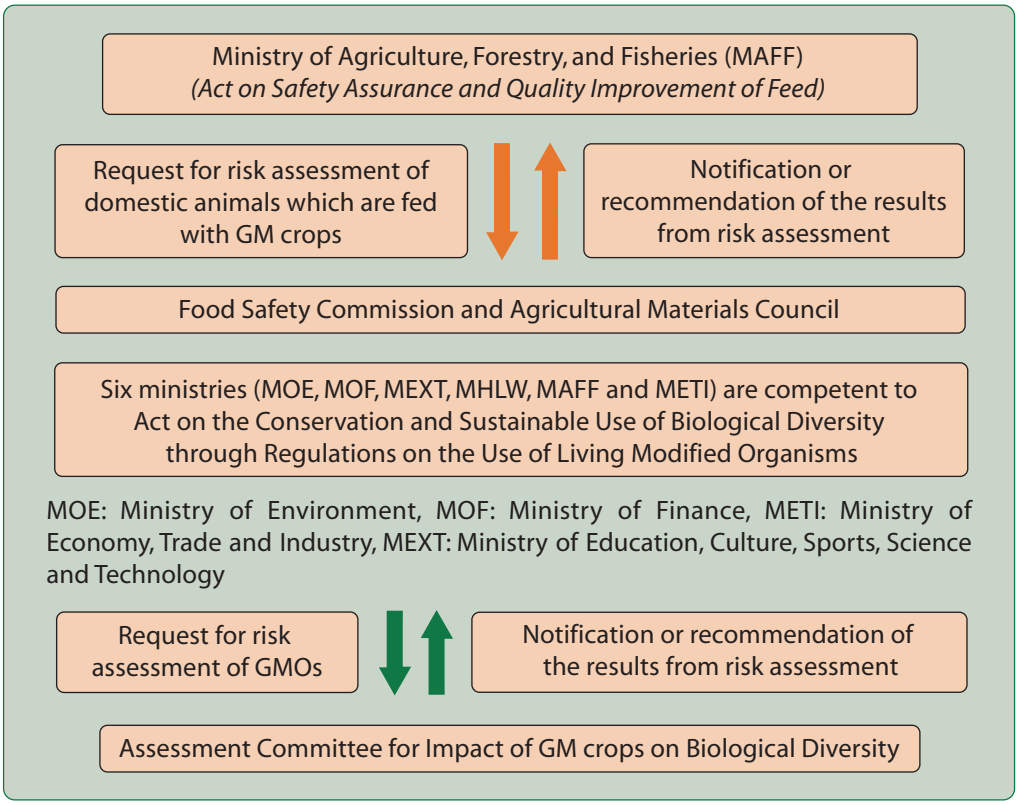

Diagram 10. Procedure on recommendation on feed safety, Japan

- Assessment of Impact on Biodiversity for commercial use of GM crops

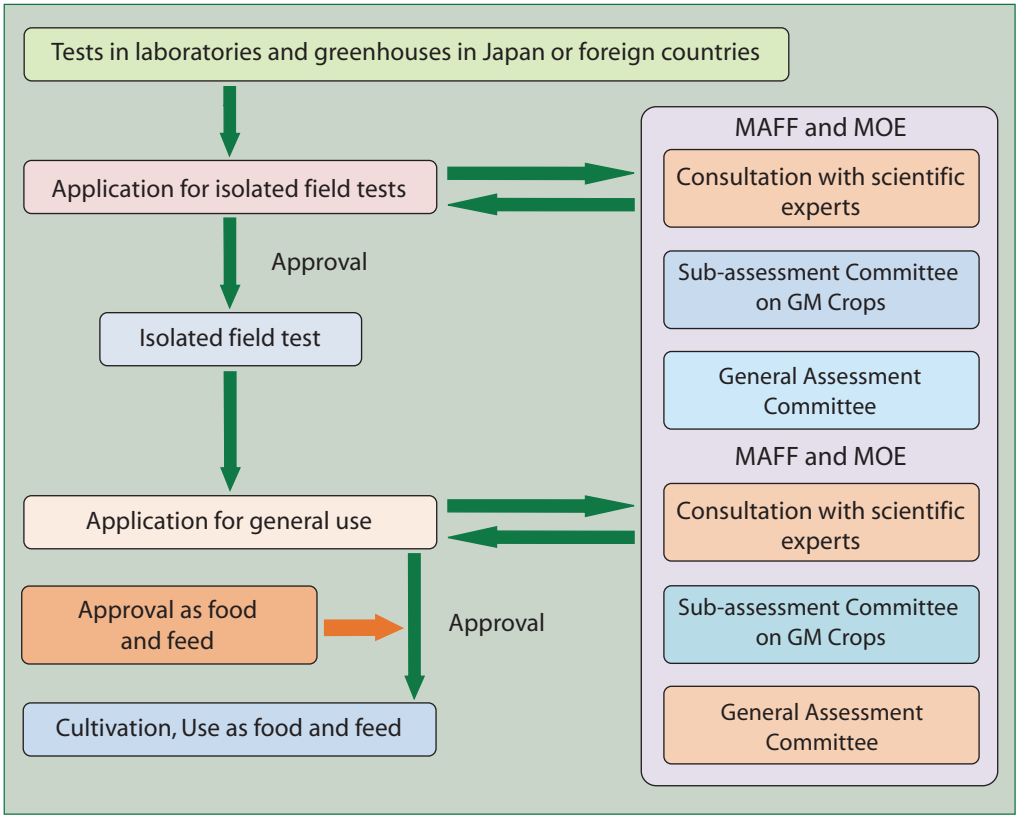

Diagram 11. Procedure for approval of GM food and feed, Japan

Thailand

The flow diagram below illustrates approval steps for importation of GM materials. Importation of approved GM materials for experimental activities must be handled in accordance with the guidelines of DOA under the supervision of the DOA's biosafety committee.

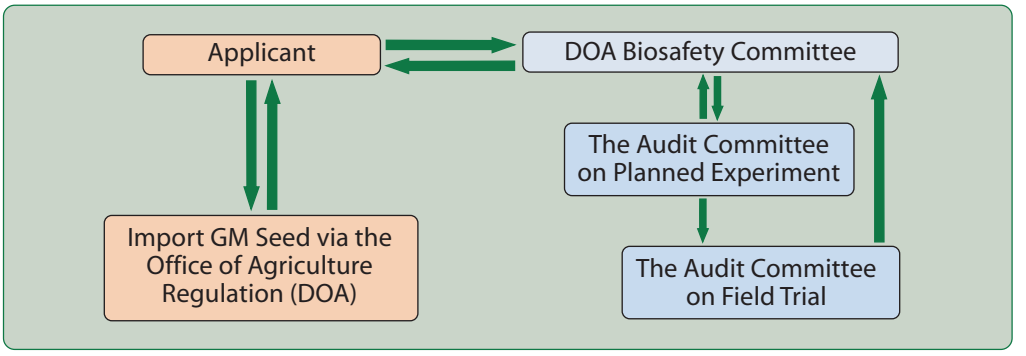

Diagram 12. Steps for approval of importation of GM materials, Thailand

4.7 Current Status of Research, Development and Use of GMOs

Bangladesh

The National Committee on Biosafety (NCB) endorsed the following activities on GMO:

- TPSP Plasmid for developing salinity and drought resistant IR-64 (Rice) – Greenhouse experiment;
- Contained and confined field trials of Bt eggplant for resistance to FESB at BARI research stations;
- Contained and confined field trials of late blight resistant potato at BARI research stations; and
- Contained trial of golden rice at BRRI.

Current R&D activities are focused on conducting confined field trials of Bt eggplant for resistance to eggplant shoot and fruit borer (ESFB), potato containing RB gene (cloned from *Solanumbulbocastanum*) for resistance to late blight disease and golden rice with provitamin A.

India

- Status of Approval

  - Only one crop has been approved – Insect-resistant Bt cotton.
  - Moratorium on Bt brinjal event EE-I has been imposed on February 9, 2010.
  - Twenty crops are under various stages of confined field trials including cotton, rice, tomato, groundnut, potato, corn, sorghum, okra, brinjal, mustard, wheat, watermelon, papaya, sugarcane, rubber, castor, banana, pigeon pea, *Artemisia annual L.* and chickpea. Traits include insect resistance, herbicide tolerance, virus resistance, nutritional enhancement, salt tolerance and fungal resistance.
  - No GM food crops or processed food except for import of GM soybean oil has been permitted. No other proposals have been received.

Indonesia

- Status of research on GE crops

  - **Rice**
    - Research Center for Rice: Golden rice (IR-64 GR, Ciherang GR)
    - Indonesian Institute of Sciences (IIS): Stem borer resistance, blast resistance, drought tolerance
  - **Soybean**
    - Indonesian Centre for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD): Pod borer resistance
    - University of Udayana: High content fatty acid

- **Papaya**
  - ICABIOGRAD: Delayed ripening
- **Potato and tomato**
  - ICABIOGRAD/Indonesian Vegetables Research Institute (IVEGRI): LB-resistant potato & MV-resistant tomato
- **Sugarcane**
  - PTPN XI: Drought tolerance; high glucose content
  - PPBP: Drought tolerance
  - Bogor Agricultural University (BAU): High phytase content

In 2011, food safety status (food safety recommendation from the Biosafety Committee and food safety certificate from the head of NAFDC) was accorded to the following GE crops:

- Maize (herbicide-tolerant, *glyphosate* NK603)
- Maize (insect-resistant MON89034)
- Soybean (herbicide-tolerant, *glyphosate,* GTS 40-3-2)
- Soybean (herbicide-tolerant, *glyphosate,* MON89788)
- Maize (herbicide-tolerant, *glyphosate* GA21)
- Maize (insect-resistant MIR162)
- Maize (insect-resistant BT11)
- Maize (insect-resistant MIR604)
- Sugarcane (drought tolerance NXT-1T)
- Maize (amylase modification 3272)

Viet Nam

Limited and large scale trials of GM crops approved since 2010 include the following:

- Monsanto: MON89034, NK603
- Syngenta: Bt 11, GA21, MIR162
- Pioneer: TC1507

None has been approved for food, feed and cultivation.

Republic of Korea

As of December 2012, Korea Biosafety Clearing House (KBCH) approved import of 82 applications of GMO as food: 9 for soybean, 45 for corn, 15 for cotton, 6 for canola, 1 for alfalfa, 4 for potato, 1 for sugar beet, and 1 for a microorganism.

For the use of GMO as feed, 85 applications were approved: 12 for soybean, 47 for corn, 17 for cotton, 8 for canola, and 1 for alfalfa. The approvals include crops with stacked traits.

At present, no GM crops are commercially cultivated in the Republic of Korea. However, research and development on genetic modification remains focused on the country's main crops such as rice, Chinese cabbage, hot pepper, potato and soybean. Except crops, animals (typically pig, chicken and goat), insects and microorganisms are being used in the production of biopharmaceutical products and artificial organs.

Generally in the Republic of Korea, GM plant development proceeds through the following steps: gene discovery, transformation, development of an elite event and risk assessment. Currently, several GM crops and animals are being developed.

Six of the GM crops are in the risk assessment step. These are: Bt rice, provitamin A rice, Bt Chinese cabbage, herbicide-tolerant rice and resveratrol synthesis rice. In the Republic of Korea, risk assessment is performed on the basis of scientific assessment. The methodologies employed include substantial equivalence, case-by-case analysis and transparent assessment which are in compliance with the international guidelines such as OECD, CODEX, UNEP, CBD and CPB.

The Philippines

For the year 2012, about 729 446 hectares of land were planted to insect-resistant corn (Bt corn), herbicide-tolerant corn (RR corn) and those with stacked traits (Bt/RR corn).

The GM crops approved for field trials include 18 proposals. Among the trials just recently conducted are the locally developed Bt eggplant field trial in four sites and DuPont Pioneer's Herculex (TC1507) and its stacks in six sites. Currently, three locally developed GM crops are being field tested in the Philippines: Bt cotton, Golden Rice and Papaya with the delayed ripening trait.

Eight corn transformation events were approved for propagation. These are (i) MON810, (ii) Bt11, (iii) NK603, (iv) GA21, (v) MON89034, (vi) MON810 x NK603, (vii) BT11 x GA21 and (viii) MON89034 x NK603. For direct use as food and feed or for processing, 62 events have been approved. These include the following crops: corn, soybean, cotton, canola, potato, alfalfa and sugar beet, approved for direct use as food and feed or for processing.

Malaysia

As of 30 May 2013, a total of 38 proposals had been given approval for release and contained use activities of LMOs and its products. Of these, 24 applications were concerned with research and development, 2 applications sought field trial of LMO and 2 release of product of LMO. Another ten applications were approved for bringing in LMO for food, feed and processing.

Japan

- Only commercial cultivation of GM blue flowers has been done in Japan so far.
- A large amount of GM products is imported as feed and for processing.
- Strict regulations on commercial cultivation of GM crops are set by several local governments.

Thailand

- Status of R&D on GM plants

  ➢ **Greenhouse and confined trials**:
  - Bt toxin for controlling the cotton bollworm; Sri Somrong 60
  - Coat protein resistance
    - tomato yellow leaf curl virus
    - chili vein-banding mottle virus
    - cowpea aphid-borne mosaic virus
    - papaya ring spot virus – 3 events

  (conducted at DOA, Mahidol, BIOTEC/KU)
  - Abiotic stress resistance: KDML105 (BIOTEC/RF)
  - Delayed ripening: papaya (BIOTEC/KU)
  - Color presentation: Orchid (KU)
  - Herbicide tolerance: Pineapple (Rajamangala University of Technology, SriviJaya)

- Field Trials

  ➢ In 1994; DOA MOAC, upon the technical recommendation of NBC, granted permission for the field trial of Calgene's FLAVR SAVR tomato, which was the first introduction and field testing of GM plant in Thailand. After that, DOA approved importation of the following five GM plants for experimentation: Bt cotton, RR corn, cotton resistant to herbicide, tomato with delayed ripeness and papaya resistant to ring spot virus.

  ➢ Four events of imported GM corn are now undergoing biosafety evaluation and risk assessment in Thailand. These are the following:
  - NK603 (HT) Monsanto and Naresuan University (preparations afoot to do the first field tests)

  Applications received for greenhouse testing:
    - Bt11XGA21 (INS XHT) Novatis and Naresuan University
    - DAS-01507XMON603 (INS XHT) Pioneer and Kasetsart University
    - GA21 (HT) Novatis, Maejo University and Ramkhamhaeng University (Phrae campus)

A moratorium on GM plant trials was imposed on 3 April 2001. A complaint from NGO activists accusing the DOA of allowing escape of GM cotton plant from experimental field into environment led the Cabinet to prohibit all field trials of GM plants until the enactment of biosafety law.

Later in 2007, the Cabinet, under the pressure from scientists and research community, lifted the GM field trial ban with condition that it must be approved by the Cabinet on case-by- case basis. It also ordered the MOAC to formulate a programme on field trials of GM crops within the government premises, identify definite location involved with stringent regulatory measures and conduct public hearings.

4.8 Requirements for GM Food Labelling

Viet Nam

Organizations and individuals circulating foods containing genetically modified organisms and products of genetically modified organisms on the market at a rate greater than 5 percent each of the components, in addition to complying with the provisions of law on goods labeling also must show the information related to genetically modified organisms on the product label.

Japan

GM crops and processed food derived from them have to meet labelling requirements based on the Act on Standardization and Proper Labelling of Agricultural and Forestry Products and Food Sanitation Act. In addition, mandatory "Made from GM Crops" labelling is required for products with nutrition different from conventional ones. For products with same nutrition as conventional ones, mandatory "Made from GM Crops of IP (identity preserved) handling" or "Made from crops without IP[5] handling" labelling is required. Voluntary labelling is proposed to describe "No detection of recombinant DNA and/or protein" or "Made from non-GM crops of IP handling."

Republic of Korea

GM food labelling in Korea is regulated mainly on the basis of the Food Sanitation Act and Agricultural Products Quality Management Act. Currently, 3 percent for GM event approved in Korea is observed as GMO threshold for unintended contamination, but none of the unapproved GMOs can be marketed.

Thailand

GM food labelling in Thailand is regulated according to the labelling requirements for GM products as laid down in the Ministry of Public Health Notification No. 251, B.E. 2545 (2002). Food containing GM soybean or corn is apparently based on the Japanese model allowing for a 5 percent tolerance.

Labelling will only be required for the top three ingredients by weight, if each ingredient constitutes 5 percent or more of the final product and 5 percent or more of that ingredient is derived from GM ingredients.

[5] IP handling" means handling GM or non-GM separately in each stage of production, distribution, processing, and transportation from producers to manufacturers not to co-mingle with others with proofs of the effective handling by documents.

4.9 Institutional Capacity Building for Biosafety

India

- UNEP/GEF – Phase II Capacity Building Project on Biosafety for Implementation of the Cartagena Protocol on Biosafety

As a Party to the CPB, the Ministry of Environment and Forests has accessed US$ 3.0 million funds from the United Nations Environment Programme (UNEP)/Global Environment Facility (GEF) to strengthen the biosafety management system in India with special emphasis on risk assessment and management, handling, transport, packaging and identification of LMOs, socio-economic considerations and public awareness. As part of this initiative, the Ministry has developed a Project for Capacity Building in Biosafety (Phase II) with a four-year time frame for completion. The approval of GEF Council was received in August 2011.

Sri Lanka

"Guidelines for the Safe Use of Recombinant DNA Technology in the Laboratory" was published in 2003 and 2005 by the National Science Foundation.

"Laboratory Manual on Detection of Genetically Modified Organisms, Food, Feed and Processed Products" was published in 2005.

Ongoing activities for the development and/or strengthening of human resources and institutional capacities in biosafety include the following:

- Institutional capacity development;
- Human resources capacity development and training;
- Risk assessment and other scientific and technical expertise;
- Risk management;
- Public awareness, participation and education in biosafety;
- Information exchange and data management including participation in the Biosafety Clearing House; and
- Scientific, technical and institutional collaboration at sub-regional, regional and international levels.
- Identification of LMOs, including their detection taking into account risks to human health
- Risk assessment & management, Biosafety Clearing House

Malaysia

A project funded by UNDP-GEF entitled "Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety" was completed in 2012. Outputs from this project include training workshops on risk assessment and publications on biosafety as well as other related activities aimed to successfully implement a domestic regulatory mechanism for biosafety.

Cambodia

The Ministry of Environment has established a Secretariat of the NSCB which has a Biotechnology lab to perform GMO detection. The biotechnology lab conducts test for insecticide and herbicide resistance in cotton, maize and papaya.

The MAFF has not yet implemented GMO detection in agricultural food. However, opportunities can be created in the General Directorate of Agriculture (GDA) under MAFF by making the recently established "Biotechnology Unit" in GDA's National Agriculture Laboratory (NAL) functional through training manpower and human capital and installation of necessary facilities.

Besides GDA, MAFF also has other institutions to perform research in agricultural biotechnology such as the Cambodian Agricultural Research and Development Institute (CARDI) and the Royal University of Agriculture (RUA). But their ability to perform biotechnology research activities remains confined to tissue culture and marker assisted in selection due to limited knowledge and number of staff as well as facilities.

Lao PDR

The UNEP-GEF Project to Implement LAO NBF (2009-2014) aims to assist Lao PDR to have a workable and transparent National Biosafety Framework by 2015, to fulfill its National Socio-economic Development Plan and implement its obligations as a Party to the Cartagena Protocol on Biosafety. The specific objectives of the project are to assist the Lao PDR to:

- integrate and incorporate biotechnology and biosafety policy into the national sustainable development plan and strategies;
- establish and consolidate a fully functional and responsive regulatory regime in line with Cartagena Protocol on Biosafety and its national needs and priorities;
- establish and consolidate a functional national system for handling requests;
- establish and consolidate a functional national system for "follow up" activities namely monitoring, inspection and enforcement; and
- establish and consolidate a functional national system for public education, awareness raising, participation and access to biosafety information like a national BCH.

Indonesia

- Biosafety Containment Facility for Plants:
  - ➢ Head house
    - – Genetic engineering laboratory
    - – Insect rearing laboratory
    - – *In vitro* culture room
    - – Soil preparation room
  - ➢ Green-houses
    - – Double doors of 6 units GH with polycarbonate, 200 mesh screen wall and equipped with shell deck, exhaust fan, chiller and air-conditioning room.
  - ➢ Screen houses

- Current status of GM Food Testing facilities

Institution	Laboratory	Methods
NAFDC	National Quality Control of Drug and Food (NQCDF)	Qualitative Nested PCR Quantitative Real time PCR
ICABIOGRAD	Biology Molecular Division Laboratory	Qualitative Conventional PCR
PT Saraswanti	GM Laboratory	Qualitative PCR, Quantitative PCR (Competitive PCR)

Table 1. Current testing facilities and methods in Indonesia

Viet Nam

Viet Nam has developed regulatory procedures for the establishment by any concerned stakeholder of laboratory facilities for conducting scientific research on GMOs and conducting trial of GMOs as shown below:

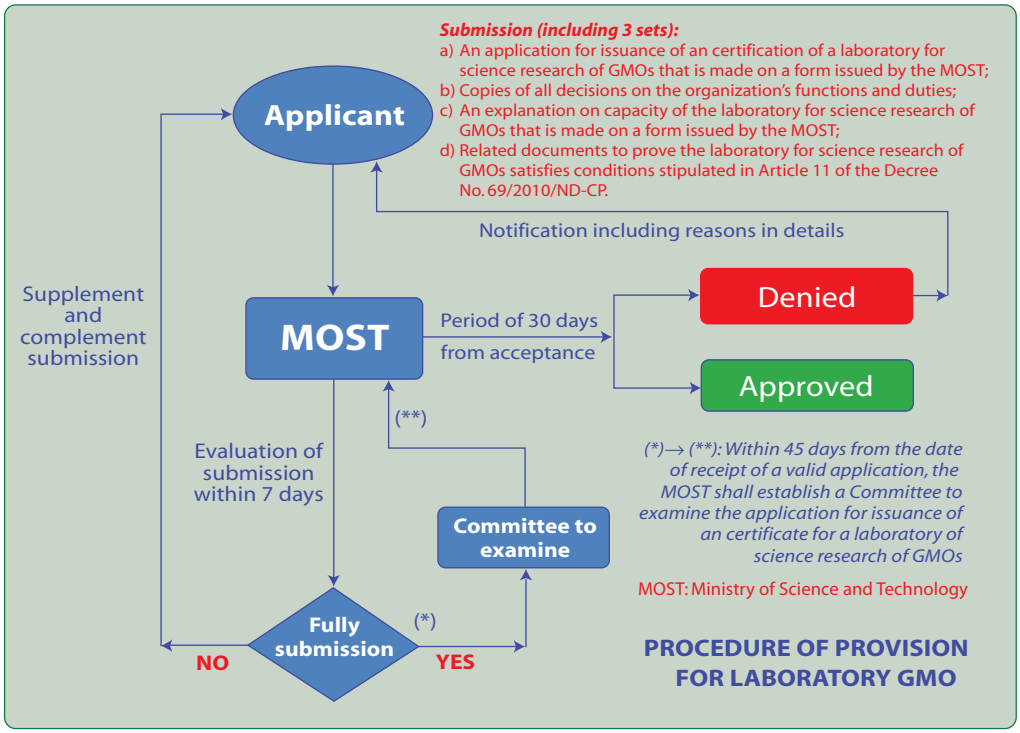

Diagram 13. **Procedure for approving laboratory GMO, Viet Nam**

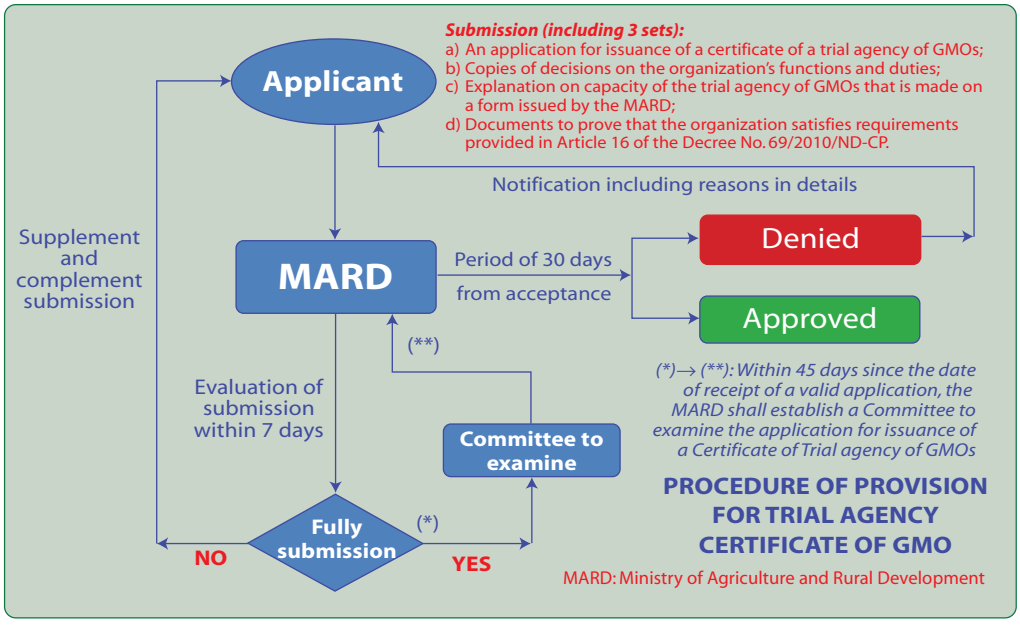

Diagram 14. **Procedure for provision of trial agency certificate of GMO, Viet Nam**

4.10 Challenges and Key Areas for Capacity Building

Bangladesh

- The key aspect of national capacity building is the development of human resources and infrastructure building in risk assessment and risk management. Scientific and technical capacities in these areas should address: (i) toxicity of transgene products to human, animals, bird, fish and soil microbes, (ii) pathogenicity, (iii) allergenicity, (iv) gene flow, (v) nutritional compositional change, (vi) digestibility and digestion products, (vii) stability of gene product and (viii) the fate of genes and gene products in food processing.
- International cooperation and collaboration should focus on training, provision of expert service and development of facilities for risk assessment.
- National collaboration among public sector, private sector, NGOs and other stakeholders should focus on exploiting comparative advantages of specific sectors in research and development, commercialization of biotechnology and dissemination of technology.

India

- Development of LMOs/GMOs;
- Risk assessment (impact on human health and environment);
- Risk management;
- Identification of LMOs/GMOs;
- Regulatory capacity building;
- Human resource development and training;
- Public awareness, education and participation;
- Information exchange and data management;
- Scientific and institutional collaboration;
- Technology transfer;
- Socio-economic considerations; and
- Sustainable use and conservation of biodiversity.

Viet Nam

The major challenges in beefing up the national capacity for biosafety regulation can be summarized as follows:

- completion of capacity building in biosafety;
- finalization of the national biosafety regulation framework;
- development of adequate human resources and facilities tailored to specific cultivation conditions and ecosystems in Viet Nam;

- lack of experiences and poor status of basic research and local technology;
- increasing public awareness about GMOs;
- addressing specific issues in IPR protection; and
- Post release monitoring of the performance of products of GM technology

Republic of Korea

- Development of infrastructure and training human resources will be very crucial in implementation of biosafety regulation. There is also a need to update old laboratory tools and equipment and to constantly stock up on reagents and supplies that are used for regulatory monitoring and related functions.
- Mounting a continuous and effective education and communication through media and outreach programmes to promote awareness on the benefits or risks of modern biotechnology are needed for public knowledge on GM crops.
- To avert future trade disruption due to asynchronous GMO approvals that could generate a negative impact in the Republic of Korea economy, a more efficient processing of GMO product applications is needed. At the same time, a more workable solution for the low-level presence (LLP) of unauthorized GMOs in imports in the Republic of Korea is required.

Sri Lanka

Major aspects of national capacity building should address the following weaknesses and deficiencies:

- inadequate research infrastructure;
- lack of sustained funding;
- fragmented research activities;
- lack of up-to-date knowledge and specialized training;
- lack of access to scientific information;
- lack of trained technicians;
- inadequate support services for supply of chemicals, laboratory supplies and equipment repair;
- weak linkages between research and extension/producers; and
- weak policy and regulatory framework for IPR

The Philippines

- Sustained and well-coordinated campaign by anti-GMO activists against regulated conduct of field trials, resulting in the past in trespassing and vandalizing field trials of biotech corn and biotech eggplant.
- A law suit filed by anti-biotech groups at the Supreme Court alleging irreversible harm caused to the environment of Philippines by conducting Bt eggplant field

trials. This is despite the stringent safety measures the Philippines government and its regulatory agencies undertake in conducting field trials including a science-based risk assessment system, with the cooperation of the technology developers, scientists and academia, public research institutions, and other stakeholders.

- Some localities in the country have current local ordinances banning the use, experiment or planting of GMOs. The National Government, in coordination with relevant stakeholders, plays an active and supportive role in the continuous awareness and information campaign in such local government units. An important aspect of capacity building should be awareness building among these local executives and legislators on the benefits of modern biotechnology through its safe and responsible use.
- Planting GMOs, specifically herbicide-tolerant corn, is blamed by some farmers and other stakeholders for causing soil erosion in certain hilly areas converted into agricultural land. To counter this prejudice and address the root causes of soil erosion ongoing efforts are focused on setting up demonstration plots showcasing the use of appropriate soil and water conservation measures such as contour farming, minimum tillage, crop rotation, natural vegetative strips, mulching and crop residue incorporation, organic farming, terracing and rainwater harvesting.
- The issue of mandatory GM food labelling with very exhaustive coverage to extend to products of animals fed with GM feeds (e.g. to include milk and egg) is persistently pursued by consumer groups. A national policy should be set in place that would strike a balance between the consumer's right to know and the cost implication of mandatory GM food labelling, taking into account the national interest.
- Capacity building should focus on formulating relevant rules and regulations to enable regulatory agencies implement the National Biosafety Framework in letter and spirit. To this effect, a joint issuance among the Department of Agriculture, the Department of Environment and Natural Resources (DENR) and the Department of Health (DOH), possibly through a joint Administrative Order (AO), can be promulgated to determine the terms of reference of work on risk assessment to include harmonized procedures and standards. The planned AO would serve as legal instruments to guide the DA, DENR and the DOH in jointly conducting the risk assessment. Currently, the Department of Agriculture, in coordination with other concerned agencies, are developing additional and/or amending relevant policies and guidelines on modern biotechnology.
- A significant part of national capacity building must address developing adequate infrastructure, trained human resources, and allocation of necessary funding for implementation of biosafety regulations. This must include modernizing laboratory tools and equipment and adequate supplies of consumables like chemical reagents and other materials that are used for regulatory monitoring and related functions. Continuous capacity building of the human resources through participation in technical conferences/seminars/workshops/meetings on biotechnology and biosafety is strongly recommended. There is also a need for

a continuous effective education and communication through media, and outreach programmes/campaigns to promote awareness on the benefit/risk of modern biotechnology.

Indonesia

- Amending of Act/Decree on biosafety and food safety following updated internationally and regionally set framework standards;
- Capacity building in risk assessment of GMO;
- Conducting method validation among the laboratories involved in GM food testing network in Indonesia and participating in international proficiency testing programmes; and
- Increasing networking and collaboration at international and regional levels.

5 Technical Session: Presentations by Resource Speakers

5.1 Risk Analysis in Biotechnology (risk assessment and risk management) by Prof Dr Desiree M. Hautea and Prof Dr Kazuo Watanabe

- Overview of risk assessment and LMOs

Discussions focused on the following areas: (i) legal context of biosafety regulation, (ii) Cartagena Protocol on Biosafety (CPB) – two key procedures for regulating the movement of LMOs (LMOs intended for deliberate release to the environment, planting or propagation) and LMOs for food, feed and processing (FFP), (iii) commonly accepted principles and basic concepts of risk assessment in CPB and Codex (Codex *Alimentarius* Commission), (iv) environmental risk assessment (ERA) areas and the problem formulation approach on risk assessment, (v) current status of LMO approvals in various countries and (vi) recently approved and upcoming products in the pipeline and the challenges these products could pose to regulatory authorities.

- Problem formulation on environmental risk assessment (ERA)

Prof Dr Watanabe introduced the problem formulation approach on risk assessment particularly for LMOs which are intended to be released deliberately to the environment. The presentation and succeeding discussion moderated by Prof Dr Hautea emphasized the importance of setting clear protection goals, formulating testable hypothesis and identification of measurable endpoints to avoid unnecessary data collection which has no relevant contribution to informing the risk assessment and risk management processes. The difference between "need to know" and "nice to know" was highlighted.

- AIA & ERA for Commodity

The deliberations were led by Prof Dr Watanabe and the succeeding discussions were moderated by Prof Dr Hautea. The difference between LMOs-FFP and LMOs for the deliberate release to the environment (planting or propagation) was highlighted. LMO-FFP (commodities intended for FFP) uses a simplified procedure for the decision making. Decision practices in majority of the LMO importing countries were based on desktop assessments of the regulatory information; although ERA, i.e. field tests, may be required on LMOs-FFP in some countries. For countries that have no experience yet in approving LMO-FFP, a pragmatic approach may be considered to facilitate the LMO-FFP importation by looking to relevant practices in other countries.

- ERA for cultivation

This session consisted of lectures and specific examples given by Prof Dr Watanabe. It also included case study exercise and moderated discussion. The first moderated discussion focused on the ERA practices implemented in the participant countries with actual experiences.

The case study exercise followed. The participants were divided into two groups, where they acted as regulators and discussed how ERA is conducted given the hypothetical application for GM maize with drought stress tolerance. The group presented their results and discussions followed. Again, project formulation approach was emphasized in delimiting the relevant risk assessment areas. Additional lectures were presented by Prof Dr Watanabe (e.g. trees and soybeans in Japan) to give examples of technical evaluation methods which take into consideration efficacious and cost-effective approaches.

- Risk Management

Prof Dr Hautea explained the basic principles of risk estimation and risk management strategies for risk mitigation. Examples of risk management strategies ranged from containment and confinement using physical and biological/reproductive barriers, up to post-release monitoring. Further discussion also included consideration of socio-economic aspects in risk management and decision-making. Supplementary lecture on post-release monitoring was presented by Prof Dr Watanabe giving the canola example in Japan, its significance for the environmental impact and bulk transportation for domestic use.

- Risk Communications

Prof Dr Hautea focused the discussion from two perspectives: communicating country decisions through the BCH and understanding how to effectively communicate a controversial issue like GMO. He emphasized the importance of communicating both the process and outcome of the risk assessment, management and decision making processes to various stakeholders. The importance of the (BCH) and the importance of providing information on decisions made by the Parties to the CPB were also stressed. Other useful databases and how to use them effectively were presented. The lecture also provided key theories on how to communicate controversial topics like GMOs and examples of experiences from other countries. During the discussion, all participants agreed on the importance of communicating to all stakeholders. Participating countries which are more advanced in implementation of biosafety regulations shared actual experiences and the protocol they have put in place to address communication issues.

- Detection of LMOs

The main lecture topics were presented by Dr Randhawa, Prof Dr Watanabe and Prof Dr Hautea complemented the efficacy and effectiveness of the specific technologies for targeted purposes based on the problem whether field monitoring, bulk shipment commodity or food. Supplementary slide set was provided for beginners as in the list.

- Food safety

The workshop focused on biosafety in the context of the Cartagena Protocol on Biosafety. However, frequent questions came up from participants on the data validation of the information submitted by the applicants on food safety particularly on LMO-FFPs. Some participants shared experiences on this aspect. In many of these countries, food safety assessment could be done by desktop analyses of submitted information as long as the data are generated by accredited laboratories in accordance with internationally accepted guidelines, e.g. CODEX on safety assessment of LMOs.

The decisions from COPMOP-6 of the Cartagena Protocol on Biosafety were briefly explained by Dr Bangpot. Dr Watanabe facilitated the discussion on the key points associated with LMOs FFP such as Article 18 on transport, identification and packaging of the LMOs, Article 26 on socio-economic consideration and Article 27 on liability and redress with Nagoya KL Supplementary Protocol.

Prof Dr Watanabe and Prof Dr Hautea provided a list of useful websites relevant to biosafety:

- Environmental risk assessment references
  - Cartagena Protocol
    https://bch.cbd.int/cpb_art15/training.shtml
    https://bch.cbd.int/protocol/e-training_RA.shtml
    https://bch.cbd.int/onlineconferences/guidance_ra.shtml
  - ISBR: http://www.isbr.info
  - ILSI-CERA: http://www.cera-gmc.org
- LMO database
  - BCH: https://bch.cbd.int
  - ISAAA: http://www.isaaa.org/gmapprovaldatabase/default.asp
  - ILSI: http://www.cera-gmc.org/?action=gm_crop_database
  - OECD: http://www2.oecd.org/biotech/
  - ICGEB: http://www.icgeb.org/~bsafesrv/databases/databases.html
  - IFPRI: http://www.ifpri.org/book-636/ourwork/program/program-biosafety-systems
  - India: http://igmoris.nic.in
  - J-BCH: http://www.bch.biodic.go.jp/english/e_index.htmlK-BCH
  - Korean BCH: http://www.biosafety.or.kr/english/index.asp
  - GMAC-Singapore: http://www.gmac.gov.sg/Index_Singapore_Biosafety_Guidelines_for_Research_on_GMOs.html
  - Australia
    http://www.daff.gov.au/agriculture-food/biotechnology/reports/maintaining_product_integrity_in_the_australian_seed_and_grain_supply_chain/appendixes/appendix_a
  - Canada
    http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1171285739616&lang=eng

- USA
  http://www.aphis.usda.gov/biotechnology/permitqa.shtml
  http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ucm346858.html
  http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/

➢ Detection
- Network of Laboratories for LMO Detection & Identification
  http://bch.cbd.int/onlineconferences/portal_detection/lab_network.shtml

➢ Food safety
- FAO
  http://www.fao.org/food/food-safety-quality/a-z-index/biotechnology/en/
  http://www.fao.org/docrep/012/i0110e/i0110e00.htm
- WHO
  http://www.who.int/foodsafety/publications/biotech/20questions/en/
- EFSA
  http://www.efsa.europa.eu/en/panels/gmo.htm
- Food Safety Commission of Japan
  http://www.fsc.go.jp/english/standardsforriskassessment/geneticallymodifiedfoodfeed_e1.html
- ICGEB
  http://www.icgeb.org/~bsafesrv/pdffiles/Article%203_7.pdf

➢ Other relevant sites
- PRRI: http://www.prri.net
- GMO Compass: http://www.gmo-compass.org/eng/home/
- CTN-Bio – Brazil: http://www.ctnbio.gov.br
- OGTR – Australia: http://www.ogtr.gov.au
- FSANZ – FFP: http://www.foodstandards.gov.au/Pages/default.aspx

➢ Other useful sites
- Academics Review http://academicsreview.org/ – Testing popular claims against peer-reviewed science
- University of California Biotech – http://ucbiotech.org/
- Genetic Literacy Project – www.geneticliteracyproject.org/
- Sense About Science: http://www.senseaboutscience.org/ – equipping people to make sense of science and scientific evidence
- Tomorrow's Table – Prof Ronald's[6] blog on genetics, food and farming
  http://scienceblogs.com/tomorrowstable/

[6] Pamela Ronald is Professor of Plant Pathology at the University of California, Davis, where she studies the role that genes play in a plant's response to its environment. Her laboratory has genetically engineered rice for resistance to diseases and flooding, both of which are serious problems of rice crops in Asia and Africa. Ronald is co-author with her husband, an organic farmer.

Summing up the discussions, the resource persons had emphasized that risk communication is the important component of the processes towards endpoint decision on the risk assessments. Transparency and participatory approaches are encouraged for the processes. Risk management and risk-benefit analyses were also explained and revisited for the consideration towards the decision making related to the final judgment of LMOs.

5.2 LMOs-FFP Testing, Monitoring and Detection by Dr Gurinder Jit Randhawa

Five presentations on "LMOs-FFP testing, monitoring and detection" were made on:

- Food safety issues on LMOs-FFP: General introduction of the concept and procedures;
- Introduction of Article 11 of the Cartagena Protocol on Biosafety on LMOs-FFP as commodity import;
- Detection of LMOs-FFP (commodity bulk shipment samples) in different sampling approaches/technologies at a designated facility (lab);
- Detection of LMOs-FFP for environmental monitoring after the importation approvals
  - ➢ approved importation as commodity, on unintentional spills by local transportation
  - ➢ monitoring of LMOs-FFP grown in fields on its association on the deliberate releases; and
- Detection of LMOs in food, including processed food.

Advances in plant biotechnology have overcome the sexual barriers encountered during conventional hybridization and the entire global gene pool of plants, animals and microorganism has become accessible for crop improvement. The recombinant technology has emerged as a potential approach to manipulate genetic architecture of the crop plants for increasing the crop productivity, better nutritional quality and reduced post-harvest losses.

The global area planted under genetically modified (GM) crops has consistently increased over the last decade reaching up to 170 million hectares in 2012, making it the fastest adopted crop technology. With the rapid development and commercialization of GM crops considerable apprehensions and concerns emerged with regard to their potential impacts on the environment and consequently on human and animal health. This calls for a systematic and scientific approach based upon comprehensive research data and a long-term policy while harnessing this new technology.

Biosafety refers to protecting the environment including human and animal health from the possible adverse effects of the transgenics and the products derived from the use of modern biotechnology. The biosafety concerns emancipate from different steps of recombinant DNA technology used in production of transgenics and also the kind of host

involved. Biosafety issues need to be addressed at all stages of development and release of transgenic crops on a case-by-case basis.

As large number of GM crops are being developed and released for field-testing and commercialization, concerns have been expressed about the potential risks associated with their impact on environment, biological diversity and human health. The risks of GM crops to the environment and in particular to the biodiversity have been extensively assessed worldwide during the last decade. The potential environmental impact of any GM crop will vary depending on the crop's reproductive behaviour, the ecological system in which it is grown, its management strategy and regulatory mechanism.

The data available so far provides no scientific evidence that the commercial cultivation of GM crops has caused environmental harm. However, a number of issues are debated because the potential long-term/cumulative effects are difficult to predict.

With the dramatic increase in global commercial cultivation of GM crops, their detection systems have also evolved at a fairly faster pace in recent years. However, the number and complexity of new events targeting multiple traits pose one of the biggest challenges in the GM diagnostic field. Given that the area under GM crops is expanding rapidly with 155 events representing 24 crops have already been commercialized globally further multiply the GM diagnostic challenge. With the commercialization of GM crops and products thereof, a cost-effective and high-throughput method of detecting GM products is required.

For the detection of GMOs at the level of DNA, Polymerase Chain Reaction (PCR)-based methods are most widely used, whereas for protein-based detection, immunoassays are predominantly used. Among the immunoassays, most commonly used is membrane-based lateral flow strip which is dipped into the prepared sample in extraction solution and the sample migrates up the strip by capillary action. As the sample flows through the detection antibody strip and the capture antibody strip, the protein of interest will accumulate and thus give a high intensity band. The enzyme-linked immunosorbent assay (ELISA), which is plate-based, is well suited to automation and simultaneous testing of a large number of samples. The advantage of ELISA in addition to qualitative diagnosis is that it can also quantify the targeted protein. There are some disadvantages of ELISA-based techniques as they require significant lead time for method development, have high up-front costs for assay development, and cannot discriminate between different transgenic events that express similar protein characteristics. Also GM products might be produced only during certain developmental stages or in certain plant parts and such GMOs are unlikely to be detected with ELISA.

Due to its high specificity and sensitivity, PCR is being utilized as the key technology in GMO detection, identification and quantification. DNA-based diagnostics can be employed for developing risk assessment strategies, which would be required to ensure public confidence in both the technology as well as the capability to regulate them effectively. These detection technologies are also required to ensure quality of the products, assist in post-release monitoring and to help solve legal disputes, if any.

For systematic detection, screening methods are the most useful step for rapid and reliable reduction of test samples which directly identifies negative samples – a step most critical to substantially reduce cost of diagnostics. Based on the results of the screening, additional tests are performed for identification purposes. A sample positive to a screening test needs to be further characterized to confirm its GM origin and to reveal the identity and copies of the transgenes present. GM-specific PCR-based tests can be grouped into categories according to their level of specificity that depends upon the target of the DNA fragment that is amplified in the PCR. These are "gene-specific," "construct-specific" and "event-specific" targeting the inserted gene, the junction between two elements of construct and the junction between the recipient genome and the inserted DNA at the integration locus, respectively. Event-specific is the most robust method which can unambiguously distinguish the genetically modified organism (GMO) of interest, for example the GM event from all other possible GMOs. Hence, the key technical requirement for authorization of GMOs in India is the provision of details of flanking sequences and an event-specific detection method for checking and monitoring of GM events and also to detect unauthorized events in the distribution chain. The developed detection methods need to be thoroughly validated across the laboratories as per the internationally accepted standards.

- **Detection:** The objective is to determine whether a planting material is GM or not, employing a preliminary screening method. These screening methods are based on the PCR detection of the screening elements such as constitutively expressed *Cauliflower Mosaic Virus (CaMV)* 35S promoter sequence or *Agrobacterium tumefaciens nos* terminator gene or commonly present selectable or scorable marker genes in cloning vectors.
- **Identification:** The purpose of identification is to find out which GM trait, inserted gene construct or transgenic event is present and whether they are authorized or not in the country. Construct-specific PCR targets the junction sequences between the adjoining DNA segments for specific detection of inserted genetic construct; whereas event-specific PCR targets the junction sequences in the integration site (plant-construct junction) to detect a specific transformation event.
- **Quantification:** If a crop or its product has been shown to contain GM trait, then it becomes necessary to assess compliance with the threshold regulation by the determination of the amount of each of the transgene present. Real-time PCR is being effectively used for quantitative analysis of transgenes.

Among the different analytical approaches for GM detection, the most direct and widely applied approach targets the genetic modification for instance the modified DNA, using the polymerase chain reaction (PCR). The PCR-based diagnostics are broadly classified as qualitative and quantitative. The tests can be based on the screening of genetic elements including promoters, markers and terminator genes, gene-, construct- or event-specific PCR, multiplex PCR and quantitative real-time PCR.

- Strategy for Detection of GM Crops

In general, the PCR-based method for complete characterization of GM crops is undertaken in a sequential manner:

➢ Testing with endogenous reference gene

The first step is amplification of endogenous reference gene to check for any PCR inhibitors present in the DNA sample and to avoid any false negative results. The endogenous reference gene is specific for a particular crop or family, e.g., *LAT52* for tomato, *Sad1*, *fs-ACP*, *Sah7* for cotton, *SPS* for rice, *SRK* for *Brassicaceae* family, exon 7 of *β-fructosidase* for *Solanaceae* family, *HMG1/γ* for rapeseed, *zein* for maize, *lectin* for soybean etc. An ideal endogenous reference gene should not exhibit allelic variation among varieties of the same species, while it should present a consistently low copy number in the different cultivars.

➢ Initial screening

The purpose of general screening is to determine the transgenic nature of a sample, *i.e.* whether the sample is GM or not. To achieve this, a screening method targeting commonly used control elements, *viz*., promoters *(CaMV 35S, nos, ocs, FMV, actin)*, terminators *(nos, E9, CaMV 35S)* and marker genes (*nptII, aadA, pat, bar, hpt, uidA*) is carried out using simplex PCR.

➢ Identification of GM crop

- **Qualitative Detection:** Targeting the specific transgenes, construct- or event-specific regions
  - ***Gene-specific PCR:*** After screening of the sample, if the results are positive, detection for the presence of specific transgenes, for particular trait in GM crop, is undertaken by simplex or multiplex PCR. In multiplex PCR, several target DNA sequences can be screened for and detected in a single reaction, hence it is cost efficient.
  - ***Construct-specific PCR:*** Construct-specific PCR has more specificity than gene-specific PCR. It targets the junction sequences between two adjoining DNA segments of the transgene construct.
  - ***Event-specific PCR:*** Event-specific PCR has the highest specificity. It targets the junction sequences in the integration site (plant genome-construct junction) to detect a specific transformation event.

- **Quantitative Detection:** PCR is considered as quantitative if an internal DNA strand is co-amplified with target DNA (competitor DNA). For quantitative determination of the amount of GM in the given sample, real-time PCR based on the fluorometric determination of the amplification process is being widely used. The main advantage of real-time PCR assays is that the amplification of target sequences can be measured directly during the reaction by measuring the fluorescence signal that develops in the course of the reaction. The amount of fluorescent will be proportional to the number of amplification cycles.

- Recent advancement in DNA-based diagnostics

Real-time PCR based ready-to-use multi target analytical system: Mostly, event-specific methods are performed independently for different events in range of crops. Ascertaining the presence of possibly several GMOs in transgenic material, food chain and to check for unauthorized events, may be time-consuming and expensive. The real-time PCR based ready-to-use multi target analytical assay for the detection of GMOs can be a rapid and ready-to-use system for the simultaneous detection of multiple GM events in a single experiment, reducing laboratory handling steps to a minimum. The system consists of 96-well-pre-spotted plates containing lyophilized primers and probes for the individual detection of targets allowing the simultaneous identification of all GM events by the use of event-specific primers and probe combinations. The ready-to-use format allows the operators to perform the complete identification analysis in a rapid way requiring only few simple steps.

Multiplex PCR-capillary gel electrophoresis: This approach involves the simultaneous detection of multiple targets by multiplex PCR-capillary gel electrophoresis with identification of amplified targets with respect to size and colour. Multiplex PCRs are performed by forward and reverse primers corresponding to primers of validated realtime PCR assays. Forward primers are fluorescently labelled with different fluorescent dyes to allow identification of each amplicon by capillary gel electrophoresis. The most-similar-sized amplicons are being labelled with different dyes.

Microarrays: Microarray (DNA chip-technology) has been developed in recent years for automated rapid screening of gene expression and sequence variation of large number of samples. Microarrays, consisting of glass supports containing specific oligonucleotide capture probes immobilized on their surface, allow the analysis of multiple sequence targets in one single assay. The main advantages of DNA microarray technology are miniaturization, high sensitivity and screening throughput. For GM detection, different DNA microarray approaches in combination with multiplex PCRs have been developed. NASBA Implemented Microarray Analysis (NAIMA) is a recently developed novel multiplex quantitative DNA-based target amplification method for sensitive, specific and quantitative on-chip detection of GMOs.

With the faster pace at which global cultivation area under GM crops is increasing, detection of GMOs has become a challenging task, as the new generation products involve a set of different genes/promoters/markers and more complex GM events with stacked/pyramided/multiple genes which are also being developed in recent past, for example: MON15985 event of cotton (Bollgard®II) with *cry1Ac and cry2Ab* genes, MON88914 with stacking of Bollgard®II with herbicide tolerance, Golden Rice with *psy*, *crt1* and *lcy* genes, triple stacked maize conferring resistance to two insect pests and herbicide tolerance, SmartStax maize with eight different genes coding for several pest resistance for below and above ground insects and herbicide tolerance of more than one available chemical herbicides in the market. In this background, the future diagnostics need to be multi-detection systems which enable a search for a high number of possible modifications in a single step.

- **Detection Methods for GM Cotton in India**

The Central Institute of Cotton Research (CICR), Nagpur, has developed three Bt cotton testing kits namely, Cry1Ac Bt-Quant, an ELISA kit, Cry1Ac Bt-detect, a dot-blot assay kit and Cry1Ac Bt express, a dip-stick format, for the detection of Bt toxin. These kits have been effectively deployed to verify the purity of Bt seed and ensure the supply of quality Bt hybrid seed to the farming community.

The National Bureau of Plant Genetic Resources (NBPGR) of the Indian Council of Agricultural Research (ICAR) is the nodal agency for importing transgenic material for research and development purposes. The NBPGR issues import permit (IP) and undertakes the quarantine processing of the imported transgenic materials as per the Plant Quarantine (Regulation of Import into India) Order 2003. The Director of NBPGR issues the import permit (IP) based on the technical clearance granted by the Review Committee of Genetic Manipulation (RCGM) of the Department of Biotechnology (DBT), Government of India. By issuing the import permit, NBPGR allocates national identity number (Exotic Collection number) to all accessions of the imported transgenic material before releasing to the importing agency/indentor. Besides quarantine processing of the imported transgenic planting materials, molecular diagnosis for the specific promoters/terminators/markers/ transgenes is also being undertaken. In the GM detection laboratory at NBPGR, DNA based (Simplex/Multiplex/Real Time PCRs) detection assays for a range of GM crops in the country has been developed. Robust DNA-based GM diagnostics for initial screening and for identification and quantification of GM content in more than ten GM crops have been developed. Some of the developed GM diagnostics are:

- For initial screening of GM crops for checking the GM status of a sample irrespective of crop and trait, PCR assays targeting commonly used markers, promoter and terminator genes in simplex and multiplex formats.
  - Hexaplex PCR assay for simultaneous amplification of commonly used six marker genes, *i.e. aadA, bar, hpt, nptII, pat* and *uidA*.
  - Heptaplex PCR assay simultaneously amplifying a combination of marker genes; *nptII, aadA, pat, uidA* and regulatory elements viz., *CaMV 35S, nos* promoters and *nos* terminator.
- Decaplex and triplex PCR assays to differentiate between two major commercialized Bt cotton events (covering more than 80 percent of the total cultivated area for GM cotton) in India, *viz*., MON531 and MON15985 along with simplex PCRs for each transgene element present in these two Bt cotton events.
- Real-time PCR based quantitative analysis of *cry1Ac* gene in Bt cotton events, MON531 and MON15985; *cry2Ab* gene in MON15985.
- Rapid and cost-effective diagnostic kits for GM cotton events *viz*. Bollgard®I (MON531) and Bollgard®II (MON15985).

GM crop/event	PCR Method	Target (s)	LOD/LOQ	Reference
MON531	Multiplex	*cry1Ac*, P-35S, T-*nos*, *nptII*, *aadA*, P-35S-*cry1Ac* construct and *Sad1*	–	Randhawa *et al.*, (2010)
	Real-time	*cry1Ac*	LOQ: 0.01%	
MON15985	Multiplex	*cry1Ac*, *cry2Ab*, P-35S promoter, T-*nos*, *nptII*, *aadA*, *uidA*, *cry1Ac* construct, *cry2Ab-CTP2* construct and *Sad1*	–	Randhawa *et al.*, (2010)
	Real-time	*cry1Ac*, *cry2Ab*	LOQ: 0.01%	
Bt cotton with *vip3A* type gene	Multiplex	*vip3A* type gene, P-35S, T-*nos*, *nptII*	–	Singh *et al.* (2008)
Bt cotton hybrids, MECH-12Bt, MECH-162Bt, MECH-184Bt	Multiplex	*cry1Ac*, P-35S, T-*nos*, *nptII*, *fs-acp1*	–	Singh *et al.* (2007)
Bt cauliflower	Multiplex	*cry1Ac*, P-35S, *SRK*	–	Randhawa *et al.*, (2008)
GM tomato with *osmotin* gene	Multiplex	*osmotin*, P-35S, *LAT52*		Randhawa *et al.*, (2009)
Bt rice (MRP 5401 *Bt*)	Simplex	*cry1Ac*	LOD: 0.01%	Randhawa & Singh (2012)
	Multiplex	*cry1Ac*, P-35S, T-*nos*, *nptII*, α-*tubulin*	–	
	Real-time	*cry1Ac*	LOD, LOQ: 0.05%	
GM potato with *AmA1* gene	Simplex	*AmA1*	LOD: 0.01%	Randhawa *et al.*, (2009)
	Multiplex	*AmA1*, P-35S promoter, T-*nos*, *nptII*, *UGPase*	–	
Bt brinjal EE1 event	Multiplex	*cry1Ac*, P-35S, T-*nos*, *aadA*	–	Randhawa *et al.*, (2012)
	Simplex	EE1 event	LOD: 0.01%	
	Real-time	EE1 event	LOD, LOQ: 0.05%	
Bt crops with *cry2Ab* gene	Simplex	*cry2Ab*	LOD: 0.1%	Kamle *et al.* (2012)

Table 2. PCR-based detection protocols for GM crops either commercialized or under different stages of field trials in India

GM detection laboratory at NBPGR participated in eight proficiency/comparative testings under ISO/IEC17043:2010 of accreditation for quality assurance and global harmonization of GM detection organized by Community Reference Laboratory, European Commission, Joint Research Centre, Italy and Grain Inspection, Packers and Stockyards Administration (GIPSA), USDA, for detecting the unknown GM contents in the samples using Real Time PCR assays.

Further details about the international agencies offering proficiency testing such as the Community Reference Laboratory, European Commission's Joint Research Centre (JRC), the Grain Inspection, Packers and Stockyards Administration (GIPSA) and International Seed Testing Association (ISTA) was also given. Dr Randhawa also made mention of various ASEAN initiatives in capacity building in the area of GM detection.

Dr Randhawa stressed that to minimize the time required as well as the costs, testing laboratories need to build up a sound decision tree to identify and quantify GMOs with the smallest number of PCRs possible. Therefore, there is an urgent need to evolve a close collaboration among various diagnostic laboratories and technology developers to work in tandem with the regulatory agencies in order to achieve the challenge of GM diagnostics for speedy commercialization and ensuring public confidence in GM crops for the benefit of society.

Dr Randhawa also introduced Article 11 of the Cartagena Protocol on Biosafety on LMOs-FFP as commodity import:

- A Party that is making a final decision regarding domestic use, including placing on the market of an LMO that may be subject to transboundary movement for direct use as food or feed or for processing, shall, within fifteen days of making that decision, inform the parties through the BCH. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the BCH. This provision does not apply to decisions regarding field trials.
- The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.
- Any Party may request additional information from the authority identified in paragraph (b) of Annex II of the protocol.
- A Party may take a decision on the import of LMOs intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of the Protocol.
- Each Party shall make available to the BCH copies of any national laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing, if available.
- A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the BCH that its decision prior to the first import of an LMO intended for direct use as food

or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

- ➢ A risk assessment undertaken in accordance with Annex III; and
- ➢ A decision made within two hundred and seventy days.

- Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of an LMO intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.
- Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.
- A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Other topics covered by her in detail were:

- Detection of LMOs-FFP (commodity bulk shipment samples) in different sampling approaches/technologies at a designated facility (lab)
  - ➢ what to detect and what to decide: choice of approaches and endpoint goals and
  - ➢ alternative technical methods for detection and sampling strategies
- Detection of LMOs-FFP for environmental monitoring after the importation approvals
  - ➢ approved importation as commodity, on unintentional spills by local transportation and
  - ➢ monitoring of LMOs-FFP grown in fields on its association on the deliberate releases

6 Conclusion and Recommendations

Conclusion

The workshop achieved its objective and was ended successfully with renewed commitments from the participating countries to reactive Asian BioNet within shortest possible time. The member countries agreed to send country information on regular basis to the Secretariat for posting in the webpage of Asian BioNet. The workshop participants came from 11 countries: 7 SE Asia (Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Thailand and Viet Nam), 3 South Asia (Bangladesh, India and Sri Lanka) and 1 Near-East (South Korea) to discuss and share experiences in the implementation of biosafety regulation in their own country. The participants were mixed – consisting of regulators from some countries and scientists particularly from countries with no/minimal experience in implementing biosafety regulations in their countries. The scientist participants appeared to have very limited knowledge and experience in biosafety regulation.

All participating countries have national biosafety framework, laws and guidelines for handling GMOs, although the status of its implementation varies considerably among the countries. Most countries have ongoing biotechnology research in the lab and greenhouse. Only a few countries have not received/processed applications for either environmental release (Article 15) or transboundary movement of LMO-FFP (Article 11). Capacity building/development is very much needed in all aspects of risk analysis (assessment, management and communications) and decision-making process. The country presentations were very useful in providing the background on the status of biosafety implementation and activities in the participating countries.

It was unanimously agreed that DOA will remain as Secretariat of "Asian BioNet" and will provide necessary administrative and logistic supports to keep Asian BioNet updated. The member countries will send all available information at country level to the Secretariat of Asian BioNet twice a year to post in the website of Asian BioNet. Decision was taken to redesign getup of Asian BioNet in cooperation with FAO.

The topics covered by the resource persons in the workshop were: overview of risk assessment and LMOs; problem formulation on environmental risk assessment (ERA); ERA for cultivation; AIA and ERA for commodity; risk management; risk communication, and detection of LMOs, which covered important aspects of biosafety.

There is an uneven status of implementation and capacities on biosafety regulation among the participating countries. Participants' feedback from both plenary and sideline discussions indicated the priority need for capacity development in risk assessment for LMO-FFP particularly on food safety assessment and effective risk communications. With regard to the conduct of the workshop, they congratulate FAO RAP/DOA for organizing the workshop. However, for future workshops, a pre-evaluation of the participants and post-evaluation of the workshop based on the assessment to be provided by the

participants are highly recommended. The countries in the region should continue to collaborate to strengthen capacity within each country in all areas of biosafety implementation. This is very important in light of the forthcoming implementation of regional economic integration that will expand to zero tariffs almost all goods by 2015.

Recommendations

1. It is recommended that participating countries prioritize the traits and crops that require biotechnological interventions so that the capacity building can be focused on technology development, risk analysis and containment requirements, including the biosafety compliant laboratory needs in the region. (Action: All countries)
2. Operations of Asian BioNet should be revitalized for effective information sharing on agri-biotechnology and biosafety. The Department of Agriculture (DOA), Thailand will continue to act as Secretariat of Asian BioNet. They will provide all administrative and logistic supports to keep Asian BioNet updated.
3. Develop a database of laboratories working in GM detection in each country with nodal persons for contact, coordination and information sharing. (Action: DOA)
4. Organize capacity building courses and workshops to harmonize/standardize processes, protocols, means and mechanisms of GM detection and sampling strategies vis-à-vis transboundary movement and domestic R&D based commercialized products. (Action: India, FAO)
5. Coordination among various national agencies involved in the regulation of GMOs should be strengthened. (Action: All countries)
6. Countries are also urged to strengthen documentation and sharing of experiences in risk assessment and risk management. (Action: All countries)
7. With assistance of FAO, participating countries in cooperation with other regional and international agencies should strengthen their efforts to improve and harmonize at national and regional levels GMO risk assessment and risk management methods. (Action: FAO, all countries)
8. FAO, in cooperation with other agencies may organize regional workshops to address emerging issues, and effective communication of risk assessment and risk management decisions. (Action: FAO)
9. The net-work meetings should be organized every two years with rotation of host countries. (DOA, FAO, all countries)
10. FAO should bring out a status report on capacity development related to biosafety in Asia. (FAO)
11. A regional project on fostering cooperation in biosafety among Asian countries should be developed. (FAO)

Annex I

Workshop Programme

Day 1 (17 June 2013)	
Time	**Programme**
08:00 – 09:00	Registration
Opening Session	
09:00 – 10:30	***Opening session*** • **Welcome address** – Mr Vili Fuavao, Deputy Regional Representative, FAO Regional Office for Asia and the Pacific on behalf of Mr Hiroyuki Konuma, Assistant Director-General and Regional Representative for Asia and the Pacific • **Inaugural address –** Mr Alongkorn Korntong, Director of Biotechnology Research and Development Office, Department of Agriculture on behalf of Mr Dumrong Jirasutas, Director-General, DOA • **Vote of thanks –** Subash Dasgupta, Senior Plant Production Officer, FAO Regional Office for Asia and the Pacific • Group photo
10:30 – 10:45	Tea Break
Overview & Status of Biosafety in Asian Countries	
10:45 – 11:45	Agricultural Biotechnology: A global perspective and regional collaboration by Dr Andrea Sonnino, Senior Agricultural Research Officer, FAO headquarters, Rome 1. Biosafety Regulations of Asian Countries by APAARI 2. Industry Views and Initiative on Biosafety Capacity Building by Ms Sonny Tababa, Director, CropLife Asia
11:45 – 12:30	Progress of Asian BioNet since 2009 (Subash Dasgupta/Dr Hathairat Urairong**)**
12:30 – 13:30	Lunch
13:30 – 15:10	Presentation of biosafety and biotechnology status in participating countries: Country presentation (each country will have 15 minutes for presentation and 5 minutes for discussion) Five countries

15:10 – 15:30	Break
15:30 – 17:10	Continue: Presentation of biosafety and biotechnology status in participating countries: Country presentation (each country will have 15 minutes for presentation and 5 minutes for discussion) Five countries
17:10 – 18:00	General discussions including additional country presentation if any
18:00 – 21:00	Welcome dinner (DOA/FAO)
Day 2 (18 June 2013)	
09:00-17:00	Risk analysis in biotechnology (risk assessment and risk management) Prof Dr Desiree Hautea and Prof Dr Kazuo Watanabe
09:00 – 10:00	I. What is LMOs-FFP? 45 minutes plus question 15 min (Prof Dr Hautea)
10:00 – 11:00	II. International governance: laws, regulation, implementation and collaboration under Cartagena Protocol on Biosafety and international organizations. 45 min plus 15 min discussion: Outline of AIA under the CPB (Prof Dr Watanabe)
11:00 – 11:15	Break
11:15 – 12:15	III. Problem formulation on environmental risk assessment and risk management for AIA. 45 min plus 15 min (Prof Dr Watanabe)
12:15 – 13:30	Lunch break
13:30 – 14:30	IV. Environmental risk assessment framework and examples of countries (EU, GMAC, Singapore, Japan, Taiwan, the Philippines etc.). 45 minutes plus 15 min (Prof Dr Hautea and Prof Dr Watanabe)
14:30 – 15:30	V. Examples of environmental risk analysis on specific LMOs-FFP (Japan, Philippines, Islamic Republic of Iran, etc.). (Prof Dr Watanabe) Cases on field assessments
15:30 – 15:45	Break
15:45 – 17:00	Risk management and risk communication (Prof Dr Hautea)

Day 3 (19 June 2013)	
9:00 – 16:30	**LMOs-FFP testing, monitoring and detection –** Dr Gurinder Jit Randhawa
9:00 – 10:15	Food safety issues on LMOs-FFP: general introduction of the concept and procedures (Dr Randhawa). One-hour talk and 15 min discussion.
10:15 – 10:45	Brief introduction of Article 11 of the Cartagena Protocol on Biosafety on LMOs-FFP as commodity import (Dr Randhawa)
10:45 – 11:00	Break
11:00 – 12:00	Detection of LMOs-FFP (commodity bulk shipment samples) in different sampling approaches/technologies: I. What to detect and what to decide: choice of approaches and endpoint goals? (Dr Randhawa)
12:00 – 13:00	Lunch break
13:00 – 14:15	Detection of LMOs-FFP (commodity bulk shipment samples) in different sampling approaches/technologies at a designated facility (lab): II. Alternative technical methods for detection (PCR, ELISA, Paper) and sampling strategies (Dr Randhawa)
14:15 – 15:15	Detection of LMOs-FFP for environmental monitoring after the importation approvals: (Dr Randhawa) 1) Approved importation as commodity, on unintentional spills by local transportation (Dr Randhawa and Prof Dr Watanabe)
15:15 – 15:30	Break
15:30 – 16:15	Detection of LMOs-FFP for environmental monitoring after the importation approvals. (Dr Randhawa) 2) Monitoring of LMOs-FFP grown in fields on its association on the deliberate releases.
16:15 – 17:00	Detection of LMOs in food, including processed food (Dr Randhawa)
18:30 – 21:00	Dinner (FAO/DOA)

Day 4 (20 June 2013)	
09:00 – 12:00	AIA (Advanced Informed Agreement): Prof Dr Desiree Hautea and Prof Dr Kazuo Watanabe
09:00 – 10:15	Decision-making on AIA and examples of the imports and field disseminations based on BCH and national repository of the AIA and domestic approvals on deliberate releases of LMOs into the environment (Prof Dr Watanabe)
10:15 – 10:30	Break
10:30 – 12:00	Current topics at CPB: Implementation questions at the member countries at the workshop (Prof Dr Hautea and Prof Dr Watanabe)
12.00 – 13.00	Lunch
13:00 – 15:00	Meeting of Asian BioNet: Where do we go from here? (Subash Dasgupta/Dr Hathairat Urairong)
15:00 – 15:30	Tea break
15:30 – 16:30	Drafting recommendations
16:30 – 17:30	Recommendations/Follow up and Conclusions-FAO

Annex II

Welcome Address

of

Hiroyuki Konuma

Assistant Director-General and Regional Representative for Asia and the Pacific

Delivered by

Vili Fuavao

Deputy Regional Representative

FAO Regional Office for Asia and the Pacific

at

the 2nd Regional Workshop on Strengthening Regional Cooperation and National Capacity Building on Biosafety in Asia

17-20 June 2013

Miracle Grand Convention Hotel, Bangkok, Thailand

Dear Mr Dumrong Jirasutas, Director-General, DOA
Distinguished participants
Respected resource persons
My colleagues

Ladies and Gentlemen

A very good morning to you all!

It is a great pleasure for me to be here to say few words in the opening ceremony of this very important **Regional Workshop on Strengthening Regional Cooperation and National Capacity Building on Biosafety in Asia**. First of all, I would like to thank the Royal Thai Government with whom FAO has been working since 2002 on "Biosafety of GMO Crops in Asia" for their continuous support and cooperation to move this issue forward. Through our joint efforts we have achieved considerable progress in capacity building of member countries on biosafety of GMO crops. However, we have to do more in future given that subject is still very complex in nature. But this subject has always received high priority from FAO and FAO Regional office has been closely working with FAO Hqs on this issue. We have therefore, tried to ensure participation of highly reputed resource persons as speakers in this workshop.

The main objective of the workshop is to assist member countries in developing required policy documents along with regulatory frameworks and other associated documents related to biosafety evaluation of biotech crops before recommending them for mass cultivation.

The workshop has three specific objectives:

1. Promote technical capacity of member countries on various issues of biosafety and LMOs associated with food and agriculture.
2. Support development of related policies and biosafety regulatory frameworks and to ensure safe evaluation of LMOs associated with food and agriculture.
3. Further strengthen regional cooperation on biosafety and LMOs associated with food and agriculture including the operationalization of established "Asian BioNet"

Expected outputs:

- Appropriate flow of adequate information associated with biosafety to stakeholders, especially on the NFPs and further decision makers at various countries ensured
- Country status report of participating countries on biosafety and LMOs presented and shared by the participants, and issues and future challenges identified
- Knowledge and skills of participants to develop biosafety rules and regulation, acts, laws, guidelines and polices (depending on the country situation) enhanced
- "Asian BioNet" is fully reactivated and its secretariat further strengthened in order to link its existing efforts for different dimensions on biosafety capacity building and information exchanges
- Regional cooperation associated with biosafety and LMO related to food and agriculture strengthened, and future load map to enhance regional cooperation formulated.

Dear All,

Understanding on biosafety matter varies from country to country and they are at different stages of development. In view of that, the process initiated by DOA and FAO should continue in future in order to enhance their capacity and understanding on biosafety.

This workshop has significance and that is why all members of ASEAN+3 countries except Brunei Darussalam are attending. It is happening when we are only two years away from the integration of ASEAN countries. Biosafety policies, rules, regulations, acts and framework will play increasingly significant roles during the integration process. With this point of view, this workshop has been aptly timed. To move forward with biosafety matters, I firmly believe that this workshop will be able to achieve above-mentioned expected outputs in the course of the two day exercises.

I would like to thank DOA again for their excellent cooperation to arrange this workshop successfully. Special gratitude goes to our resource persons for giving their valuable time to attend this workshop. We are also grateful to Mr Andrea Sonnino from FAO, Hqs and APAARI Representative for having with us.

Thank you again and wish you a pleasant stay in Bangkok.

Annex III

Opening Remarks

by
Mr Alongkorn Korntong
Director of Biotechnology Research and Development Office
Department of Agriculture
on the occasion of the Opening Ceremony
of
Regional Workshop on Strengthening Regional Cooperation and
National Capacity Building on Biosafety in Asia
17 June 2013
Miracle Grand Hotel, Bangkok

Mr Vili Fuavao, Deputy Regional Representative,
FAO Regional Office for Asia and the Pacific
Distinguished Participants
Ladies and Gentlemen

First of all, I highly apologize to inform that the Assistant Director-General cannot join this open ceremony today because he has an urgent obligation received last Friday, which he has to be a representative for presentation on the next year budget request of the Department of Agriculture at Ministry of Agriculture and Cooperatives. I am entrusted to be his representative for delivering opening remarks today.

On behalf of the Department of Agriculture and on my own behalf, I would like to express our very warm welcome to all of you. It gives me great pride and honor to preside over the opening ceremony of the Regional Workshop on Strengthening Regional Cooperation and National Capacity Building on Biosafety in Asia which is scheduled to be held for four days from 17 to 20 June 2013, here in Bangkok, the home for the FAO Regional Office for Asia and the Pacific.

I am delighted with the very warm cooperation and gesture shown by all relevant stakeholders. I also would like to acknowledge the effort concerted by the biosafety team of FAO, the Biotechnology Research and Development Office of the Department of Agriculture, and all other relevant Biosafety Agencies from the ASEAN Countries and to all countries all over the Asia and the Pacific Region.

It is a fact that different countries in the Asia-Pacific region are at different stages of development with regard to agricultural biotechnology. It is also a fact that agricultural biotechnologies represent a broad range of technologies used in food and agriculture for genetic improvement, conservation of genetic resources, plant and animal disease diagnosis among others. However, it is just but natural for some other people who always

perceive the negative side of biotechnology as Genetically Modified Organisms (GMOs) or Living Modified Organisms (LMOs). This kind of thinking could only be corrected if we have strong capacity on biosafety.

As I read in between lines of the workshop module, the key words I noted from the specific objectives for this workshop are the promotion of technical capacity on biosafety, support for policies and regulatory frameworks, and further strengthening regional cooperation on biosafety through Asian BioNet. I would like therefore to urge all of the distinguished participants to contribute your expertise on how we could attain these vital and crucial objectives for building the capacity on biosafety in Asia.

I would also like to make special mention about the Asian BioNet. The Asian BioNet is the major outcome of the Project entitled "Capacity Building in Biosafety of GM Crops in Asia" (GCP/RAS/185/JPN)" which was implemented by FAO Regional Office for Asia and the Pacific, during 2002-2005. The Asian BioNet is one platform for the acquisition of knowledge and capacity development in biotechnology, development of national biosafety policy, and further strengthening of biosafety network. Thailand thru its Biotechnology Research and Development Office of the Department of Agriculture, expresses its capacity and readiness to serve as the Asian BioNet Secretariat. Thailand therefore, would like to request for your support to Thailand as the Asian BioNet Secretariat and would like to encourage your commitment and active participation to this Asian BioNet.

In conclusion, I would like to express on behalf of the Department of Agriculture and on my personal behalf, our very warm welcome to all of you. I wish you all a pleasant stay and productive deliberations.

Having said this, I now declare the Regional Workshop on Strengthening Regional Cooperation and National Capacity Building on Biosafety in Asia now open.

Thank you very much.

Annex IV

Closing Remarks
by
Subash Dasgupta
20 June 2013

Distinguished participants
Respected resource persons;
My colleagues
Ladies and Gentlemen
Good afternoon to you all!

I was extremely glad to have been informed that through your hard work for the last four days, we have been able to achieve the objectives of the workshop and I therefore, thank you all for your joint efforts in making this workshop successful.

A lot of new scientific knowledge and information relevant to biosafety were discussed in this workshop which was very useful for our participants and it is our expectation that experience gathered here will be used at the country level.

The workshop also resulted in the drafting of 10 concrete recommendations which will undoubtedly help to develop the country capacity on handling biosafety issues in more appropriate ways.

FAO will review all recommendations very carefully and will identify appropriate interventions, if necessary and as always, will be happy to assist in the implementation of these recommendations.

I express my sincere gratitude to the resource speakers for their tireless efforts in order to provide maximum information to the participants. We hope that participants will try their best to further disseminate acquired knowledge, thanks to this workshop. We would also like to thank all the participants who managed to come to Bangkok within a short period of time. We are very grateful to CropLife Asia for sending the participants to this workshop.

Special thanks go to the Department of Agriculture (DOA). It would not have been possible to arrange this workshop so successfully if we didn't have their direct support. I extend my thanks to all the colleagues of the DOA involved in arranging this workshop for their hard work and we hope that such type of cooperation between DOA and FAO will continue in future as well.

Dear all, let us not call this the end. Let us instead work together for better future of our nations. I hope communication among us will be continued and strengthened though

newly reactivated Asian BioNet and would like to thank DOA again for agreeing to be the Secretariat of the Asian BioNet. I do hope you will send your country information regularly to add to the Asian BioNet.

Thank you all again and wish your safe return to your home country.

Annex V

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