REPORT OF THE REGIONAL BIOSAFETY WORKSHOP

30 November to 4 December 2009
Bangkok, Thailand

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
REGIONAL OFFICE FOR ASIA AND THE PACIFIC, BANGKOK
AND
DEPARTMENT OF AGRICULTURE
MINISTRY OF AGRICULTURE AND COOPERATIVES
THE ROYAL THAI GOVERNMENT

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
REGIONAL OFFICE FOR ASIA AND THE PACIFIC
BANGKOK , THAILAND

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I. INTRODUCTION

The Regional Biosafety Workshop was held during 30 November to 4 December 2009 at Rama Gardens Hotel, Bangkok, Thailand. The list of participants and workshop programme are attached as annexes 1 and 2. A total of 33 participants from 13 countries (Bangladesh, Cambodia, China, India, Indonesia, Malaysia, Myanmar, Pakistan, Philippines, the Republic of Korea, Sri Lanka, Thailand and Viet Nam), together with representatives of FAO attended the workshop. The Republic of Korea, Cambodia and Myanmar joined the workshop as new members whereas the other ten countries were the beneficiary countries of the prior project "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 during 2002 to 2005 with the financial support of the Government of Japan and successfully completed in December 2005. The major objectives and expected outputs of the workshop are given in the programme which can be found in annex 2.

The Deputy Regional Representative, FAO Regional Office for Asia and the Pacific (FAO/RAP), Bangkok, Thailand, delivered the Opening Speech on behalf of the FAO Assistant Director-General and Regional Representative for Asia and the Pacific. The Director, Office of Biotechnology Research and Development, Department of Agriculture, Ministry of Agriculture and Cooperatives, the Royal Thai Government, delivered the Welcome Address on behalf of the Director-General, Department of Agriculture, Ministry of Agriculture and Cooperatives, the Royal Thai Government.

II. OPENING OF THE WORKSHOP

The workshop commenced on 30 November 2009 at 09.00 hours with the inaugural speech of Mr Hiroyuki Konuma, Officer-In-Charge and Deputy Regional Representative, FAO Regional Office, Bangkok, Thailand. In his opening speech, Mr Konuma welcomed the participants on behalf of Mr He Changchui, Assistant Director-General and Regional Representative for Asia and the Pacific, FAO, Regional Office, Bangkok, Thailand for participating in the workshop. Mr Konuma informed them that the basic purpose of the week-long workshop was to enhance the capacity of member countries by providing up-to-date information on different aspects of biosafety and to ensure that farmers and governments can make better decisions on how to use the results of technological developments while protecting farmers, consumers and the environment. The workshop also aimed to further strengthen the established communication network/platform (Asian Bio-Net) and to update the 2004 *Benchmark document on the needs and present status of capacity building in biosafety of GM crops in Asia* published under the prior project "Capacity Building in Biosafety of GM Crops (GCP/RAS/185/JPN)" funded by the government of Japan that ran during 2002 to 2005.

Mr Konuma stated that FAO has been assisting its member countries since 1999 on this vital issue by providing policy advice, technical assistance and capacity building, as well

as updating their capacities through better access to science-based information, training, workshops, seminars, and by enhancing the laboratory facilities of some countries. Mr Konuma informed the participants that FAO's expectation from the workshop was very high and hoped that the workshop would be able to meet this expectation. He thanked the Royal Thai Government for agreeing to continue acting as host country of the Asian Bio-Net. The text of the full speech of Mr Konuma is attached in annex 3.

Dr Alongkorn Kornthong, Director, Office of Biotechnology Research and Development, Department of Agriculture, delivered the welcome address on behalf of the Director-General, Department of Agriculture (DOA). He welcomed the participants on behalf of the DOA and on his own behalf and said that it gives him a great honour and pleasure to address the opening session of the Regional Biosafety Workshop. He expressed his satisfaction to learn that a list of highly respected scientists working in the field of biotechnology and biosafety are here to deliver on important topics that are much given attention and talked about in the region today.

Dr. Kornthong said that countries in the region are at different stages of development with regards to biosafety. He emphasized on need to focus on capacity building to fully implement the biosafety policy. In this sense, he congratulated FAO for coming up with this very timely and relevant workshop, in order to address pending issues on biosafety that needs our immediate attention.

On behalf of the DOA, he especially acknowledged the FAO Regional Office for Asia and the Pacific for financing the workshop. In closing, once again, he welcomed all to Thailand and wishes a productive workshop and an enjoyable stay here in the city of Bangkok. The text of the full speech of Dr Alongkorn Kornthong is attached in annex 4.

III. KEYNOTE ADDRESS

Dr K. V. Prabhu, Head, Division of Genetics, Indian Agricultural Research Institute, New Delhi, India delivered a keynote paper titled "Agricultural biotechnology: a global perspective and regional collaboration", on behalf of Mr Andrea Sonnino, Senior Agricultural Research Officer, Research and Extension Unit, FAO, Rome, who could not attend the workshop because of a prior commitment at the FAO, Rome. He highlighted that the new challenges require renewed efforts, and the responsibility of biosafety related decision making rests on the national authorities. There is a need to strengthen the national biosafety systems and develop regional collaboration to take full advantage of the emerging opportunities. The major weaknesses in some of the Asian countries include the absence of sufficient policy and regulatory frameworks, weak institutions, a limited number of trained personnel and inadequate public information and participation. Apart from these, the challenges of assessing and managing the risks associated with the release of new Genetically Modified Organisms (GMOs) in complex and diverse ecosystems (centres of origin) increase the cost of regulations. However, considering the huge potential of GM crops in sustainable crop production, application of biotechnological developments in the Asian countries is essential. To achieve this objective, the need for enhanced collaboration among participating countries was emphasized.

IV. LEAD PRESENTATION

Professor (Ms) Desirée M. Hautea, Professor of Genetics, Molecular Biology and Biotechnology, University of the Philippines, Los Banos, Philippines and Member of the Department of Agriculture Scientific and Technical Review Panel for risk assessment of GM crops, gave a presentation on risk analysis in biotechnology (with emphasis on GM plants). The presentation provided the participants with information on the basic concepts of biological risks and the principles and detailed methodologies of the risk analysis processes. The focus was primarily on the environmental risk assessment of genetically modified (GM) crops although attention was also given to some aspects of food/feed safety assessment. Some examples were given to illustrate the methodology of risk assessment and risk management processes. Current issues in risk assessment were discussed such as stacked traits and a biotic stresses.

Risk analysis is used in its broadest sense as an integrated process consisting of three major components: risk assessment, risk management and risk communication. Risk assessment is the scientific (and most crucial) part of the risk analysis process. Although regulatory frameworks for risk assessment vary among countries, some common general principles were adopted in assessing the risks posed by GMOs to human health and the environment. Risk assessment is science-based and must comply with high scientific standards. Risk should be assessed on a case-by-case basis and conducted in a step-by-step or structured manner. Risks should be compared in the context of the risks posed by the non-modified counterpart. This requires appropriate comparator and well-established baseline information. Risk management is the second and decision-making component of the process of risk analysis. It is concerned with evaluating whether the risks identified by the risk assessment process are acceptable and manageable, then selecting and implementing the control measures as appropriate to ensure that risks are minimized or controlled. Risk management measures could include containment/confinement strategies and post-release monitoring. Risk communication to various stakeholders underpins the risk assessment and risk management processes. It strengthens the over-all process of risk analysis by helping to define the issues and providing the link and the feedback mechanism that informs the two processes. In communicating risks, it is important to remember that risk perception among various stakeholders may differ considerably. The results of the risk assessment and risk management processes should be communicated in a transparent and user-friendly manner. Risk analysis applied in the broad sense separates the risk assessment from risk management. In practice, however, this separation is rarely clear-cut and variation in its implementation exists among countries and across regulatory institutions. Harmonization of the different methods used in risk assessment and risk management on a regional/international basis is needed. More research is needed to fill the knowledge gap particularly for other GMOs and traits.

Dr K. V. Prabhu, Head of Division of Genetics and In-charge of the National Phytotron Facility, Indian Agricultural Research Institute, New Delhi, India presented a paper on the biosafety management aspects of dealing with GM plants under containment. The

safety levels associated with risks faced were explained as safety level 1 for low level risks, safety level 2 for medium level risks, safety level 3 for moderately high risks and safety level 4 for high level risks. The features of the containment levels to manage these risks were explained by describing the biosafety containment level 1 to level 4. Each containment level was taken with reference to the different transgenic events assessed for the risks associated with the gene, product or possible risk to environment and health. Multiple examples were taken from real experience with pictures of each experiment being managed in the containment. It was concluded that for most of the productivity and sustainability related agricultural research, GMO safety level containment of level 1 and 2 were acceptable but in a few cases containment level 3 would be required when dealing with resistance to viruses or other pathogens such as Ug99. The different set-ups required and the means to manage them to meet the GMO safety needs were also explained to the participants. It was recommended that those involved should be clear about the needs as assessed and accordingly should design the containment level without getting into the most stringency based containment in each institution. A separate recommendation was made on how the "screen house" GMO containment facility structure should be designed crop-wise to screen for the best event before implementing a confined field trial. A design being developed in India was described as a model for the purpose.

Dr (Ms) Hathairat Urairong, Deputy Director, Biotechnology Research and Development Office, Department of Agriculture, Thailand, delivered a presentation on the current status of plant biotechnology development and application in Thailand. The country has had an active programme for the development of GM crops for over ten years, which has led to the development of GM tomato carrying the coat protein gene of tomato yellow leaf curl virus, GM papaya for the resistance to papaya ring spot virus, GM chili for resistance to chili vein banding mottle virus, and GM rice variety- Khaw Dawk Mali 105 with pyrroline-5-carboxylate synthesise (P5CS) for salt and drought tolerance. The most advanced development is of virus resistant GM papaya generated in collaboration with Cornell University - the transgenic lines were found to have excellent resistance under field conditions. In 2001, a moratorium was imposed by the Cabinet, prohibiting the farm-scale trials of GM plants because of the concerns of NGOs related to environmental safety. In 2005, the moratorium was lifted and GM crops field trials were allowed in fields belonging to the government if there is no objection from the public, and Cabinet approval is given prior to the start of the trial. Apart from the development of GM crops, biotechnological tools such as marker aided selection (MAS) and gene tagging are being used extensively to develop improved varieties, for resistance to abiotic and biotic stresses and improved quality of plants such as rice, rubber tree, oil palm, fruit crop, energy crop, tomato, potato, peanut, soybean, waxy corn, etc. The country also has active programmes for the production of efficient biofertilizers and bio-control agents minimizing crop losses. The biotechnological tools have also been used for the development of diagnostic kits to detect economically important plant viruses and bacteria pathogens. Some of the major constraints in utilizing the benefits of biotechnology are lack of clarity on national policy on GM crops, negative attitude of NGOs towards GM crops, inadequate funding on biosafety, and the limited number of well-trained researchers and regulators. She highlighted the need for field trials for biosafety evaluation of GM crops such as GM papaya, improved public perception and

awareness regarding GM crops, evaluation of the economic impact of the GM crops, enhancement of capacity building for regulatory bodies, and preparation for the management of the co-existence of GM and non-GM crops.

Dr Banpot Napompeth, Member, Cartagena Protocol Committee, Ministry of Natural Resources and Environment, Thailand, presented a detailed report on "Capacity Building in Biosafety of GM Crops in Asia", based on the success achieved in the Project GCP/RAS/185/JPN. This project was successfully implemented between 2002 and 2005 by the FAO and had the following objectives: to strengthen the national capacities for the biosafety of GM crops; to establish an Asian Network on Biosafety for harmonizing biosafety measures; and to support and promote research and technology development for the safe and environmentally sustainable use of GM crops. The project effectively assisted the participating countries in national capacity building on biosafety of GM crops by organizing various activities such as National Stakeholders Workshops, Regional Consultations, Focal Points Meetings and Regional Training Workshops, and by the establishment of a project Web site and by the publication of documents, training manuals and other materials. Dr Banpot highlighted the importance of the Asian Bio-Net, which is being hosted by Thailand in collaboration with all the participating countries and interested organizations to ensure continued management of the information sharing system. He also informed the workshop participants that the expenses of basic activities covering the exchange of information on technical aspects of biosafety in Asian countries through the Web site (http://it.doa.go.th/asianbionet/) were initially met by FAO. The Asian Bio-Net, however, needs revitalization for effective utilization. He summarized the status of biotechnology in the ten participating Asian countries at the end of the project in 2005, and discussed in detail the status of National Biosafety Frameworks and Regulations in Thailand. The Final draft of the "Biosafety of Modern Biotechnology Act", completed at the end of 2007, was approved in principle by the Cabinet on 23 January 2008, and currently is being scrutinized by the Office of the Council of State before submission to the parliament for enactment.

Dr (Ms) Gurinder Jit Randhawa, Principal Scientist, National Research Centre for DNA Fingerprinting, National Bureau of Plant Genetic Resources, Pusa Campus, New Delhi, India gave a presentation titled "GMO Detection: Emerging Scenario". As the area under commercial cultivation of GM crops is increasing dramatically, the regulatory requirements to detect the presence/absence of GM traits in these crops and products have also become more complex and challenging. Reliable and sensitive GM detection assays are useful to a broad range of stakeholders as these assays help to ensure public confidence in both technology and the ability to regulate it effectively and also to solve legal disputes if they arise. For the detection of GMOs at the DNA level, Polymerase Chain Reaction (PCR)-based methods are used mainly, whereas for protein-based detection, immunoassays are predominantly used. Among the immunoassays most commonly used is membrane-based lateral flow strip. The strip is dipped into a prepared sample in an 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 plate-based enzyme-linked immunosorbent assay (ELISA) 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 certain inherent 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. Moreover, GM products might be produced only during certain plant developmental stages or in certain plant parts and such GMOs are unlikely to be detected with ELISA.

Because of its high specificity and sensitivity, PCR is being utilized as the key technology in GMO detection, identification and quantification. Corresponding to the different levels of specificity, the GMO detection techniques can be categorized as: 1) screening methods, targeting the control elements present in GMOs, e.g. CaMV 35S promoter, nos terminator; 2) gene specific methods, targeting the gene of interest; 3) construct specific methods, targeting the junction between adjacent elements of the construct, e.g. a region spanning the promoter and the gene of interest; and 4) event specific methods, the most specific, targeting the junction between the host genome and the inserted DNA.

DNA-based detection strategies are based on PCR and probe hybridization. The various PCR strategies currently used for GMO detection are Qualitative PCR, Multiplex PCR, Quantitative Competitive PCR (QC-PCR) and Real Time PCR (RT-PCR), whereas Southern Hybridization and DNA Chip Technology are used as probe hybridization-based detection techniques.

DNA chip technology has been explored as a rapid and simultaneous detection and monitoring technique of transgenic elements in GM crops and products thereof. The microarray method or DNA chip technology is time-saving and allows the detection of a large number of genes, including promoter, foreign gene, endogenous control gene, reporter gene, selection marker gene, and stop sequence with great precision.

With the faster pace at which the global cultivated area under GM crops is increasing, detection of GMOs will become more complicated in the near future. The time has come now to put in place the detection procedures and protocols of GM planting material in different crops.

Dr (Ms) Gurinder Jit Randhawa made a second presentation titled "Global and regional initiatives in the area of GM detection". She discussed in detail the international agencies offering proficiency testing such as the International Seed Testing Association (ISTA), the Grain Inspection, Packers and Stockyards Administration (GIPSA) and the European Commission's Joint Research Centre (JRC), which is responsible for networking of European GM detection laboratories. She also mentioned various ASEAN initiatives in capacity building in the area of GM detection.

V. COUNTRY REPORTS

The status of biotechnology and GM crops in the 13 participating countries - Bangladesh, Cambodia, China, India, Indonesia, Malaysia, Myanmar, Pakistan, the Philippines, the Republic of Korea, Sri Lanka, Thailand and Viet Nam - was presented by the respective Focal Points. The status of the application of plant biotechnology in these countries falls into four major groups. One group is represented by China, India and the Philippines, which are mega-biotech countries growing GM crops on >50 000 ha; the second group is represented by Indonesia and Malaysia, which have approved commercial cultivation of GM crops; the third group is represented by Thailand, which has developed GM crops, but their field release has not been approved; the fourth group consists of the remaining seven countries, which are in the process of developing GM crops.

1. Bangladesh

Bangladesh signed the Cartagena Protocol on Biosafety (CPB) in 2000 and ratified it in 2004. To fulfil its obligation to the CPB, biosafety guidelines were developed and adopted in 2008, although the first draft of the guidelines was already available in 1999. Bangladesh has established a National Committee on Biosafety (NCB), a Biosafety Core Committee (to monitor and implement biosafety guidelines, policies, acts and rules developed by the NCB), and an Institutional Biosafety Committee. All the agricultural research institutes, namely Bangladesh Agricultural Research Institute (BARI), Bangladesh Institute of Nuclear Agriculture (BINA), Bangladesh Rice Research Institute (BRRI), Bangladesh Jute Research Institute (BJRI), Bangladesh Livestock Research Institute (BLRI), and Bangladesh Forest Research Institute (BFRI) and some of the universities such as Bangladesh Agricultural University (BAU), Dhaka University (DU), Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU), etc. have established well equipped molecular biology/ biotechnology laboratories. A modern biotechnology laboratory with greenhouse facilities has been developed at BARI. Many scientists have been trained abroad to pursue biotechnological research work. The main research focus is on the development of Bt eggplant for resistance to fruit and shoot borer and GM potato for resistance to late blight, GM tomato for resistance to leaf curl virus, and GM okra for resistance to yellow vein disease. The procedures for the approval of GM crops need to be simplified, and the intellectual property right issues need to be addressed. Three high level committees are in place to oversee and guide the implementation of biosafety guidelines. These are: The National Committee on Biosafety (NCB); The Biosafety Core Committee (BCC), and The Institutional Biosafety Committee (IBC). These three committees have their own terms of reference and hierarchy. NCB's activities include drafting and adopting of legislation/measures to ensure the safety of humans and the environment whereas the responsibility of BCC is to monitor the implementation of biosafety guidelines, policies, acts and rules promulgated by the NCB. The IBC is empowered to enforce all biosafety regulations at the institute level, having power to recommend any project/programmes to cease its activities if it is believed that the continuation of the project/programme may bring harm to laboratory staff, the public or the environment. The paper recommended strong collaboration with international and national researchers to exchange information on their laboratory activities. It also recommended that biosafety guidelines should not be confined to only

agricultural GMOs/LMOs, but should also be extended to all other GMOs/LMOs; and the procedure for applications and approval of biotechnologically developed materials/products should be simplified.

2. Cambodia

Cambodia is an agrarian country with a population of about 14 millions, 90 percent of which are farmers. Agriculture is the driving force of the economy with rice as the predominant crop. In Cambodia, the National Biosafety Framework (NBF) was established on 30 June 2004 to fulfil the national obligation under the Cartagena Protocol. Although the document is widely used as a reference document in handling GM crops, it has not been approved yet. The government has also developed a law on the management of quality and safety of products and services (under the Ministry of Commerce). The law on the biosafety of Living Modified Organisms (LMOs) management and control was passed by the National Assembly in February, 2008. The current application of biotechnology focus is on the use of tissue culture for the propagation of a variety of orchids and the conservation of banana land races, and the selection of land races and breeding lines developed by some international institutions. A biotechnology laboratory was established in 2006. The Ministry of Environment and the Ministry of Commerce are responsible for enforcement of the law on biodiversity and biosafety which has already been passed by the National Assembly. Part of this law also covers the GMOs and LMOs applications, risk assessment, management and public awareness. The Ministry of Agriculture, Forestry and Fisheries and the Ministry of Industry, Mines and Energy are responsible for enforcing the law on seed management and plant breeder rights which was passed by the National Assembly. The Cambodia Agricultural Research and Development Institute (CARDI) and other line departments of the Ministry of Agriculture, Forestry and Fisheries set strategies and activities to apply biotechnology to crops yield and quality improvement. However, the knowledge of biotechnology research and its applications to ensure food security and food safety, e.g. GMO products, is still limited in terms of significant operating costs and human capabilities. Thus GM biotechnology is still not officially registered or licensed for import and distribution in the country. The country needs capacity building to develop an effective biotechnology management system, as well as various regulatory frameworks on the management of biotechnology R&D and to ensure food safety in Cambodia. Capacity building of the authorities appointed by the government to be responsible for the management of biotechnology R&D and food safety is another area where the country needs external support. The paper recommended the promotion of biotechnology R&D, which also includes GMOs, through collaboration and dialogue between industrialists, public sector scientists, regulatory authorities and non-governmental organizations. The paper concluded by saying not to deny people access to a new technology that may address their present problems, so long as they are fully informed of the potential risks and benefits and can make their own choice.

3. China

China is the most populated country in the world. With only approximately 7 percent of the world's arable land, China is feeding over 20 percent of the world's population. In order to continue to feed its people, it must find more efficient agricultural production

methods. To this end, China has taken great strides in developing GM technology and it is spending hundreds of millions of dollars each year for GMO research and development. In 2008, a special project for GM crop development was started with a budget allocation of US$ 3.5 M. By mid-2009, over 3 350 applications were approved for contained field testing of GMOs. China has approved for commercialization six GM crops (Bt cotton, delayed ripening tomato, virus tolerant sweet pepper, colour changed petunia, Bt poplar and virus resistant papaya) and four GM microbes/vaccines (vaccines for pig diarrhoea, pseudo-rabies and bird flu, and GM yeast for accumulating phytase as feed additive) . In 2008, Bt cotton covered 3.8 M ha, accounting for 70 percent of the cotton area in China. Twenty-six GM varieties of maize, canola, cotton and soybean were approved for import as raw materials for processing. The country has put in place a robust biosafety framework. In order to strengthen the management of GMOs research and development, the State Science and Technology Commission of China issued a safety administration regulation on genetic engineering in 1993 and regulations on the safety of agricultural GMOs were issued in 2001. In January 2002, the Ministry of Agriculture issued three implementing regulations on safety assessment, import/export, and labelling of agricultural GMOs. The National Agricultural GMO Biosafety Committee (BC) is the major player in the process of biosafety management. The committee meets twice each year to evaluate all biosafety assessment applications related to experimental research, field trials, environmental release, and commercialization of agricultural GMOs. A biosafety monitoring system has been established in each of the national GMO production regions. Emergency and risk prevention systems have been set up to improve the monitoring and supervision of environmental safety of agricultural GMOs. As GMO detection and risk assessment are required to be based on standardized methods, the technical standardization committee was established in October 2004. By the end of 2008, about 80 standards on biosafety had been issued covering GMO detection, testing and assessment. Till now, 35 organizations have been certified by the Ministry of Agriculture. The major issues of concern are most of the patent genes belong to foreign companies, biosafety issues are neglected during the study period giving more emphasis to GMO development rather than safety, challenges in unapproved and even approved GMO detection because of the absence of approved protocols and reference materials, and problems in risk identification for novel traits and the standardization of experimental design and protocol needs to be studied further. In GMO biosafety legislations, existing regulations are limited to agricultural GMOs, and need to be extended from agricultural GMOs to all GMOs. Taking into account the standards of the Cartegena Protocol on Biosafety, relevant legislations and policies must be developed at national level and further harmonized with the regional and international regulations. The appendix in the regulation for biosafety assessment of agro-GMOs and the methods of GMO biosafety assessment need to be revised. In addition, the procedures for application and approval need to be regulated further.

4. India

India has developed a well structured biosafety framework. The Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms (HMO)/Genetically Engineered Organisms or Cells, 1989 under the EPA (1986), also known as “Rules 1989”, govern all activities involving research and development of products containing

GMOs / LMOs, including transgenic crops, pharmaceutical products, industrial products, food and feed. The country has established various statutory bodies for the regulation and monitoring of GMOs, such as the Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committees (IBSCs), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Approval Committee (GEAC), State Biotechnology Coordination Committees (SBCCs), and District Level Committees (DLCs). The country has developed various biosafety guidelines since 1990: 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; and Protocols for the Safety Assessment of Genetically Engineered Plants, 2008. India approved commercial cultivation of Bt cotton in 2002, and the area covered by Bt cotton has increased to 7.6 M ha in 2008, which accounted for 82 percent of the total area under cotton. In early 2010, the second GM crop and the first GM food crop, i.e. BT eggplant is expected to be approved for commercial cultivation. Several other GM crops are in the pipeline for approval. These include cabbage, corn, groundnut, pigeon pea, castor, tomato, rice, okra, cauliflower, potato, sorghum, etc. for various traits such as insect resistance, herbicide tolerance, virus resistance, drought tolerance, salt tolerance, fungal resistance, etc. India has actively participated in the regional initiatives on biosafety.

5. Indonesia

The Government of Indonesia has adopted a precautionary approach to accepting genetically engineered products. Ultimately, the decision to adopt any particular GMO product must be justified on strong scientific grounds. A regulatory process was initiated in 1996 by approving Law no. 7 concerning food (GMO food safety was detailed in article no. 13 of Law no. 7). In 1997, the Ministry of Agriculture issued a decree on the Biosafety of Genetically Engineered Agricultural Products allowing the establishment of a Biosafety Committee (BC) and a Biosafety Technical Team (BTT). The Biosafety Committee is constituted as an *ex-officio*-inter-departmental team, whereas, the members of the Biosafety Technical Team (BTT) are multi-disciplinary scientists from different institutions, universities, NGOs, the Ministry of Science and Technology, the Department of Health, the Department of Forestry, and the Ministry of Environment. The Ministry of Science and Technology is the leading agency dealing with the Biosafety Clearing House (BCH). The focal point for environmental safety is the Ministry of Environment and the focal point for food safety is the Ministry of Health's *ex-officio*-inter-Departmental team. In 1998, a set of Guidelines for Environment Risk Assessment (general, plant, animal, fish, and micro-organisms) was adopted. A Joint Ministerial Decree on Biosafety and Food Safety of Genetically Engineered Agricultural Products was issued in 1999 and led to the establishment of the Biosafety and Food Safety Committee (BFSC) and the Biosafety and Food Safety Technical Team (BFTST)". In the same year, Presidential Decree no. 19 on "Labeling of packaging processed foods derived from GMO" came into force. The government ratified the Cartagena Protocol on Biosafety in 2004 and also issued Presidential Decree no. 28 on safety, quality and nutrition of food in the same

year. Presidential Decree no. 21 adopted in 2005, was the basic document on the biosafety of genetically engineered products, R&D, containment and field testing, the obligation to conduct risk assessment of GMOs before environmental release and direct use for food and processing, monitoring and mitigation, and the establishment of regulatory bodies. The National Drugs and Food Control Agency developed guidelines for assessing food safety in 2008. The government approved GMO testing guidelines in 2008 and Bt cotton (MON531/757/1076), RR cotton (MON1445/1698), Bt corn (MON810), RR corn (GA 21) and RR soybean (GTS40-3-2) have passed environment safety assessment. Potato, free amylose cassava, Bt rice and drought tolerant sugar cane are under different stages of field testing under R&D of transgenic crops. In Indonesia, a GMO testing network was established in 2006 comprising representatives from several institutions (public research, university and public companies). A containment facility has been developed at the Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD), and the BC has completed biosafety assessment of GM cotton, corn and soybean. Indonesia has developed some future plans to amend the act/decree on biosafety and food safety to accommodate updated information on regional and international standards and increase networking and collaboration with international and regional agencies on biosafety.

6. Malaysia

Malaysia, a mega biodiverse country, has a strong R&D programme for developing GM crops. Malaysia adopted a biotechnology policy in 2005 which envisages biotechnology as a new economic engine for Malaysia. Biotechnology policy is underpinned by nine policy thrusts. The country is developing banana for fusarium resistance, chili for virus resistance, oil palm for insect resistance, papaya for delayed ripening and virus resistance, pineapple for resistance to blackheart disease, rice for resistance to fungi, and rubber for bio-pharming. Malaysia has already put in place a biosafety framework. It developed the Guidelines on the Release of GMOs in 1997, placed in the parliament the Biosafety Bill in 2006/07, passed the Biosafety Act in 2007/08 and in 2008/09 the Biosafety Regulations were developed. The objective of the Biosafety Act is to establish the National Biosafety Board, to regulate the release, importation, exportation and contained use of LMOs, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity. The primary responsibilities for environmental management and formulation of legal instruments, policies, guidelines to safeguard the environment, including the issue of biosafety lie with the Ministry of Natural Resource and Environment (NRE). The main contents of the Biosafety Act include: (a) the establishment of a national biosafety board; (b) approval for the release and import of GM crops; (c) notification for export, contained use and import for contained use; (d) risk assessment and a risk management and emergency response plan; and (e) enforcement. Biosafety regulations to enforce the implementation of the Biosafety Act have been drafted and are being considered by the NRE. After final consultations with concerned stakeholders, biosafety regulations will be submitted to the Attorney General's chambers for follow-up. A biosafety core team has already been formed to act as the competent authority and one-stop-centre for all activities relating to biosafety. Biosafety guidelines for containment, guidelines for

institutional biosafety committees and the use of GMOs and related materials will be available soon.

7. Myanmar

The current focus on biotechnological assessments and applications include plant micro-propagation, application of anther culture in crop breeding, molecular breeding, varietal identification and fingerprinting, GMO detection and non-GMO certification. Myanmar is a member country to the United Nations Convention on Biological Diversity (UNCBD). The government took the decision to develop a national biosafety framework in accordance with the objectives of the UNEP/Global Environment Fund (GEF) programmes in 2003 with financial support from the GEF under the supervision of UNEP. The major objectives of the biosafety framework are: to conserve the existence of natural flora and fauna of the country; to develop the systematic use of modern biotechnology in modification of genes of living organisms; and to provide a regulatory framework in which trade and the use of LMOs are to be carried out in a manner that does not threaten the health of humans and the environment. As an outcome of the project, the second draft of the national biosafety framework was completed in 2008. Important points considered in developing the biosafety regulatory system are clarity, transparency, consistency, workability or enforceability and adaptability.

8. Pakistan

The contribution of agriculture to national GDP is 25 percent and it employs nearly 50 percent of labour and is responsible for more than 80 percent of export earnings. Population pressure (the population will reach about 210 million in 2022 from its population of nearly 160 millions in 2007), arable land scarcity, pest and diseases, and salinity and water logging are serious threats to the development of agriculture in the country. Pakistan has been facing post-green revolution problems such as yield stagnation, environmental concerns and resource shortages. The country's livestock population is 137 million head and feed production shortages for livestock and poultry are also becoming an emerging problem. Wheat, rice, maize, legume crops, oil crops and vegetables are the main food crops of the country, and cotton, sugar cane and tobacco are major cash crops. Some location-specific minor crops and value-addition crops are also grown. The country's capacity to address World Trade Organization (WTO) matters, patents issues and a market economy is also weak. The Government of Pakistan took a decision in the 1980s to use modern tools and techniques of biotechnology in order to increase the productivity and production of agricultural crops. As a result, Pakistan made good progress in developing tissue culture protocols for potato, sugar cane, banana and some medicinal plants with a view to their commercialization. The country is developing GM cotton for insect and virus resistance, GM potato for virus resistance, GM sugar cane for insect resistance, and wheat for drought and salt tolerance. Some of the insect resistant cotton lines are ready to be released. Currently, six GM crops (cotton, wheat, sugar cane, potato, tomato and tobacco) are under different stages of testing. Efforts to develop different guidelines to ensure safe testing and adoption of GM crops started in the late 1980s and biosafety rules and national biosafety guidelines were approved by the competent authorities in April, 2005. A science-based, case-by-case evaluation process prior to commercial release of GMOs and a post-release/marketing evaluation and

monitoring system has been developed. The National Commission on Biotechnology is the responsible body to monitor the implementation of national biosafety guidelines. The Commission meets regularly under the Ministry of Environment. The government organizes workshops and seminars for capacity building, creating public awareness, risk management and risk management of GMOs. These activities are irregular and inadequate because of a shortage of funds. The future plans include: (a) development of a coherent national policy and legislation for the biosafety of GMOs; (b) implementation of plans for the commercial release of GM crops; and (c) capacity building for the biosafety of GM crops, including human resource development, public awareness, and development of infrastructure for biosafety.

9. Philippines

In 2001, the government of the Philippines issued the policy statement on biotechnology, reiterating the government policy to promote the safe and responsible use of modern biotechnology. In 2002, the Department of Agriculture (DA) issued the guidelines for importation and release into the environment of plants and plant products derived from the use of modern biotechnology. This paved the way for the Philippines to become the first country in Asia to approve the market release of a GM food/feed crop in 2003. On 17 March 2006, through Executive Order No. 514, a National Biosafety Framework (NBF) was established, prescribing guidelines for coordinated implementation of biotech policies among concerned agencies, strengthening the existing National Committee on Biosafety, and for other purposes related to the safety of products derived from modern biotechnology. The NBF covers all aspects of biosafety, from development, adoption and implementation of all biosafety policies, measures, and guidelines; and in making biosafety decisions concerning research and development, handling and use, transboundary movement, release into the environment and management of regulated articles (or GM products). The DA biosafety Web page (www.biotech.da.gov.ph) and the related Philippines Biosafety Clearing House Web page (http://bch.dost.gov.ph) were established to provide detailed information on the policies related to the biosafety of GM crops, risk assessment, capacity building, area under GM crops, etc. The information related to capacity building includes the listing of academically-accredited biosafety courses across the world, many of which have helped in enhancing the capability of the regulators in implementing the biosafety regulations. Currently, concerned agencies are developing additional policies and guidelines on risk assessment for plant incorporated protectants in pest protected plants (through the Fertilizer and Pesticide Authority) and risk management policy for handling low level presence (LLP) in GM crops. The country has also modernized the molecular laboratory of the DA Plant Quarantine Service for the detection of GMOs and plant pathogens. Following very rigorous risk assessments, the country approved the importation of GM crops with single or stacked trait products for direct use as food and feed or for processing. It also approved the commercial cultivation of five GM corn events (MON810, NK603, Bt11, Stacked corn, GA21). To date, the area planted with GM crops in the Philippines has increased from 11 000 ha in 2003 to 320 000 ha in 2008, making the Philippines one of the mega-biotech countries in the world. In November 2009, approval was given to 11 field trial applications, including the locally developed delayed ripening papaya and Bt eggplant. The country continues to face several obstacles to the successful implementation of the policies and guidelines on

modern biotechnology. These include technical challenges (risk assessment, monitoring and detection of GMOs), organizational challenges (lack of required staff for regulation activities and harmonization policies with other agencies) and political challenges (anti GMO campaign/provincial ordinance which bans the entry of GMOs) that need urgent attention and action. The country presentation strongly recommended continuous capacity building through participation in national and international workshops/seminars and meetings. Consultation/dialogues with stakeholders to settle certain issues hampering the development of policy on LLP, discontinued products and delisting are essential to resolve the issues and move forward in the right direction. Strengthening the capacity of the staff and recruitment of additional manpower involved in biosafety regulation are also needed. The need for an effective information, education and communication programme to promote acceptance of GM crops by various stakeholders, including policy makers, was also emphasized. The last recommendation was to create/improve awareness on the nature and benefits/risk of biotechnology through media training, networking and outreach programmes.

10. Republic of Korea

Biotechnology is considered as a main engine of growth for South Korea in the twenty-first century. Various kinds of GM crops are at different stages of risk assessment for commercial uses. The Republic of Korea developed a national biosafety framework and an LMO law, and these entered into force on 1 January 2008. With a population of 48.6 million, the country's self-sufficiency level in food and feed production is only 27 percent (2007). The country imports GM crops both for food and feed. A biotechnology promotion act was approved in 1983 followed by the first basic plan for biotechnology promotion (1993 to 1996). The second basic plan for biotechnology promotion was approved under the name of Biovision 2016 (2007 to 2016). The biotechnology promotion act laid the foundation for development and use of GM crops. This document covers four broad areas: bioresource and genomics; development and biosafety of GMOs; functional foods; and diagnosis of animal disease and sanitation. The basic principles included in the framework for risk assessment of GMOs follow the recommendations of the Organisation for Economic Cooperation and Development (OECD), Codex Alimentarius, United Nations Development Programme/Convention on Biodiversity/Cartagena Protocol on Biosafety (UNDP/CBD/CPB). These are: (1) application of scientifically sound assessment; (2) case-by-case evolution; (3) cost-effective methods; and (4) transparency. However, the consumers have a more negative opinion of GMOs in the Republic of Korea compared to other Asian countries.

11. Sri Lanka

Sri Lanka is an agrarian country growing a wide range of agricultural crops and one of the world's 34 biological diversity hot spots. In Sri Lanka, biotechnology development is at an early stage. It is being applied for micro-propagation of a variety of horticultural crops, DNA fingerprinting for the identification of varieties and validation of hybrids, disease diagnosis, and marker-assisted selection. The necessity to develop GMOs in a variety of crops for resistance/tolerance to abiotic and biotic stresses and to promote biotechnology applications in various fields is recognized in the country, although a limited number of biotechnology research activities are being carried out in a dispersed

way without much coordination and collaboration. Sri Lanka signed the Cartagena Biosafety Protocol in 2000 and ratified it in 2004. The Ministry of Environment and Natural Resources is the focal point for implementation of the Protocol. The government undertook the project entitled "National Biosafety Framework Sri Lanka" in 2003 with five main elements of a national biosafety policy: a regulatory regime; administrative systems; risk assessment and management; public participation, and development. The National Policy for Biosafety and the National Biosafety Framework have been developed to encourage the development and utilization of GM crops. Importation of GM foods after assurance of safety was gazetted in 2006 and took effect in 2007. Guidelines for safe manufacturing of GM crops are being developed.

12. Thailand

Thailand recognizes the importance of biotechnology in enhancing the quality of people's lives and in increasing food security in a sustainable manner and as an alternative option to increase the yields of food and feed crops. At the national level, the National Biosafety Committee (NBC) was set up in 1993. Since then, Thailand has allowed GMOs testing at the field level under public sector control but has not approved any GMO products for commercialization. The National Biosafety Framework (NBF) was established in 1999. Thereafter, Thailand signed the Convention on Biological Diversity (CBD) in 2002 and became party to the CBD in 2004 and the Cartagena Protocol on Biosafety (CPB) in 2006. The scope and priorities of the NBF were identified after this latter date. The country has been following the CPB rules in developing a Biosafety Act. In early 2009, the Office of Natural Resources and Environmental Policy and Planning developed and finalized the report on the NBF for Thailand as well as the biosafety draft for a proposed Biotechnology Act. Although Thailand was an early adopter of biosafety guidelines among the ASEAN countries both for laboratory works and field testing and planned release, development and approval of its biosafety legislation has moved very slowly. Efforts to develop/draft the Biosafety Act as the national biosafety legal and regulatory framework started in 2003 but a draft has yet to be finalized. The draft was sent to the Office of the Council of State for legal review in April 2008 and it is expected that the review process will be finalized early in 2010. The country does not have any law on biosafety but some specific laws related to research on GMOs crops are under consideration.

13. Viet Nam

In Viet Nam, biotechnology has been identified as an essential and important prerequisite for achieving national goals. Biotechnology has been extensively used for: (a) micro-propagation of a large number of horticultural crops, and for the production of haploid rice; (b) molecular characterization of plant genetic resources, particularly of rice, vegetables and forest trees; and (c) marker-assisted selection of rice, maize, vegetables, cotton, tea, coffee and sugar cane. Efforts are being made to develop GM maize, cotton, soybean and some forest trees. The government has adopted phase-wise biotechnology programmes in agriculture and rural development under the umbrella programme "Outlook 2020". The government has decided not to proceed to promote GMO rice in the country until 2020. Current GMO priority crops are maize, cotton and soybean. Successful implementation of Outlook 2020 will lead to the development of new crops

that will cover 70 percent of the total area planted in which the share of transgenic crops will be 30 to 35 percent. It is also stated in Outlook 2020 that by 2020, biotechnology will share over 50 percent of the contribution of science and technology to agricultural crops. An action plan to implement the Cartagena Protocol was initiated in 2007. This includes the development of: (i) a biodiversity law covering the biosafety of LMOs and genetical material received from LMOs (2008); (ii) regulations on the field trials of GM crops (2009); and (iii) regulations on the biosafety of LMOs and products made from LMOs (in preparation). The major challenges faced by the country relate to the lack of understanding about the safety of GMOs among the scientists and media, lack of well-trained and experienced manpower, lack of infrastructure for risk analysis, and inadequate funding, weak institutional capacity and no enforcement system.

FAO initiative to update the *Benchmark document on the needs and present status of the capacity building in biosafety of GMOs in Asia* published in 2004

Professor Anupam Varma, FAO Consultant, introduced the objectives for preparing the updated version of the *Benchmark document on the needs and present status of the capacity building in biosafety of GMOs in Asia*, which was developed and published in 2004 by the FAO Project (GCP/RAS/185/JPN) "Capacity Building of GM Crops in Asia" and which enabled the project to identify the areas of strengths and weaknesses and gaps in the ten participating Asian countries. The areas of strengths and weaknesses and gaps included human resources, research and technology development, infrastructure, risk assessment and management, and policies and regulations related to the development and utilization of GMOs. The participating countries were found to vary greatly in their capacity for regulating GMOs. The benchmark document effectively assisted the participating countries in capacity building in biosafety of GM crops by the implementation of a number of activities.

During the last five years considerable progress has been made in the countries which participated in the above project, in developing and establishing biosafety frameworks for the utilization of GM crops. The FAO assisted the participating countries in arranging various activities such as the national stakeholders workshops, regional consultations, focal points meetings, regional training workshops, establishment of Asian Bio-Net, publication of training manuals and other related publications. The FAO also provided support in the establishment of National Biosafety Frameworks, with the financial assistance from United Nations Development Programme (UNDP), the World Bank (WB), the United Nations Environment Programme (UNEP), Global Environment Fund (GEF), etc. FAO also helped some countries to enhance their laboratory facilities. However, the capacity to ensure the biosafety of GMOs in the Asian countries, including the ten countries that participated in the earlier project, continues to vary greatly. In 2004, China, India and the Philippines were the only three participating countries growing commercial GM crops on about 1.45 M ha. Since then, the area under GM crops in these countries increased to 11.75 M ha, and only two other countries of the region – Indonesia and Malaysia – have given regulatory approval for GM crops. Therefore, it was felt that a fresh analysis of the biosafety practices in various Asian countries was needed, as was the identification of areas requiring strengthening for adequate capacity building in all the

participating countries, so that the benefits of GM technology are uniformly made available across the region. The countries that participated in the project in 2004 included Bangladesh, China, India, Indonesia, Malaysia, Pakistan, the Philippines, Sri Lanka, Thailand and Viet Nam. Now three more countries – Cambodia, the Republic of Korea and Myanmar – have also joined, and Lao PDR has expressed interest in joining the ongoing effort.

In order to strengthen further the capacity to ensure the biosafety of GMOs in the participating countries of Asia, an updated version of the 2004 benchmark document is being developed with the following objectives:

- to analyze the biosafety practices in the participating countries;
- to identify and formulate options to develop common tools and share resources (human resources and facilities); and
- to identify areas requiring strengthening of the national capacities for the development of human resources, research and technology infrastructure, regulations and policies for assessing and managing the biosafety of GM crops.

The document will include relevant information on the status of development of human resources, research and technology, infrastructure, regulations, policies and practices related to the biosafety of GMOs, to facilitate transparent, science-based and objective regulatory and policy decisions and harmonized biosafety. The overall purpose is to promote trade and commercialization of GM crops. Furthermore, the document will identify the relative strengths, weaknesses and gaps in the participating countries and the region as a whole for meeting the above objectives. A questionnaire, being prepared in consultation with Messrs. Andrea A. Sonnino and Subash Dasgupta, will be sent to the Focal Points of the participating countries. All Focal Points will be requested to send their responses within two weeks after the receipt of the questionnaire. The participants were also informed about other information sources, which will be used for information retrieval. These will include the FAO BioDec and Asian Bio-Net Web sites. The information from various sources and the responses received from the Focal Points will be used to develop the draft document, which will be circulated among the relevant technical units of the FAO and the participating country Focal Points for comments. The final document will be printed and circulated by the FAO.

The participants discussed in detail various aspects of the information to be provided in the questionnaire and in updating the 2004 benchmark document. The Focal Points also highlighted the capacity building needs of their respective countries

VI. CONCLUDING SESSION

In his concluding remarks, Mr Konuma, Deputy Regional Representative, FAO/RAP expressed his satisfaction knowing that all ten participating countries of the previous project and members from three non-participating countries attended the workshop. He hoped that after returning home, participants would give more time and make sufficient

effort to assist their respective governments with the enhanced knowledge gathered here to further strengthen their Biosafety Frameworks. Mr Konuma mentioned that during the last five days, participants have had opportunities to learn more about the latest developments in the field of biotechnology, GMO risk analysis, GMO testing in greenhouses, GMO detection activities in the laboratory and they visited a biosafety greenhouse in Thailand. They have also had the opportunity to visit Ajinimoto Co. (Thailand) Ltd. where they saw the laboratory facilities and the biosafety handling system for micro-organisms.

Mr Konuma also expressed satisfaction in seeing that the Asian Bio-Net Web site was successfully reactivated and presented to the participants. However, he emphasized that success for continued operation of the Web site will depend on how frequently the Focal Points will provide up-to-date country information to feed the Web site. Together with the FAO and the participants, Mr Konuma expressed belief that the proper running of the Asian Bio-Net Web site will be an important tool to create regional cooperation among the participating countries.

Mr Konuma informed the participants that steps are underway to update the 2004 benchmark document prepared under the previous project. It will be another step forward to know what relevant changes have occurred in the participating countries since the completion of the project in 2005 and also to incorporate information obtained from three new participating countries. An appeal was made to all Focal Points to complete the questionnaire in consultation with other concerned agencies in their respective countries and to send all requested information to the FAO as early as possible. A plan to publish the updated benchmark document was mentioned and the published document will be sent to the member countries for their information and further use, as appropriate.

In closing, Mr Konuma thanked the Government of Thailand and the Department of Agriculture (DOA) for their pro-active support and cooperation in making the programme a success and expressed hope that the cooperation will continue further. He indicated that the Asian Bio-Net Web site is the platform for the participating countries to work together in future and hoped that the DOA will continue its support to update this Web site regularly. He also thanked all participants for coming to the workshop. He offered his special thanks to the international and national experts for their efforts and technical inputs to make the programme a success. He assured that FAO is always ready to assist its member countries to provide technical supports if required. He wished all participants a safe return to their home countries.

Before concluding the workshop, Mr Konuma distributed certificates to all participants.

VII. RECOMMENDATIONS

1. Prioritise the traits and crops that require biotechnological interventions in each country so that the capacity building can be focused on technology development, risk analyses and containment requirements including the biosafety compliant laboratory needs in the region. On the basis of the above, classify the safety levels required for the

assessed risks to recognize the level of containment facilities, laboratories and the human resources required to manage the assessed risks in the containment facilities.

2. There is a need to have institution-level shortlisting of individuals in each country to develop a list of containment managers (including the public and private sector) for possible coordination in hosting an Asian Containment Managers' Group (ACMG) for a monthly on-line or off-line conference, and a Web site for comments and information sharing.

3. Based on the experiences in countries where there is already a legislature/system in place for standards, an optimum level harmonized model of containment to manage each safety level needs to be designed with dos, don'ts and protocols formulated for adoption – (guideline development for minimum standards and not restricted). List the different categories of barriers (primary physical, secondary physical and biological barrier – time and space) within a containment to be employed and the methods to achieve the containment along with the harmonized means and mechanisms to achieve the containment by participating countries. One agency may be identified in each country as the nodal regulatory agency to validate, coordinate and harmonize the containment regulation *vis à vis* implementation procedures in place.

4. Establish a regional network of experts working in GM detection and also a database of GM detection laboratories in the country (nationally and internationally accredited) with nodal persons for contact, coordination and information sharing along with hyperlinking with global GM detection laboratories, e.g. Joint Research Council (JRC) of the European Commission (EC) and of the regional laboratories, e.g. ASEAN, or in Asian Bio-Net, GM detection can have hyperlinks with the recent literature on GM detection.

5. Organize capacity building training 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.

6. Shortlist minimum human capacities required for GM detection and sampling processes *vis à vis* the biological risks associated with the GMOs and develop an optimized list of items of equipment, infrastructure facilities, consumables, disposal mechanisms/protocols for waste management for GM detection and safety within a working environment.

7. Participating countries, in cooperation with other regional and international agencies, should strengthen its efforts to improve and harmonize risk assessment and risk management methods used in relation to GMOs at the regional level. FAO may also

facilitate a process whereby countries with established risk assessment and management systems can assist other countries seeking to establish or improve their risk assessment and risk management processes.

8. FAO, in cooperation with other agencies may organize regional workshops and projects to address emerging issues related to risk assessment, risk management and risk communication and also FAO in cooperation with other institutions may continue to improve the capacity of risk assessors, risk managers and policy makers in communicating the findings of the risk assessment and risk management decisions in a clear and user-friendly manner.

9. Countries are urged to strengthen links between risk assessment, risk management and risk communication activities. Better coordination, for example, should be developed among various agencies involved in the regulation of GMOs. Countries are also urged to strengthen documentation and sharing of experiences in risk assessment and risk management through Asian Bio-Net.

10. FAO and member countries, in cooperation with other institutions, may facilitate the establishment of a network of biosafety practitioners (e.g. risk assessors, containment managers, DNA detection, biosafety communicators) to provide the platform for harmonization and standardization of methods used in risk assessment and risk management at the regional level.

ANNEX 1

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ANNEX 2

WORKSHOP PROGRAMME

منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

Regional Biosafety Workshop

Bangkok, Thailand, 30 November to 4 December 2009

Background

Despite their great potential for significant improvement in crop production and agricultural development, advances in modern biotechnology (often referred to as genetic engineering) have also triggered debates on their positive and negative impacts on the environment and human health. Although the major area of concern is the unintended changes in biological diversity, there are also issues of concern related to the socio-economic consequences of biotechnology as well as ethical issues. These remind us that the tools and techniques derived from the rapid advancement of modern biotechnology must be used and developed with adequate safety measures so as not to harm the environment and human health.

Biosafety measures are designed to reduce and eliminate the potential risks resulting from the application of biotechnology and its products. They encompass policies/laws/acts/decrees/regulations/rules that are required to ensure that products developed through the application of modern biotechnology tools and techniques are safe for the environment and human health. Biosafety measures are still evolving by redefining/revising/refining/incorporating new rules and regulations into the existing procedures, with new information coming out from the research/case studies and practical applications of these measures on the ground. Different countries are at different stages in terms of development and application of biosafety measures.

The formulation and implementation of biosafety measures that are prerequisites for the development and application of modern biotechnological tools and techniques for crop improvement require effective institutional capacity for assessment of their impact on the environment and human health. Development of in-country expertise is essential to make locally appropriate and timely decisions. All these emphasize the importance of developing biosafety capacity at country and regional level.

The context for biosafety measures has dramatically changed along with the rapid expansion of genetically modified crops since their introduction in the early 1990s. In 2009, more than 125 million hectares were planted with GMO crops worldwide, with 40

percent in developing countries. Thus development of biosafety expertise, policies and procedures can be a stepping stone to facilitate improved biosafety for all aspects of crop improvement and agricultural development. The earlier a country plans to adopt biosafety measures, the earlier it can reap the benefits of biotechnology and the less danger there is from any harmful effects associated with it.

FAO has been assisting its member countries since 1999 to develop country capacity with the aim to develop their own biosafety legislations and set up regulatory bodies in an effort to reduce and eliminate potential risks resulting from biotechnology and its products. In addition, FAO is also helping in harmonizing biosafety regulations at the subregional, regional and global level. As biosafety measures are evolving based on field and practical experience and learning across the world, FAO is helping member countries to stay updated on the latest developments in this field and developing strong networking among these countries so they can reap the benefits of sharing ideas and experiences. As a part of this important initiative, FAO arranged a week-long biosafety workshop with the following specific objectives:

Objectives

1. To update participants on the most recent advancements in the field of biosafety.
2. To contribute to creating a common understanding of biosafety-related issues among the participating countries.
3. To establish a base for expanded collaboration at regional level.

Expected Outputs

1. The current status of the network at regional level and in respective countries is updated;
2. Specific collaborative needs for further strengthening and operationalization of the “Asian Bio-Net” network are identified; and
3. Participating countries are appraised on the latest developments in this field and participants are provided with new technical information on biosafety and their knowledge and technical capacity in biosafety are enhanced.

Content

The goal was to engage participants and encourage the sharing of experience in order to gain new perspectives and ideas for enhancing country-specific current biosafety programmes and networking. The workshop focused on theoretical and practical issues of biosafety, including laboratory tools and techniques used for the improvement of crop and agricultural products.

Participants

All ten focal points - Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka Thailand, and Viet Nam - of the previous project

"GCP/RAS/185/JPN- Capacity building in biosafety of GM crops in Asia" along with one officer working directly in the biotechnology laboratory were invited to participate. In addition, the governments of Cambodia, Japan, Lao PDR, Myanmar and the Republic of Korea were requested to send participants from their respective countries to attend the workshop. As the host country, ten participants from Thailand were invited. A total of 40 participants were expected.

Provisional Agenda

Day-1 (30 November 2009)
Monday

08.00 — 09.00 hrs	**Registration**
09.00 — 10.00 hrs	**Opening session** • **Opening Speech by Mr Hiroyuki Konuma, DRR , FAO-RAP, Thailand** • **Welcome Address by Mr Alongkorn Kornthong, Director, Biotechnology Research and Development Office, Department of Agriculture, Ministry of Agriculture and Cooperatives, Royal Thai Government** • **Introduction of the participants** • **Announcement of programme and timetable** • **Group photograph**
10.00 —10.30 hrs	**Tea break**
10.30 —11.00 hrs	**Agriculture biotechnology: A global perspective and regional collaboration by Mr Andrea Sonnino, Senior Agricultural Research Officer, Research and Extension Unit, FAO, Rome**
11.00 —11.30 hrs	**Current status of plant biotechnology development and application in Thailand by Ms Hathairat Urairong, Deputy Director, Biotechnology Research and Development Office, DoA, Royal Thai Government**
11.30 —12.00 hrs	**Open discussion**
12.00—13. 00 hrs	**Lunch break**
13.00 — 17.30 hrs	**A presentation of biosafety and biotechnology status in participating countries (each country will have 15 minutes for presentation and 5 minutes for discussion)**

Day-2 (1 December 2009)
Tuesday

09.00 — 16.30 hrs	**Risk analysis in biotechnology by Professor Desiree Hautea (Philippines). Moderators and rapporteurs will be selected from participating countries**

Day-3 (2 December 2009)
Wednesday

09.00 — 12.00 hrs	**GMO testing in greenhouse and monitoring by Director, Biotechnology laboratory, Thailand and Dr Gurinder Randhawa (India)**
12.00 — 14.00 hrs	**Lunch**
14:00 — 16.30 hrs	**GMO detection activities in the laboratory**

Day-4 (3 December 2009)
Thursday

09.00 — 16.30 hrs	**Field visit**

Day-5 (4 December 2009)
Friday

09.00 — 12.00 hrs	**Discussion on the preparation of the updated version of the 2004 benchmark document, introduced and facilitated by Professor Anupam Varma (India)**
12.00 — 13.00 hrs	**Lunch**
13.00 — 14.00 hrs	**Recommendations and their adoption**
14.00 — 15.00 hrs	**Closing ceremony**

ANNEX 3

OPENING SPEECH

of

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

delivered by

Hiroyuki Konuma
Deputy Regional Representative
FAO Regional Office for Asia and the Pacific

at the

Regional Biosafety Workshop
Bangkok, Thailand, 30 November – 4 December 2009

Mr Alongkorn Kornthong, Director, Office of Biotechnology Research and Development, DOA,
Distinguished participants,
Colleagues from FAO headquarters and technical experts,
Ladies and Gentlemen,

Very good morning to you all.

On behalf of Mr He Changchui, FAO Assistant Director-General and Regional Representative for Asia and the Pacific and also on my own behalf, I welcome you all to this "Regional Biosafety Workshop".

It is a privilege for me to be with you today for the opening session of the Regional Biosafety Workshop, which is being jointly organized by FAO and the Government of Thailand. I take this opportunity to convey our sincere gratitude to Department of Agriculture (DOA) for hosting this important gathering and making excellent arrangement for the meeting, I also wish to thank you all for participating in this very important and timely workshop. We are particularly happy to have all ten focal points of the member countries accompanied by one technical officer from each respective country, delegates from some new countries and quite a large number of

participants from the host country, Thailand. I thank you in advance for your technical contributions to the workshop.

The basic purpose of this week-long workshop is to further the capacity of member countries by providing up-to-date information on different aspects of biosafety and to ensure that farmers and governments can make better decisions on how to use the results of technological developments while protecting farmers, consumers and the environment. In the course of the next five days, you will be updated on some emerging issues in biosafety which will challenge agricultural professionals and policy-makers, and discuss matters in response to these challenges. You will also have the opportunity to visit laboratories and the field to interact with Thai experts and farmers. This workshop also aims to further strengthen the communication network/platform established under the prior project "Capacity building in biosafety of GMO crops" funded by the Government of Japan.

The workshop will also undertake the task of updating the benchmark document prepared in 2004 namely "needs and present status of capacity building in biosafety of GMO crops in Asia". We have tried our best to assemble high-level technical experts in the field from this region. I would like to recognize them all here today to provide technical support to this workshop. I would like to thank them for their participation despite of heavy schedule.

Dear participants,

While technological advances hold great potential for agricultural development and food security, biotechnology must be developed and used with a clear pro-poor policy and adequate safety measures to avert any negative impacts on the environment and human health. FAO has been assisting its member countries since 1999 on this vital issue by providing policy advice, technical assistance and capacity building, as well as updating their capacities through better access to science-based information, training, workshops, seminars, and in some countries by enhancing their laboratory facilities. It is heartening to see that biosafety is now of concern to every member country and that they are increasingly working together to raise awareness and understanding of and commitment to biosafety in order to provide better food and food security to their people.

In an era of information and communication technology and within a knowledge based society, FAO firmly believes that an electronic communication network is a strong and cost-effective tool for quick dissemination of information on biosafety related matters, and also recognizes the immense potential of such types of networks in contributing to agricultural development and food security.

As you are aware, our previous project contributed to the establishment of a network platform – Asian Bionet. We are very grateful to the Government of Thailand for having agreed to host the "Asian Network on Biosafety (Asian Bionet)". Thailand has kindly agreed for maintaining and managing the website through its direct support since the project was completed in 2005.

Now is the right time to take stock of the latest developments in biosafety related matters within the region – five years after completion of the project "GCP/RAS/185/JPN: Capacity Building in the Biosafety of GMO Crops in Asia". I do hope that, in the course of the next five days, the ten beneficiary member countries of the project, as well as non-participating country delegates present here, will jointly elaborate on the status of biosafety in their respective countries in the context of new regional and global settings.

As mentioned earlier, FAO has also undertaken initiatives to update the publication *Benchmark document on the needs and present status of capacity building in biosafety of GMO crops in Asia* which was published in 2004 with support from the prior project. An updated version of the document will provide us with a critical comparison of the strengths, weaknesses, gaps and opportunities in the countries and the region in terms of their national capacity building with regard to human resources, research and technology development infrastructures, regulations and policies for assessing and managing biosafety risks of GMO crops in Asia.

Dear all,

Biosafety is an integral component of the FAO Biosecurity Framework that has been adopted by FAO's governing bodies to promote a strategic and integrated approach to analyze and manage risks to crops, livestock and people. At regional and subregional levels, FAO works with member countries to establish agricultural biotechnology and biosafety networks and to promote technical collaboration and regional approaches to harmonize biosafety procedures, policies and regulations. Today's workshop is a part of FAO's broad strategy to assist member countries in building their information-sharing capacities for biosafety and safe use of modern biotechnologies.

I am very pleased to know that the Government of Thailand has agreed to continue being the host country of the already established biosafety platform. I hope that the Government of Thailand will assist other member countries to obtain updated information on biosafety related issues through the platform and the website, which will be updated based on the outcomes of this workshop and maintained with the Thai Government's continued funding support. I would also like to thank the government authorities for taking a leading role in organizing this workshop and I believe that cooperation between FAO and Thailand will be further strengthened in the future.

Before concluding, I wish to stress my high expectation of the outcomes of these deliberations and discussions. I hope that you will come up with concrete recommendations and commitments for further follow-up actions including full oparationalization of the network; Asian Bionet which can only be maintained and further promoted as an effective platform and network based on the contributions and full commitment by each of you here today.

On behalf of the FAO Regional Office for Asia and the Pacific, I wish to assure you that we will continue to remain committed to working with you on this important matter for food security and sustainable agriculture in the region.

Thank you all.

ANNEX 4

WELCOME ADDRESS

of

Mr Somchai Charnnarongkul
Director-General
Department of Agriculture
Ministry of Agriculture and Cooperatives

delivered by

Dr Alongkorn Kornthong
Director
Biotechnology Research and Development Office
Department of Agriculture

at the

Regional Biosafety Workshop
Bangkok, Thailand, 30 November – 4 December 2009

Mr Hiroyuki Konuma, Deputy Regional Representative, FAORAP,
Distinguished participants,
Colleagues from FAO headquarters and technical experts,
Ladies and Gentlemen,

(First of all, I highly apologize to inform that the director-general can not join this occasion today because he has another obligation commanded by the minister. He has been assigned to be a representative of department to join Ruam Jai Pak Rak Nai Luang activity which is jointly hosted by Tourist Authority of Thailand, Ministry of Tourism and Ministry of Agriculture and Cooperatives. The activities will take place at the royal flora glorify garden, Chiangmai. Its objective is to express Thai people's loyalty to his majesty the King on the occasion of the King's birthday on the fifth December. As a result, I am entrusted to be his representative for delivering welcome address 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 honour and pleasure to preside and address the opening of this occasion on the Regional Biosafety Workshop. I am very much delighted to learn that a list of highly respected scientists in the field of biotechnology and biosafety are here to deliver on important topics that are much given attention and talked about in the region today.

Countries in the region have different stages of development with regards to biosafety. Some countries who have not yet initiated any policy on biosafety have given highest priority to establish such policies. As for Thailand, the adoption of biosafety

protocol into law should be set as the first priority and then a clear-cut plan of implementation should also be established. The policy on the national biosafety legal framework is vitally important, and most of all there should be laws or legal mechanisms to support the protocol. We need to focus on capacity building to fully implement the biosafety policy. As a strategy for consumer protection, it must develop the capacity to conduct risk assessment, risk management and field trials. The capacity to develop biosafety clearing house mechanisms is however limited by the availability of resources that each countries have. The sector should develop coordination among governments on biosafety, the capacity for data management and information sharing and strengthen the research network system. In this sense, I would like to congratulate FAO for coming up with this very timely and relevant workshop, in order to address pending issues on biosafety that needs our immediate attention.

At this point, I would also like to congratulate you all for your gesture of commitment to share your knowledge, experiences and your valuable suggestions that would enable all the stakeholders to be informed on the most recent advancements in biotechnology and current status of biosafety policy strategies. At the conclusion of this workshop, the delegates are expected to have a common understanding of biosafety-related issues among the participating countries, and importantly to establish a wide network to strengthen further the regional collaboration in biosafety.

I would like to thank the organizing committee and colleagues at the Biotechnology research and development office, Department of agriculture who have devoted a great deal of time to organizing this training workshop. On behalf of the Department of Agriculture (Thailand), I would especially like to acknowledge the FAO Regional Office for Asia and the Pacific for its financial support for this workshop.

In closing, once again, I would like to take this opportunity to welcome you all to Thailand and wish you a productive workshop and an enjoyable stay here in the city of Bangkok. I hope that you would also join us in celebrating His Majesty's 82nd birthday.

I thank you for your kind attention.