

# Biosafety

NEWSLETTER



ISSUE 05

OCTOBER 2013

**NEW GUIDELINES:**  
**Risk Assessment of Genetically  
Modified Microorganisms**

**Environmental  
Risk Assessment of Genetically  
Modified Plants in Malaysia**

**Confined Field Trial  
of Living Modified Plants in Malaysia**

**SPECIAL REPORT:**  
**Self Regulatory Mechanism  
Through IBC**

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## MESSAGE FROM THE CHIEF EDITOR



**Mr. Letchumanan Ramatha**  
**Director General, Department of Biosafety**  
**Ministry of Natural Resources and Environment (NRE)**

Welcome to the fifth edition of the Biosafety Newsletter!

As of June 2013, the National Biosafety Board (NBB) had made decision on 14 applications on approval for release of LMOs and 24 notifications on activities in contained use. The capacity to handle and process all these applications was made possible through the NRE-UNDP-GEF Biosafety Capacity Building Project which came to an end last year. This Project has helped to build institutional capacities through training and human resource development in various areas and enabled the Department and other government agencies to acquire sufficient capacities in risk assessment and risk management.

Final outputs of this project include the development of 3 biosafety guidelines namely; Risk Assessment of Genetically Modified Microorganisms, Environmental Risk Assessment of Genetically Modified Plants in Malaysia and Confined Field Trial of Living Modified Plants in Malaysia. These guidelines will be very useful to all public and private organizations, working on modern biotechnology, specifically involving LMOs.

The success of this project provided a basis for the Department to apply for another GEF funding to address those areas of biosafety that need capacity building for example liability and redress, socioeconomic considerations and awareness programmes on biosafety to facilitate public participation. As various challenges are expected to come, the Department has to continuously formulate strategies to sustain the development of biosafety capacity in the country. These may include to i) coordinate inspection and compliance regulatory functions with relevant agencies; ii) provide sustainable capacity building in risk assessment, risk management and risk communication as new LMOs are developed and the technology evolves; iii) integrate socio-economic impact into decision making on release applications; iv) find a sustainable way to use the detection services for risk management, such as using this service only for products with identified high risk; v) develop streamlined procedures for the existing officers to cope efficiently when applications increase.

Apart from that, the Department is also focusing on the establishment of a domestic framework for liability and redress for damage resulting from LMOs. For this purpose, a study will be undertaken to suggest viable options. This is also in line with one of the key decisions made during the Sixth Meeting of the Parties to CPB (COP-MOP 6) that requested the Parties to the CPB that have not yet done so to initiate and expedite their internal processes leading to ratification, approval or acceptance of or accession to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

Biosafety, Always Our Priority!

## GUIDELINES ON RISK ASSESSMENT OF GENETICALLY MODIFIED MICROORGANISMS

If you are working with Genetically Modified Microorganisms (GMM) and are not sure how to do a risk assessment of your activity, you should refer to this Guideline. It is divided into two parts and provides elaborate instructions on how to conduct a risk assessment for (a) GMM not associated with plants and (b) GMM associated with plants.

Microorganisms covered under the first part include adeno-associated viruses, adenoviruses, baculoviruses, herpesviruses, poxviruses, retroviruses and RNA viruses. Risk assessment of a GMM not associated with plants focuses primarily on risk to human health. Hazard is identified associated with the recipient, donor organism, vector and insert where appropriate. Guidance is also given for assessment posed by inserted sequences, routine cloning and expression work using attenuated *Escherichia coli*, bacterial gene delivery systems and work

with cell cultures. Based on the assessment done, guidance is given on containment to control/minimize the risk through safe work procedures, facility design and equipment.

The second part of this Guideline focuses on risk assessment of GMM associated with plants, namely viroids, virusoids, viruses, bacteria, fungi, protozoa and algae. Risk assessment focuses on risks to the environment and guidance on containment level and control measures needed for protection in a plant facility are given in this part of the guideline.

Some examples of risk assessment are shown to the user to show the application of the risk assessment principles given in these guidelines. It highlights that risk assessment must be done before a GM-BSL is determined for an activity involving a GMM.

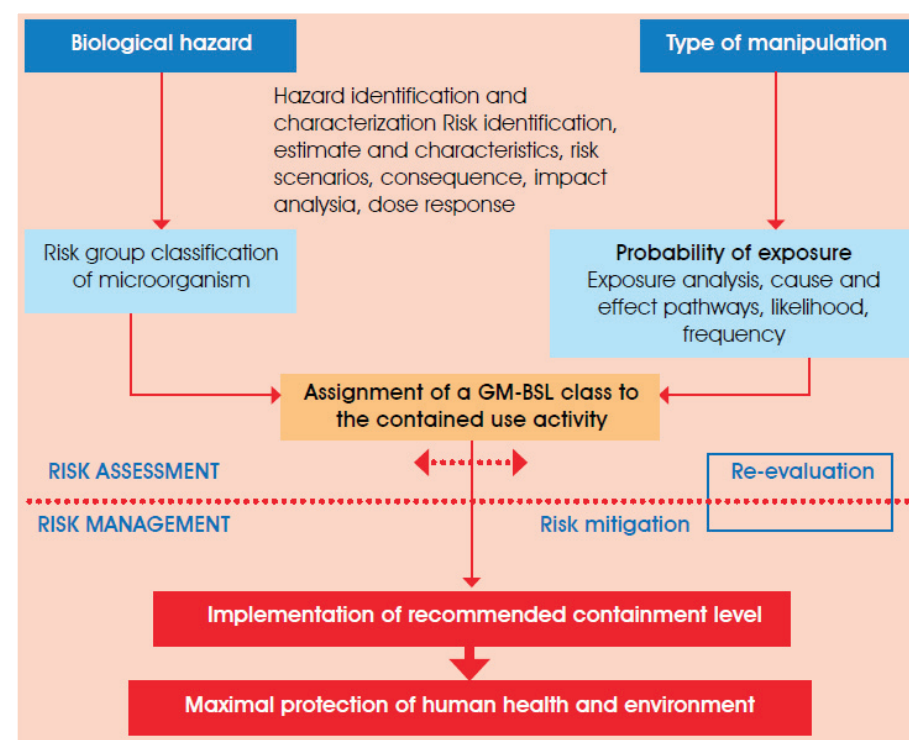


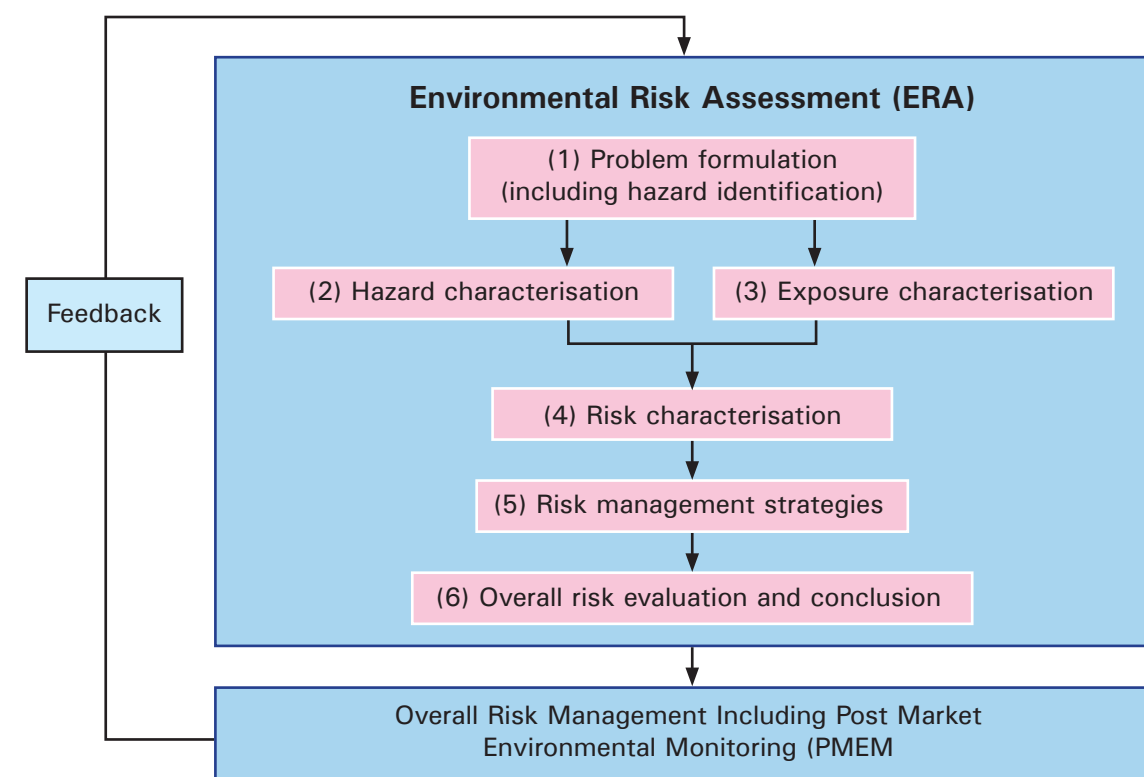
Figure 1:  
Identification of biological hazards and determination of the Risk Groups and biosafety level (GM-BSL) of the GMM

## GUIDELINES ON ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS IN MALAYSIA

This Guideline gives details on the Environmental Risk Assessment (ERA) of Genetically Modified (GM) plants in Malaysia. It covers ERA of applications for the cultivation of GM plants, as well as for the import of food and feed containing or consisting of GM plants, or produced from GM plants. The guideline covers chapters on:

|     |                                                                       |      |                                                                          |
|-----|-----------------------------------------------------------------------|------|--------------------------------------------------------------------------|
| i   | Environmental Risk Assessment                                         | vii  | Interaction of the GM plant with non-target organisms                    |
| ii  | General Considerations in ERA                                         | viii | Impact of specific cultivation, management and harvesting techniques     |
| iii | Risk Assessment of GM plants containing stacked transformation events | ix   | Effects on bio-geochemical process                                       |
| iv  | Persistence and invasiveness, including plant-to-plant gene flow      | x    | Effects on human and animal health                                       |
| v   | Plant to microorganism gene transfer                                  | xi   | Post-market environmental monitoring plan                                |
| vi  | Interaction of the GM plant with target organism                      | xii  | ERA activities with plant-associated genetically modified microorganisms |

The objective of ERA, on a case-by-case basis, is to identify and evaluate potential adverse effects of the GM plant, direct and indirect, immediate or delayed (including cumulative long-term effects) on the receiving environment/s where the GM plant will be released. The European Food Safety Authority (EFSA, 2010) proposed that ERA follows six (6) steps as in Figure 2.



Source: EFSA (2010)  
Figure 2: Six steps in an environmental risk assessment

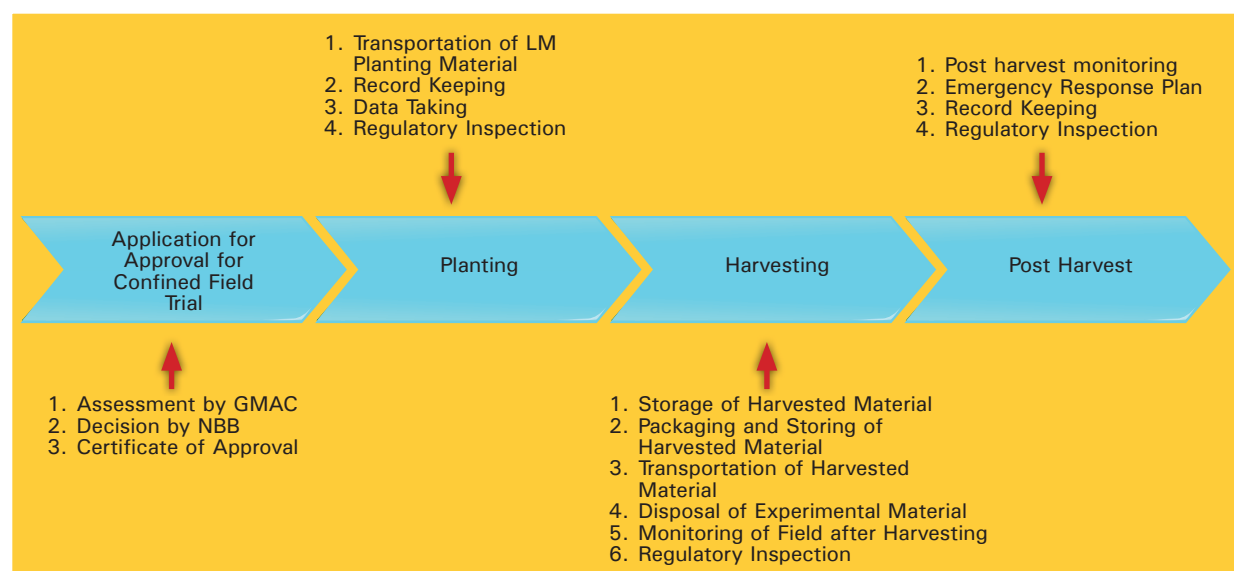
The Guidelines do not consider issues related to traceability, labeling or co-existence. Neither do they cover socio-economic and ethical issues, focusing primarily on potential environmental risk arising from GM plants.

## GUIDELINES ON CONFINED FIELD TRIAL OF LIVING MODIFIED PLANTS IN MALAYSIA

The objective of this Guideline is to provide researchers with the necessary practices when conducting a Confined Field Trial (CFT) of LM plants or crops to fulfill biosafety regulatory compliance. It also gives guidance on practices that will prevent pollen or seed dissemination into and within the environment, persistence of

the LM plant or any of its parts and its progeny in the environment, and to prevent entry of the LM plant or plant products into the human food or animal feed chain. The confined field trial process is shown in Figure 3.

Figure 3: Confined Field Trial Process



Important chapters in the guidelines:

### Chapter 2: Application form for confined field trial.

This chapter introduced a standard form (NBB/A/ER/10/FORM A) for an applicant to seek approval for CFTs. The application form contains sufficiently detailed instructions to allow the applicant to complete the form correctly and expeditiously.

### Chapter 3: Transportation And Storage Of Experimental Living Modified Plants

This chapter provides guidance on appropriate measures on the transport and storage of experimental LM plants and plant material for CFTs to ensure that there is no unintended release.

### Chapter 4: Management of confined field trials.

This chapter outlines practices that can be followed to ensure the safe management of CFTs of LM plants during the entire growing period as well as after harvest.

### Chapter 5: Sampling, record, keeping and disposal

This chapter of guidelines and procedures for sampling, record keeping and disposal of material during an approved CFT is effective for any release activity, or any importation of LM plant material for release upon issuance of a certificate of approval.

### Chapter 6: Post-harvest management of confined field trial

This section provides a general guideline applied to all CFTs of LM plants for practices that can be undertaken to contribute to the safe management of trial sites after final harvest and during the mandated post-harvest period.

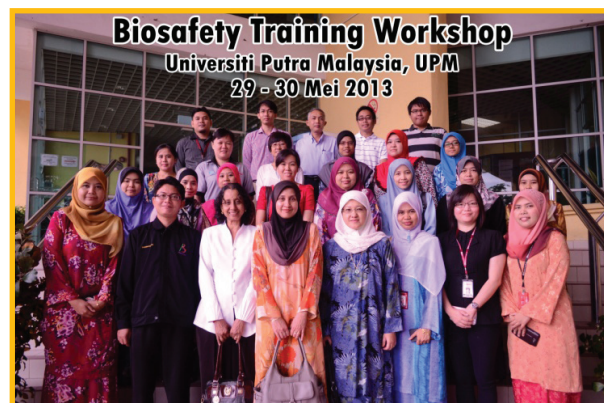
## CAPACITY BUILDING ACTIVITIES

### i) Title: Biosafety Training Workshop

| Date                 | Venue                                      |
|----------------------|--------------------------------------------|
| 19-20 September 2012 | Universiti Teknologi MARA Shah Alam (UiTM) |
| 25 September 2012    | ACGT Sdn Bhd                               |
| 17-18 October 2012   | Malaysia Genome Institute (MGI)            |
| 23-24 October 2012   | Universiti Putra Malaysia (UPM)            |
| 8-9 May 2013         | Agro-Biotechnology Institute (ABI)         |
| 29-30 May 2013       | Universiti Putra Malaysia (UPM)            |

The Department of Biosafety jointly organized the Biosafety Training Workshop with UiTM, ACGT Sdn. Bhd., MGI, UPM and ABI during the period of Sept 2012 to May 2013. The main objective of the workshop is to create awareness among the researchers, lecturers and laboratory personnel on the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and on the Biosafety modules. The workshops are designed to be interactive with the aim of stimulating thinking and encouraging two way communication.





- ii) **Title** : Institutional Biosafety Committee (IBC) Workshop  
**Date & Venue** : 8-10 May 2012 - Novotel Hotel, Kuala Lumpur

The Department of Biosafety and United Nations Development Programme (UNDP) jointly organized this workshop. The three days' workshop attempted to provide further guidance and updates on Biosafety as well as to create a healthy networking among the IBC members. At the same time, the workshop was an eye opener for research institutes that are carrying out research activities involving LMOs and in the process of setting up their IBC.



## AWARENESS ACTIVITIES

**Title:** Biosafety Awareness Programmes/Activities

| Date                | Venue                                                                         |
|---------------------|-------------------------------------------------------------------------------|
| 3-4 November 2012   | Road show and exhibition at Paya Indah Wetlands World Life Week Carnival 2012 |
| 19-20 February 2013 | Exhibition and MyBiotech@School Activity at BioBorneo, Kota Kinabalu, Sabah   |

As part of our awareness programmes and activities, the Department of Biosafety conducted a road show with the local residents of Dengkil in Selangor. This was also in conjunction with the Wildlife Week Celebration 2012 which was held on 3 - 4 November. The aim of the road show and exhibition was to educate and create awareness among the public about the biosafety issues in Malaysia and also to promote their involvement in providing comments during our public participation process.

The Department of Biosafety also participated in the BioBorneo Conference 2013 in Kota Kinabalu, Sabah on the 19 -20 February 2013. During this event, the Department of Biosafety was involved in the exhibition and also participated in the MyBiotech@School activity which was organized by the Ministry of Science, Technology and Innovation. The objective of the Department's involvement in this activity was to create awareness among the higher secondary students on the Biosafety Act and its Regulations which comes hand in hand with modern biotechnology activities. The activities involved a video presentation as well as interactive games.



## INTERNATIONAL MEETING/WORKSHOP

### i) **Sixth Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP/6)** Hyderabad, India, 1-5 October 2012

The sixth meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP 6) was held from 1-5 October 2012 in Hyderabad, India. As reported, some 1500 delegates from more than 100 countries attended the meeting. Malaysia participated in this meeting with



a 5 members delegation headed by Director General, Department of Biosafety. The meeting adopted several key decisions among others on: the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (the

Supplementary Protocol); unintentional transboundary movements of LMOs; socio-economic considerations; and risk assessment and risk management.

#### **Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress**

Discussions focused on national efforts to achieve ratification of the Supplementary Protocol, with some countries emphasizing capacity building and establishing national priorities; and the need for awareness-raising at the national level, including an explanatory guide for the Supplementary Protocol. The Supplementary Protocol will enter into force 90 days after the 40th ratification. Until June 2013, 14 parties have ratified/acceded the Supplementary Protocol. Malaysia will work towards creating a legal framework to facilitate the accession to

the Supplementary Protocol. This will start with carrying out of a comprehensive study on the legal requirements and available instruments, leading to possible options for consideration.

#### **Socio-economic Considerations**

The meeting was able to achieve broad consensus that socio-economic considerations require substantive engagement. Delegates realized that the first step towards addressing socio-economic considerations in a meaningful way is to develop conceptual clarity on what constitutes socio-economic considerations under the Protocol. Building consensus on the need to establish an Ad hoc Technical Expert Group (AHTEG) to conduct this basic work enabled delegates to envision the next steps. Many delegates felt that socioeconomic consideration has been firmly established as one of the main substantive issues to be developed at future COP/MOPs.

#### **Risk Assessment and Risk Management**

The guidance materials for risk assessment is a great achievement as it is the first time some guiding materials consistent with the requirement of the protocol has been produced together with guidelines for specific areas such as genetic mosquitoes etc. It was produced by the AHTEG in which Malaysia is also a member. Despite numerous references emphasizing the voluntary nature of the guidance and the broad understanding that it would be tested and further revised, delegates could not agree to endorse and operationalize the guidance. The meeting decided to call for another round of improvements by requesting a structured approach to testing and subsequent revision. The guidance will be used and tested accordingly by the Genetic Modification Advisory Committee (GMAC) in their risk assessment work.

### **Unintentional Transboundary Movements of LMOs**

Protocol requires each Party to take appropriate measures to notify affected States when it knows of an occurrence under its jurisdiction resulting in a release that leads to an unintentional transboundary movement of a LMO. In such cases, the meeting encourages Parties to use the above guidance on risk assessment and establish mechanisms for emergency measures. The meeting also requested Parties to provide views and information to the CBD Secretariat six

months prior to COP/MOP 7 on any challenges and experiences relating to the implementation of this agenda item.

On financial resources, both AHTEGs (Risk Assessment, and Socio-economic Considerations) would be subjected to voluntary contributions. The meeting however urged Parties to give priority to national biosafety plans and projects under GEF to ensure support for the implementation of the Protocol.



Opening of the COP-MOP 6 on 1st October 2012

**ii) Workshop on the Implementation of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress**  
Tokyo, Japan, 21-22 Feb 2013

Each country has its own unique legal, political and administrative systems to respond to their international obligations under multilateral environmental agreements. In responding to the Supplementary Protocol on Liability and Redress at the national level, each country would have to confront its legal, political and administrative systems in the domestication process. To this end, the Government of Japan has initiated this workshop with the support of CBD and brought together participants from various regions including a few ratified countries such as Latvia and Mexico. As Japan has not ratified the Supplementary Protocol pending domestic legislation in place, they have made this workshop as a platform to learn from experiences of other countries in developing and implementing liability and redress regimes on damage by living modified organisms to biological diversity with special reference to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (NKL-SP).

During this workshop, participants, including Malaysia, shared their country's experiences,

including how to implement core elements of the Supplementary Protocol. SCBD has urged Malaysia to take necessary steps to expedite the accession process as the protocol is carrying the name of our capital city. Besides the presentation, the workshop also discussed in depth key challenges faced by the Parties to the Cartagena Protocol in their domestic implementation in preparation for ratification, and to provide possible solutions to overcome those challenges. Visits to several agencies related to biosafety in Japan were held on second day of the workshop.

Overall, the workshop was quite successful in exchanging countries' experiences in the transposition of the core elements of the NKL-SP, such as the response measures to damage and the entities responsible to take response measures so that the ratification and accession process can be further facilitated. Malaysia can adopt approaches taken by Japan in coming out with domestic framework for liability and redress law.



Participants of the workshop

**iii) Asia-Pacific Regional Training Workshop on Public Awareness, Education and Participation Concerning the Safe Transfer, Handling and Use of LMOs**  
Hanoi, Vietnam, 25-29 March 2013

The CBD organized the Asia and the Pacific regional workshop to enhance the capacity of Parties of the Cartagena Protocol on Biosafety and other Governments in the region to effectively implement the programme of work and to share experiences and lessons learned. The programme of work includes four programme elements: capacity-building, public awareness and education, public access to information, and public participation. Twenty two participants from fifteen party countries (Malaysia, Indonesia, Cambodia, Mongolia, Vietnam, Laos, Thailand, Fiji, Japan, Bhutan, Bangladesh, Korea, Pakistan, China and Philippines) and three participants from 1 non-party country (Iraq) attended the five day workshop. There were also participants from inter-governmental organizations and non-governmental organizations.

The specific objectives of the workshop were: (a) To introduce participants to key concepts, tools and legal instruments relevant to public awareness, education, access to information, and participation concerning the safe transfer, handling and use of living modified organisms; (b) To facilitate exchange of information, experiences, best practices and lessons learned in promoting public awareness and education, access to information and participation concerning living modified organisms; and (c) To discuss strategies for enhancing regional and subregional cooperation in the implementation of the programme of work on public awareness,

education and participation at the national and regional levels. The last segment of the workshop introduced the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress with a view to raising awareness of its objective and core requirements as well as the challenges and opportunities regarding its ratification and implementation.

The workshop included a series of thematic lectures by practitioners, case-study presentations, interactive group discussions and special sessions involving hands-on practical exercises and role-plays. At the end of the workshop, all participants were requested to give their feedback and ideas on the strategies for promoting regional cooperation in the Asia Pacific in public awareness and education, public access to information and public participation concerning living modified organism. The list was later discussed and member states were asked to share the responsibilities in committing to all the strategies suggested.

On the whole, the workshop was successful in exposing the participants to each member state's experiences and their current program and how far they have advance in dealing with issues on biosafety especially on their program of work related to public awareness, education and participation concerning the safe transfer, handling and use of LMO.



Participants of the workshop

## SPECIAL REPORT

### 1 SELF REGULATORY MECHANISM THROUGH INSTITUTIONAL BIOSAFETY COMMITTEE

In compliance with the Malaysian Biosafety Act 2007 and other related regulations, any organization, which undertakes modern biotechnology research and development, shall establish an Institutional Biosafety Committee (IBC). This is to ensure that any LMO/rDNA research, conducted at or sponsored by the organization, irrespective of the source of funding, complies with the Act and other related regulations and Malaysian Laws relating to import and export, human, plant and animal health, environment and biological diversity. The IBC shall be registered with the National Biosafety Board (NBB) by submitting Form G (NBB/IBC/10/FORM G) which is available on the Malaysian Biosafety Clearing House (BCH) website. There is no fee imposed in registering the IBC but the respective institutions need to update their activities to NBB on annual basis and also to update any other changes made

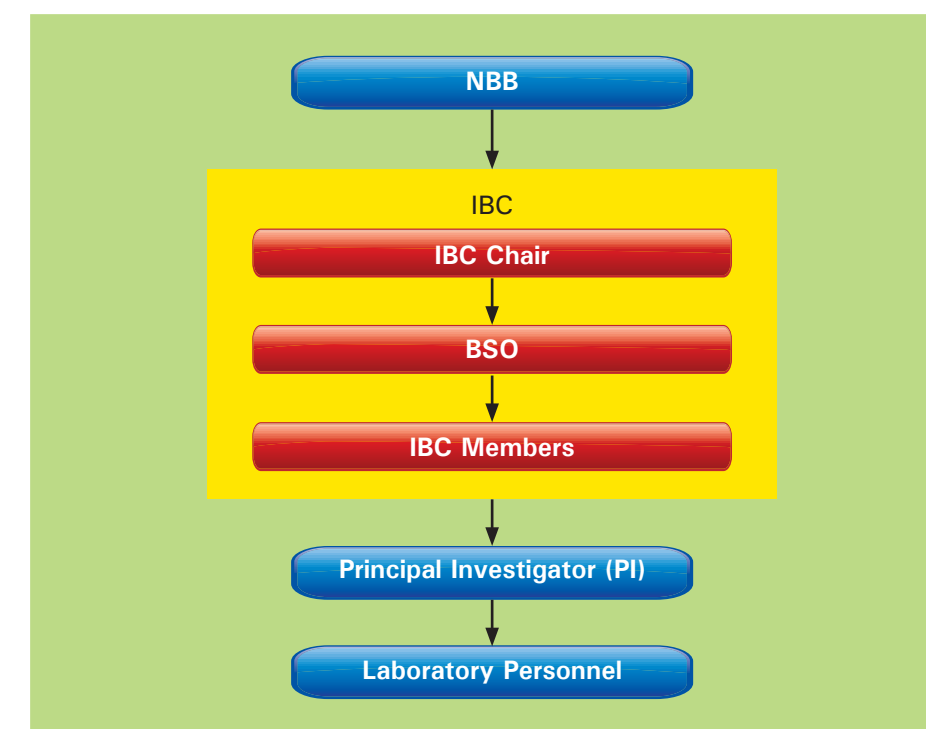
to their IBC. The IBC should have a minimum composition of a Chairman and a Biosafety Officer (BSO) and they may consult with NBB through the Department of Biosafety to address problems and issues pertaining to the organization's IBC, policies, applicable laws (state and federal) and other biosafety standards of conduct and practices. The scope of the IBC review includes LMO/rDNA activity notifications and applications, modifications and extensions of approved project, exemptions, incidents and personnel exposure, biosafety manuals and also laboratory inspections. The Department also conducts an IBC Seminar annually to provide guidance address issues and provide updates on Biosafety as well as to create a healthy networking among the IBC members. Up to June 2013, there are 27 research institutes/public & private universities that have registered with the Department.

Therefore it is ideal to say that the IBC of the respective institutes regulate their own activities while the Department monitors them. There is also a strong need for the regulators (Department of Biosafety) and researchers to work together to create an enabling environment for modern biotechnology R&D and at the same time ensuring that human, plant and animal health, biological diversity and the environment is conserved.



Figure 4: Responsibilities of IBC

Figure 5: Organizational structure of the IBC in monitoring modern biotechnology activities



#### LIST OF REGISTERED IBCS (AS OF JUNE 2013)

- |                                                                  |                                                                 |
|------------------------------------------------------------------|-----------------------------------------------------------------|
| 1) Universiti Malaya (UM)                                        | 17) Malaysian Nuclear Agency                                    |
| 2) Universiti Sains Malaysia (USM)                               | 18) Agro Biotechnology Institute, Malaysia (ABI)                |
| 3) Universiti Putra Malaysia (UPM)                               | 19) Institute Pharmaceutical & Nutraceutical Malaysia (I-Pharm) |
| 4) Universiti Malaysia Sabah (UMS)                               | 20) Sime Darby Sdn. Bhd                                         |
| 5) Universiti Teknologi Malaysia (UTM)                           | 21) Craun Research Sdn. Bhd.                                    |
| 6) Universiti Teknologi MARA (UiTM)                              | 22) BioValence Sdn. Bhd.                                        |
| 7) Universiti Kebangsaan Malaysia (UKM)                          | 23) ACGT Sdn. Bhd.                                              |
| 8) Universiti Malaysia Kelantan (UMK)                            | 24) Glycos Bio Asia Sdn. Bhd.                                   |
| 9) Universiti Malaysia Sarawak (UNIMAS)                          | 25) Cerca Insights Sdn. Bhd.                                    |
| 10) University Nottingham Malaysia Campus                        | 26) Cancer Research Initiatives Foundations                     |
| 11) Monash University Sunway Campus                              | 27) Malaysia Genome Institute (MGI)                             |
| 12) International Medical University (IMU)                       |                                                                 |
| 13) Institute Medical Research (IMR)                             |                                                                 |
| 14) Malaysian Agriculture Research Development Institute (MARDI) |                                                                 |
| 15) Malaysian Palm Oil Board (MPOB)                              |                                                                 |
| 16) Forest Research Institute of Malaysia (FRIM)                 |                                                                 |

## 2 AN OFFICIAL VISIT BY BHUTAN DELEGATION TO THE DEPARTMENT OF BIOSAFETY

The increased biosafety capacity in Malaysia has been noted by other countries that are in the process of developing national biosafety frameworks. Staff members from the Department have been invited to share the Malaysian biosafety experience at international meetings and few countries have expressed interest in visiting Malaysia to learn from our local biosafety experience. The most recent was the visit by a delegation from Bhutan which delegation comprised of six officials from the Ministry of Agriculture and Forests, Royal Government of Bhutan on 22 March 2013 to the Department of Biosafety's office in Putrajaya.

This visit was aimed to study how the biosafety regulatory body in Malaysia carries out its functions that will enable Bhutan delegates learn elements of an effective regulatory system. During the visit, Director General of Biosafety delivered his presentation to the delegates to give an insight of the Malaysian biosafety regulatory framework. The topics covered include regulatory processes for approval and notification, key elements of the Biosafety Act, monitoring aspects and challenges in implementing the Act. The agencies that were involved in meeting with the Bhutan delegates were Department of Agriculture, Department of Veterinary Services, Department of Chemistry and Malaysian Quarantine and Inspection Services.

The visit provided opportunities to Bhutan delegates to obtain first hand information on the experience of the various agencies in Malaysia that are involved in regulatory activities or related activities involving LMOs. It proved to be useful for them to learn from these agencies and the delegates were able to build a network of contacts with the regulatory officers for future references.



Exchange of gifts between Mr. Letchumanan Ramatha, Director General of Biosafety, Malaysia and Mr. Karma Dorji, Executive Director, Bhutan Agriculture and Food Regulatory Authority



Delegates listening to the presentation

## 3 GEF4 BIOSAFETY CAPACITY BUILDING PROJECT SUCCESS STORY

This project Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety aimed to help build Malaysia's national capacity for implementing the Biosafety Act 2007, which included the provisions needed to implement national obligations as a Party to the Cartagena Protocol on Biosafety (CPB). As there was insufficient capacity in the fields of risk assessment, risk management, risk communication and administrative and regulatory implementation, the project was conceived to support Malaysia in building these capacities to undertake the biosafety tasks required by the Biosafety Act.

The three-year project was approved in May 2006 and implemented in March 2007. The delayed implementation was a result of the parliamentary process related to the passing of the Biosafety Act. Following a request for an extension, the project ended in June 2012. The main stakeholders identified for this project, were the relevant ministries and government agencies; the public and private sector biotechnology community; scientists involved in risk assessment and risk management; advocacy groups; and the interested public. The Project Inception Report identified six intended outputs and eight expected outcomes from the project

while planned activities were divided between the six components of the project.

The main success of the project is the implementation of the national biosafety framework in the country. Malaysia has a transparent biosafety process with the capacity to receive, review and publish decisions on applications for activities with LMOs. Other successes include the wide diversity of biosafety stakeholders that participated in the implementation process and a significant level of capacity building in the major aspects of biosafety regulation.

Lessons learnt during the project included the value of using in-house human resources to manage the implementation so that the expertise remains within the biosafety institutions at the end of the project. Challenges for the Department in implementing the project included the need to balance the demands from stakeholder groups that promoted and those that rejected modern biotechnology and its application in Malaysia. The Department has achieved a commendable level of neutrality and credibility in the execution of their biosafety activities and in the distribution of funding from this project.

The terminal evaluation for this project was undertaken in May 2012. It serves to promote accountability for the resources use and to document and provide feedback on the lessons learned. The evaluation included a review of documentation, discussions with the implementing agency and interviews with key stakeholders. Based on the functioning of the Department, the involvement of the relevant ministries, the judicious use of funding, the Government of Malaysia's strong co-funding of the activities, and the positive feedback from stakeholders, this project implementation was evaluated as Highly Satisfactory. In the evaluation report, it is also recommended that Malaysia applies for additional GEF funding to address those aspects of the national biosafety process that still need capacity building for implementation.

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Biosafety publications from the project

## LATEST BIOSAFETY PUBLICATIONS



**Title: Guidelines on Risk Assessment of Genetically Modified Microorganisms**

This Guideline is essential for all public and private organizations, working on modern biotechnology, specifically involving genetically modified microorganism so as to conduct a proper risk assessment that will enable safely handling and ensure protection of human, plant and animal health, the environment and biological diversity.

**Title: Guidelines on Environmental Risk Assessment of Genetically Modified Plants in Malaysia**

This document provides guidelines for the environmental risk assessment (ERA) of genetically modified (GM) plants in Malaysia. It covers ERA of applications for the cultivation of GM plants, as well as for the import of food and feed containing or consisting of GM plants, or produced from GM plants.



**Title: Guidelines on Confined Field Trial of Living Modified Plants in Malaysia**

The objective of this Guideline is to provide researchers with the necessary practices when conducting confined field trial of living modified plants or crops to fulfill biosafety regulatory compliance.

## LIST OF APPROVED EVENTS AND RELEASE ACTIVITIES (As of June 2013)

|    | EVENT/PRODUCT                                                            | PURPOSE                 | APPLICANT                     |
|----|--------------------------------------------------------------------------|-------------------------|-------------------------------|
| 1  | Roundup Ready Soybean GTS-40-3-2                                         | Food, Feed & Processing | Monsanto                      |
| 2  | Roundup Ready Corn NK603                                                 | Food, Feed & Processing | Monsanto                      |
| 3  | Yieldgard Corn Borer Corn MON 810                                        | Food, Feed & Processing | Monsanto                      |
| 4  | Rootworm Corn MON 863                                                    | Food, Feed & Processing | Monsanto                      |
| 5  | Ice-Structuring Protein (ISP)                                            | Food                    | Unilever                      |
| 6  | GM Mosquito OX513A (My1)                                                 | Field Trial             | Institute of Medical Research |
| 7  | TMOF Yeast – Mousticide Rice Husk and Mousticide Wettable Powder         | Release to environment  | EntoGenex Sdn. Bhd            |
| 8  | SYN-Bt11-1 - YieldGard™ Maize                                            | Food, Feed & Processing | Syngenta                      |
| 9  | ACS-GM5-3 - Herbicide-tolerant Soybean (A2704-12)                        | Food, Feed & Processing | Bayer                         |
| 10 | Genetically modified carnation, Dianthus caryophyllus L.                 | Placing on the market   | Suntory Holdings Ltd.         |
| 11 | MON 89788 glyphosate tolerant Soybean (Roundup Ready 2 Yield™)           | Food, Feed & Processing | Monsanto                      |
| 12 | T25 Herbicide-tolerant Maize                                             | Food, Feed & Processing | Bayer                         |
| 13 | TC1507 Herbicide tolerant and insect resistance Maize                    | Food, Feed & Processing | Du Pont                       |
| 14 | Confined field evaluation of delayed ripening transgenic Eksotika papaya | Field Trial             | MARDI                         |



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