BIOSAFETY NEWSLETTER

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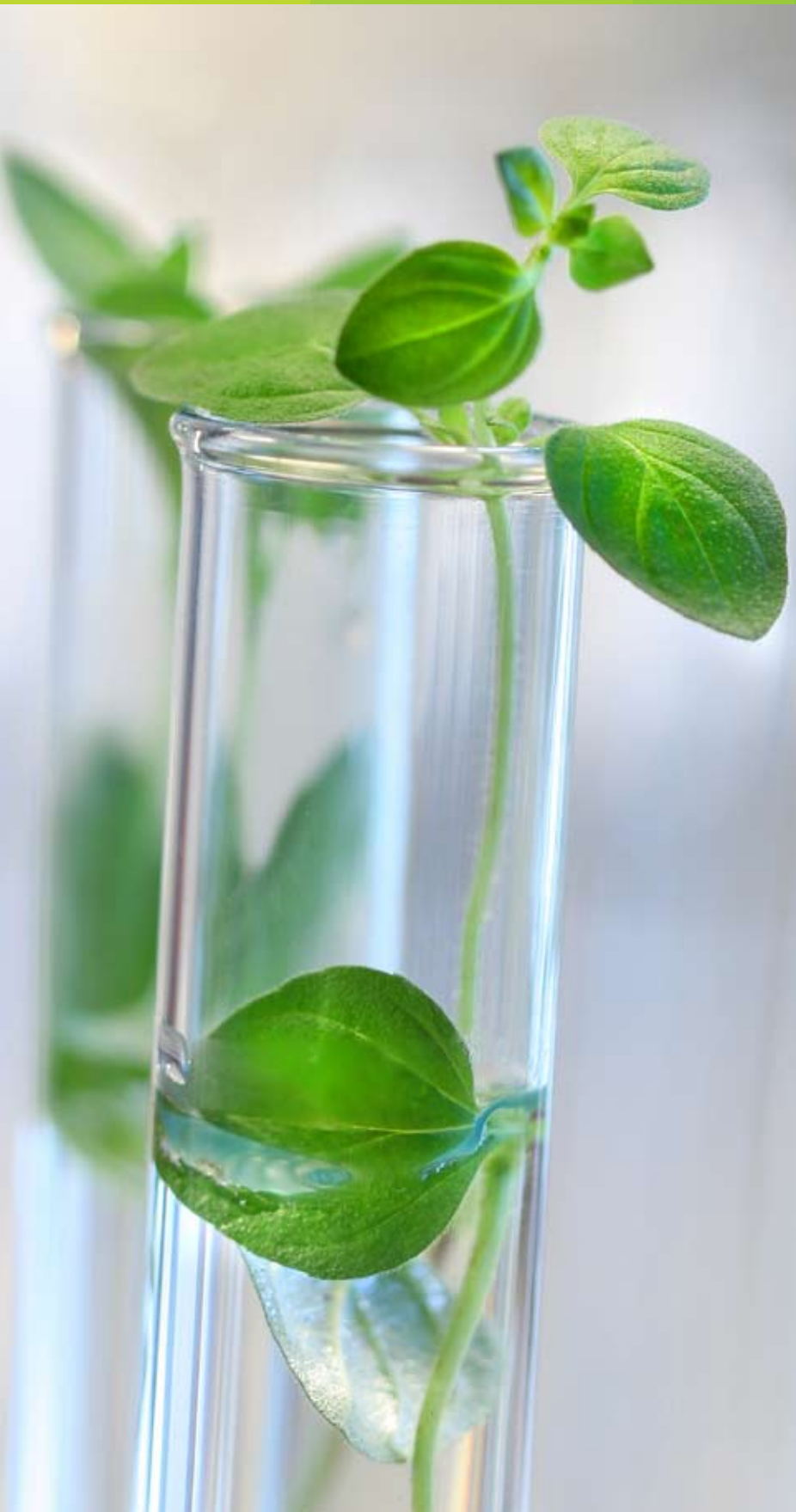

Guidelines for Biosafety Compliance
IBC Guidelines & Guidelines for Contained Use Activity of LMOs

Genetic Modification Advisory Committee (GMAC) Workshop
4-6 November 2009 at the PJ Hilton

Sabah & Sarawak Stakeholders' Workshop on Biosafety
Conducted in Kota Kinabalu & Kuching

GEF

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Erratum
We would like to make a correction that Institute Medical Research (IMR) had jointly organised The Risk Assessment Workshop on Transgenic Insect which was conducted on 13-15 November 2008.

MESSAGE FROM THE CHIEF EDITOR

Welcome to the second edition of the Biosafety Newsletter. The period following the inauguration of the first edition of the Biosafety Newsletter in April 2009 recorded a remarkable overall progress in biosafety efforts.

The Biosafety Core Team (BCT) has been further strengthened with the addition of 12 new members. Several important consultation meetings to finalise the Biosafety Regulations were held, namely Ministerial Level Meetings on the Implementation of the Biosafety Act 2007 and Meetings with related Ministries/ Agencies and Industries. At the regional front, the BCT was involved in organizing the Regional Meeting on Genetically Modified Organisms (GMO) Detection and the Southeast Asian Forum on the Draft Regional Technical Guidelines for Risk Assessment of GMOs.

Under the Ministry of Natural Resources and Environment - United Nations Development Programme - Global Environment Facility (NRE-UNDP-GEF) project, several capacity-building efforts were undertaken. These included workshops on Risk Assessment on Transgenic Crop Plants and Transgenic Trees and for potential candidates of the Genetic Modification Advisory Committee (GMAC); the participation of scientists in the Management of Containment Facilities Workshop and a special workshop on GMO Analysis using Real Time Polymerase Chain Reaction (PCR).

To educate the public, main stakeholders were invited to participate in a Workshop on Biosafety in Kuching, Sarawak and Kota Kinabalu, Sabah. In addition, five Awareness Programmes were conducted in collaboration with the Malaysian Nature Society (MNS) and the Chemistry Department, on topics such as "GM Food – Food for the future?" and "Biosafety - What, Why and How?"

There has also been significant growth in the development of R&D facilities in biotechnology in Malaysia. The highlight was the completion of the state-of-the-art plant biotech facility at University Malaya. This greenhouse facility will encourage, facilitate and provide the support for academics, students and their industry partners to take their research forward from the laboratory to practical applications and to enable compliance with International Biosafety Standards. However, the most significant achievement for Biosafety was the coming into effect of the Biosafety Act 2007 on 1st December 2009 after much challenges.

Meanwhile, we are sadden by news on the demise of Dr Low Fee Chon (fondly known as Fee Chon) who passed away on 26th September 2009. She pioneered biosafety work both in Malaysia and globally and was a driving force in pushing our local biosafety agenda forward through her involvement in the initial drafting of the Biosafety Bill. She also made contribution as a member of the GMAC and also in formulating local guidelines on biosafety. The late Fee Chon was the Regional Coordinator for Biosafety (Asia), for the United Nations Environment Programme (UNEP) Regional Office for Asia and the Pacific (ROAP) based in Bangkok. Our condolences to her family.

Finally, we would like to extend our heartfelt appreciation to Dr Vilasini Pillai, the former National Project Coordinator for the NRE-UNDP-GEF Biosafety Project, who has taken on the position of Scientist in Residence at the Office of the Science Advisor, Ministry of Science, Technology and Innovation (MOSTI). Dr Vilasini has done an excellent job in enabling the project to take off and in coordinating the participation and input from various stakeholders in building capacity in biosafety in Malaysia. The project will continue with a new National Project Coordinator on board soon.

We hope you find this issue useful and informative. In the next issue of the Biosafety Newsletter, readers can look forward to more news and highlights, such as the National Biosafety Board, GMAC, Biosafety Regulations, Institutional Biosafety Committee Guidelines for Contained Use Activity and also the User Guide.

Biosafety, It's Our Priority!

Mr Letchumanan Ramatha
Head of Biosafety Core Team Ministry of Natural Resources & Environment

GUIDELINES FOR BIOSAFETY COMPLIANCE

Prepared by
Dr Vilasini Pillai

Resident Scientist of National Science Advisor Office, MOSTI

The Ministry of Natural Resources & Environment is drafting two guidelines for biosafety compliance with the help of experts from universities and research institutes. The topics covered in the guidelines are Setting Up an Institutional Biosafety Committee (IBC) and Contained Use Activity of Living Modified Organisms (LMOs). Both these guidelines will be useful for all organisations who are involved in conducting research and development on modern biotechnology. The purpose of these guidelines is to ensure that these activities comply with the *Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010* and other related government regulations and policies to safeguard human health and the environment. These two documents were then independently reviewed by a committee comprising of Malaysian experts with over 30 years of experience in conducting research development activities in modern biotechnology.

Guidelines for Institutional Biosafety Committees (IBC): Use of Living Modified Organisms and Related Materials

The IBC is a formal expert committee of an organisation, chaired by the head of the organisation or his designate (a suitable senior officer). In the draft *Biosafety (Approval and Notification) Regulations 2010*, any organisation (both public and private), which undertakes modern biotechnology research and development, shall establish an IBC which must be registered with the Board. *The "Guidelines for Institutional Biosafety Committees (IBCs): Use of Living Modified Organisms and Related Materials"* outlines the setting up of IBCs, role of IBCs and the processes that must be followed when obtaining, using, storing, transferring, or destroying LMO/rDNA materials. It also provides explanations of the relevant regulatory requirements and procedures. Scope of IBC responsibilities include activities and research involving LMO/rDNA materials that are:

- Conducted by organisation members
- Sponsored by the organisation and/or other parties
- Conducted using the facilities at the organisation
- Stored at any of the facilities at the organisation

The responsibilities of the IBC include, but are not limited to, the following:

(A) To provide guidance to researchers on biosafety policies and issues in the use of LMO/rDNA research, including safety of laboratory workers and other members of the organisation

(B) Periodical review of LMO/rDNA research conducted at the organisation for compliance with the *Biosafety Guidelines for Contained Use Activity of LMOs* and recommend approval for those research projects that are found to conform to the guidelines. This pertains to initial and continuing review and approval of modifications to proposals and activities

(C) Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO/rDNA research

(D) Notify the researcher of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of LMO to the National Biosafety Board (NBB)

(E) Assess and set biosafety containment levels (BSL) for LMO/rDNA research and modify containment levels as necessary

(F) Adopt and implement emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research

(G) Review and report to the Head of the organisation and to the NBB of any significant problems with or non-compliance of the *Biosafety Guidelines for Contained Use Activity of LMOs* and any significant research-related accidents or illnesses

Other information found in these guidelines include responsibilities of the biological safety officer and researchers, IBC membership, scope of reviews done by IBC on projects, manuals, procedures, training,etc., personnel notification sequence and actions required for reporting of incidents and spills and emergency situations, record keeping for activities and incidents, laboratory inspections and other related information.

Biosafety Guidelines for Contained Use Activity of LMOs

This guideline gives details on the Biosafety Levels (BSL) for containment as well as the safe practices for working with LMOs and products of these organisms. Adoption of this guideline is essential for all public and private organisations working on modern biotechnology so as to safely handle, store and transfer LMOs as well as products of such organisms without endangering individuals, the public, biodiversity and the environment.

This guideline should be used in addition to relevant legislations, guidelines and references that involve containment facilities. Organisations intending to carry out contained use activities involving LMOs and related materials are required to use this guideline to determine the BSL and facility type required. The principles of risk assessment for the activity conducted and also the classification of risk groups for microorganisms are given so that the BSL will be appropriate for the type of activity conducted.

The guideline covers activities such as:

(A) Experiments involving LMOs and products of such organisms
(B) Development or production of LMOs, and products of such organisms
(C) Breeding or propagation of LMOs
(D) Growth and/or culture of LMOs
(E) Import or export of LMOs
(F) Transport of LMOs
(G) Disposal of LMOs and products of such organisms

The objective of these guidelines is to assist in:

- Identifying the BSL for containment of any LMO activity
- Specifying work procedures under the various containment levels
- Outlining the minimum requirements for setting up facilities for contained use activities of LMOs
- Identifying equipment requirements under the different containment levels

Five categories of physical containment are described in this guideline, which are:

- Genetic Modification of Microorganisms (GM-BSL)
- Genetic Modification of Plants (GP-BSL)
- Genetic Modification of Animal (GA-BSL)
- Genetic Modification of Insects (GI-BSL)
- Genetic Modification of Aquatic Organisms (GF-BSL)

Under these categories, detailed information is given on the minimum requirements for setting up the laboratory facility, specific work procedures under the various containment levels and identification of equipment required for the different BSL. Guidance is also given on disposal of LMO and related wastes, biological waste packing, labeling and movement, treatment methods for biohazardous waste, storage of LMOs and related materials.

These two guidelines mentioned above shall be published and made available to all researcher organisations. A copy of the guidelines will also be made available on the NRE biosafety website: *www.biosafety.nre.gov.my*

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) WORKSHOP

4 – 6 November 2009, PJ Hilton

Prepared by
Shereen Wong Pui Cheng

Assistant of UNDP-GEF Biosafety Project Coordinator

Participants of the workshop

The Ministry of Natural Resources & Environment (NRE) and United Nations Development Programme (UNDP) organised a 3-day workshop for nominated candidates of the Genetic Modification Advisory Committee (GMAC) from 4-6 November 2009. This workshop was fully funded by the NRE-UNDP-GEF Biosafety Project. This workshop is part of the efforts of the project to build capacity among regulators and scientists to undertake science based risk assessment and management effectively. A total of 40 participants who were nominated by their relevant agencies to be part of GMAC attended the workshop. The resource persons for this workshop were from NRE as well as invited regulators from biosafety regulatory agencies of Austria and Australia.

The workshop started with a talk from Mr Letchumanan Ramatha, the Head of the Biosafety Core Team, NRE who spoke on 'GMAC as a Risk Assessment Body in the Malaysian Biosafety Act'. Mr Letchu explained about the functions and responsibilities of GMAC. The other presenter from NRE was Dr Anita Anthonysamy who shared with the participants on Provisions for Research & Development on Field Experiments with LMO in Malaysia. She outlined the scope of Biosafety Act 2007, function and responsibilities of Institutional Biosafety Committee (IBC) and explained about the application process to get approval for field experiments.

Dr Michael Eckerstorfer from the Austrian Federal Environmental Agency spoke about the framework for Risk Assessment of GMOs in the European Union (EU) and focused on recent developments in the regulatory process there. There are two regulatory frameworks to regulate GMOs, which are Directive 2001/18/EC on deliberate release and placing on the market of GMOs and Regulation (EC) 1829/2003. The current framework features are long term consideration and cumulative environmental impacts, re-evaluation of approvals including existing products, clear labeling provisions and measures to guarantee traceability and mandatory monitoring of products placed on the market. He said that there have been developments in the Environmental Risk Assessment guidance documents which involved stakeholder participation and also a move towards transparent and harmonised risk assessment procedures, issues such as long term effects, benefits and risks assessment of socio-economic factors and specific regional characteristics (receiving environment and sensitive and protected areas) will be taken into consideration. These initiatives are to strengthen Member State's responsibility for cultivation of GMOs. A discussion of a legally binding risk assessment is also underway. These discussions have already been initiated and are ongoing.

Dr Michael Dornbusch from the Office of Gene Technology Regulator (OGTR), Australia continued the session by presenting the structure and procedure of risk assessment of GMOs in Australia. Risk analysis methodology, which includes risk assessment, risk management and risk communication is applied to identify and manage the risk. In doing the risk analysis, there are simple questions which regulators will use as a guide, like what might happen, does anything need to be done about the identified risk,

Resource persons and organizers of the workshop

can the risk be managed, what treatment measures are available? In management of risks, he shared that one way which OGTR manages potential risks for field trials is to issue license with conditions. He also spoke about how Risk Communication is practiced by OGTR.

Dr Helmut Gaugitsch, also from the Austrian Federal Environmental Agency spoke about International Framework for Guidance on Risk Assessment of GMOs. Dr Gaugitsch informed the participants that under the Cartagena Protocol on Biosafety (CPB), an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management was established as a decision from the COP-MOP 4 in 2008. The AHTEG is in the process of developing a road map to provide guidance on how to undertake risk assessment on LMOs. The last framework that he mentioned was the Codex Alimentarius which has guidelines for safety assessment of food derived from rDNA plants.

Apart from the lectures, the participants were given the opportunity to have hands-on experience of conducting risk assessments of transgenic maize and banana using the draft road map developed by AHTEG as guidance document. The resource persons guided the participants to identify potential adverse effects that the LMOs might have on the environment including human health, estimation of likelihood of these potential adverse effects being realised, an evaluation of the consequences should these adverse effects be realised, an estimation of the overall risk posed by the LMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realised and finally a recommendation as to whether or not the risks are acceptable or manageable with strategies to mitigate these effects. The GMAC workshop was also used as a platform to test the utility of the draft Roadmap to conduct risk assessments.

On the third day, participants did role play in a mock public hearing under the risk communication session. The panel consisted of participants who were elected to play the role of GMAC members (2), 1 regulator and 1 applicant. That mock public hearing was for a project where the applicant proposed to plant genetically modified papaya. The hearing started with the GMAC members and regulator giving their view about the proposed project and then the floor was opened for discussion to the 'public'. There were many queries from the floor about the safety of the papaya for consumption as well as the planting itself. It was a very interactive session where the panelists were able to effectively convey the message even to participants who played the role of 'public' who were completely unaware of biotechnology. The panelists handled the queries very well in a diplomatic and informative manner. The participants not only had fun in the role playing session but at the same time experienced how a public hearing would be like.

Overall, the workshop received good response from the participants and they looked forward to the next workshop to further enhance their capacity in performing risk assessment and management.

WORKSHOP ON MANAGEMENT OF CONTAINMENT FACILITIES

21 May 2009, Cititel Kuala Lumpur

Prepared by
Ng Cheah Wei

She was the previous Research Officer attached to CEBAR, Universiti Malaya

Officials from Ministry of Natural Resources & Environment and University of Malaya

One of the main components of the ***Capacity Building Project for Implementation of Malaysia's Biosafety Act 2007*** is to specifically develop national capacities in biosafety that is required to carry out risk assessments with appropriate scientific and technical skills and to enforce biosafety regulations, requiring monitoring, inspection and detection capabilities.

In view of this, the Biosafety Project in collaboration with the Centre of Biotechnology in Agriculture Research (CEBAR), University of Malaya (UM), is organising a series of workshops towards meeting the goals in building capacity among regulators and scientists to undertake science based risk assessments effectively in their respective roles as well as to familiarise them to the requirements of the Biosafety Act 2007. Despite a greater awareness of biosafety and biocontainment practices, there is still a need for expert capacity building to deal with the many different criterias required for the different activities. This applies not only to both genetically modified and non modified organisms but also to potentially hazardous organisms.

The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the external environment to potentially hazardous agents. The term "containment" is used in describing safe methods for managing infectious or potentially hazardous agents in the lab environment where they are being handled or maintained. The application of appropriate biosafety and containment principles and practices can help scientists and laboratory workers to minimise the risks, if any, associated with work involving these agents.

For infectious microorganisms, handling remains a main source of infection among laboratory workers. There is a steady increase in both the number of laboratories handling pathogens and in the number of scientists wishing to import new or exotic strains for further studies. Laboratory workers can minimise the risks associated with work involving these infectious agents through the application of appropriate biosafety and containment principles and practices.

On the other hand, containment facilities for transgenic organisms, be it plants or otherwise, is a pre-requisite of most biosafety practices prior to risk assessment even if the organisms have a history of safe use. This is also a stardard requirement in most biosafety regulations and the levels of containment required is dependent on very specific criterias.

With this in mind, NRE with funding from the UNDP-GEF Biosafety project, CEBAR and Tropical Infectious Diseases Research and Education Centre (TIDREC) of UM organised the **Management Of Containment Facilities Workshop**, the first in a series of workshops specially designed for scientists, technicians and students to familiarise

Participants of the workshop

Participants of the workshop

themselves with safe laboratory and greenhouse practices and techniques, safety equipment and facility design. The workshop's objective was to give guidance to government, industry, university, hospital and other public health and microbiological laboratories in their development of biosafety policies and programmes as well as provide information and recommendations on the management, design, construction and certification of appropriate containment facilities.

This workshop was held on 21 May 2009 at Cititel, Kuala Lumpur. A total of 120 participants from various sectors turned up for this workshop. There were two sessions running concurrently, whereby the participants could choose whether they wanted to attend the session that covered the topic of Management Principles of Containment Facilities for Plants or the session that covered the topics of Management of Containment Facilities for Biosafety Level 3 (BSL 3).

The Management Principles for Plant Containment Facility session was led by Mr Robert Kerslake, an internationally recognised expert in design, construction and operation of glasshouse and controlled environment facilities from Australia. With extensive management experience on research facility construction projects, Mr Kerslake gave the participants an overview of the general requirements for certification of Biosafety Level 2 (BSL 2) containment facilities with an aim to familiarise the participants with biosafety practices. This will ensure that appropriate containment facilities are designed, constructed and commissioned. Details on the work procedures in a Biosafety Level 2 (BSL 2) containment facility and the importance of safety guidelines and the responsibilities of trained facility personnel were presented. He gave a briefing on specifications and certifications of a Biosafety Level 2 (BSL 2) facilities in reference to the new UM transgenic greenhouse. The participants had the opportunity to visit this facility and explore the 4,000 square feet greenhouse which is situated at the UM campus in Kuala Lumpur. This greenhouse is designed to comply with plant containment Biosafety Level 2 (BSL 2) requirements and is the first transgenic plant facility in the country that has been accredited with international standards.

The Management of Biosafety Level 3 (BSL 3) session was led by Dr Felix Gmuender from B&H Singapore and Dr Paul Huntly from DNV Singapore. Dr Felix Gmuender gave an overview of the containment facilities of Biosafety Level 3 (BSL 3) and shared with the participants about the working practices in a Biosafety Level 3 (BSL 3) and ways to enhance safety. He concluded his session with a talk on Certification of Biosafety Level 3 (BSL 3): Key to safe operation. Dr Huntly then continued to talk on the risk assessment for BSL 3 facilities and shared with the participants some examples from Singapore. Finally, he talked on Emerging trends in biosafety and biosecurity.

In summary, both sessions were very interesting and had achieved its objectives as participants received comprehensive information on safe laboratory and greenhouse practices and techniques, safety equipment and facility design and even had the opportunity to visit a local transgenic greenhouse facility with international standards.

PLANT BIOTECHNOLOGY FACILITY
UNIVERSITY OF MALAYA

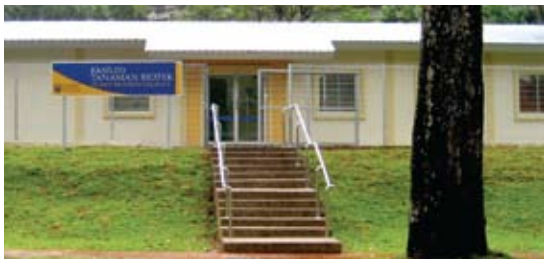
Prepared by Akmal Adilah Idris, CEBAR, UM

Reviewed by Assoc Prof Dr Jennifer Ann Harikrishna, Head of CEBAR, UM

The University of Malaya (UM) has moved a step further in the field of biotechnology with the completion of the transgenic greenhouse at the end of May 2009. The opening was officiated by the Malaysian Minister of Science, Technology and Innovation, Datuk Seri Dr. Maximus Johnity Ongkili on 1st December 2009. The facility, known as the Plant Biotech Facility (PBF), was built to comply with international biosafety standards for research in plant biotechnology according to Physical Containment Level 2 of the Australian Office of the Gene Technology Regulator (OGTR) Guidelines for Physical Containment Facility.

The PBF is a research facility of the Centre for Research in Biotechnology for Agriculture (CEBAR), UM, consisting of greenhouse facilities and office space. An area of 21m (L) x 9.4m (W) x 2.7m (H) is divided into an ante room and three greenhouses, whilst the office space area is 16 m (L) x 6 m (W). The PBF is a free–standing building, facing East-West, isolated from faculty complexes and vegetation areas to allow maximum illumination into the greenhouse.

The greenhouse structure is made from stainless steel and heavy duty maintenance-free clear anodised aluminum, providing a durable, non-rusty and cost-effective structure, also strength to withhold the glazing material for roofing and wall. The entire roof and wall is built with twin wall polycarbonate glazing, an easy to clean material, guaranteed up to 15 years to be free from discoloration, light weight, resistant to impact, excellent insulation and light transmission properties and is 200 times stronger than glass.



Plant Biotech Facility, University of Malaya

Plant Biotech Facility, University of Malaya

The interior of the greenhouse facility is divided into an ante room and 3 greenhouses. The ante room serves as an airlock entry point to the greenhouse area from the office space. Here, personnel entering the greenhouse will change into protective clothes and shoes. The ante room is equipped with stainless steel hand washbasins, an emergency shower, eye wash area, and a room for autoclaving to sterilise plant materials prior to disposal. The floor in the ante room is covered with epoxy coating, an easy to clean material making it suitable for potting of plants.

Every greenhouse is equipped with an Environmental Control System (ECS) that is designed to be of independent use, ensuring that the environment in every room is customised according to user preferences. The ECS is able to maintain the internal temperature to a minimum of 20°C and a maximum of 33°C, while humidity level is kept within 60% to 80%. These conditions are set to provide optimal growth conditions for both temperate and tropical plants.

The ECS as mentioned above was achieved by installation of a refrigeration cooling system and motorised retractable thermal screens that can be controlled via the Building Management System (BMS). The refrigeration cooling system in every greenhouse is equipped with two air-conditioner units and a humidifier. The two air-conditioner units are set to operate at an 8 hour interval each, while

From left: YBhg Datuk Dr Gauth Jasmon (Vice Chancellor, UM), YB Datuk Seri Dr Maximus Johnity Ongkili (MOSTI Minister), Dr Yusmin Yusof, and Assoc Prof Dr Jennifer Ann Harikrishna

the humidifier is on standby for the whole day and runs only when the humidity level is outside the pre-set conditions.

The motorised retractable thermal screens, are fixed under the glazing of every greenhouse to allow 50% penetration of light when closed and to control the loss of heat at night. This thermal screen can be automatically controlled, as required via the BMS or manually according to specific requirements of the different plants.

The BMS relies on the readings collected from the Thermohumidistat Sensor that is placed in every greenhouse unit as an automatic reset mechanism. The Thermohumidistat Sensor will detect the temperature and humidity levels in every greenhouse at all times and the readings will be recorded and stored in a monitoring computer. This system has made it easier for personnel to check on environmental parameter fluctuations or system errors during the period when they are not in the greenhouse.

Each greenhouse is installed with four rows of benches and each bench can accommodate up to 570 pots of plants varying according to plant size. Two of the greenhouse units are fixed with galvanised steel roller benches to achieve maximum space usage and to allow easy cleaning of any spills from the non-corroding surfaces. On each bench, two long pipes with button holes completed with dripper ends are installed for irrigation and are controlled by the BMS.

The Irrigation process is set according to specific requirements of plants grown in each greenhouse unit and every pipe connected to every bench can be controlled manually. Irrigation pipes for the greenhouses are connected to a dedicated water tank placed inside the facility compound, also connected to a smaller centralised fertigation system.

Waste water from every greenhouse will pass through removable stainless steel meshes and will be collected inside an interceptor pit located in each room, then passes through a single gully trap into the sewer. Additionally, every other opening, such as fresh air vents and relief air vents are screened with 30/32 stainless steel wire mesh to control insect movement into the greenhouse.

Musa cv. Berangan planted on the bench with drippers connected to each polybag

The PBF is fenced and gated as a security measure. Greenhouse accessibility is through the door separating office space and ante room, based on thumb print identification. Thumb print identification is also applicable for entry to every greenhouse unit, thus allowing only authorised personnel to enter the facility.

With the completion of the PBF, researchers in UM can progress their research forward so that their outputs can be taken to the next stage of commercialisation and at the same time be in compliance with International Biosafety Standards and local legislation.

WORKSHOP ON GMO DETECTION & ANALYSIS

Prepared by
Jasbeer Kaur

Senior Scientist from Department of Chemistry Malaysia

Group photo of participants attending Module 1

The Department of Chemistry (DOC) under the Ministry of Science, Technology and Innovation (MOSTI) is playing an important role in providing scientific and technological support to the country. It also promotes collaboration with other agencies on the scientific and technical needs required for method development and implementation. The DOC as the ASEAN Reference Laboratory and National Reference Laboratory for GMO detection has also organised numerous courses in GMO detection since 2005 under the European Commission-ASEAN program involving analysts from ASEAN countries. Therefore in 2009, the DOC was approached by (Ministry of Natural Research and Environment) NRE to assist the UNDP-GEF project to build institutional capacity in GMO detection among various stakeholders in Malaysia.

Besides creating awareness and increasing knowledge on GMO, biotechnology and biosafety among the regulatory and enforcement agencies, the scope of the training courses is to assist staff of control laboratories to become accustomed with molecular detection techniques, and to help them adapt their facilities and work programmes to include analysis that comply with worldwide regulatory acts in the field of GMO testing. The main objectives of this project is to support Malaysia to:

- Develop capacity for GMO detection among various agencies
- Enhance scientific and institutional capacities for GMO detection among agencies that are already doing GMO detection
- Develop information sharing and coordination between agencies with regards to GMO issues

With these objectives in mind, two workshops were conducted by the DOC in 2009; 5-8 May (Module 1) and 2-6 November (Module 2) at the GMO Testing Laboratory in Petaling Jaya. The target group were

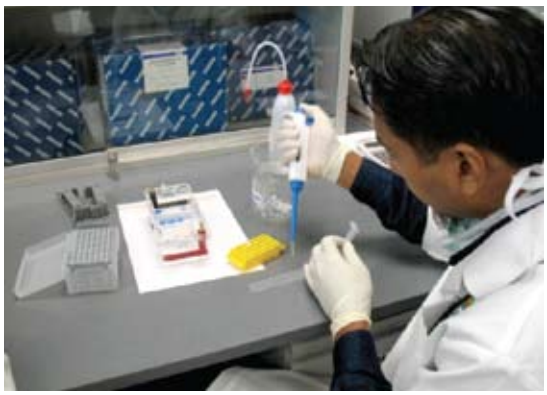
Facilitators interpreting the result after the experiment

participants from relevant ministries, agencies and local universities. Module 1 was attended by 20 participants while 10 participants from Module 1 were invited to attend Module 2. The DOC was the lead trainer for Module 1 while two Austrian experts were the lead trainers for Module 2.

Facilitators explaining the method of the experiment to the participants

The UNDP Module 1 course was designed to teach basic molecular detection techniques to personnel with analytical knowledge, but with no or little expertise in this specific domain. The topics included: overview of GMOs, GMO labeling, DNA extraction and purification, DNA quantification, DNA quality assessment, gel electrophoresis, qualitative GMO screening, data handling, data management, data interpretation, data reporting and good laboratory practices. Module 2 was expanded to cover broader issues such as sampling, certified reference material (seed-based and plasmid-based), approaches in GMO screening and quantification using real-time PCR, method verification, monitoring strategies and biosafety. Knowledge of these techniques was transferred to participants through presentations, publications and hands-on training. Technical details were also provided to trainees as written outlines. As a permanent source of information, the DOC prepared training manuals and CDs which were used by the experts in the courses.

Dr Frank Narendja briefing the participants on the method to conduct the experiment



Participant takes turn to do the experiment

In conclusion, the feedback and comments received from the participants and external trainers were very positive. The training programmes would certainly help in the harmonisation of requirements and procedures among stakeholders in Malaysia. This should continue so that the networking is maintained, which is very crucial in this new and emerging scope of testing. Given the state of the science of GMO analysis, further similar activities should be undertaken in this field and it is hoped that the NRE-UNDP-GEF project will continue to play a leading role in financing such capacity building programs. The DOC will continue to work closely with the various implementing agencies with the same level of excellence to provide future trainings to stakeholders.

SABAH & SARAWAK STAKEHOLDERS' WORKSHOP ON BIOSAFETY

Prepared by
Shereen Wong Pui Cheng

Assistant of Biosafety Project Coordinator

Minister of Tourism, Culture and Environment of Sabah officiating the workshop

Mr Federick John George opening the workshop on behalf of the Director of SPU Sarawak

Ministry of Natural Resources & Environment (NRE) and United Nations Development Programme (UNDP) conducted public awareness workshops on Biosafety in Sabah & Sarawak. This initiative was part of the efforts to create awareness amongst stakeholders on the need for biosafety, compliance requirements to the Biosafety Act, the activities of the UNDP-NRE-GEF Biosafety Capacity Building Project and other related issues. This was the first road show to Kuching and Kota Kinabalu to build capacity to enable effective implementation of the Biosafety Act. The success of these workshops is attributed to the help and coordination from the Sarawak State Economic Planning Unit (SPU) and Sabah State Economic Planning Unit (SPU), Sarawak Biodiversity Center (SBC) and Sabah Biodiversity Center (SaBC).

The topics covered in the workshops are: Impact of LMOs on the Environment and the Need for Regulations, The Methods of LMO Detection and Monitoring, Overview of LMOs & What's in Store for Us, Scope of Biosafety Act and Introduction to the NRE-UNDP-GEF Biosafety Project.

Participants at the workshop in Kota Kinabalu

The responses from the stakeholders were overwhelming and they participated actively throughout the whole session, especially in the breakout group discussions which was conducted on the second day. The stakeholders were given the opportunity to share their views and identify the gaps for biosafety capacity building.

Outputs from the initiated discussions include the suggestion by the participants from Sarawak Stakeholders' Workshop to set up the Sarawak Biosafety Council to monitor and implement

Participants at the workshop in Kuching

biosafety with regards to LMOs. The gaps identified for Biosafety capacity building in Sarawak are lack of:

- expertise in performing risk assessment and GMO identification
- awareness and understanding of the Biosafety Act 2007
- funding to upgrade the facility, training and conduct risk assessment

A few of the important feedbacks captured from the discussion from Sabah stakeholders are:

- enabling the Chemistry Department of Sabah to be the referral centre for Sabah & Sarawak.
- making the research and development in biosafety an important agenda in Universiti Malaysia Sabah and having sponsorship for postgraduate studies in biosafety.

Overall, the workshop received good response from the participants and they were looking forward to the second series of the workshop to further enhance the capacity of Sarawak and Sabah in implementing the Biosafety Act 2007.

PUBLIC AWARENESS INITIATIVE

Prepared by
Prasad Vasudevon

Project Officer MNS

Datuk Abu Bakar Ali delivering his opening remarks

Mr Nazir Khan bin Nizam Khan talking about the Biosafety Act 2007

The Ministry of Natural Resources and Environment (NRE), United Nations Development Programme – Global Environment Facility Project (UNDP-GEF) and Malaysian Nature Society (MNS), jointly organised a half day seminar to feature the Biosafety Act 2007 entitled *Akta Biokeselamatan 2007: Apa, Kenapa dan Bagaimana?* on 14 November 2009. This initiative is part of the efforts of MNS to assist the Ministry on raising awareness on the implementation of the Act among all levels of society. This seminar was held at JKKK Hall of Kampung Gelugor, Kertih, Terengganu. A total of 76 participants from the local community participated in this seminar. The seminar started off with opening remarks by Datuk Abu Bakar Ali, advisor for the ECOCARE volunteer group, and followed by two presenters in this seminar.

Mr Prasad Vasudevon introducing modern biotechnology

The first speaker was Mr Prasad Vasudevon of MNS, who gave a presentation on the Introduction to Modern Biotechnology - its benefits and potential risks. He explained the definition of modern biotechnology, research work in the pipe-line and the different types of Genetically Modified Food (GMF) available. The second presenter was Mr Nazir Khan bin Nizam Khan from the Biosafety Core Team at NRE, who spoke on the Biosafety Act 2007: What, Why and How? He presented an overview of the Act, the importance of the Act and how it relates with international and domestic legislations. He also deliberated on the operationalisation of the Act to effectively regulate Living Modified Organisms (LMOs) and products derived from them.

Participants listening intently to the presentations

The participants showed keen interest in the topics presented and raised questions on statistics of LMO/GMF products found in the local markets, clarification on the terms used in the Act, and also enforcement of the Act. They were also curious on the research status of LMO/GMF within the country and voiced their concerns on consumer health and protection to our local biodiversity as well as to indigenous knowledge. Dr Ismarizan and Mr Mohamad Jasmali Mat Yusop from Universiti Kebangsaan Malaysia (UKM) presented a demonstration on DNA Extraction after the seminar. It was followed by a hands on session for the participants using basic equipments found in the laboratory.

The seminar received good response from the participants, and most of them looked forward to more informative seminars such as this in the near future.

Participants taking part in the DNA extraction session and exhibition

Event Calendar

Date	Event	Organiser(s)
15-19 June 2010	3rd meeting of the group of the Friends of the Co-chairs on Liability and Redress in the context of the Cartagena Protocol on Biosafety *Venue: Kuala Lumpur, Malaysia*	Secretariat of the Convention on Biological Diversity (SCBD) http://www.cbd.int
01-13 Aug 2010	Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms *Venue: Science Park/University of Tromsø, Norway*	GenØk- Centre for Biosafety www.genok.com/ Tel: +47 77 64 55 46 Fax: +47 77 64 61 00 E-mail: biosafety10@genok.org
27 Sept – 01 Oct 2010	"An Introduction to the Risk Analysis of Current Genetically Modified Organisms (GMOs) and their Products, and to Possible Issues Raised by Novel GMOs in the Future" *Venue: Trieste, Italy*	International Center for Genetic Engineering and Biotechnology http://www.icgeb.org/meetings-2010.html E-mail: courses@icgeb.org
11-15 Oct 2010	Fifth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 5) *Venue: Nagoya, Japan*	Secretariat of Convention on Biological Diversity (SCBD) http://www.cbd.int
15 - 20 Nov 2010	11th International Symposium on the Biosafety of GMOs (ISBGMO 11) "The Role of Biosafety Research in the Decision Making Process" *Venue: Buenos Aires, Argentina*	International Society for Biosafety Research (ISBR) http://www.isbgmo.info/

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