Biosafety

NEWSLETTER

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Regulations and forms under Malaysian Biosafety Act

Feature Article:

Introduction to Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

CONTENTS

EDITORIAL BOARD FOR THE BIOSAFETY NEWSLETTER

MESSAGE FROM THE CHIEF EDITOR

Welcome to the third edition of the Biosafety Newsletter. Since April 2010 following the second edition of the Biosafety Newsletter, there has been several significant progress in biosafety efforts in this country.

Following the enforcement of the Biosafety Act on 1 December 2009, the National Biosafety Board (NBB) was established on 15 March 2010. The NBB is the decision making body under the Biosafety Act and to date, four meetings have been held. Members of the Genetic Modification Advisory Committee (GMAC) which provides advice on scientific and technical matters in particular on risk assessment and risk management were appointed on 25 May 2010. Current Chairman of the GMAC is Dr. Ahmad Parveez Ghulam Kadir from the Malaysian Palm Oil Board (MPOB) and to date, GMAC has met more than 10 times. Earlier the Biosafety Core Team was upgraded to become the Department of Biosafety (JBK) effective on 24 May 2010. The JBK will act as a secretariat to the NBB and GMAC and the implementing agency of the Biosafety Act. Finally and most recent was the enforcement of Biosafety (Approval and Notification) Regulations 2010 on 1 November 2010.

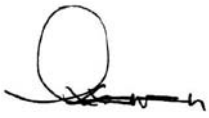
NBB is responsible to make decisions pertaining to the release, importation, exportation and contained use of any living modified organisms (LMO) and its products derived from modern biotechnology.

Last year, the NBB has approved a field trial (a limited mark-release-recapture project) involving transgenic mosquitoes. The GMAC played a fundamental role in the risk assessment and provided excellent support to the JBK, NBB as well as the Minister of Natural Resources and Environment.

In addition to processing applications for approvals and notifications for the consideration of GMAC and NBB, the focus will also be placed on efforts to build capacity and awareness of biosafety. These include conducting training workshops and road shows at universities and research institutions as well as organizing awareness seminars for selected stakeholders. Publication on variety of reading and reference materials on biosafety have been produced. In enforcement and monitoring activities, careful planning and concerted effort involving other enforcement agencies such as Malaysian Quarantine and Inspection Services (MAQIS), Royal Malaysian Customs Department, Royal Malaysian Police and the Department of Agriculture will be formulated.

Even though it has been a rugged journey for this Act to become a reality, it is a positive and promising beginning for Malaysia to take a proactive approach towards protecting human health and the environment from the possible adverse effects of the products of modern biotechnology as well as to fulfill Malaysia's obligation under the Cartagena Protocol on Biosafety.

Biosafety, It's Our Priority!



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REGULATIONS AND FORMS UNDER MALAYSIAN BIOSAFETY ACT

KEY BIOSAFETY MILESTONES

1996	GMAC formed administratively
1997	Guidelines (Release of GMOs) - Administrative
1998	Strategy XI of the National Policy on Biological Diversity - legal framework on Biosafety
2000	Signed the Cartagena Protocol on Biosafety (CPB)
2003	Ratified - Protocol in force
2004	Hosted the First Meeting of Parties (MOP1)
2005	Policy Thrust 7 National Policy on Biotechnology
2006 / 7	Biosafety Bill in Parliament
2007	Biosafety Act passed in Parliament
2008 / 9	Biosafety Regulations Drafted
2009	Biosafety Act Enforced
2010	NBB & GMAC formed; Biosafety Department established
2010	**Biosafety Regulations enforced**

Essentially, the Biosafety Act (the Act) is a law which aims to establish the National Biosafety Board and to regulate the release, importation, exportation and contained use of living modified organism (LMO) and products of such organisms. In addition, the Act aims to uphold the Precautionary Principle so as to protect human, plant and animal health, the environment and biological diversity. Overall, the Act also aims to achieve sustainable development of modern biotechnology in Malaysia.

Section 69 of the Act says that for the better carrying out of the provisions of the Act, the Minister may, upon consultation with the Board, make such regulations as may be expedient or necessary. Section 69(2) goes on to state that, without prejudice to this general power, regulations may also be made for several matters including (but not limited to) matters relating to: the application for release and import activities, risk assessment and risk management reports, etc.

The Minister may, upon consultation with the Board, make such regulations as may be expedient or necessary for the better carrying out of the provisions of this Act.
- Section 69 (1) of the Act

This is how most laws are implemented in Malaysia and many common law jurisdictions hence no question should arise whether this is a usual mode of implementing laws. Books have been written about this (example of a standard text book: Legislative Drafting by GC Thornton, 4th edn (1996) Butterworths pp. 340 on). It appears that European practice is similar. See for example, Regulation (EC) No 1829/2003 of the EU Parliament and of the Council on GM food and feed - which lays down procedures for the authorization and supervision of GM food and feed.

MAIN PARTS OF BIOSAFETY REGULATIONS

Part I	Preliminary
Part II	Institutional Biosafety Committee
Part III	Approval for any Release Activity and Importation of LMOs
Part IV	Certificate of Approval
Part V	Notification
Part VI	Appeal
Part VII	Miscellaneous

BIOSAFETY FORMS

NBB/A/ER/10/FORM A
Approval for Release Activities of Living Modified Organism (LMO) (Research And Development Purposes In All Field Experiments) or Importation of LMO That is Higher Plant

NBB/A/ER/10/FORM B
Approval for Release Activities of Living Modified Organism (LMO) (Research And Development Purposes In All Field Experiments) or Importation of LMO Other Than Higher Plants

NBB/A/ER/10/FORM C
Approval for Release Activities (Second Schedule, 2-6) or Importation of Living Modified Organism (LMO) That is a Higher Plant and Product of Such Organism

NBB/A/ER/10/FORM D
Approval for Release Activities (Second Schedule, 2-6) or Importation of Living Modified Organism (LMO) Other Than a Higher Plant and Product of Such Organism

NBB/N/CU/10/FORM E
Notification for Contained Use and Import for Contained Use Activities Involving Living Modified Organism (LMO) for Biosafety Levels 1,2,3 and 4.

NBB/N/Ex/10/FORM F
Notification for Export of Living Modified Organisms (LMO)

NBB/IBC/10/FORM G
Registration of Institutional Biosafety Committee (IBC)

The Government has set up the Biosafety Regulations Advisory Committee (BRAC) in January 2008 to draft the biosafety regulations. BRAC consists of representatives of various stakeholders - including industry representatives, various Ministries, consumer groups, non-governmental organizations, research and academic institutions. After several consultations including two ministerial level meetings, the Biosafety (Approval and Notification) Regulations 2010 (the Regulations) was finalized and came into force on 1 November 2010. Following that, biosafety forms were finalized and used. The Regulations set out the details on: the different criteria to apply for different activities; the procedure and content of the applications; the time lines, the incurred fees, the details required for the risk assessment and management reports as well as the emergency response plan, the decision-making criteria and the procedure for appeals.

Part II of the Regulations requires any organization, which undertakes modern biotechnology research and development to establish an Institutional Biosafety Committee (IBC). It plays an advisory and monitoring role at the institutional level on behalf of the National Biosafety Board. This is to ensure that any modern biotechnology research activities comply with the Act and other related regulations and legislation. The IBC shall be registered with the Board by submitting Form G (no fees).

Part III of the Regulations deals with release activities and importation of LMO while Part V is mainly about LMO used for contained use and exportation. Any application for approval must be submitted to the Director General (DG) of Biosafety through the relevant form (Forms A/B/C/D) depending on type of release activities together with the prescribed fees. Similarly for notification, the applicants should inform of their intentions through submission of Form E or F. All activities involving research and development (Forms A/B/E) should be submitted only after the IBC has done an assessment.

FEES FOR APPROVAL

TYPE OF APPLICATION	FEES
Field Experiment below 5 hectares per location	RM 100
Field Experiment 5 to 10 hectares per location	RM 250
Field Experiment above 10 hectares per location	RM 500
Commercial field release (approved LMO)	No charge
Other Release activities (Schedule 2 of the Act)	RM 5,000

FEES FOR NOTIFICATION

TYPE OF NOTIFICATION	FEES
Contained Use	No charge
Export	No charge

OPERATIONALISATION OF NATIONAL BIOSAFETY BOARD (NBB), GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) AND DEPARTMENT OF BIOSAFETY

FIRST NATIONAL BIOSAFETY BOARD MEETING

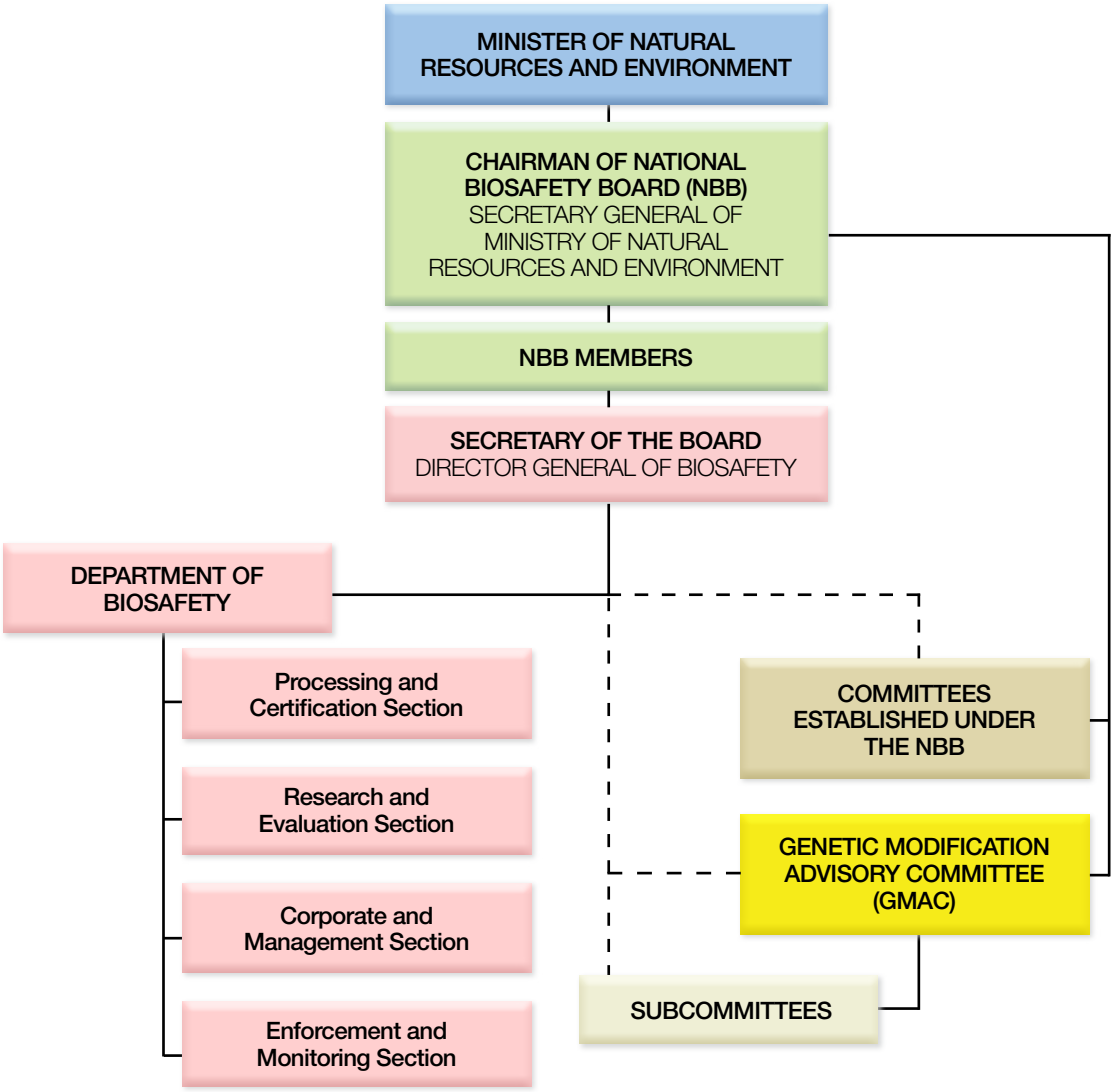
The National Biosafety Board (NBB) as stated under Section 4 of the Biosafety Act 2007 (the Act) has been established since 15 March 2010. The NBB will act as a decision making body under the Act and is responsible to make decisions pertaining to the release, importation, exportation and contained use of any living modified organisms (LMO) and its products derived from modern biotechnology. The Chairman of the NBB is the Secretary General of the Ministry of Natural Resource & Environment (NRE) and its members comprise of representatives from the Ministry of Agriculture and Agro-based Industry, Ministry of Health, Ministry of Plantation Industries and Commodities, Ministry of Domestic Trade, Co-operatives and Consumerism, Ministry of International Trade and Industry, Ministry of Science, Technology and Innovation, and four other persons with knowledge and experience in disciplines or matters relevant to this Act.

FIRST GMAC MEETING

The Genetic Modification Advisory Committee (GMAC) is established under Section 6 of the Act to provide scientific, technical and other relevant advice to the Minister of Natural Resources and Environment or the NBB. GMAC was formed on 25 May 2010 during the first meeting of NBB. Members of GMAC consist of experts from various science-based and other relevant disciplines working with Government agencies, research institutes, private sectors and Non-Governmental Organizations (NGO).

To enable NBB and GMAC to operationalize, the Department of Biosafety (JBK) was formed on 24 May 2010 led by Director General (DG) of Biosafety. According to subsection 4(4) of the Act, the DG shall be the Secretary of the NBB and shall carry out such duties as may be imposed by the NBB. Apart from becoming secretariat of the NBB, GMAC and committees/ sub-committees established under the NBB and GMAC, JBK will act as one stop centre for all activities relating to biosafety.

The application for approval for any release activities and importation must be submitted to the DG of Biosafety. The DG will ask for recommendations from the GMAC on the application of the release and import of LMO. After completion of assessment by GMAC, a recommendation report will be forwarded to the NBB. In addition, NBB also reviews input from relevant Government agencies and view of the public before making a decision. Accordingly, the NBB may grant the certificate of approval to the approved person and impose any terms and conditions. The NBB may review any approval decisions at any time, if found necessary under specific conditions.



INTERACTIONS BETWEEN NBB, GMAC & JBK

For exportation of LMO, the exporter must comply with requirements set up by the importing country. In order to commence contained use activities, the applicants should inform the NBB of their intentions through Form E, submitted to the DG.

The DG will then issue a letter of acknowledgement to the notifier. After which the notifier may commence the activity. Subsequently, the DG will refer the notification to the GMAC. In response to this, the GMAC will then make its recommendation to the NBB on whether the activity is being conducted with sufficient biosafety measures.

NBB will then make its decision. For exportation of LMO, the exporter must comply with requirements set up by the importing country. The applicants merely inform NBB of their intention through Form F, submit to the DG and provide proof of compliance to the importing country.

CAPACITY BUILDING ACTIVITIES WORKSHOPS AND SEMINARS

WORKSHOP ON THE IDENTIFICATION AND DOCUMENTATION OF LIVING MODIFIED ORGANISM (LMO)

25-29 January 2010
The Royale Bintang Hotel, Kuala Lumpur

Participants of the workshop

The Department of Biosafety and United Nations Development Programme (UNDP) in collaboration with the Secretariat of Convention on Biological Diversity (SCBD) jointly organized this workshop.

The objective of the workshop is to introduce to customs and enforcement officers, who are based at the entry points on the requirements of the Cartagena Protocol on Biosafety (CPB), regarding the identification and documentation of LMO, and also the techniques/methodologies that may be used for the implementation of these requirements. This workshop aimed to be a hands-on training workshop which provided the participants the opportunity to acquire theoretical and practical knowledge on the identification and documentation of LMO.

On the third day, the participants had the opportunity to do some laboratory exercises at the Department of Chemistry. They used Protein-based and DNA-based methods to perform the basic detection of the LMOs. Participants were overwhelmed with these experiments as it was their first experience in conducting an experiment in the laboratory. The participants also had the opportunity to visit and observe sampling activities at North and West Port, Port Klang. A total of 50 participants from the Malaysian Quarantine and Inspection Services (MAQIS), Ministry of Health (MOH) and Department of Agriculture (DOA) attended the workshop.

RISK COMMUNICATION ON TRANSGENIC INSECTS WORKSHOP

30 March-1 April 2010
Hilton Hotel, Petaling Jaya

The Department of Biosafety and UNDP in collaboration with the Biotechnology Product Cluster, University Malaya jointly organized this workshop.

A total of 45 participants from research institutes, universities and NGOs attended this workshop. This workshop was to enable the researchers to be armed with basic skills in risk communication so that effective communication on the potential benefits and risks associated with transgenic insect technologies can be made to all key stakeholders. During the workshop, the participants were divided into groups for the role play.

They were given scenarios to discuss and prepare for a media conference to put into practice what they have learnt, which included communication objective, key messages and anticipating questions. All the interviews and press conference were videotaped and reviewed together for discussion and evaluation. Even though it was the first time for most of the participants to record interviews or conduct a media conference, surprisingly most participants were able to handle it quite well.

WORKSHOP ON MEASUREMENT UNCERTAINTY AND METHOD VALIDATION IN GMO ANALYSIS

27 - 30 April 2010
Department of Chemistry, Petaling Jaya

Participants of the workshop

The Department of Biosafety and UNDP in collaboration with the Department of Chemistry jointly organized this workshop. This workshop was an extension of Module II – Workshop on GMO Analysis using Real Time PCR that was held on 2-6 November 2009. The workshop aimed to provide exposure and hands-on training on GMO detection to the participants. Extensive hands-on experiments followed by result analyzing and evaluation were conducted. All of the experiments were repeated to allow the participants to familiarize and master the skills. The participants of the workshop consisted of scientists and technicians from universities and research institutes.

BIOSAFETY AWARENESS SEMINAR

29 September 2010
MARDI Station, Cameron Highlands

Participants and facilitators of the workshop

This seminar was jointly organized by Department of Biosafety, UNDP and Malaysian Nature Society (MNS). It was held specifically to the public including farmers and students. The main purpose of the seminar was to create awareness among the public on modern biotechnology development and the role of Biosafety Act 2007. Besides presentations, there was also DNA extraction demonstration and by the MNS.

RISK ASSESSMENT WORKSHOP ON TRANSGENIC MICROBES

23 - 25 November 2010
Novotel Hotel, Kuala Lumpur


Participants of the workshop

This workshop was organized by the Department of Biosafety and UNDP. A total of 60 participants from local universities, research institutes and government agencies who are conducting research in modern biotechnology participated in this workshop. Its objectives were to review the current model for risk assessment of transgenic microbes and build capacity of scientists and regulators in risk assessment and management to facilitate decision making process under the Biosafety Act. This workshop also aimed to be a hands-on training workshop so as to provide participants with the opportunity to acquire theoretical knowledge as well as apply what they had learnt into practical exercise.

SEMINAR ON THE MALAYSIAN BIOSAFETY REGULATORY FRAMEWORK

9 December 2010
Kuala Lumpur Convention Centre (KLCC)


Participants and speakers of the workshop

This seminar was organized by Malaysian Biotechnology Corporation in collaboration with the Department of Biosafety. The main objective of the seminar was to explain to the participants on the operational details of the Biosafety Act 2007 and the Biosafety Regulations 2010. Over 60 participants from the BioNexus companies, universities and research institutions attended the seminar. The highlight of the seminar was the panel discussion and Q&A session where participants were able to obtain further explanation and clarification on biosafety issues or concerns from the members of the panel.

WORKSHOP ON GENETICALLY MODIFIED FOOD SAFETY ASSESSMENT

13-15 December 2010
The Royale Chulan Hotel,
Kuala Lumpur


Participants of the workshop

This workshop was jointly organized by Department of Biosafety and UNDP with the aim to introduce the concepts and principles of GM food safety assessment and to provide practical hands-on training to scientists and regulators for potential risk assessors/science advisors. The topics presented during the workshop include role of Codex Alimentarius Commission (CAC) in setting food safety standards, concepts and principles of safety assessment, relevance of host and donor organism, modification method, molecular characterization, assessing toxicity and allergenicity of novel proteins.

WORKSHOP ON LOW LEVEL PRESENCE OF PRODUTCS OF ARGRICULTURAL BIOTECHNOLOGY IN FOOD AND COMMODITY SHIPMENTS

25 January 2011
Cititel MidValley,
Kuala Lumpur


Participants of the workshop

This workshop was organized by Department of Biosafety in collaboration with the Asia-Pacific Economic Cooperation (APEC). A total of 89 participants comprising mainly of The Royal Malaysian Customs and Malaysian Quarantine and Inspection Services (MAQIS) officers attended the workshop. In this workshop, participants had the opportunity to share expertise, experience and knowledge of issues related to Low Level Presence (LLP). Five speakers were invited to share their experiences at this workshop. Although LLP policy has not been determined yet in Malaysia, this workshop helped to provide an early exposure to the enforcement agencies at the entry points of the country on what LLP is all about.

CAPACITY BUILDING ACTIVITIES
INTERNATIONAL MEETING / SEMINAR / TOUR

1) FIFTH MEETING OF THE CONFERENCE OF THE PRTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY (COP-MOP5)

11-15 October 2010, Nagoya, Japan

The fifth 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-MOP5) was held from 11-15 October 2010 in Nagoya, Aichi Prefecture, Japan. Approximately 1,600 participants representing parties to the Protocol and other governments, UN agencies, intergovernmental and non-governmental organizations, academia and industry attended the meeting. The Malaysian delegation was led by Mr. Letchumanan Ramatha, Director General, Department of Biosafety (JBK) and other members included Dr. Vilasini Pillai (MOSTI), Dr. Maizura Ithnin (MPOB), Mr. Nazir Khan Nizam Khan (JBK) and Mr. Johnny Andrew (JBK).

The meeting adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (the Supplementary Protocol) and 16 other decisions on: the Compliance Committee; the Biosafety Clearing–House (BCH); capacity building; the Roster of Biosafety Experts; experiences with documentation requirements for handling, transport, packaging and identification (HTPI) of living modified organisms (LMO) for food, feed and processing (LMO-FFPs); HTPI standards; rights and/or obligations of parties of transit of LMO; monitoring and reporting; assessment and review; the Strategic Plan and multi-year programme of work (MYPOW); cooperation with other organizations, conventions and initiatives; risk assessment and risk management; public awareness and participation; financial mechanism and resources; and the budget.

The adoption of the Supplementary Protocol was greeted as an important success against the background of complex and often protracted negotiations. It was also a proud moment for Malaysia because the Supplementary Protocol carries the name of two cities, Nagoya and Kuala Lumpur. The Supplementary Protocol fills an important gap in the implementation of the Biosafety Protocol. Some praised it as a catalyst for action not only on biosafety but also in other areas of liability and redress for damage to the environment, others raised concerns on its questionable legal effectiveness, noting that much of the original substance has been lost in the six-year negotiation processes.

Overall, delegates felt that COP-MOP5 had been successful in creating a basis for advancing the implementation of the Biosafety Protocol. The sixth meeting, COP-MOP6 will be held in India in 2012.

2) HOLISTIC FOUNDATIONS FOR ASSESMENT AND REGULATIONS OF GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISM.

01-13 August 2010, Science Park / University of Toronto, Norway

This biosafety course is held bi- annually and organized through the Gateways Institute Programme under the Norwegian Government. It is conducted in the picturesque grounds of the University of Tromsø, Norway. The course is designed to provide policy makers, regulators, scientists and NGOs/civil society leaders, specifically from developing countries (ODA-countries), the knowledge and training necessary to develop a holistic view on the issues surrounding genetically modified organisms (GMOs). The goal is to empower the participants with transdisciplinary information on GMOs, in order to critically evaluate the issue from their own perspective and country needs. Lectures, laboratory demonstrations, group work on case studies and discussions formed the basis of the course, which aimed to offer biosafety capacity building within a holistic framework.

The course covered a wide range of topics from science/technical topics to issues relevant to the developments in modern biotechnology such as precautionary approach, addressing scientific uncertainties, ethics, international regulatory instruments and socio-economics. The topics covered by the various modules were conducted through lectures by resource persons. There were 2 case studies presented (experience of South Africa and Bolivia) to share actual situation on the ground and give exposure to challenges that need to be overcome.

Laboratory sessions were conducted to give hands-on experience in DNA extraction and also detection methods such as Polymerase Chain Reaction. The principles behind the detection methods were also explained. Another session was conducted on the handling and observation of Daphnia magna (this organism is used for environmental studies to detect toxicity and changes in the environment). It was a very exciting time for some of the course participants who have never been inside a laboratory (such as those from legal background) and were wearing lab coats and holding the pipette for the first time of their lives!

During the breakout sessions, participants were in smaller groups and were assigned to have discussions on a given scenario. The first issue focused on analyzing of molecular information given for a mock application and the other issue was a scenario of dealing with GM contamination. All course participants submitted a country report in order to share the status of biosafety in their respective countries and local experiences in implementation. Malaysia was one of the countries chosen for the Country Report presentation. This session provided an opportunity to get clarifications as well as learn and identify similar challenges in implementation of local biosafety regulatory mechanisms.

It was not all work and no play at this course. In spite of the tightly packed schedule, a few social events were organized as well such as a barbeque dinner at a cozy hill rest house called Skihytta, an official dinner at a restaurant in town and even a movie night! In addition, there were also plenty of informal outings among the participants to many of the interesting sites there to explore in this panoramic city such as the Arctic Cathedral, the Polar Museum, cable car rides and botanical gardens and to even see some reindeers at the University grounds.

This training course was very informative and provided up to date information to its participants. It is suitable for people with any background as training was provided on all aspects of biosafety. The network built among the course participants is also useful to exchange information among the various countries. There are follow-up Specialist Courses that are made available to alumni of the Core Course which are conducted bi-annually and there will be one to look forward to in August this year.

3) STUDY TOUR TO OFFICE OF GENE TECHNOLOGY REGULATOR (OGTR), AUSTRALIA

8-12 November 2010, Canberra, Australia

The Office of Gene Technology Regulator (OGTR) which situated in the capital city of Australia, Canberra, has been in operation for 10 years to provide administrative support under the Australian Gene Technology Act 2000. This Act has many similarities to Malaysia the Biosafety Act 2007. Therefore, it was a good place for the newly established Department of Biosafety to have a study tour.

In line with the aim of exchanging information about the Malaysian and Australian regulatory schemes, a team of 5 officials from the Department of Biosafety participated in this study tour. This study tour had given a great opportunity to the Malaysian representatives to explore the operations of the Australian Regulatory system for genetically modified organism (GMO) administered by the OGTR.

The programme of the study tour comprised presentation, case study, discussion and sites visit over 5 days. The presentation was delivered by the head of units in order to give an insight of the operation systems to the delegates. The topics covered include regulatory processes for environment release and contained dealing. Overview of the policy framework, post release review, monitoring and compliance were highlighted. Electronic database, Gene Technology Information Management System (GTIMS) that is being used by the OGTR to record and manage all dealings with GMO was introduced. With the guidance from the experienced evaluators, the delegates were guided to conduct case studies using the risk analysis model which was developed by OGTR in assessing applications.

With the aim to learn the corporation and coordination between other regulatory agencies in monitoring and compliance when responsibility overlaps, OGTR had provided an opportunity to the delegates to meet with other Australian regulatory agencies such as Food Standards Australia New Zealand (FSANZ), Australian Pesticides & Veterinary Medicines Authority (APVMA) and Australian Quarantine Inspection Service (AQIS).

A monitoring visit to the Commonwealth Scientific and Industrial Research Organization (CSIRO) Black Mountain Laboratories was also organized. Delegates toured the Physical Containment (PC) 2 laboratories and contained screen house and met some members of the CSIRO's Institutional Biosafety Committee (IBC), which functions as an interface with the OGTR. The delegates took the opportunity to understand better the functions of the IBC and mechanism of self regulating the organization in order to comply with the act.

Overall, this study tour was successful and fruitful in obtaining first hand information on the experience of OGTR and various agencies in Australia that are involved in regulatory activities of GMO. Finally, a strong network with OGTR and relevant agencies has been established and the contacts will be good resources for the department to refer in running the office and regulating GMOs locally.

FEATURE ARTICLES

REGULATORY ASPECTS OF GM MOSQUITO EXPERIMENTAL RELEASE IN MALAYSIA

The National Biosafety Board (NBB) on the 5 October 2010 made a decision to grant an approval with terms and conditions to the Institute of Medical Research (IMR) for a field trial to release genetically modified (GM) male mosquitoes. This approval permits the release of male genetically modified (GM) Yellow Fever mosquitoes, Aedes aegypti OX513A(My1) strain and male non-GM Aedes aegypti mosquitoes (wild type) to conduct a field trial entitled "Limited Mark-Release-Recapture (MRR) of Aedes aegypti wild type and OX513A(My1)".

The approval process is not as simple as it is made out to be by some parties as approval is given on a case by case basis and based on the merits of the application. In the case of the GM mosquito application, the application went through a few reviews within the institution itself, i.e. Research Review Committee, the Medical Research and Ethics Committee and the Institutional Biosafety Committee, before being submitted to the Department of Biosafety. Within the Department of Biosafety itself, the application went through several rounds of consultations by the Genetic Modification Advisory Committee (GMAC) before recommendations were made by GMAC to the National Biosafety Board (NBB). This GM mosquito experiment has been running for about 5 years prior to the field experiment that was approved by the NBB. Laboratory and semi-field containment trials have been diligently conducted before the proposal for a field experiment.

Prior to the decision of the NBB, public announcements were imposed on the IMR to publicize the proposed field experiment. This was done in August 2010 for a period of 30 days. Further information about the proposed field trial, as well as invitation to submit comments and opinions were publicized through the Department's website. This enabled a collation of inputs from scientists/ experts, academicians, Non-Governmental Organizations (NGOs), private companies and every concerned member of the public both local and from abroad. These inputs were submitted to the NBB for consideration in making a decision. The Department of Biosafety had also proactively issued letters to nine environmental related NGOs in Malaysia to get inputs for the proposed experiments.

The recommendation of GMAC to the NBB was for an approval with terms and conditions. Proper risk management strategies which include to be followed. Additionally close monitoring was done to ensure that the terms and conditions imposed are implemented on the ground. The role of the Department of Biosafety is as a regulator of this activity, and not the implementer of the field trial (as frequently misunderstood). Release made in Bentong, Pahang was in an uninhabited forest area and all the terms and conditions set for release in that area have been observed by the IMR. They submitted a letter from the Bentong Municipal Council dated 11 November 2010 to the Department of Biosafety as proof of consent for the trial to be conducted at the proposed sites.

Some of the basis of NBB is decision –

- The proposed field experiment is only for a limited small scale release and does not endanger biological diversity or human, animal and plant health when proper risk management strategies are followed as stipulated through the terms and conditions imposed with the approval.
- Risks identified for this field experiment were quite low in the context of a Limited Mark-Release-Recapture field trial. However, for a larger scale release, these risks will be re-evaluated.
- Only male mosquitoes are released and male mosquitoes do not bite or carry the dengue virus. The Standard Operating Procedures for sorting the male mosquitoes for the release has been assessed and approved by GMAC.
- Upon completion of the field trial, responsible site management is imposedto ensure that the area is completely cleared of any released GM mosquitoes.

i.e. the monitoring period is extended and also additional fogging will be done to ensure that there are no residue GM mosquitoes in the environment.

- NBB, through the Department of Biosafety, will closely monitor the implementation of the field trial to ensure compliance at every stage of the release.
- Science based issues/uncertainties highlighted by researchers well versed with the issue were taken seriously and included in the scientific assessment by GMAC.

A letter from the Bentong District Health Office dated 9 November 2010 was submitted to the Department verifying the absence of tetracycline and any aquaculture, poultry and pharmaceutical industries within a vicinity of 500 meters of the release site. The District Health Office also confirmed that the site selected has been free from any dengue outbreak for at least 3 months.

The mandatory public notification imposed by the Department for uninhabited site was also adhered to before the release. After consultation with GMAC and also following current procedure of public notification involving sites by other agencies, the public notice put up by IMR as instructed, for an uninhabited site was through the display of notice boards in the vicinity of the area to inform that –

- a field trial involving GM mosquitoes will take place;
- the proposed time period for the release;
- contact details of the implementer;
- information about the field trial; and
- warning for public not to enter the site

These signboards were displayed in the area for a period of three weeks before the release had taken place. The Department sent its officers to inspect the uninhabited field site to ensure compliance with imposed terms and conditions. The reported average flight distance of wild type Aedes aegypti mosquito is limited to about 200 meters only. The Department, during its survey of the release site, found that there was no occupancy in the area of the point of release within a radius of 500 meters. Therefore, there was no possible exposure to any persons in or around the area that required any additional consultation or public notification.

The actual date of release was very much dependent on the weather conditions. Due to the uncertainty of weather, the actual date of release was only determined 72 hours prior to release as weather predictions are taken to be reliable for only 72 hours ahead of time. The Department was notified of the release during that short time period for the purpose of monitoring the release. On the day of release on 21 December 2010, besides officers from the Department of Biosafety, there was an independent observer from the Academy of Sciences Malaysia. After the completion of the experiment, IMR was required to conduct fogging so that the area is free of GM mosquitoes as a mechanism for risk management.

The purpose of the field trial conducted by IMR is to obtain important information such as the flight distance and longevity of the male GM mosquitoes compared to the wild type. This data is necessary before any decision can be made to proceed with subsequent trials which may eventually lead to the next stage, which is a population suppression trial. Should the applicant decide to proceed to the next stage, a fresh application will have to be submitted to the NBB and careful assessment will be done again, taking also into consideration the results obtained through this present field trial. It must be stressed that prior to this field trial, semi-field controlled experiments have already been conducted at IMR. Following the standard step-by-step approach in the production of a GM organism, this limited field trial is necessary to compare the results obtained through the semi-field controlled experiments to data obtained through this field trial to make headway in the use GM mosquito technology.

INTRODUCTION TO NAGOYA - KUALA LUMPUR SUPPLEMENTARY PROTOCOL ON LIABILITY AND REDRESS TO THE CARTAGENA PROTOCL ON BIOSAFETY

The The Nagoya – Kuala Lumpur Supplementary Protocol is a treaty intended to supplement the Cartagena Protocol on Biosafety. Its adoption marks the completion of the negotiations that started in earnest in 1996 at the first meeting of the Open-ended Ad Hoc Working Group on Biosafety, an intergovernmental working group mandated by the second meeting of the Conference of the Parties to the Convention on Biological Diversity to negotiate a biosafety protocol. Malaysia had played a very active role in this and even hosted two of the final rounds of negotiations, and hence sharing the honour with Japan, of having the protocol named after Kuala Lumpur and Nagoya

A number of countries believed, from the outset of the negotiations on a biosafety protocol, that there was a need to establish liability and redress rules that specifically apply to living modified organisms (LMOs) or to activities involving such organisms. It was argued that there must be an obligation to take responsibility and to provide redress in the event risks associated with LMOs materialize and damage occurs. In that regard, Article 27 of the Biosafety Protocol took the first step, i.e. recognizing that damage could result from the transboundary movements of LMOs and, therefore, a multilateral process to discuss the matter was necessary. The subsequent negotiation process was, therefore, focused on issues such as the definition of damage, the attribution of responsibility to a person or persons for that damage and the kind of response measures that need to be taken to redress the damage or to prevent it, and what the nature of the instrument resulting from the negotiations should be. The Supplementary Protocol is a response to and fulfillment of Article 27 of the Biosafety Protocol.

The objective of the Supplementary Protocol is to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health by providing international rules and procedures in the field of liability and redress relating to LMOs.

The Supplementary Protocol defines “damage” as an adverse effect on the conservation and sustainable use of biological diversity that is measurable and significant. It also provides for an indicative list of factors that should be used to determine the significance of an adverse effect. Once the threshold of significant damage has been met, the need for response measures arises. The Supplementary Protocol is the first multilateral environmental agreement to define “damage to biodiversity. Traditional damage, which is common in third-party civil liability instruments, and which includes personal injury, loss or damage to property or economic interests, is not covered by the Supplementary Protocol.

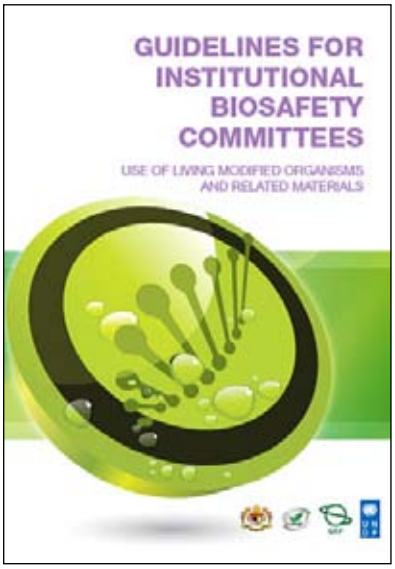
The Supplementary Protocol is the second liability instrument to be concluded in the context of a multilateral environmental agreement following the 1999 Protocol on Liability and Compensation to the Basel Convention on the Transboundary Movement of Hazardous Wastes (the “Basel Protocol”). The Basel Protocol adopts a civil liability approach, in particular in its definition of damage.

The Supplementary Protocol is open for signature at the United Nations Headquarters in New York until 6 March 2012 and will enter into force 90 days after being ratified by at least 40 Parties of the Cartagena Protocol on Biosafety. This Protocol is a prominent achievement for the global community, that is relentlessly pushing forward the agenda of conservation, and it was very aptly adopted in the International Year of Biodiversity.

LATEST BIOSAFETY PUBLICATIONS

GUIDELINE FOR INSTITUTIONAL BIOSAFETY COMMITTEES

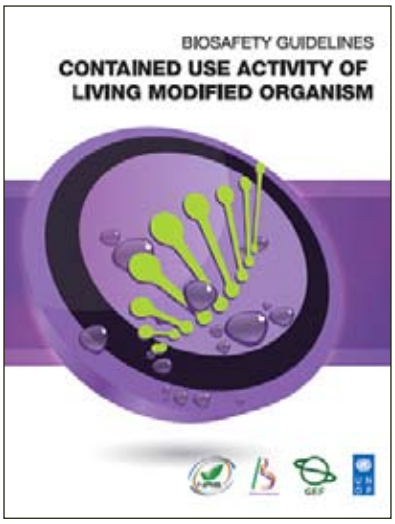
Use of Living Modified Organisms and Related Materials



This guideline outlines the setting up of an Institutional Biosafety Committees (IBC), role of IBC and processes that must be followed when obtaining, using, transferring, storing or destroying LMO/rDNA materials. It also provides explanations of the relevant regulatory requirements and procedures. Other information found in this guideline include responsibilities of the biological safety officer (BSO) and researchers, IBC membership, various types of review done by IBC, actions required for reporting of incidents and spills and other related information.

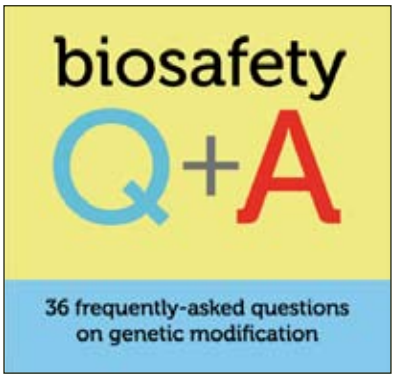
BIOSAFETY GUIDELINES

Contained Use Activity of Living Modified Organism



Any organization that intends to carry out contained use activities involving LMO and related materials are required to use this guideline to determine the biosafety level (BSL) and facility type required. This 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, plant and animal health and the environment.

BIOSAFETY Q&A CARD



Do you have any questions on genetic modification or Biosafety? If Yes, please quickly refer to our latest publication on Q & A card. It is colourful and attractive consisting 36 frequently-asked questions. The answers are in layman terms and you will find it easy to understand the topics from DNA, modern biotechnology, genetically modified food, Biosafety Act and many other interesting topics!

* These document can be downloaded from www.biosafety.nre.gov.my

Event Calendar

Date	Event	Organiser(s)
5 - 9 Sept 2011	First International Workshop on the Food and Environmental Safety Assessment of Genetically Modified Animals. *Venue: Buenos Aires, Argentina*	International Center for Genetic Engineering and Biotechnology (ICGEB) http://www.icgeb.org
11 - 23 Sept 2011	Agricultural Biotechnology: An International Short Course *Venue: MSU, USA*	Michigan State University, USA http://msu.edu/
19 - 23 Sept 2011	Problem Formulation: A Strategic Approach to Risk Assessment of GMOs *Venue: Trieste, Italy*	International Center for Genetic Engineering and Biotechnology (ICGEB) http://www.icgeb.org
31 Oct - 3 Nov 2011	International conference on Modern Biotechnologies: Sustainable innovation and regulatory needs *Venue: Penang, Malaysia*	GenØk – Centre for Biosafety http://www.genok.com
14 - 16 Nov 2011	Workshop on Capacity-building for Research and Information Exchange on Socio-economic Impacts of Living Modified Organisms *Venue: New Delhi, India*	Secretariat of the Convention on Biological Diversity (SCBD) http://www.cbd.int
17 - 18 Nov 2011	Asia and Pacific Regional Workshop on the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety *Venue: New Delhi, India*	Secretariat of the Convention on Biological Diversity (SCBD) http://www.cbd.int
20 - 22 Nov 2011	First International Workshop on Bioethnics and Ethical Aspects of Biosafety *Venue: Tehran, Iran*	International Center for Genetic Engineering and Biotechnology (ICGEB) http://www.icgeb.org
21 - 25 Nov 2011	Asia-Pacific Regional Training of Trainers' Workshop on the Identification and Documentation of Living Modified Organisms *Venue: New Delhi, India*	Secretariat of the Convention on Biological Diversity (SCBD) http://www.cbd.int