

Biosafety

NEWSLETTER ISSUE 04

OCTOBER 2012

**User Guide to the
Biosafety Act and
Regulations**

**Biosafety Education
Video**

Feature Article
Socio-Economic
Considerations in
Decision-Making on
LMOs: Malaysia's
Context





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MESSAGE FROM THE CHIEF EDITOR

Welcome to the fourth edition of the Biosafety Newsletter!

In October 2010, Malaysia for the first time in the history could make decisions on living modified organism (LMO) based on a proper legal framework, processes and appropriate machineries in place. As of October 2012, the National Biosafety Board had made decision on 4 applications on approval for release and 9 notifications on activities in contained environment. As stipulated under the Biosafety (Approval and Notification) Regulations 2010, any organisation that undertakes modern biotechnology research and development (R&D) activities will have to establish an Institutional Biosafety Committee (IBC) for the purpose of providing guidance and monitoring activities relating to modern biotechnology within its organization. To date, 26 IBC had registered with the National Biosafety Board. This is as a result of our intervention through training and issuance guidelines on establishment of IBC.

As a next step, having established and operationalised a system of processing applications, the Department of Biosafety now focuses on enforcement and monitoring of LMO. Apart from that, the focus will continue from where the NRE-UNDP-GEF Biosafety Capacity Building Project which has come to an end on 30 June 2012 has left us in particular on efforts to build capacity and awareness of biosafety. The Project has helped to establish a regulatory system in Malaysia in addition to building institutional capacities through training and human resource development in various areas relevant to biosafety which involved the Department staff, members of the National Biosafety Board/Genetic Modification Advisory Committee and members of stakeholder organizations. As a result, the Department and other government agencies have now acquired sufficient capacities in risk assessment and risk management. The independent consultant appointed by UNDP has rated the project as Highly Satisfactory. We will continue to conduct training workshops and road shows at universities and research institutions as well as organizing awareness seminars for selected stakeholders. Publications on a variety of reading and reference materials on biosafety produced under the Project will be promoted and circulated to a wide spectrum of public.



Biosafety, Always Our Priority!

A handwritten signature in black ink, appearing to read 'Letchumanan Ramatha'.

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

USER GUIDE TO THE BIOSAFETY ACT AND REGULATIONS

The Biosafety Act was passed by the Parliament on 11 July 2007. However when comes to implementation, it was not easy to reach consensus from the Non Governmental Organisations and modern biotechnology industries. Nevertheless in light of outcome of several rounds of negotiation between all stakeholders and the new policy by the Government to promote the growth of biotechnology, important understandings were reached and the legal framework was adjusted to make the law an enabling piece of legislation accepted by all. Accordingly, the Act was enforced effective 1 December 2009, two years after it was passed by the Parliament. This was followed by development of appropriate forms for application for release and notification for research works. As provided under the Act, and the understanding with stakeholders, the Biosafety (Approval and Notifications) Regulations 2010 was formulated and enforced effective 1 November 2010. The Act, Regulations, Application Forms and Institutional Biosafety Committee (IBC) Guidelines form the key elements of the biosafety legal framework in Malaysia.

As part of Government enabling approach in implementing the biosafety law, User's Guide to the Biosafety Act and Regulations has been developed. It was part of the targeted output under the NRE-UNDP-GEF Biosafety Capacity Building Project and Department of Biosafety has engaged Centre of Excellence for Biodiversity Law (CEBLAW), University of Malaya to come out with this User's Guide. First chapter of the User's Guide provides some background information about the national regulatory scheme for LMOs which include the development



history of the national regulatory scheme, instruments that form part of the national regulatory scheme and the main components the scheme. The next chapters in the User's Guide cover each of the key aspects of the scheme including:

- Activities involving LMOs that are, and are not, regulated under the national regulatory scheme;
- Regulation of import of LMO;
- Regulation of release activity involving LMO;
- Regulation of contained use of LMO;
- Regulation of export of LMO;
- Regulation of products of LMO;
- Confidential business information;
- Review of decisions made under the legislation;
- Reporting, monitoring and enforcement;
- The Malaysian Biosafety Clearing House Website; and
- Fees and charges

The User's Guide is explanatory only and is intended to help organisations and individuals undertaking activities involving LMOs to understand how the national regulatory scheme works. It does not dispense with the need to read and understand the Biosafety Act 2007 and the Biosafety Regulations 2010 and, where necessary, obtain independent expert advice. The User's Guide should also be read together with the following documents:

- Application forms for persons wishing to carry out activities involving LMOs under the legislation (which are also included as Appendices to the User's Guide for easy reference);
- The Guidelines for Institutional Biosafety Committees: Use of Living Modified Organisms and Related Materials;
- The Biosafety Guidelines for Contained Use Activity of Living Modified Organism; and
- Forms relevant to the establishment and operation of IBC.



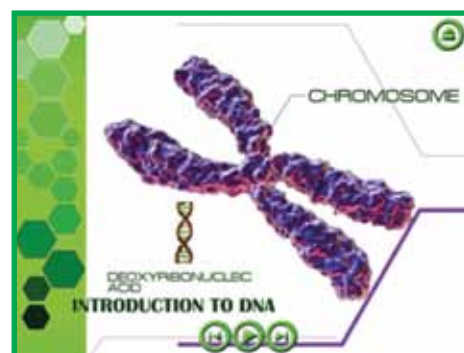
It is expected that the User's Guide will be used as an ongoing resource for applicants or users of the regulatory scheme. Copies of the User's Guide and the above documents may be downloaded from the Malaysian Biosafety Clearing House Website.

BIOSAFETY EDUCATION VIDEO

Public awareness, education and participation are fundamental elements for the effective implementation of the Biosafety Act. It's also important because it could enhance various stakeholders' understanding on the regulatory role of the Department of Biosafety, functions of the Genetic Modification Advisory Committee and the National Biosafety Board. Besides the use of website, publications and electronic mass media, video could also become the most effective tool for the dissemination of biosafety information especially among public including students.

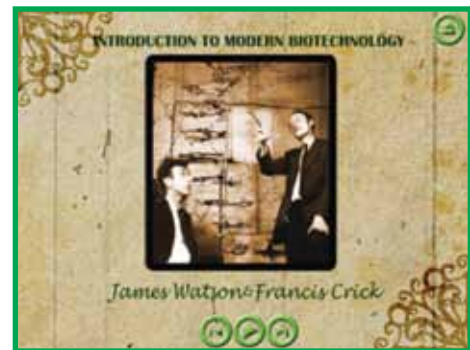
On that basis, the Department of Biosafety together with Malaysian Nature of Society (MNS) and Malaysian Biotechnology Information Centre (MABIC) had produced an education video on biosafety. The video, which is produced in two languages (Malay and English) and is approximately 18 minutes long, divided into the following chapters:

1. Introduction to DNA



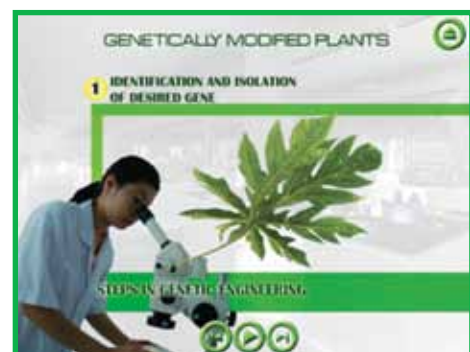
This chapter gives brief introduction of DNA, or deoxyribonucleic acid, which determines our physical characteristics - what we look like, our ailments etc. Many also believe that DNA is partly responsible for our behaviour.

2. Introduction to Modern Biotechnology



Biosafety and modern biotechnology are very much related to each other. To create awareness on biosafety, public especially without science background need to have some basic knowledge on modern biotechnology. This chapter focuses on history of biotechnology including genetic engineering technique where genes can be moved and combined beyond the taxonomic family, between plants, insects, bacteria, and animals.

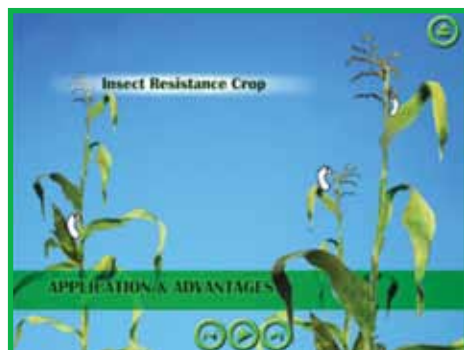
3. Steps in Genetic Engineering



This chapter explains steps involved in genetic engineering to produce genetically modified plants in a simple language. The steps involved are: 1) identification and isolation of desired gene; 2) transformation of desired gene;

3) identification of transformed gene; and 4) field testing.

4. Application and Advantages



The benefits of modern biotechnology for the human kind are discussed in this chapter.

5. Risks of Modern Biotechnology



Although various benefits can be obtained from modern biotechnology, there are possible risks in terms of environment as well as issue on health, socio-economy and ethics. This chapter highlights on these aspects.

6. Research and Development of LMO



This chapter briefly explains on the current status of LMOs development around the world including in Malaysia. It also touches on potential area for development of new LMOs in future.

7. Biosafety Act 2007



The most important chapter in this video is on the Biosafety Act. This chapter not only explains on process involved in approval and notification but also provides some background/history of biosafety regulatory framework in this country.

It is hoped that through this video, public will become more aware of the issues and processes related to LMOs and to have access to relevant information in order to make informed choices and actions, and be able to participate effectively in the decision-making processes. Public participation in the decision-making process is crucial for facilitating transparency and accountability, and strengthening public support for the decisions taken regarding LMOs.

CAPACITY BUILDING ACTIVITIES: WORKSHOPS AND SEMINARS

(i)

Title	Biosafety Training Workshop
Date & Venue	24-25 May 2011 ; Malaysia Agricultural Research and Development Institute (MARDI)
	13-14 July 2011 ; Universiti Sains Malaysia (USM)
	20-21 Sept 2011 ; Sime Darby Technology Center
	28-29 Sept 2011 ; Malaysia Palm Oil Board (MPOB)
	19-20 Oct 2011 ; University of Malaya (UM)
	24-25 May 2012 ; University Malaysia Sarawak (UNIMAS)

The Biosafety Training modules were designed with the expertise from the GMAC members to equip the Institutional Biosafety Committee (IBC) members with relevant knowledge

and skills in reviewing and monitoring activities related to living modified organism. There are five modules in this 2-days training workshop:

Module	Title	Topics
1	Introduction	Biosafety Act, Regulations and IBC Guidelines
2	Containment Facilities & Work Practices in BSL 1 & 2	Genetically modified microorganism, plant and animal
3	Biosafety Practices	Movement, transport, storage, disposal of LMO and related materials
4	Risk Assessment	Define and differentiate between hazard and risk, understanding likelihood and consequences, risks associated with LMO and matrix for risk assessment
5	Risk Management	Risk mitigation, control measures and emergency response plan

Modules 1, 4 & 5 are compulsory but 2 & 3 are optional. The institute will decide if these topics need to be covered. In order to keep the attention of the participants, the slides were developed with less word and enhanced with more

pictures. The workshops were designed in an interactive way with the aims to stimulate thinking and encourage 2-ways communication. Group exercises were developed for each topic to enhance understanding.



Workshop at MARDI



Workshop at Sime Darby



Workshop at MPOB



Workshop at UM

(ii)

Title	Media/Crisis Communication Workshop
Date	2-3 November 2011
Venue	Hilton Hotel, Petaling Jaya

This workshop was jointly organized by Department of Biosafety and UNDP-GEF Biosafety Project. It was conducted by TQPR, a competent public relation company which regularly conducts customized media communication training. The workshop uses self teaching role-play and video playback method and is customized to the Department needs to build the capacity.

The objective of the workshop was to acquaint participants with how the media works, the different interview formats and how to effectively communicate key messages when talking to the media, how to handle tricky questions and to role-play various client-related media scenarios, and/or crisis communications.



Some of the screenshots during the workshop

(iii)

Title	'Biosafety, DNA & You' Workshop
Date	10-11 November 2011
Venue	University of Malaya

Realizing the importance of creating awareness about modern biotechnology and biosafety, the Department of Biosafety working together with Center for Research in Biotechnology for Agriculture (CEBAR), University of Malaya, supported by the UNDP-GEF Biosafety Project, had organized 'Biosafety, DNA & You' workshop. It was

targeted for media representatives with the aims to increase the knowledge, understand the complementary role of biosafety to biotechnology as well as provide a hands-on experience on this technology. A total of 10 media representatives and 10 officers from Department of Biosafety and relevant agency attended the workshop.



Practical session during the workshop

(iv)

Title	Workshop on Genetically Modified Organisms Protein Detection Technique
Date	14-15 February 2012
Venue	Chemistry Department, Petaling Jaya

The Department of Biosafety and UNDP-GEF Biosafety Project in collaboration

with the Chemistry Department jointly organized this workshop. The workshop

aimed to provide exposure and hands-on training on GMO detection based on the protein detection technique to the participants. Extensive hands-on experiments followed by result analysing and evaluation were conducted. All of

the experiments were repeated to allow the participants to familiarise with and acquire the skills. The participants of the workshop were consisted of scientists and technicians from universities and research institutes.



Participants of the workshop

(v)

Title	Seminar on Biosafety to Freight Forwarders
Date	7 March 2012
Venue	Wisma SFFLA, Klang

This seminar was organized by Department of Biosafety together with UNDP-GEF Biosafety Project and Selangor Freight Forwarders and Logistics Association (SFFLA). The objectives of the seminar were to raise awareness among participants about modern biotechnology and Biosafety.

It also aimed to create awareness among participants about Cartagena Protocol on Biosafety, Biosafety Act and their obligation as importers/ freight forwarder as well as to build their capacity in searching for biosafety related information using Biosafety Clearing House.



Participants of the seminar

(vi)

Title	Second National Report to the Cartagena Protocol on Biosafety Consultation Workshops
Date & Venue	15 Sept 2011; Kuala Lumpur (1 st workshop)
	19 Sept 2011; Kuching (2 nd workshop)
	20 Sept 2011; Kota Kinabalu (3 rd workshop)
	27 Sept 2011; Kuala Lumpur (4 th workshop)

As Party to the Cartagena Protocol on Biosafety, Malaysia has to submit National Report on the implementation of the Cartagena Protocol every 4 years. Malaysia submitted its Interim National Report in 2005 and followed by 1st National Report in 2007. The 2nd National Report was scheduled to be submitted by 30 September 2011. To comply with this obligation, Malaysia has secured funding under the “GEF Support to Preparation of the Second National Biosafety Reports to the

Cartagena Protocol on Biosafety”. This fund has been used by the Department of Biosafety to organize 4 consultation workshops (as listed above) on the preparation of the 2nd National Report. Among the issues discussed were transit of LMOs, capacity to detect LMOs, capacity to conduct risk assessment, capacity building activities and socio-economic considerations. The Report was finally submitted on 30 September 2011 after considering all feedbacks received the consultation process.

(vii)

Title	Biosafety Clearing House Training Workshop
Date & Venue	8-10 Feb 2012; Wisma Sumber Asli, Putrajaya (1 st workshop)
	27 Feb-1 March 2012; Menara UOA Bangsar (2 nd workshop)
	2-3 April 2012; Wisma Sumber Asli, Putrajaya (3 rd workshop)

These workshops were organized by the Department of Biosafety and were part of activities under the “UNEP-Division of Environmental Law and Conventions (DELC)-GEF Project for Continued Enhancement of Building Capacity for Effective Participation in the Biosafety Clearing House (BCH)”. 1st workshop was aimed for Government officers (for example Custom and Quarantine officers, Competent National Authorities, etc.) with responsibilities for implementing the biosafety law. The 2nd workshop was targeted for key

stakeholders and potential users of the BCH including universities and research institutions while the 3rd workshop was aimed for relevant stakeholders including the State Governments and Non Governmental Organisations. UNEP has contracted BCH Regional Advisors to assist with design and delivery of the first two workshops mentioned above. Overall, these workshops provide participants with better understanding of the format of BCH records as well as the procedures for registering and publishing biosafety-related records.



Participants and Regional Advisor of the 2nd National BCH Training Workshop



Participants of the 1st National BCH Training Workshop



Participants of the 3rd National BCH Training Workshop



INTERNATIONAL MEETING/WORKSHOP/ TOUR

i) First International Workshop on the Food and Environmental Safety Assessment of Genetically Modified Animals

Buenos Aires City, Argentina, 5-9 September 2011

This workshop was jointly organized by the Argentine Ministry of Agriculture, Livestock and Fisheries, (SAGyP, Biotechnology Directorate), International Centre for Genetic Engineering and Biotechnology (ICGEB), United Nations University Biotechnology Programme for Latin America and the Caribbean (UNU-BIOLAC) and International Life Sciences Institute (ILSI Argentina) from the 5-9 September 2011. Genetically modified animals intended for commercial production are approaching the market as research and development in this field is quite advanced. As a result, international organizations and the national authorities of a number of countries are developing frameworks for the food and environmental safety assessment of genetically modified animals. Currently, there is a need for information and experience exchanges between regulators working for regulatory agencies, professionals working on animal biotechnology and experts in the field of biosafety research. This Workshop reviewed the emerging elements of regulatory frameworks for the food and environmental safety assessment of genetically modified animals and related technologies. It was attended primarily by professionals working in regulatory agencies, researchers working on animal biotechnology and experts in the field of biosafety research. The main objectives of the workshop were disseminating information, enhancing cooperation and providing capacity building. This event

was attended by 116 participants from 31 countries. It is interesting to note that 35% of the participants were resource persons.

This workshop started with introduction to development of GM animals and also the most recent developments in GM animals' technology. In the aspect of environmental biosafety assessment, some international guidance documents and resources were introduced, for example by the *Ad Hoc Technical Expert Group* under the Convention of Biological Diversity, the European Food Safety Authority as well as the Organisation for Economic Co-operation and Development (OECD). This was followed by sharing of national experiences for safety assessment of GM cattle, the salmon fish and confinement methodologies for experimental releases of GM animals. The third day was focused on food safety.

It touched on some internationally recognized guidelines such as GM food safety assessment are the Codex Alimentarius Guideline, FAO/WHO and also the Food and Drug Authority of USA. After that, there was also an introduction to the Canada Regulatory System for GM Animals. This was followed on some technical presentation on assessment methodology – on nutritional content, toxicity, allergenicity and methods of analysis. Socio economic issues, labeling of foods derived from GM animals, ethical and public perception issues were addressed on the last day of the workshop.



A visit was organized to animal gene cloning facility and transgenic animal farm for the participants to see how animal cloning is done and the animals that were successfully cloned in that facility. The participants were also taken to another facility where some transgenic cows have been developed.

This workshop provided information from various perspectives on GM

animals– from technology developers, academia as well as regulators. The experience shared by the various resource persons has been very useful. It gave a basis for issues to address for further development of GM animal technology in a safe manner but also taking into consideration practical solutions so as not to hinder the development.



A cloned sheep in Argentina



Transgenic cows in Argentina

ii) The Gateways Partners' Specialized Biosafety Course: Insects Vaccines and Stress Tolerant Plants & The Gateways Partners' Biosafety Conference: Tough Choices – New Biosafety Decisions in High Stake Arenas

Tromso, Norway, 16-24 August 2011

The “International Biosafety Course on Insects, Vaccines and Stress-tolerant Plants” was attended by 67 participants around the world representing governments, NGOs, research institutions and universities. Director General of Department of Biosafety, Mr. Letchumanan Ramatha and Genetic Modification Advisory Committee (GMAC) member, Professor Helen Nair had attended as resource persons and participants.

The objective of the course was to give participants balanced information and an introduction to the tools required to

evaluate new technologies, from their own perspectives and for their countries' need.

It was a fruitful experience as our presentation has raised the profile of Malaysia *vis a vis* our Biosafety Policy and its implementation as evidenced through the approval process for the first limited mark, release and recapture field release of genetically modified mosquitoes.

It would be a good opportunity to participate in the course/conference on a selective basis.

iii) Asia Sub-Regional Training of Trainers' Workshop on the Identification and Documentation of LMO

New Delhi, India, 21-25 November 2011

Asia Sub-Regional Training of Trainers Workshop on the Identification and Documentation of Living Modified Organisms (LMO) under the Cartagena Protocol on Biosafety was organized at New Delhi, India from 21 to 25 November 2011. Customs officials and enforcement officers from 13 countries of the region namely Cambodia, India, Indonesia, Lao People Democratic Republic, Malaysia, Mongolia, Philippines, Saudi Arabia, Sri Lanka, Syria Arab Republic, Thailand, Vietnam and Yemen participated in the workshop.

The objective of the workshop was to introduce to the participants the requirements of the Cartagena Protocol on Biosafety regarding the identification and documentation of living modified organisms and to the techniques and methodologies that may be used to ensure the implementation of these requirements. It also aimed at facilitating the exchange of information and national experiences on the implementation of the identification and documentation requirements under the Protocol. The workshop was jointly organized by National Bureau of Plant

Genetic Resources (NBPGR), New Delhi and International Centre for Genetic Engineering and Biotechnology (ICGEB) New Delhi.

Participants had the opportunity to do some laboratory exercises at ICBEB and NBPGR. They used Protein-based and DNA-based methods to perform detection of the LMOs. The participants also visited and familiarized with the Plant Protection, Quarantine and Storage Station at Rangpuri and Depot at Tuglakabad where samples are received and documented before being sent to laboratory; Plant Quarantine Facility at NBPGR, New Delhi where samples are received, tested and reports prepared; and Phytotron Facility at the Indian Agricultural Research Institute, Pusa Campus, New Delhi.

The training course has been very informative and provided up to date information. It is suitable for officers involved in LMO enforcement activities. The facilitators gave good presentations and were able to give practical examples. The network built among the participants will also be useful to exchange information.



Participants of the workshop



iv) Working visit to Indian Biosafety Regulatory Bodies

New Delhi, India, 5-9 December 2011

A study tour of Malaysian Biosafety Delegation to various Biosafety Regulatory Government Agencies in New Delhi, India during 5-9 December 2011 was aimed to study how Biosafety regulatory body in India carries out its functions and to enable Malaysian delegates learn elements of an effective regulatory system.

The agencies that involved in meeting with Malaysian delegates were Biotech Consortium India Limited (BCIL), Ministry of Environment and Forests (MoEF), Department of Biotechnology, International Centre for Genetic Engineering and Biotechnology (ICGEB), University of Delhi, National Phytotron

Facility, National Bureau of Plant Genetic Resources (NBPGR), Inland Container Depot, Tughlakabad and National Plant Quarantine Station.

This study tour has provided opportunities to obtain first hand information on the experience of various agencies in India that are involved in regulatory activities or related activities involving GMOs. It proved to be useful to learn from these agencies and meet the officers in person, as they are very experienced and have been involved in these regulatory activities. Furthermore, the delegates were able to build a network of contacts with the regulatory officers for future references.

v) 8th Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Capacity-Building Activities & 9th meeting of the Liaison Group on Capacity-Building for Biosafety

Prague, Republic Czech, 12-16 March 2012

These meetings may be considered as special gatherings at the Ministry of the Environment in Prague, the Czech Republic where representatives of selected countries and individuals by name were invited to participate in discussions in relation to matters decided by previous COP-MOPs with the view to make appropriate coordination and submit recommendations for the consideration of the next COP-MOP. It is the first time that Malaysia has been invited to attend the Liaison Meeting.

The meeting agendas comprised of the discussion of issues including capacity-building for detecting, preventing and managing illegal transboundary movements of living modified organisms (LMOs), capacity-building needs and initiatives for post-release monitoring of LMOs and comprehensive review of the action plan for building capacities

for the effective implementation of the Cartagena Protocol on Biosafety. Comprehensive review of the updated action plan, frameworks for the assessment of capacity building needs and measures to improve the coordination mechanism for the effective implementation of the action plan for building capacities for the effective implementation of the Protocol were discussed in the meetings.

These meetings of a small group of people had a chance to know forthcoming issues and recommendation in the area of capacity building in Biosafety much in advance of MOP6 scheduled in October 2012 in Hyderabad. Our participation apart from contributing to enrich the discussions and learning something new, most importantly the networking with colleagues from other nations, experts and the secretariat.



FEATURE ARTICLES

i) STAKEHOLDERS' AWARENESS ON BIOSAFETY REGULATIONS IN MALAYSIA

Background of the Study

During the final year of NRE-UNDP-GEF Biosafety Capacity Building Project implementation, one of the targets was to come out with a report on the perception of the public on modern biotechnology and biosafety including whether the public was aware of the Biosafety Act and the existence of biosafety regulatory body in this country as well as on impact of the publicities carried out so far. Thus, the project conducted a survey to study the stakeholders' perception on biotechnology and biosafety. This study was mainly aimed at collecting information and established a baseline data on stakeholder awareness and perception towards modern biotechnology in particular genetically modified organism (GMO), biosafety and the regulatory body.

A total of 1,047 respondents from six stakeholder groups were surveyed. These groups consisted of:

- 1) Regulatory bodies/enforcement bodies/policy makers (100 respondents);
- 2) Research institutions & universities (101 respondents);
- 3) Non-government organisations (NGOs), religious bodies and organic shops (101 respondents);
- 4) Industry players (100 respondents);
- 5) Media and educators (101 respondents); and
- 6) Consumers (544 respondents).

These stakeholders were selected based on two main considerations:

(a) involvement in the area of modern biotechnology and biosafety inclusive of developing the national biosafety framework; and (b) having interest/concerns on the subject. The survey was conducted in the Klang Valley which is where major universities, R & D institutions and biotechnology related industries are located. In addition, it was anticipated that the stakeholders in the Klang Valley might have better knowledge or exposure to modern biotechnology and thus were able to participate more meaningfully in the survey.

Questionnaires were the main instrument for data collection. The questionnaire was in Malay and English and consisted mainly of close-ended questions covering the following five sections:

- 1) Knowledge on modern biotechnology – This section gathers data that was used to assess the level of knowledge of the stakeholders on modern biotechnology;
- 2) Perception on genetically modified food – This section assesses how the stakeholders perceive genetically modified (GM) food;
- 3) Willingness to consume GM food – This section assesses the willingness of the stakeholders to consume GM food;
- 4) Awareness of biosafety legislations – This section assesses the awareness and knowledge of the stakeholders on biosafety regulations in Malaysia; and
- 5) Basic socio-demographic data



However, for the purpose of this article, only findings of the fourth section i.e. on awareness of biosafety legislations be highlighted here.

Finding from the Survey

In general, stakeholders' awareness towards biosafety legislations in this country is still very low. Except for those from research institutions and universities and regulatory bodies/enforcement bodies/policy makers, not many respondents are aware that there is a law in Malaysia to regulate activities involving GMO.

As shown in Table 1 below, the awareness level on the law among respondents from regulatory bodies/enforcement bodies/policy makers/research institutes & universities and industry players are reasonable ranging from 43.4% to 61.4%. As expected, the consumer group has the lowest level of awareness at 18.4%. On the response on who have heard about the Department, except for the consumer group, all the rest have a response level of 43% to 83.2%. On whether they have read about the Act, a similar trend can be observed.

Table 1: Awareness of biosafety regulations

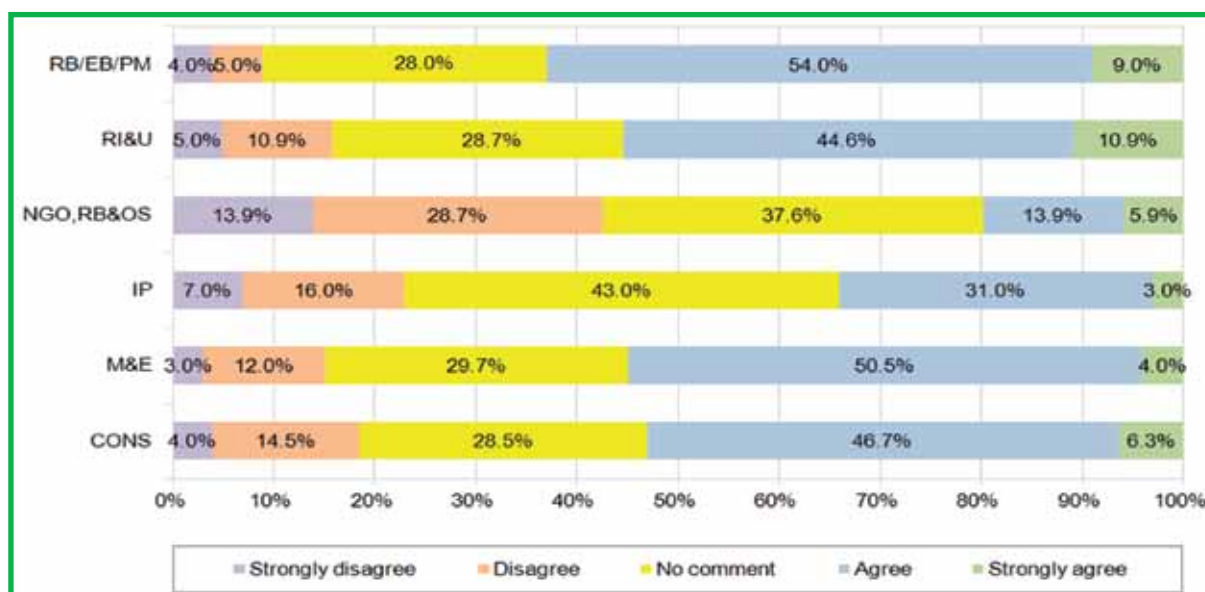
Stakeholder group (%)						
	RB/EB/PM	RI&U	NGO, RB&OS	IP	M&E	CONS
<i>Are you aware of any laws or regulations in Malaysia to regulate the dealings of GMO?</i>						
Yes	54.5	61.4	23.8	43.4	27.7	18.4
No	9.1	15.8	40.6	22.2	27.7	47.4
Not sure	36.4	22.8	35.6	34.3	44.6	34.2
<i>Have you heard of the Department of Biosafety?</i>						
Yes	74.7	83.2	43.0	52.0	51.5	19.9
No	18.2	12.9	51.0	30.0	32.7	68.9
Not sure	7.1	4.0	6.0	18.0	15.8	11.2
<i>Have you heard or read about the Biosafety Act?</i>						
Yes	45.0	74.3	23.8	38.0	34.7	7.6
No	48.0	22.8	70.3	53.0	54.5	82.8
Not sure	7.0	3.0	5.9	9.0	10.9	9.6

*RB/EB/PM = Regulatory bodies/enforcement bodies/policy makers; RI&U = Research institutions & universities; NGO, RB&OS = NGOs, religious bodies & organic shops; IP = Industry players; M&E = Media & educators; CONS = Consumers

On the Government's capability of handling GMO matters, most stakeholders were generally positive except members from NGOs, religious bodies and organic shops and industry players. About 20% of respondents from NGOs, religious bodies and organic shops agreed on this statement

compared to industry players with 34%. However, it is interesting to note that about 42% of the NGOs, religious bodies and organic shops disagreed to the statement as oppose to 20% agreeing. In the case of the industry players, 34% agreed and 23% disagreed.

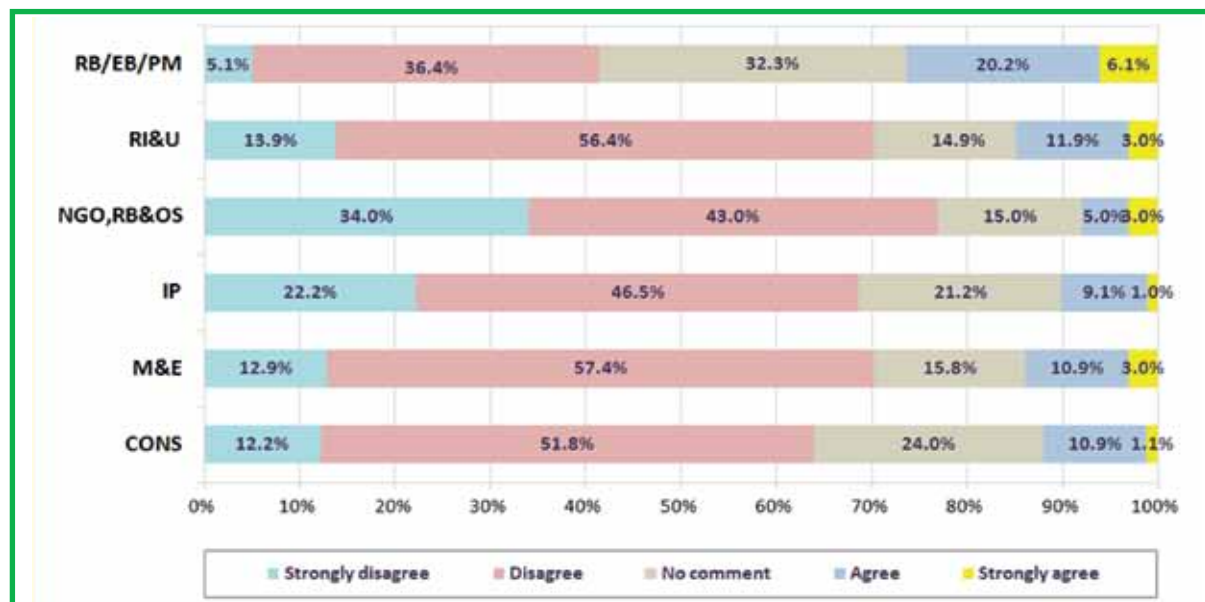
Figure 1: The Government is capable of handling GMO matters



In general, all stakeholders group felt that the public awareness activities on GMO conducted by the Government are insufficient. In fact, most of the feedbacks received from the

respondents were on lack of information about biosafety, low exposure of the subject matter to the general public and the need to conduct more awareness activities and stakeholder consultations.

Figure 2: The public awareness activities on GMO conducted by the Government are sufficient



The results obtained through this survey are very critical to the Department of Biosafety as it will generate an initial baseline data and can be used

as appropriately, to develop a more effective roadmap to raise awareness about biosafety to various stakeholders.



ii) SOCIO-ECONOMIC CONSIDERATIONS IN DECISION-MAKING ON LMOs: MALAYSIA'S CONTEXT

Provision in the Cartagena Protocol

The Cartagena Protocol on Biosafety under Article 26 establishes the right of Parties to take into account socio-economic considerations arising from the impact of living modified organisms (LMOs) on the conservation and sustainable use of biodiversity in reaching a decision on whether to import LMOs especially with regard to the value of biological diversity to indigenous and local communities. Under paragraph 1 of the Article, the Protocol appears to limit the scope of socio-economic considerations that governments may take into account in regulatory decisions to such circumstances as the impact of the import of LMOs on –

- The continued existence and range of diversity of the biological resources in the areas inhabited or used by indigenous or local communities;
- The loss of access to genetic and other natural resources, as a result of biodiversity loss, previously available to indigenous or local communities in their territories; or,
- The loss of cultural traditions, knowledge and practices in a particular indigenous or local community as a result of the loss of biological diversity in the community's territory. (Mackenzie et al. 2003)

Paragraph 2 of the same Article, however, encourages Parties to the Protocol to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially – but not limited to – impacts on indigenous and local communities. Socio-economic considerations are relevant to domestic biosafety decisions and not just to transboundary movement of LMOs. In this regard, countries may incorporate into their domestic regulatory regimes on biosafety socio-

economic considerations other than those explicitly included in Article 26, as long as these rules comply with any other international obligations by which they may be bound (Garforth 2004). At the same time, keeping to the spirit and letter of the Protocol, it could be prudent if Parties are to avoid disputes with their trading partners, such as complaints under the World Trade Organization (WTO). The WTO rules tend to emphasize decision-making procedures that rely on rules and regulations that center around scientific risk assessments, while limiting decision-making based on non-safety issues. The strict emphasis on scientific risk assessments under the WTO, are sometimes relaxed within implementation agreements, such as the Sanitary and Phytosanitary Measures agreement (Zepeda 2009).

Provision on Socio-Economic requirement in the National Legal Framework

Consistent with the Cartagena Protocol under Article 26 which states, socio-economic considerations should be taken into account in implementing the national biosafety law, section 35 of the Malaysian Biosafety Act states –

“The Board or Minister shall not be prevented from taking a decision, as appropriate, under Part III or Part IV, where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of living modified organisms or products of such organisms on human, plant and animal health, the environment and biological diversity and may also take into account socio-economic considerations”.

Part III of the Biosafety Act refers to the approval process for release and import, Part IV to the notification process for export, contained use and import for contained use

It was not easy to get the industries to accept the provision on “may also take into account socio-economic considerations”. As more clarity was requested on these terms, the Biosafety (Approval and Notification) Regulations 2010 in section 25 on socio-economic considerations provides extended explanation as follows –

“The Board or the Minister, in taking into account socio-economic considerations pursuant to section 35 of the Act, may consider –

- a) the changes in the existing social and economic patterns and means of livelihood of the communities that are likely to be affected by the introduction of the living modified organisms or products of such organisms;
- b) the effects of the religion, social, cultural and ethical values of communities arising from the use or release of the living modified organisms or products of such organisms”.



Considerations of Socio-Economic Aspects in Decision Making

Socioeconomic considerations are important and sometimes even crucial in safeguarding the interests of indigenous and local communities in technology adoption. However, without clear parameters for the scope of socio-economic considerations of LMOs within the Cartagena Protocol, Malaysia uses the provision under section 25 of the Biosafety (Approval and Notification) Regulations 2010. The legal experts had great difficulty to include section 25 of the Regulations due to the possibilities of many interpretations of such a provision. It was clear then that this provision will have to be supported by some practical guidelines.

However, to date there are not many countries that have carried out socio-economic analysis for the consideration in the decision making about LMOs. Furthermore, socio-economic in this regard is an area gradually emerging

and will take a long lead time before a proper framework for economic analysis could be established. Thus for the time being, it is likely that socio-economic considerations as is applied in other areas may be adopted as appropriately. In Malaysia, socio-economic considerations may become very important if the plantation industry of the primary commodities like oil palm, rubber, cocoa and others migrate into LMOs options of high productivity or high value added products at some stage. The small holders will then face problems of having to compete with plantations owners in selling their non-LMOs products. However, such problems may be resolved based on current experiences in related sectors.

In Malaysia, dealings with LMOs are mainly related to import of genetically modified (GM) grains. So far the National Biosafety Board (NBB) has approved six types of grains. As these grains will not be able to grow in this country, the possibilities of any socioeconomic problems are quite remote. All approvals on such grain are imposed with appropriate terms and conditions including submitting regular reports of spillage and clear labeling of the product from importation down to all levels of marketing stating that it is only for the purpose of food, feed and processing and is not to be used as planting material. As corn is grown in some parts of Malaysia, growth of spilled GM grains during transportation may pose contamination though the probability is very low. With this present trend it might take a long time before GM plants are released into the environment and as such the emerging issues on socio-economic.





So far Malaysia has not come across any socio-economic situations in the conservation and sustainable use of biodiversity as highlighted by Mackenzie et al. (2003) as the country is still in its infancy in the development of modern biotechnology. However, with the fast developments in biotechnology in other parts of the world, LMOs will continue to come into the country and the biosafety regulatory body in Malaysia will have to be vigilant to minimise impact especially with regard to the value of biological diversity to indigenous and local communities.

The consistently growing socio-economic problems arising from the increasing death cases caused by dengue fever from Yellow Fever Mosquito (*Aedes aegypti*) in Malaysia and in many parts of the world have facilitated the release of genetically modified mosquitoes and other genetically modified products like TMOF (Trypsin Modulating Oostatic Factor) to reduce the population of wild mosquitoes. In both cases, the release could also be supported by the fact that country may partly own the intellectual property right of the innovations.

In order to seek for more inputs on socio-economic consideration, it is important that a wider public consultation is carried out including through surveys. Though sometimes there may be multiple submissions on the same issue, particularly when some championing bodies are driving the submission, it would still be a worthwhile exercise to do as it may be



able to identify a spectrum of issues and views.

It is understandable that due to the nature of the subject, to include socioeconomic considerations in the decision making based on detailed analysis is indeed difficult, time consuming and an expensive job. Parties have their sovereign right to decide what is appropriate to their society based on facts in hand. However decision may be reviewed when new and credible information is made available.

Setting up Socio-Economic Committee under the National Biosafety Board

Malaysia realises that in the future socio-economic issues may play an important role in the decision making on LMOs. As such it was recommended to the NBB that a Socio-Economic Committee is set up similar to the Genetic Modification Advisory Committee as the Biosafety Act provides for such an option. It is important that such a committee be established at the earliest possible time to enable members to build their capacity in this area. However, as socio-economic issues can be very sensitive at times, and based on experiences in other areas such as environment, the NBB decided to set up just an informal advisory group. The Board is now hunting for experts from institutions of higher learning who are experienced in socio-economic analysis and who can be groomed in socio-economic analysis as applied to LMOs. The group when established and fully operational is expected to advise the NBB on request and on a case by case basis.

A synergetic event to the above was the launching of the National Bioethics Council (NBC) of Malaysia under the Ministry of Science, Technology and Innovation in May 2012 with the aim to provide advice, resolve and manage bioethical issues in the country. It was also aimed at promoting ethics in science and technology so that the development would not give



contradicting impact on human and moral values, especially concerning the environment, social, health, culture, laws and religions. The council's main term of reference is mainstreaming bioethics and disseminating information on bioethical issues among people from all walks of life, including scientists. Although its general focus will be on technology applications and issues concerning stem cell, genetically-modified organism, animal testing and synthetic biology, attention would also be given to integrity issues and matters constituting a conflict of interest. The council comprises experts from various disciplines related to bioethics, scientist and non-scientist, policy makers and stakeholders entrusted to collectively study the issues and challenges faced by the country in promoting new technologies. The establishment of National Bioethics Council opens a window for consultation by NBB thus complementing its effort. As this is a new set up, the working mechanism between the NBC and the NBB will have to be periodically reviewed to ensure effectiveness.

Malaysia had its priority right to set up a working legal framework on handling

living modified organisms. The Biosafety Act 2007 has been crafted with a small window on the possibilities of including socio-economic considerations in decision making. Though the Regulations 2010 has expended this consideration further, it seems it is still insufficient to create a framework of parameters for a comprehensive socio-economic analysis. Such being the case reasonable and practical approaches were taken for the inclusion of the same.

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LATEST BIOSAFETY PUBLICATIONS

USER'S GUIDE TO THE BIOSAFETY ACT AND REGULATIONS

The User's Guide provides a clear overall picture of every aspect of the Biosafety Act 2007 and the Regulations to help better understanding and compliance with the requirement of the Act. The Guide includes chapters on each of key aspects of the scheme including activities involving LMO, regulation dealing with LMO, review decision made under the legislation, application fees etc. The Guide was written in user-friendly language and the legal provisions are rendered in non-legalistic and plain English.



BIOSAFETY EDUCATION VIDEO

This video is part of Department of Biosafety's effort to increase public awareness on LMO and biosafety. The video is produced in Malay and English and approximately 18 minutes long. It is divided into 7 chapters including introduction to DNA and modern biotechnology, steps in genetic engineering, risks and benefits of genetic engineering, status of LMO development and the Biosafety Act 2007.



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