Newsletter

Biosafety

vol. 06
October 2014

Special Report:

Status of Notified Contained Use Activities involving GMO in Malaysia

Integrated Enforcement and Monitoring Framework on **Biosafety** Page 06

Table of Contents

Message from
The Chief Editor

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

Welcome to the sixth edition of **The Biosafety Newsletter!**

Malaysia has been playing an active role in the deliberations of important subject matters such as risk assessment and socioeconomic consideration etc. under the Cartagena Protocol on Biosafety since its implementation. I must say that Malaysia has also achieved a significant progress in regard to having in place a comprehensive legal framework and operationalizing it.

On 11 September 2013, the world community has marked the tenth anniversary of the entry into force of the Protocol. In conjunction with this, we have organized some activities including an exhibition during the Workshop on Biotechnology Commercialization and Trade in APEC Economies – Biosafety Regulatory Perspective in September 2013 to portray Malaysia's achievement in the area of biosafety.

In the previous Biosafety Newsletter issue, we made a special coverage on self-regulatory mechanism through Institutional Biosafety Committee (IBC). To date, 34 IBCs had registered with the National Biosafety Board. In this issue, we report progress on notification for contained use activities. As of 30 June 2014, the National Biosafety Board has approved 47 contained use activities involving LMO happening in 17 institutions. More applications are expected in the future as these number accounts for only half of registered IBCs. The Department is always ready to help any institutions that are having difficulty in making a submission for notification. I also wish to highlight that the IBC reports are very important documents to the Department for monitoring purposes and to identify ways to help the IBC function better.

From a regulator point of view, having a national legal framework on biosafety is not enough. Even more important is to have the capacity to do a comprehensive risk assessment and risk management. As modern biotechnology and biosafety are relatively new to us, our experts must be given continuous training as well as exposure to interdisciplinary requirements. If we want sound biosafety to be in place we should enforce proper biosafety standards. Thus, researchers involved in modern biotechnology are encourage to also factor in biosafety components in their request for funding. This is important since biosafety data including risk assessment and risk management is vital in the considerations for commercialization of LMOs.

Biosafety, Always Our Priority!

Special Report

Status of Notified Contained Use Activities involving Genetically Modified Organism (GMO) in Malaysia.

Since the Biosafety Act 2007 was enforced on 1 December 2009, various capacity building and public awareness activities have been carried out at national and institutional level throughout Malaysia. Efforts taken by the Department of Biosafety to create awareness and increase knowledge on biosafety practices, implementation of the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 have started to pay off as this can be seen by the significant increase in the number of notifications for contained use activity received by the Department over the past few years as shown in Figure 1.

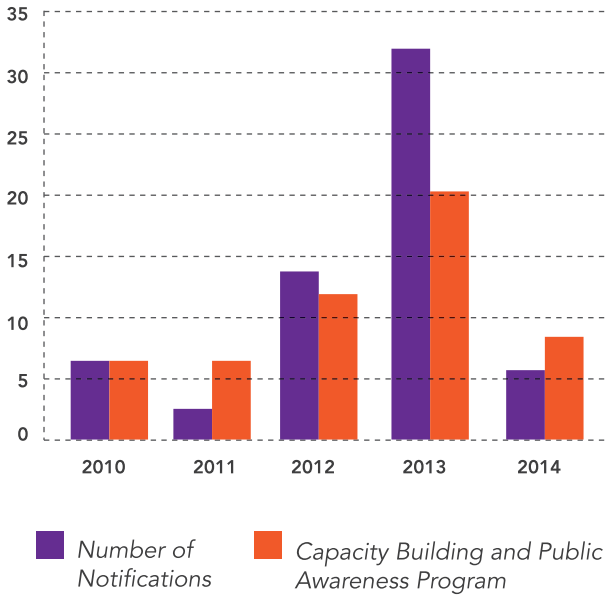


Figure 1: Notified Contained use activities of Genetically Modified Organisms in Malaysia

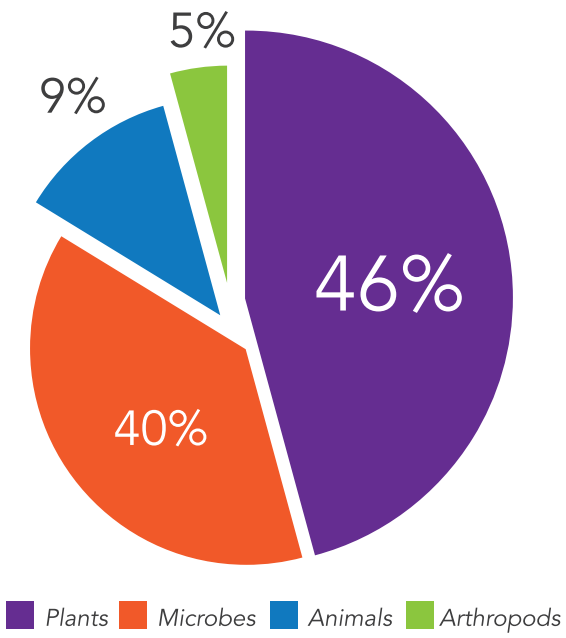


Figure 2: Classification of GMOs in the contained use activities Notifications received by the Department of Biosafety

A total of 58 notifications have been received and processed by the Department from December 2010 until July 2014. There were 27 research activities involving plants, 23 research activities involving microorganisms, 5 research activities involving animals and 3 research activities involving arthropods. The percentages are shown in Figure 2.

Biosafety Level	Number of research activities
Biosafety Level 1 (BSL1)	20
Biosafety Level 2 (BSL2)	38

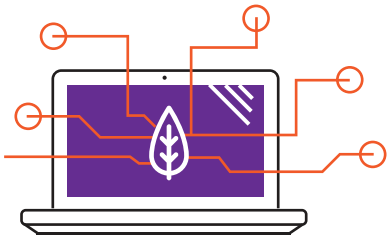
Table 1: Biosafety Level of contained use research activities involving GMOs

So far the Department has not received any application for contained use activities involving GMO under BSL3 category.

Several monitoring and inspection visits have been conducted to ensure these facilities comply with the requirements of Biosafety Level as classified. The visits to these facilities involved officers from the Department, members of the Genetic Modification Advisory Committee (GMAC) and Sub-committee on Monitoring under GMAC.

Even though the number of notification has increased over the years, the Department is still committed to carry out training and awareness activities on biosafety. These activities are mainly targeting students, researchers and lecturers at the universities, research institutions and private companies that deal with GMO.

Integrated Enforcement and Monitoring Framework on Biosafety



The Department of Biosafety through its Monitoring and Enforcement Section is responsible to ensure all activities involving genetically modified organism (GMO) in Malaysia are in compliance with the Biosafety Act 2007. The Department together with relevant agencies and Sub-committee on Monitoring under The Genetic Modification Advisory Committee (GMAC) carry out monitoring and enforcement activities throughout the year. Among the agencies that involved are the Department of Malaysian Quarantine and Inspection Services (MAQIS), Department of Agriculture, Ministry of Health and Department of Chemistry.

In order to create an effective enforcement mechanism with all these agencies, the activities carried out are categorized as:

i) Inspection and monitoring at points of entry e.g. port for vessel;
ii) Field inspection and monitoring at farms and markets for food and agricultural products;
iii) Monitoring the facilities that are carrying out GMO related activities

The Department is working closely with MAQIS for inspection and sampling activities on GMO products that are carried out at maritime border (seaports). Currently, these activities are mainly focus at the Northport and Westport of Port Klang, Johor Port in Pasir Gudang and Penang Port (Butterworth Container Terminal/Dermaga Ayer Dalam). The major dry bulk imports that are passing through Port Klang are fertiliser, wheat, sugar, maize, soya bean and feed meal. At the port, sample of trade commodities such as maize, soybeans, rice and wheat will be taken to detect if it is a GMO. If needed, these samples will be sent to the Department of Chemistry for further analysis. The monitoring and inspection activities are also focus at Malaysia-Thailand border points of entry e.g. Rantau Panjang and Pengkalan Kubor where by sample of fresh vegetables and fruits that are coming from Thailand will be taken.

Inspection of the grain consignment at Port Klang (Westport) by MAQIS enforcement officers.

GM grain analysis with Quick Comb Kit done by MAQIS – taken in Port Klang (Westport)

Samples of vegetables and fruits collected at Rantau Panjang and Pengkalan Kubor Custom & Immigration Quarantine Complex (CIQ)

Monitoring activities at supermarkets/wet markets (e.g. Pasar Borong Selangor), have been carried out starting this year. It is an extension to the on-going inspection activities on farms e.g. in Cameron Highlands that has started in 2011 with the help from the Department of Agriculture. All samples taken from these activities were sent to the Department of Chemistry for analysis.

The monitoring activities on research facilities are equally important particularly those facilities that had been approved by the National Biosafety Board to ensure compliance with the terms and conditions imposed. These activities also involve technical experts from the Sub-committee on Monitoring under GMAC.

> The monitoring activities on **research facilities are equally important**

Inspection activities to the research facilities.

As a strategy to strengthen the current enforcement, the Department is in the process to develop an enforcement matrix that will provide guidance to various regulatory agencies involved in regulating modern biotechnology activities in Malaysia. It will spell out their regulatory roles and responsibilities. This matrix will also facilitate coordination and the exchange of information and expertise on biosafety. The inter-agency meeting to discuss about this matrix was held in July 2013.

Despite all the efforts that had been done so far, much focus are still needed on enforcement aspect for effective implementation of the Biosafety Act.

Inter-agency meeting to discuss the enforcement matrix

Capacity Building Activities

Title :
Biosafety Training Workshop

Date & Venue :
21-22 August 2013 - Malaysian Nuclear Agency
18-19 September 2013 - Universiti Malaysia Terengganu
26 November 2013 - ACGT Sdn. Bhd.
16-17 April 2014 - Monash University Malaysia

The Department of Biosafety jointly organized the Biosafety Training Workshop with Malaysian Nuclear Agency, Universiti Malaysia Terengganu, ACGT Sdn. Bhd., and Monash University Malaysia during the period of August 2013 to April 2014. The main objective of the workshop is to create awareness among the researchers, lecturers and laboratory personnel on the biosafety regulatory framework and some good laboratory practices when dealing with Living Modified Organisms (LMOs). The workshops are designed in an interactive way with the aims to stimulate thinking and encourage two ways communication.

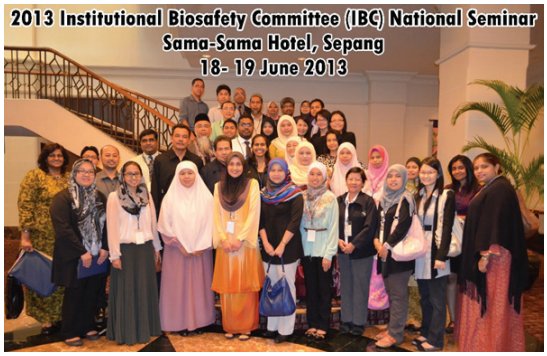
Capacity Building Activities

ii

Title :
2013 Institutional Biosafety Committee (IBC) National Seminar

Date & Venue :
18-19 June 2013 - Sama-Sama Hotel, KLIA Sepang

This annual Institutional Biosafety Committee (IBC) seminar aimed to provide further guidance and updates on biosafety as well as to create a healthy networking among the IBC members. At the same time, the seminar is an eye opener for research institutes carrying out research activities involving LMOs and in the process of setting up their IBC. A total of 40 participants representing 21 IBCs attended the seminar.



"40 participants representing 21 IBCs"

Capacity Building Activities

iii

Title :
Workshop on Biotechnology Commercialization and Trade in APEC Economies – Biosafety Regulatory Perspective

Date & Venue :
4-6 September 2013 - Le Meridien, Kuala Lumpur

The Department of Biosafety and Malaysian Biotechnology Corporation Sdn. Bhd. jointly organized this workshop with financial support from APEC. It was intended as a platform for participants to share knowledge and experience on issues related to regulatory aspects of biosafety, particularly in the commercialization of modern biotechnology research.

In conjunction with the workshop, Department of Biosafety launched the Malaysian Biosafety Handbook which contains 6 biosafety guidelines developed through the Capacity Building Project on Biosafety NRE-UNDP-GEF. The workshop was officiated by YB. Dato' Sri Dr. James Dawos Mamit, Deputy Minister of Natural Resources and Environment. A total of 75 participants attended the workshop consisting of representatives from government agencies, private sector, universities and representatives from several APEC countries.

Capacity Building Activities

iv

Title :
Biosafety Clearing House Training Workshop

Date & Venue :
9 July 2013 - International Medical University, Kuala Lumpur

The Department of Biosafety and International Medical University (IMU) jointly organized this workshop. This one day workshop attempts to provide awareness among the IMU's staff and student about the importance of Biosafety Clearing House (BCH) portal as a source of reference to LMOs information. Demonstration was given on how to register records and searching for information related to LMOs in the BCH.

v

Title :
GMO Detection Training for Bhutan's Officials

Date & Venue :
24 March-4 April 2014 - Department of Chemistry, Petaling Jaya

The increased capacity of Malaysia in biosafety has been noted by other countries that are in the process of developing their biosafety frameworks. In April this year, the Department of Chemistry conducted a training workshop specifically to officials from Bhutan on GMO detection. The training was divided into 3 phases. First phase was to expose the officials with Malaysia's biosafety regulatory framework. Second phase focused on sharing Malaysia's experience on how GMO detection is done at the port. For the final phase, the officials were trained to conduct a qualitative screening of the GMO samples for further verification in determining the type of GM event detected.

"demonstration was given on how to register records and searching for information"

Public Awareness, Education & Participation Activities

Title :
Biosafety Awareness Programs and Activities

Date & Venue :
6-8 June 2013 - Exhibition at National Biotech Seminar 2013, Pulau Pinang
29 September 2013 - Road show at River of Life Public Outreach Program (ROL-POP), SMK Taman Melawati,KL
26-27 October 2013 - Road show at Malaysia Environment Week, Putrajaya
28 November 2013 - TV Show at Hello on Two, RTM 2
5-7 May 2014 - Exhibition at BioBorneo 2014, Universiti Malaysia Sarawak

During the reporting period, the Department took part in several biotechnology and environmental awareness programmes that were organized nationwide. These include 2 road shows with local residents of Sekolah Menengah Kebangsaan Taman Melawati in Kuala Lumpur and during the Malaysia Environment Week 2014 in Putrajaya. The Department's objective in taking part with this kind of events was to educate and create awareness among the public about biosafety and how they can participate in the decision making process.

The Department was also involved in exhibitions during the National Biotech Seminar 2013 in Pulau Pinang on 6-8 June 2013 and BioBorneo 2014 in Kota Samarahan, Sarawak on 5-7 May 2014. As both event were targeted to researchers, the Department created awareness on the need to comply with the Biosafety Act.

The Department also recognized mainstream media as an important platform to promote awareness. For this reason, the Director General of Biosafety and Chairman of GMAC appeared live on television for RTM 2's Hello on Two show on 28 November 2013 to discuss about GMOs and biosafety.

National Biotech Seminar 2013, Pulau Pinang

River of Life Public Outreach Program (ROL-POP), Sekolah Menengah Kebangsaan Taman Melawati

Malaysia Environment Week, Putrajaya

TV Show at Hello on Two, RTM 2

BioBorneo 2014, Universiti Malaysia Sarawak

Participation in International
Meetings/workshops

01 Ad Hoc Technical Expert Group (AHTEG) Meeting on Socioeconomic Considerations
Seoul, Korea, 17-21 February 2014

The meeting of the AHTEG on Socio-economic can siderafons was attended by 27 experts from 23 countries and relevant international organizations. Participants were invited to share their views and propose elements which they believed would contribute to achieving conceptual clarity on socio-economic considerations. Accordingly, each participant made suggestions of elements which was later compiled and made available for discussion by the group. The compilation that was prepared included sections on general principles, methodologies and points to consider.

During the discussions, some participants expressed the need for clarifying the relationship between risk assessment and socio-economic considerations and the extent to which human health-related issues could be addressed as socio-economic considerations. Some participants emphasized the importance of identifying provisions from international agreements that were relevant to socio-economic considerations in decision-making on living modified organisms.

Full report of the meeting can be accessed at
http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=5336

02 FAO Technical Consultation on Low Levels of GM Crops in International Food and Feed Trade
Rome, Italy, 20-21 Mac 2014

The Technical Consultation was open to all Food and Agriculture Organization of The United Nations (FAO) Members and Observers and was attended by a total of 220 people. The participants included 201 delegation members from 90 countries, 10 observers, 4 intergovernmental organization participants and 5 external speakers, as well as several FAO staff members. The overall objective of the Consultation was to facilitate international discussion among FAO Members on low levels of genetically modified (GM) crops in international food and feed trade. The results of the FAO technical analyses on the topic were prepared for presentation and discussion. The scope of the Consultation was technical and exploratory, providing a forum for experts to present the results of their research findings on the issue.

It is the prerogative of participating FAO Members to utilize the findings for relevant national policies, regulations and guidelines. The Consultation was not intended to make recommendations on any decisions or policies that national authorities might make under their own legislative framework. The FAO Technical Consultation was designed to contribute to: i) Raising awareness of the issue of low levels of GM crops in food and feed, and associated factors, and possible impacts on food security; and ii) Improving the understanding and recognition of various points of view of the issue from relevant stakeholders.

Relevant documents for this consultation is available at
http://www.fao.org/food/food-safety-quality/a-z-index/biotechnology/LL/en/

Participation in International
Meetings/workshops

03

Workshop of the Network of Laboratories for the Detection and Identification of Living Modified Organisms
Ispra, Italy, 25-27 November 2013

The specific objectives of the workshop were to develop: a) a detailed implementation strategy for the detection and identification of LMOs consisting of a plan of action to assist Parties in making progress toward the outcomes of the Strategic Plan; and b) a set of recommendations identifying possible key players and specific activities to assist in the implementation of the plan of action in (a).

The workshop was attended by 24 participants from 22 countries as well as four observers from organizations [Global Industry Coalition (GIC), GenØk - Centre for Biosafety, and International Seed Testing Association (ISTA)].

The workshop started with an overview of the Protocol's provisions and recent developments related to the detection and identification of LMOs. Then followed by presentations made by participants on issues that are relevant to the detection and identification of LMOs, with a focus on the exchange of experience and challenges in detecting unauthorized and/or unintentionally released LMOs and gaps in current methodologies in order to establish a basis for discussions.

Full report of the meeting can be accessed at
http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=5324

04

3rd UNEP-KBCH Asian Regional Workshop on Biosafety Clearing House
Siem Reap, Cambodia, 18-20 November 2013

Korea Biosafety Clearing House together with the United Nations Environment Programme (UNEP) and Cambodia's Ministry of Environment, held the 3rd UNEP-KBCH Biosafety Clearing House Asia Regional Workshop in Siem Reap, Cambodia. The workshop was attended by a total of 36 participants from 13 countries.

They discussed ways for providing, maintaining and sharing of LMO-related information of each country, as well as the means for sharing the current status on Public Awareness, Education and Participation, and resolving the challenges that countries face, together with plans for further development.

Participants presented the difficulties they faced in promoting public awareness on LMO and biosafety, cooperation with domestic institutions, and evaluation and monitoring for implementation of the Protocol. They also emphasized the need for inter-regional cooperation, to facilitate sharing and learning from each of their experiences.

A consensus was formed among participants, that in order to promote public awareness and educational campaigns, countries need to make use of national policies and programs on biosafety issues, information and other educational material, simplified data on biosafety and biotechnology, and social media.

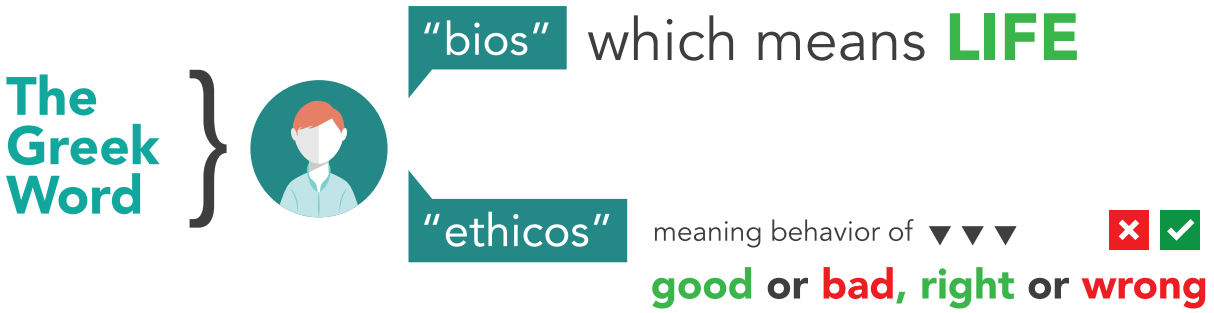
Feature Articles:

01 Bioethics in the Implementation of the Biosafety Act 2007

Ethics is simply about what we ought or ought not to do. Bioethics is one branch of ethics and was coined in 1926 by Fritz Jahr. It is derived from the Greek word "bios" which means life and the word "ethicos" meaning behavior of good or bad, right or wrong. According to the Universal Declaration on Bioethics and Human Rights 2006 by UNESCO, bioethics is a complex field of study as it involves various disciplines. It covers questions on moral values, theories and practicality. It is applied on medical and life sciences as well as relationship between human and biosphere (ecosystems) - refer to Box 1. Just because something is technically possible does not mean that it should be done. So, where then do we draw the line? Bioethics helps to determine these boundaries.

Biotechnology offers great benefits and has vast potential to be an engine of growth in Malaysia. However, it must be guided by biosafety and bioethics. This is clearly spelt out in the National Biotechnology Policy Statement 2005 - "Innovation to create wealth by utilizing and advancing biotechnology for socio-economic benefits of the nation in accordance with established social and ethical norms". It is important to consider bioethical, legal and social issues raised through any novel advancements in biotechnology from an early stage. Society can play a role to evaluate policies and regulate the development of these advancements in biotechnology through an ethical analysis. This is a systematic approach for society to figure out the right moral decision by providing society with a good understanding of the science and information behind biotechnology.

Bioethics serves as a barometer of acceptance, resistance, or apathy towards new advancements in biotechnology. It is important for society to have a say in a decision making process involving environmental matters on the basis that greater public awareness and involvement implies improvement in environmental protection. Ignorance to the incorporation of bioethics might be detrimental to the progress of biotechnology. Some fundamental principles on bioethics are stated in this Universal Declaration on Bioethics and Human Rights to provide guidance on developing rules that emphasize respect for human dignity, human rights and fundamental freedoms. A baseline is set that all human beings possess equal rights, and should be given a chance to exercise their freedom to choose (autonomy).



Under the Universal Declaration on Bioethics and Human Rights, there are five bioethics principles that are closely related to the implementation of the Biosafety Act as shown below:

Five Bioethics Principles

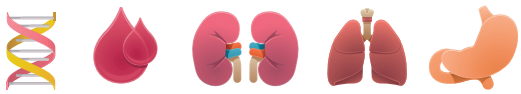
	BIOETHICS PRINCIPLES	UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS	BIOSAFETY ACT 2007
I	Protection of Environment	Human beings play a role in the protection of the environment, the biosphere and biodiversity (Article 17)	Objective of the Act is to protect human, plant and animal health, the environment and biological diversity
II	Autonomy in Decision	Autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others (Article 5)	• National Biosafety Board makes own decisions based on local scenario, not merely emulating decisions by other countries • Mandatory labeling is required for all Living Modified Organisms (LMOs), items containing LMOs, and products of such organism (s.61). This is to ensure consumer choice.
III	Risk Assessment and Management	Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted (Article 20)	• It is mandatory to submit risk assessment & risk management report for getting approval of any modern biotechnology activities. • Any persons conducting modern biotechnology activities must comply with the minimum risk mitigation measures determined by the National Biosafety Board (s13)
IV	Public Engagement	• Transparency in decision making • Appropriate sharing of knowledge • Seeking expression of all relevant opinions (Article 18)	• Information regarding applications/decisions are disclosed for public view (s60) • It is mandatory to conduct a public consultation in decision making for release of LMOs and its products (s14c)
V	Respect of Human Vulnerability/Personal Integrity	In applying/advancing scientific knowledge, individuals/groups of special vulnerability should be protected and the personal integrity of such individuals respected (Article 8)	Socio-economic considerations may be taken into account when making decisions on application for approval or notifications (s35) including consideration that may affect the indigenous people

Due to the unique implications of activities involving modern biotechnology, bioethics consideration is fundamental in the implementation, promotion and regulation of modern biotechnology. Identification of common grounds is important to find standards that might be acceptable in local bioethics consideration by engaging society as well as stakeholders. It is sometimes said that science moves so quickly that bioethics has difficulty in keeping up. In view of that, on 9 July 2010 the Government of Malaysia established the National Bioethics Council of Malaysia (Majlis Bioetika Negara) to play a role as an advisory panel that discusses and resolves bioethical issues that may have an impact concerning the environment, social, health, culture, laws and religions and Malaysian society in general.

In conclusion, application of bioethics principles is important for the development and acceptance of modern biotechnology from our society. Therefore it has been aptly incorporated through the implementation of the Biosafety Act 2007.

Box 1: Some examples of issues commonly discussed related to bioethics.
Source: Educating Bioethics Committees: Guide No.3. 2007. Paris: UNESCO.

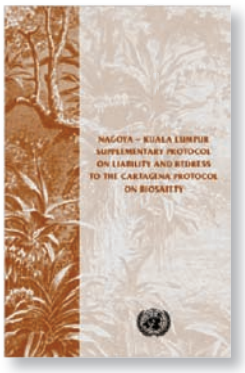
a) Human Procreation - natural and artificial.
b) Commodification of human organs, tissues, cells
c) Unrestrained scientific freedom leading to innovations that may harm future generations.
d) Biotechnologies serving non-beneficial ends.
e) Genetic enhancements - 'perfect babies', 'youthfulness/agelessness'
f) Implications of limiting biological research.
g) Providing equitable access to new biotechnologies.



Commodification of } **Human Organs Tissues Cells**

02 The Formulation of Low Level Presence Policy

Malaysia has identified biotechnology as one of the new income sources of the nation and envisioned it as the engine of growth for knowledge based economy. Being a megabiodiverse country, Malaysia also has great concern to ensure that the nation's biological resources are well safeguarded. The National Policy on Biological Diversity 1998 which calls for the sustainable utilization of biological resources among others through biotechnology. This was further augmented with the establishment of the National Biotechnology Policy in 2005. This Policy provides a conducive environment for research and development (R&D) and industry growth through leveraging on country's existing strength and capabilities.



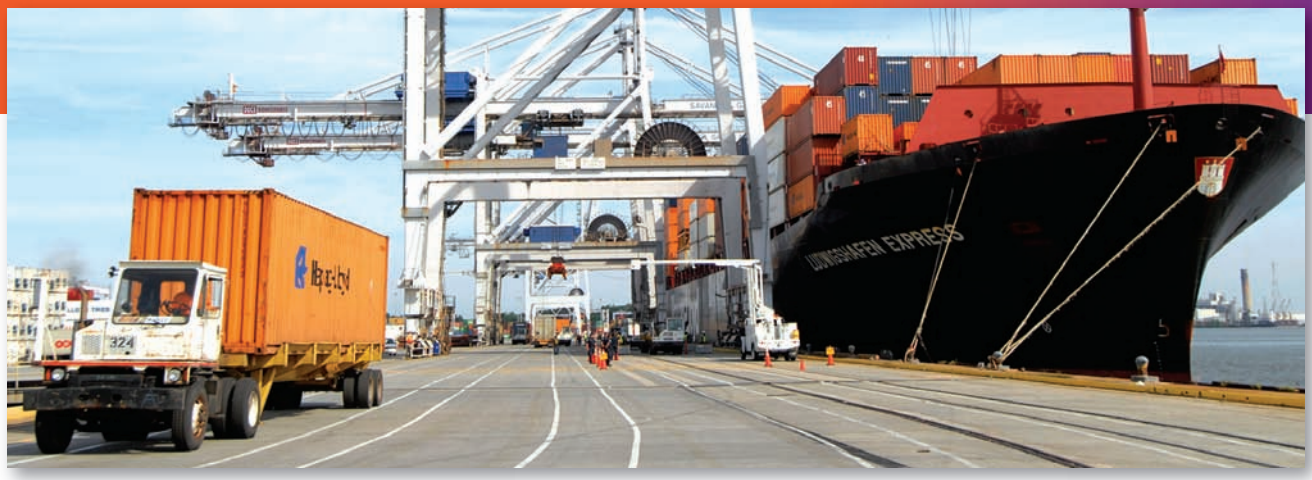
However, the emergence of living modified organism (LMO) through modern biotechnology has led to concerns about its potential harmful effects on the environment and human health. These concerns were addressed through the Convention on Biological Diversity, which provided a framework to negotiate the Cartagena Protocol on Biosafety (CPB), which regulates international transboundry movement of LMO. CPB was adopted on 29 January 2000 and aims to ensure the potential adverse impact of modern biotechnology is minimized and managed in a manner that does not have a negative impact on biodiversity and human health. Since its adoption, the Protocol has received remarkable support and steady progress in its implementation. The number of parties to the Protocol continues to grow, and currently stands at 167. Malaysia signed the Protocol on 24 May 2000 and subsequently ratified it on 3 September 2003. In October 2010, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress was adopted to supplement the CPB. The Supplementary Protocol specifies the measures that need to be taken in response to damage resulting from LMO that find their origin in a transboundary movement.

At the national front, the Biosafety Act 2007 (the Act) was passed by Parliament on 11 July 2007. The Act came into force on 1 December 2009 while the Biosafety (Approval and Notification) Regulations 2010 came into force on 1 November 2010 to implement the Act. Together they represent a national scheme for the regulation of LMO and products of LMO. As of 30 June 2014, 11 applications for import for release of genetically modified (GM) products for the purpose of food, animal feed and processing have been approved under the Act.

However, Malaysia at the moment does not have a policy to handle unintended, low levels of unauthorized GM materials that could be found in imported grain, food and feed products. These materials could have been authorized for commercial use or sale in one or more countries but not in Malaysia, being a country of import. There are number of factors that contribute to comingling: pollen flow; mixing during harvesting, transport, storage and processing; human error; and accidents. This is known as low level presence or adventitious presence. While low level presence can be minimized, in pratice it cannot be eliminated entirely and is not unique to crops enhanced through biotechnology. As a result, allowances for low level presence have been recognized in laws, regulations and standards.

Under the current regulatory approach, any presence of an unauthorized GM product in the Malaysian marketplace is considered "regulatory non-compliance". Therefore, grain or seed shipments that contain even trace amounts of a GM product unauthorized in Malaysia would be considered non-compliance and this triggers a risk assessment of the low level presence situation.

The intent of the risk assessment is to examine the risk to the food and feed supply and the environment. The risk management process uses this risk assessment, along with other factors, to determine the most appropriate level of intervention required to make the situation compliant with the regulations.



This would require developers either to have their GM product approved in Malaysia or to put measures in place to remove the product from the marketplace and the environment. In these situations, even if a risk assessment shows that the product is not likely to pose a risk to health and safety, the developer is required to be in compliance.

With the increasing number of GM products being developed globally for commercial production, low-level presence is unavoidable. A growing number of countries have established risk assessment procedures for approving the import of biotech crops and their derivatives. However, many of these countries have not, as yet, adapted processes to address the potential low level presence in their imports of GM material already authorized and produced in other countries, but not yet approved (and therefore not intended to be present) in the importing country. This gap has the potential to cause significant trade disruptions, as well as place significant burdens on the importing country's authorities when such presence is detected. The situation will only become more prevalent as more and more new biotech plants are developed and enter into market at different rates in different countries.

In this context, the exact levels of acceptable LLP tolerances must be decided within individual countries. The setting of tolerances therefore implies a weighing of risk and economic considerations. Higher LLP tolerances can limit trade disruptions and associated economic costs but may be viable only when no significant food, feed or environmental safety concerns exist. Lower tolerances imply higher costs as segregation becomes more costly and trade disruption more likely. The systematic evaluation of the potential economic impacts of alternative LLP policies is therefore an important part of national LLP risk management strategies.

As LLP policy is crucial to keep food, feed and the environment safe, while providing transparency and predictability for imports and minimizing disruptions to trade, it is timely for Malaysia to formulate a policy and assess every practical approach for managing low-level presence.

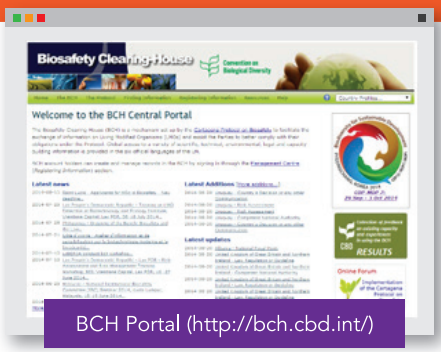
03 Biosafety Clearing House (BCH): A Central Information Marketplace

The Biosafety Clearing-House (BCH) is an information exchange mechanism established by the Cartagena Protocol on Biosafety to assist Parties to implement its provisions and to facilitate sharing of information on, and experience with, living modified organisms (LMOs).

BCH established as part of the clearing-house mechanism of the Convention on Biological Diversity, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs and also to assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

The BCH functions like a "central information marketplace" where the providers and users of biosafety information interact and exchange that information in a transparent manner. To fulfill its role, the BCH has been designed to make finding and providing information as clear and intuitive as possible, for example by providing common formats and standardized terminology (controlled vocabulary). In addition, the BCH website is available in all six UN languages. Governments that are not Parties to the Protocol are also encouraged to contribute appropriate information to the BCH. All information available in the BCH is considered as non-confidential and categories of information available are listed in Table 1.

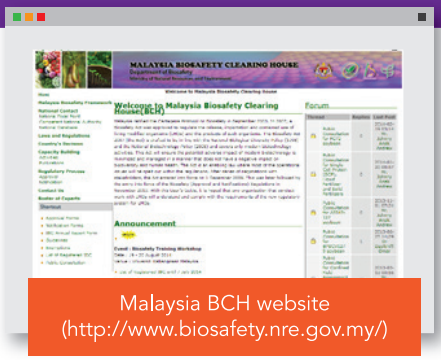
The Importance of the BCH



BCH Portal (http://bch.cbd.int/)

- The BCH assists Parties and other stakeholders in different ways in the implementation of the Protocol. For example, it provides a "one-stop shop" where users can readily access or contribute relevant biosafety-related information. This would assist Governments to make informed decisions regarding the importation or release of LMOs.
- Information in the BCH is owned and updated by the users themselves, thus ensuring its timeliness and accuracy. By allowing easy and open access to key information, the BCH also fosters greater transparency in the implementation of the Protocol and this facilitates effective participation of the public and civil society in the decision-making process.
- The BCH also facilitates scientific and technical cooperation between Parties and other relevant stakeholders, for example by allowing interested stakeholders to access or contribute information on existing biosafety capacity-building activities thus facilitating coordination and synergy between various initiatives.
- For industry and other stakeholders the BCH allows easy access to information vital to their activities, including details of the national contacts, relevant laws and regulations governing LMO activities and the decisions and declarations made by Parties, especially with regard to transboundary movements.

Malaysian Biosafety Clearing House



Malaysia BCH website (http://www.biosafety.nre.gov.my/)

Provides information about –

- Implementation of the Biosafety Act (such as the members of the National Biosafety Board, introduction about the Department of Biosafety, members of the Genetic Modification Advisory Committee, process flow and many others).
- Upcoming activities and events related to biosafety are highlighted such as trainings and public awareness activities.
- Public announcements of applications for release of LMOs or products of LMO to get input from public so that a decision can be made by incorporating public opinion.
- Latest decisions by the National Biosafety Board on any approvals granted.
- Documents that can be downloaded such as the Biosafety Act 2007, Biosafety Regulations 2010, Guidelines and other publications, Biosafety Newsletters, Fact Sheets and decisions of the National Biosafety Board, forms for applications and a lot more.

Table 1: Categories of Information Available in BCH

CATEGORIES	INFORMATION
NATIONAL CONTACTS	• **National focal points (NFPs)** -provides contact details of the NFPs of different Parties. • **National point of contact for receiving notifications regarding unintentional transboundary movements of LMOs**-provides details of contact for receiving notifications pertaining to unintentional transboundary movements of LMOs and emergency measures as required by the Protocol. • **BCH national focal points (BCH-NFPs)**- provides names and addresses of BCH national focal points responsible for maintaining their country's information in the BCH. • **Competent national authorities (CNAs)**- provides names and addresses of Competent National Authorities designated by each Party. CNAs are responsible for performing the administrative functions required by the Protocol, including handling of notifications and communicating to the notifier and to the BCH decisions regarding importation or release of LMOs. • **National databases**- provides links to national databases relevant to the implementation of the Biosafety Protocol.
LAWS AND REGULATIONS	• **National laws, regulations, and guidelines**-provides existing laws, regulations and guidelines for implementation of the Protocol. • **Bilateral, regional and multilateral agreements**- provides bilateral, regional, and multilateral agreements and arrangements of each party for the implementation of the Protocol.
DECISIONS AND DECLARATIONS	• **Decisions on LMOs under Advance Informed Agreement (AIA) procedure** -provides decisions resulting from the implementation of the AIA procedure under the Protocol. • **Decisions on LMOs for direct use as food or feed, or for processing (LMOs-FFP)** - provides information related to final decisions taken by Parties regarding domestic use, including placing on the market, of an LMO-FFP that may be subject to transboundary movement. • **Other decisions & declarations** - provides information pertaining to other decisions and declarations, which are not covered by the two categories outlined above.
RISK ASSESSMENTS	• **Risk assessments** - includes summaries of risk assessments/ environmental reviews of LMOs generated by a regulatory process, including relevant information regarding products thereof (namely, processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology).
UNIQUE IDENTIFICATION	• **Unique Identification**-provides a registry of unique identification classifications as a key to access records in the BCH, such as the OECD's unique identifiers for transgenic plant lines for LMOs-FFP.
CAPACITY-BUILDING	• **Capacity-building opportunities**- provides information on available or upcoming short-term capacity-building opportunities such as: technical assistance, scholarships and fellowships, personnel exchange/internships, scientific and technical cooperation, and others. • **Capacity-building projects and initiatives**: This database was established by the Secretariat to facilitate access to information on various capacity-building projects and other relevant initiatives. Such initiatives are generally long-term (i.e. 6 months or more) and include several activities implemented over a period of time. • **Capacity-building needs and priorities**: This section includes information on national and regional capacity-building needs and priorities for implementing the Protocol, as identified by national governments.
ROSTER OF EXPERTS	• **Experts** - provides access to the roster of experts established by the Conference of the Parties to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of LMOs.
OTHER RESOURCES	• **Relevant sites and tools** - provides links to international and national websites that provide information relevant to biosafety. • **Bibliographic information** - allows users to conduct searches for bibliographic information related to biosafety. • **Downloadable files** - provides downloadable files includes printable forms (such as nomination forms for the roster of experts), biosafety-related documents (such as the Capacity-Building Action Plan), and PDF extracts from the databases that are updated daily (such as lists of focal points and competent national authorities).

LIST OF APPROVED EVENTS AND RELEASE ACTIVITIES
(As of 30 June 2014)

	EVENT/PRODUCT	PURPOSE	APPLICANT
1.	Roundup Ready Soybean GTS-40-3-2	Food, Feed & Processing	Monsanto
2.	Roundup Ready Corn NK603	Food, Feed & Processing	Monsanto
3.	Yieldgard Corn Borer Corn MON 810	Food, Feed & Processing	Monsanto
4.	Rootworm Corn MON 863	Food, Feed & Processing	Monsanto
5.	SYN-Bt11-1 - YieldGard™ Maize	Food, Feed & Processing	Syngenta
6.	ACS-GM5-3 - Herbicide-tolerant Soybean (A2704-12)	Food, Feed & Processing	Bayer
7.	MON 89788 glyphosate tolerant Soybean (Roundup Ready 2 Yield™)	Food, Feed & Processing	Monsanto
8.	T25 Herbicide-tolerant Maize	Food, Feed & Processing	Bayer
9.	TC1507 Herbicide tolerant and insect resistance Maize	Food, Feed & Processing	Du Pont
10.	CV 127 (Imidazolinone-Tolerant) soybean	Food, Feed & Processing	BASF
11.	A5547-127 LibertyLink® (Herbicides-tolerant)	Food, Feed & Processing	Bayer
12.	Ice-Structuring Protein (ISP)	Food	Unilever
13.	Genetically modified carnation, Dianthus caryophyllus L.	Placing on the market	Suntory Holdings Ltd.
14.	GM Mosquito OX513A (My1)	Field Trial	Institute of Medical Research
15.	Confined field evaluation of delayed ripening transgenic Eksotika papaya	Field Trial	MARDI
16.	TMOF Yeast – Mousticide Rice Husk and Mousticide Wettable Powder	Release to environment	EntoGenex Industries Sdn. Bhd.
17.	Single Cell Protein (SCP), Liquid Fertilizer and Solid Fertilizers (co-produced with L-Methionine E.coli KCCM11252P and E.coli KCCM11340P)	Release to environment	CJ Bio Malaysia Sdn. Bhd.

Department of Biosafety
Ministry of Natural Resources and Environment
Level 1, Podium 2
Wisma Sumber Asli, Precinct 4
62574 Putrajaya, Malaysia
Tel : +603 8886 1580 • Fax : +603 8890 4935 • URL : www.biosafety.nre.gov.my
For more information,
please send your queries to biosafety@nre.gov.my