NEWSLETTER

# BIOSAFETY

OFFICIAL NEWSLETTER FOR NRE

ISSUE
07
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# MESSAGE FROM **CHIEF EDITOR**

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

*Welcome* to the **7th** *edition* of the Biosafety Newsletter!

This year marks the fifth year of the implementation of Biosafety Act 2007. After the Act was enforced in December 2009, the National Biosafety Board, the Genetic Modification Advisory Committee, the Department of Biosafety (DOB) and biosafety regulations were established in 2010 to enable the biosafety institutional framework operationalizes in Malaysia. In that 5 years period, biosafety has progressed very well though in some aspects improvement can still be made. The progress became possible because of the success of the Global Environment Facility (GEF) enabling project on biosafety that was carried out from 2008 until 2012.

As a way forward, we will embark into another GEF project entitled "Institutional Capacity to Enhance Biosafety Practices in Malaysia", expected to start by end of this year. This project aims to strengthen the biosafety management system in Malaysia with special emphasis on thematic interventions to facilitate handling and decision making of living modified organisms. The execution of this project is very timely to assist Malaysia in responding to some decisions made during the seventh meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 7) that was held from 29 September - 3 October 2014 in Pyeongchang, South Korea.

To support the project, we also made a request for projects under 11th Malaysian Development Plan. By having biosafety related projects under national development plan, it shows Government's commitment towards biosafety and also our efforts in mainstreaming biosafety into national agenda. We hope both projects will complement each other and successfully further strengthen biosafety capacity in Malaysia. The Department of Biosafety will continue to deliver its best performance to make this happen.

For this edition, we share latest updates including activities that we have organized or participated and some articles that can provide a good insight on current biosafety issues. These include summary of the reports from the studies that we have conducted under the development budget. We also strive to be different in the way we produce the newsletter. Some of the articles in this newsletter were contributed by our own experts and perhaps in our next edition, we would be able to get more experts to contribute.

**BIOSAFETY** "ALWAYS OUR **PRIORITY!**"

# REPORT

## i) Getting to know the 'Form E'

Any person who intends to be involved in modern biotechnology activities such as developing, handling or even importing living modified organisms (LMOs) for contained use needs to get permission from the National Biosafety Board before starting the activity. This permission is obtained by submitting the Form NBB/N/CU/15/Form E or more widely known as the 'Form E' to the Director General of the Department of Biosafety through the Organization's Institutional Biosafety Committee (IBC). The IBC is a formal expert committee that is set up in R&D organizations for the purpose of monitoring modern biotechnology activities and ensuring compliance to the requirements of the Biosafety Act.

<u>The following activities are regulated and require a submission of a Notification through Form E:</u>

- Conducting modern biotechnology activities that are not exempted [List of exempted activities are available in the First Schedule of Biosafety (Approval and Notification) Regulation 2010]
- Conducting R&D (contained use activity) involving developing LMOs
- Importing LMOs for contained use
- Commercially producing the LMO/ using the LMO for commercial production (Non R&D work)

These activities involving LMOs may be conducted in various types of facilities such as laboratories, glass house, growth room etc. This includes all types of containment levels such as BSL1, BSL2, BSL3 and BSL 4. However the same Form E is used for notification of all these types of premises.

<u>Basically, Form E is split into a few sections based on the types of information required:</u>

- **Preliminary Information**
  Basic information should be provided here such as contact details of applicant, the organization and details of importer, if any.

- **Institutional Biosafety Committee (IBC) assessment report**
  This is a compulsory requirement for submission of Form E for R&D work. The IBC will independently assess and make its recommendation for the activity proposed. This section is exempt for non R&D work.

- **Signatures and statutory declaration**
  The statutory declaration is needed to ensure that the applicant and IBC take the necessary precaution and responsibility to provide accurate information in the Form E.

- **Part A : General information of the project team members**
  The people involved and authorized to handle the LMOs should be listed here.

- **Part B : Project introduction to describe the proposed activities**
  A description of the activity, time period to conduct the activity as well as an indication of where the activity will be conducted (if more than one premises involved) is given in this section.

- **Part C : Description of LMO for contained use activities**
  Details about the LMO should be given here such as the name of the parent organism, donor organism, gene of interest etc.

- **Part D : Risk Assessment and Management**
  A risk assessment matrix template is provided to assist the applicant in developing a risk assessment and risk management strategies for the activity. Supporting documents should be provided to justify the assessments. In addition, the applicant is also required to provide Standard Operating Procedures (SOP) for activities such as disposal, decontamination and transportation. The SOP provided should be detailed and in a proper SOP format. An Emergency Response Plan is required to be developed and given in this section.

- **Part E : Details of the premises being used for the confined activities**
  Details of the premises being used are to be given here, such as the address, contact number of the facility manager etc. The applicant may list more than one premises for the activity.

- **Part F : Confidential Business Information (if any) claim**
  Any information given through the submission of the Form E may be claimed as Confidential Business Information (CBI) if it fulfills the criteria that :

  i) it is not known generally
  ii) has commercial value or
  iii) reasonable steps have been taken to keep the information secret.

The applicant is required to provide a justification for the declaration.

- **Part G : List of References**
  Applicant may provide a compilation of references used for the risk assessment or the description of the activity.

A detailed explanation on the required information is provided in the Explanatory notes for Form E which can be found at the reverse side of the form. The information provided in the form will be used to evaluate the activity, risk assessment, risk management and the emergency response plan. Therefore, it is important to provide accurate information that is as comprehensive as existing scientific knowledge would permit, and supported by credible data, where available. If there are any further queries during the assessment process from the Department of Biosafety, the Genetic Modification Advisory Committee or the National Biosafety Board, the applicant will be informed in writing with the specific requests. The National Biosafety Board will issue a decision within 90 working days. However, the Director General may issue a Letter of Acknowledgement for the Form E that is received and the activity may commence after that while the assessment process is going on. There is no payment of fee imposed for submission of Form E.

The Form E and the example of completed Form E can be downloaded through the Malaysia Biosafety Clearing House website :
**http://www.biosafety.nre.gov.my**

## ii ) Institutional Biosafety Committee (IBC) Responsibilities

Institutional Biosafety Committee (IBC) is a formal expert committee of an organization undertaking modern biotechnology R&D which involves use of any LMO/rDNA materials. An organization that establishes a new IBC is required to register such entity with the National Biosafety Board (NBB) as accordance to the subregulation 5(2) of the Biosafety (Approval and Notification) Regulations 2010. This can be done by submitting a complete Form G (NBB/IBC/10/FORM G). Membership composition of the IBC includes IBC Chair, Biological Safety Officer, IBC Secretary, and IBC members. List of registered IBCs can be found at **page 25** of this Newsletter.

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

a. Provide guidance to principal investigator (PI) on biosafety policies and issues in the use of LMO/rDNA research, including safety of laboratory personnel and other members of the organization;
b. Recommend approval for LMO/rDNA research projects that are found to conform to Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and periodically reviewing these research projects;
c. Assess and monitor the facilities, procedures, practices, training and expertise of personnel involved in LMO/rDNA research
d. Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of LMO/rDNA to the NBB;
e. Assess, monitor and set containment levels for LMO/rDNA research for contained use activity undertaken within a facility where the IBC is established;
f. Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient;
g. Adopt and implement emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research;
h. Review and report to the Head of the organisation and to the NBB any significant problems with non-compliance of the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses;
i. Ensure the information provided in the relevant application form (Approval/Notification) is correct and complete before submitting to Department of Biosafety;
j. Establish and monitor the implementation of policies and procedures for the purpose of handling living modified organisms; and
k. Submit a complete IBC Annual Report yearly to NBB via email biosafety@nre.gov.my.

| Year | Number of registered IBCs | IBC Reports submitted |
|---|---|---|
| 2011 | 20 | 19 (95%) |
| 2012 | 26 | 22 (84.6%) |
| 2013 | 32 | 29 (90.6%) |
| 2014 | 34 | 27 (79.4%) |

Table 1: IBC Reports submitted from year 2011-2014

In summary, IBC facilitates NBB in ensuring R&D based institutions comply to the Biosafety Act and Biosafety Regulations when dealing with modern biotechnology activities. All relevant forms i.e. Form G, IBC Annual Report, IBC Assessment of Project Proposal Involving Modern Biotechnology Activities, IBC Incident Reporting Form, IBC Occupational Disease / Exposure Investigation Form, IBC-Project Extension and Notice of Termination including the list of registered IBCs are made available and can be downloaded from the Malaysia Biosafety Clearing House Website at :
**http://www.biosafety.nre.gov.my**

## iii) Study on the Establishment of a Regulatory Framework for Liability and Redress for Damage Caused by LMO

Article 27 of the Cartagena Protocol on Biosafety (CPB) provides for further negotiations to develop rules on liability for damage that may result from the transboundary movement of living modified organisms (LMOs). This resulted in the adoption of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB (NKL SP) on 15 October 2011. The NKL SP establishes international rules and procedures to address response measures in the event of damage or sufficient likelihood of damage to the conservation and sustainable use of biological diversity resulting from LMOs that find their origin in transboundary movements. Pursuant to that, a study was conducted by the Centre of Excellence for Biodiversity Law (CEBLAW) with the aim to suggest viable options for the establishment of a regulatory framework for liability and redress for damage caused by LMOs in Malaysia, in fulfilment of Malaysia's obligations under the NKL SP.

The study began by setting out Malaysia's obligations under the NKL SP as they relate to the development of such a regulatory framework. An assessment and gap analysis of the existing statute and common law in Malaysia were carried out, in order to determine the extent to which the current law is capable of addressing damage caused by LMOs in the manner required by the NKL SP as well as to identify any gaps in the current law. It then set out the substantive legal issues that need to be addressed by any such regulatory framework, and provides an overview of the manner in which these issues have been dealt with by existing liability and redress frameworks in jurisdictions. The study was concluded by presenting several options for implementing a regulatory framework for liability and redress for damage caused by LMOs within Malaysia's existing legal framework, highlighting the advantages and drawbacks of each.

Three consultations have been conducted respectively with the federal government departments and agencies on 13 January 2015; the Sabah Government on 23 January 2015; and Sarawak Government on 19 March 2015. A total of 12 government agencies and NGOs have provided their written comments to the draft study. Final report of the study has taken into consideration, and addressed these comments.

Based on the findings, currently there is no existing statute, including the Biosafety Act 2007, that contains any provisions dealing specifically with civil liability for damage resulting from LMOs. This excludes the possibility of implementing such a regime through regulations or other subsidiary legislation made under any of these statutes. For this reason, there are currently two main avenues open to Malaysia in implementing such a regime. The first is through appropriate legislative amendments made to the Biosafety Act, in dealing with the issues outlined above. The second is through the enactment of a new statute, focusing solely on liability and redress for damages caused by LMOs. As the first option involves less legislative time compared to the second possibility, thus the first choice is preferred. The first option would also benefit in consolidating all statutory provisions relating to the risks and damage arising from LMOs into a single Act.

Regardless of the method through which a legal framework for liability and redress for damage caused by LMOs is implemented, such a regime should clearly set out the damages that are recoverable, which might include damage to the environment or to biodiversity as well as damage of a socio-economic and cultural nature. Where damage to the environment or to biodiversity is included, a method for calculating the compensation recoverable - such as by reference to the costs of reinstatement or rehabilitation - should be set out, given the difficulty of assessing such damage on a monetary basis. The standard of liability applicable should be strict rather than fault-based, bearing in mind the difficulty of establishing fault in such cases; this would also be consistent with the position adopted by most of the countries whose legal frameworks for redress and liability have been surveyed, as well as the position prevailing in Malaysian in relation to nuclear damage under the Atomic Energy Licensing Act 1984.

The regime should also identify clearly the parties to whom liability will be channelled, in particular the producer or developer of the LMO in question. Bearing in mind the difficulties of establishing causation and the possibility that multiple parties might be responsible for the same damage, it might be advisable to also provide for joint and several liability, which would allow claimants to recover full compensation from only one party, as well as presumptions that would have the effect of relaxing the burden of proof borne by claimants. The parties who are entitled to bring claims for such damage should also be clearly identified; in particular, given the diverse nature of damage to the environment, it might be advisable to specify that claims in respect of such damage may be brought by the Government of Malaysia or the relevant State Government, and possibly by individuals or organizations acting in the public interest.

As any damage caused by LMOs may take a long period of time to manifest, it would be advisable for the regime to provide for a limitation period that is calculated on the basis of the date on which the claimant could reasonably have become aware of the damage, rather than the date on which the damage itself occurred. In relation to the provision of financial security, it is suggested that a compensation fund along the lines of that provided for under the Biosafety Act be established. This might be coupled with a provision requiring applicants under the Biosafety Act to secure and maintain the appropriate insurance, though some research into the availability of such insurance in the market will be necessary to ensure that this is practicable.

## iv) A Baseline Study on the Germination Rate of GM Corn and GM Soya Seeds that are Imported Into Malaysia for the Purpose of Food, Feed and Processing

Malaysia currently imports substantial amount of genetically modified corn and soya bean for the purpose of food, feed and processing (FPP). While some of these genetically modified grains' imports were approved by the National Biosafety Board (NBB), nevertheless some enters our shores without prior consent. However, to date, none are approved for planting. During the inland transportation of these GM seeds and grains, spillage can occur, and the spilled seeds may germinate and grow into feral GM plants. The seed producers maintain that all imported seeds and grains are heat treated prior to leaving the country of origin, and thus the viability and likelihood of germination are very low.

This study was proposed to investigate the viability of these imported seeds, evaluate the likelihood of feral population of GM plants, and assess the risk of genetic contamination of the environment. It was found that imported corn kernels and soya bean seeds in general are highly viable and are able to germinate. This applies to both GM and non-GM varieties. Certain countries imposed restrictions on seed imports, whereby all grains and seeds are required to undergo a deactivation process to reduce the viability to near zero. An example is deactivation by mechanical crushing. Deactivation however, increase the cost of seed imports. Thus, while this study indicates that imported corn kernels and soya bean seeds can retain a high degree of viability and germinates well, deactivation is only recommended if the additional cost is minimal.

Spilled GM corn kernels can germinate and grow, while there is no observation of GM soya bean growing. While spilled corn kernels are able to grow and become established, the risk to the environment is minimal due to the short life span of corn, the inability of corn seeds to self-disseminate, and the fact that corn is not a popular crop in Malaysia and is seldom grown on a large scale. Furthermore, such feral plants are usually found near major transportation roads, where non-GM corn is not likely to be planted. GM corn however can persist in the environment through the propagation of small plots due to ignorance, and from repeated cycles of spill and growth.

**Thus the study recommended the followings:**

i. Seed deactivation is the best method to mitigate all risks arising from unintended spillage and growth. However, this is not recommended as it will incur extra costs.

ii. The current practice where immediate clean up and reporting is required for spilled grains and seeds should be maintained. It is unclear, legally, which party should be responsible for this.

iii. A dialogue can be held with transport companies to discuss and implement practical steps to prevent spillage during loading, transport and unloading.

iv. While the risk of genetic contamination by feral corn populations is small, in line with the precautionary principle, it is nevertheless prudent to prevent such feral population from flowering and seed setting. This can be effectively achieved by monitoring the major exit route of landing ports and cutting down volunteers on a regular basis.

v. Similar preventive measures can also be applied to the vicinity of factories and livestock farms receiving the grains. An initial survey can be conducted to establish if spilled seeds and feral populations are present, after which the owners can be advised appropriately.

vi. The current practice of clearly labeling of all GM seeds and grains should be maintained. The message that these seeds and grains should not be used for planting should be emphasized.

vii. An awareness campaign can be organized to educate smallholders and farmers in areas where corn is commonly grown in small sales.

viii. The current practice of requiring a post-market monitoring and reporting should be maintained.

*"The seed producers maintain that all imported seeds and grains are heat treated"*

## CAPACITY BUILDING ACTIVITIES

# i) Biosafety Training Workshop

**Date & Venue :**

3-4 June 2014 - University of Nottingham Malaysia Campus
19-20 August 2014 - Universiti Kebangsaan Malaysia
23 September 2014 - AIMST University
14-15 October 2014 - Universiti Tunku Abdul Rahman
17 November 2014 - Malaysian Nuclear Agency
3-4 March 2015 - Taylor's University
14-15 April 2015 - Universiti Tun Hussein Onn Malaysia

The Department of Biosafety had jointly organized the Biosafety Training Workshop with several institutions/organizations during the period of June 2014 to May 2015. The main objective of these workshops was to create awareness among the researchers, lecturers and laboratory personnel on the Biosafety Act 2007 and Biosafety Regulations 2010 including some biosafety modules. The workshops are designed in an interactive way with the aim to stimulate thinking and encourage two-way communication.


# ii) 2014 National Institutional Biosafety Committee (IBC) Seminar

**Date & Venue :**

18-19 June 2014 - Cititel Mid Valley Hotel, Kuala Lumpur


The Department of Biosafety organized this two days' seminar. This annual event attempts 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 that are carrying out research activities involving LMOs and in the process of setting up their IBC.

# iii) Workshop on Socioeconomic Considerations

**Date & Venue :**

25 November 2014 - Concorde Hotel, Kuala Lumpur

This workshop was organized by the Department of Biosafety as a platform to gather valuable views from various stake holders in the context of socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities in accordance to Article 26 of the Cartagena Protocol on Biosafety.

This workshop also aimed to obtain reviews and collates inputs on the Elements of a Framework for Conceptual Clarity on Socio-Economic Considerations during the first meeting of the Ad Hoc Technical Expert Group on Socio-economic Considerations (AHTEG).

# iv) Stacked Events Workshop

**Date & Venue :**

5 February 2015- Cititel Mid Valley Hotel, Kuala Lumpur

The Department of Biosafety and International Life Sciences Institute (ILSI) Southeast Asia Region jointly organized this workshop with the objective to raise awareness and to generate dialogue on the scientific principles underlying safety assessments of stacked event products. Through this effort, best practices for when and how to conduct safety assessments of stacked event products can be shared amongst key researchers.


# v) Consultation Workshop for the Draft Final Report of Liability and Redress Study

**Date & Venue :**

31 March 2015 - Parkroyal Hotel, Kuala Lumpur

The workshop was organized by the Department of Biosafety with the aimes to engage all relevant stakeholders in giving inputs to the draft final report of liability and redress study. Through this workshop, the improvement can be made on the tenets of a biosafety liability and redress system and identify issues for further discussion and consensus in order to create a comprehensive final report.






## vi) Workshop on Sampling Procedures

**Date & Venue :**

14-16 April 2015
Hotel Crystal Crown
Harbour View, Port Klang, Selangor

The Department of Biosafety together with Padiberas Nasional Berhad (BERNAS) jointly organized this workshop. The workshop aimed to be a platform for participants to share knowledge and experience on commodity grain sampling for accurate detection of GMO presence, to provide practical training for staff on duty to take samples of grain commodities at entry points and to finalize relevant standard operating procedures for sampling

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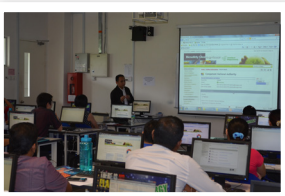
## vii) Biosafety Clearing House Training Workshop

**Date & Venue :**

16 October 2014 – Universiti Tunku Abdul Rahman

The Department of Biosafety and Universiti Tunku Abdul Rahman (UTAR) jointly organized this one day training workshop targeting to UTAR's staff and student on the importance of Biosafety Clearing House (BCH) portal as a source of reference to LMOs information. Participants were taught on how to use applications in the BCH to retrieve important information related to LMO domestically and worldwide.

# viii) Visit by Delegation from Brunei

**Date & Venue :**

24 April 2015 – Department of Biosafety, Putrajaya

Department of Biosafety and the Food Safety and Quality Division, Ministry of Health hosted a group of delegates from Brunei on 24th April 2015. The delegates was briefed on DOB's experience in dealing GMO and the implementation of biosafety law. Meanwhile, Ministry of Health shared their experience in enforcing labelling regulations of genetically modified food.


***BioJohor 2014***,
*Persada Johor International Convention Centre, Johor Bahru*

# PUBLIC AWARENESS ACTIVITIES

## BIOSAFETY AWARENESS PROGRAMMES/ACTIVITIES

**Date & Venue**

25-27 August 2014 - Exhibition at BioJohor 2014, Persada Johor International Convention Centre, Johor Bahru
21 March 2015 - Johor Bio Talent Boot Camp, Universiti Teknologi Malaysia, Johor Bahru
20-21 April 2015 - Exhibition at BioBorneo2015, Magellan Sutera, Sutera Harbour Resort, Kota Kinabalu, Sabah

As part of awareness programmes and activities, the Department of Biosafety was involved in a few exhibitions including BioJohor 2014 at Persada Johor International Convention Centre, Johor Bahru and BioBorneo 2015 at Magellan Sutera, Sutera Harbour Resort, Kota Kinabalu, Sabah.

In addition to that, the Department also participated in an exhibition and seminar during the Johor Bio Talent Boot Camp programme at Universiti Teknologi Malaysia, Johor Bahru. These programmes aimed to educate and create awareness among the public about biosafety issues in Malaysia and how they can participate in the decision making process.

***Johor Bio Talent Boot Camp,***
*Universiti Teknologi Malaysia, Johor Bahru*


***BioBorneo 2015,***
*Magellan Sutera, Sutera Harbour Resort, Kota Kinabalu, Sabah*

# PARTICIPATION IN THE INTERNATIONAL MEETINGS / WORKSHOPS:

## 2nd International Workshop for Regulation of Animal Biotechnology - Preparing Markets for New Animal Product Opportunities

• Brasilia, Brazil, 18 - 21 Aug 2014

i)

Animals that are produced using biotechnologies and intended for commercial production are gradually entering the market. As a result, international organizations and the national authorities of several countries are developing frameworks for the food and environmental safety assessment for products based on animal biotechnology. As animals from biotechnology origin mature and grow, we need to evaluate where we are today and plan for what we need to do for tomorrow. Building on the 1st international animal biotechnology regulatory workshop in Argentina (2011), this workshop reviewed the emerging elements of regulatory frameworks for the food and environmental safety assessment of products from animals produced using animal biotechnologies, including cloning, genetic engineering, and gene editing. It was intended primarily for a global exchange among professionals working for regulatory agencies, biosafety specialists and animal biotechnology and production experts.

## 7th Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 7)

• Pyeongchang, South Korea, 29 Sep - 3 Oct 2014 •

ii)

Some 650 participants representing Parties to the Protocol and other governments, UN agencies, intergovernmental and non-governmental organizations, academia and industry attended this meeting. The meeting adopted 14 decisions on: compliance; the Biosafety Clearing-house (BCH); financial mechanism and resources; cooperation with other organizations, conventions and initiatives; improving the efficiency of structures and processes; the budget; handling, transport, packaging and identification of living modified organisms (LMOs) (Article 18); the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (the Supplementary Protocol); risk assessment and risk management; socio-economic considerations; monitoring and reporting; assessment and review of the effectiveness of the Protocol; unintentional transboundary movements and emergency measures; and contained use of LMOs.

Delegates generally welcomed the meeting's outcomes, noting that the decisions on risk assessment and socioeconomic considerations, in particular, provided a mandate to advance work on important elements of the Protocol during the upcoming inter-sessional period. Some, however, expressed concern that COP-MOP 7 did not engage in the development of further guidance on specific aspects of risk assessment and unintentional transboundary movements, and wondered whether future COP-MOPs, which will in all likelihood be held concurrently with the CBD COP and Nagoya Protocol COP-MOP will offer sufficient opportunity to tackle issues specific to the Biosafety Protocol.

## 13th International Symposium on the Biosafety of Genetically Modified Organism

• Cape Town, South Africa, 9 - 13 Nov 2014 •

iii)

The ISBGMO is a biennial, international meeting organized under the auspices of the International Society for Biosafety Research (ISBR). It brings together academics, technology developers, regulatory authorities, non-government organisations and other credible stakeholders involved in all aspects of biosafety and offers a unique opportunity to share information and experiences and engage in open and meaningful dialogue on biosafety research, risk analysis, policy and regulatory matters. With the theme *"Advancing ERA of GMOs to Address Biosafety in a Global Society"*, the goal of the symposium was to advance the standing of biosafety research around the world and shape the ways in which GM technology is applied and regulated. It was the first time that the ISBGMO is hosted in Africa and approximately 450 delegates from at least 50 countries attended the symposium.

## Asia Regional Capacity-Building Workshop on Mainstreaming Biosafety into National Biodiversity Strategies and Action Plans and Resource Mobilization

• Ulaanbaatar, Mongolia, 9 - 13 Feb 2015 •

iv)

This workshop was organized in response to the COP-MOP 7 decisions to enhance the capacities of Parties in Asia to advance the integrated implementation of the Convention and the Cartagena Protocol on Biosafety through effective integration of biosafety into NBSAPs and national development plans in line with the Strategic Plan for the Protocol and the relevant Aichi Biodiversity Targets. It also aimed to increase the capacity of Parties to mobilize resources for the implementation of the Protocol and to ratify the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress. A total of 25 participants from 15 countries attended the workshop.

# SPECIAL COVERAGE

# GM FOOD LABELLING IN MALAYSIA

By Department of Biosafety

An increasing number of countries are now growing genetically modified (GM) crops. One of the consequential concerns arising from the proliferation of these GM foods relates to labelling of these products. One of the reasons for labelling is to provide information to consumers. It is based on the consumer's right to know. Consumers can then confidently decide whether or not they want to eat GM foods, according to their cultural or dietary preferences.

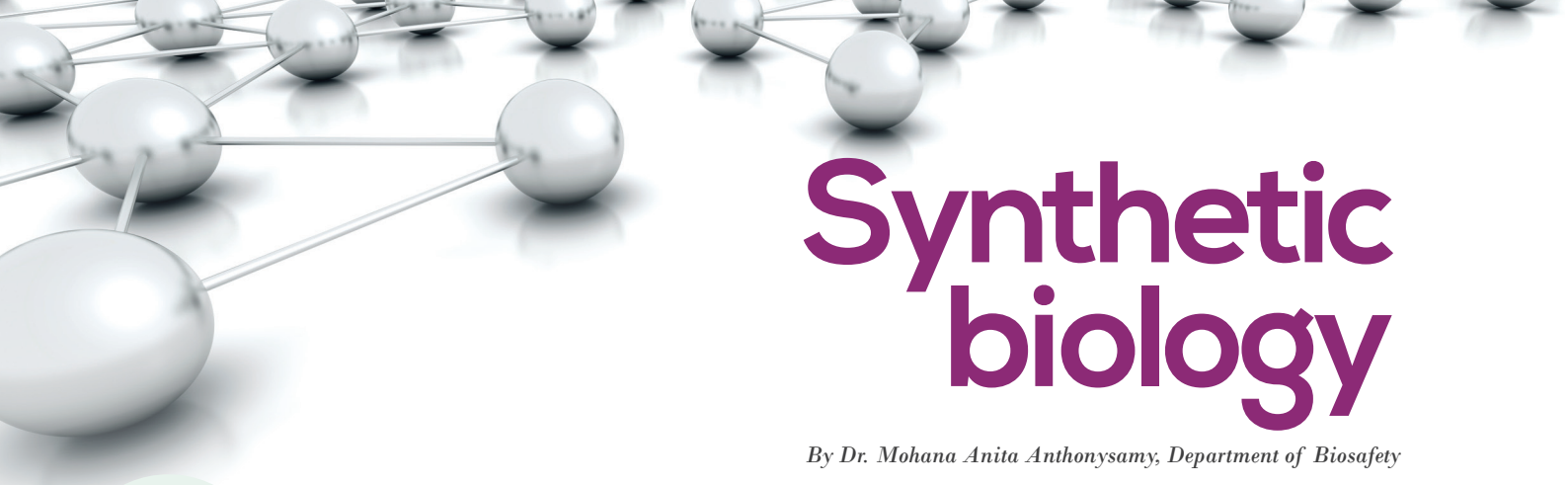
**CONSUMERS CAN DECIDE...**

On 14 June 2010, new regulations regarding the labelling genetically modified organisms (GMOs) in food have been enacted in Malaysia through amendments to the Food Regulations under the Food Act 1983. It came into forced in July 2014 and are intended to give consumers proper information through labelling, as to whether a package contains GM food or ingredients as well as whether the product is derived from the use of GM technology.

These regulations are also in accordance with provision in the Biosafety Act 2007 under section 61 which states that *"All living modified organisms, items containing living modified organisms and products of such organisms shall be clearly identified and labelled in a manner to be prescribed and the requirements for such identification and labelling shall be in addition to any other written law."*

The GMO labelling regulations in Malaysia makes it mandatory for both products that are composed or contain GMOs, as well as those that are produced from but do not contain GMOs to be labelled on the front of the packaging in an appropriately visible manner on the label . Additionally, a unique feature of Malaysia's GMO labelling regulations is that it requires the declaration of the "origin of gene" from which the modified gene in the product is derived from.

To implement these new regulations, the Food Safety and Quality Division under the Ministry of Health have developed a Guideline on Labelling of Foods and Food Ingredients Obtained through Modern Biotechnology. According to the guidelines, the labelling requirements shall only apply to the three (3) main ingredients in the ingredient list and shall not apply to foods which contains, consists of or produced from GMO in a proportion not more than 3% of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable. For the purpose of these regulations, only those GM events that have been approved by the National Biosafety Board are deemed to be the permitted events for foods and food ingredients obtained through modern biotechnology.



# Synthetic biology

*By Dr. Mohana Anita Anthonysamy, Department of Biosafety*

Synthetic biology (SynBio) is an emerging area of biotechnology that allows scientists to redesign or create new biological systems and pathways. Due to its immense potential, synthetic biology has been the focus of many scientific and ethical debates. The definition of synthetic biology itself is heavily debated, not only among natural scientists but also in the human sciences, arts and politics. There are many definitions of synthetic biology available and this can be seen through the various references available just on the internet developed by interest groups, regulators, academia and many others.

The European Commission has described synthetic biology as the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms to alter living or non-living materials (European Commission 2014). The International Civil Society Working Group on Synthetic Biology refers to synthetic biology as the use of computer-assisted, biological engineering to design and construct new synthetic biological parts, devices and systems that do not exist in nature and the redesign of existing biological organisms, particularly from modular parts (ICSWGSB 2011).

One clear explanation of synthetic biology is found in the Pfleger Lab website. It states that synthetic biology combines elements of engineering, mathematics, chemistry, and biology to synthesize novel systems from characterized biological components. Reference is made to the illustration by Andrianontoandro et al, (Figure 1) that compares the goal and methods of synthetic biology to the computer engineering hierarchy, whereby every constituent part is embedded in a more complex system that provides its context.

With rapid advances in DNA sequencing and synthesis technologies, synthetic biology has evolved from classic recombinant DNA technologies wherein a small number of genes were actively manipulated, synthesis of chromosome, whole genome editing, synthetic cell genesis, to a state where small genomes can be synthesized and transformed into protoplasts to enable self-replication. The next generation of synthetic biologists will develop the tools and understanding necessary to build cells or microorganisms from scratch.

Like other engineering disciplines, synthetic biologists apply fundamental principles of mathematics, computer and science to assemble useful devices and products. The difference in this case is the ability of biological systems to self-replicate and evolve.

| Synthetic biology research involves |
| --- |
| (a) Identifying new biological components and quantitatively characterizing their biochemical or biological function |
| (b) Developing tools for quick assembly of novel systems comprised of biological components |
| (c) Engineering novel systems to solve problems and |
| (d) Optimizing the performance of biological systems in the context of an evolving organism. |

Living organisms created or modified using synthetic biology techniques fall within the definition of "living modified organisms resulting from biotechnology" as defined by the Convention on Biological Diversity (CBD) and therefore subjected to regulations under the provisions of Articles 8(g) and 19.

Such living organisms will also fall under the definition of "living modified organisms" under the Cartagena Protocol for Biosafety.

Note:
*This content of this article has been produced from Malaysia's interventions on the issue of synthetic biology and was reviewed by the Malaysian representatives to the Open-ended Online Forum on Synthetic Biology organized by the Cartagena Protocol on Biosafety.*

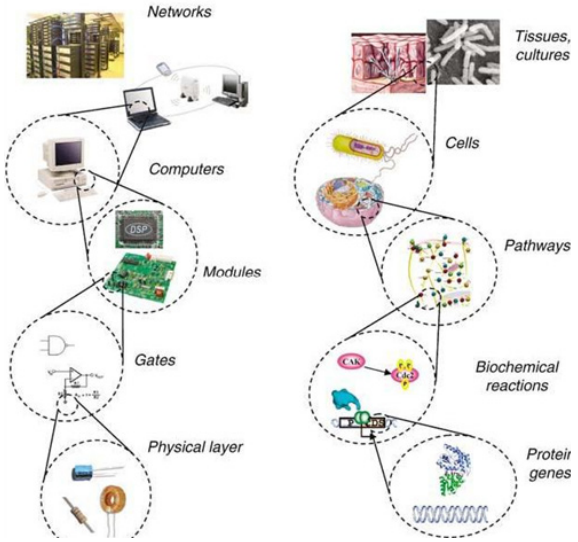



*Figure 1: A possible hierarchy for synthetic biology is inspired by computer engineering. Source: Andrianontoandro et al, 2006.*

Therefore, the requirements of the Cartagena Protocol apply pertaining to the transboundary movement, transit, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. In order to work out the practicalities of this, an Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology has been set up to further discuss issues pertaining to this topic.

Majority of synthetic biology thus far have used microbes to produce alternatives to naturally-occurring or petroleum-based molecules. One such example is the production of artemisinic acid in engineered yeast with the aim of manufacturing an alternative to the naturally occurring anti-malarial drug artemisinin, which is derived from Artemesia plants.

Other examples are the production of fuels such as biodiesel and isobutanol, pharmaceutical drugs (e.g. to lower blood sugar levels in adult with type 2 diabetes) and flavourings/fragrances (e.g. vanillin). There are several applications where synthetic biology and biological diversity may possibly intersect, such as, bioenergy, agriculture and chemical production, amongst other things. Such usages may impact biodiversity, either positively or negatively, at various levels including at the level of genes, species and ecosystems.

In a recent online forum organized by CBD on synthetic biology, Dr. Jim Thomas, from the Action Group On Erosion, Technology and Concentration (ETC Group) pointed out several specific applications of synthetic biology that deserve close attention because of their potential impact on biodiversity :

a) Gene Drives - these can potentially alter population structures and deliberately 'drive' engineered traits (sterility, resistance etc.) through an entire population. This sort of genetic-driven population-level engineering is novel and should be approached with extreme caution.

b) Enhanced photosynthesis - applications of synthetic biology (including genome editing) to increase photosynthetic abilities of algae, crops etc. are on the rise and constitute a significant intervention that could increase invasiveness, impact carbon and oxygen cycles etc.

c) De-extinction - engineering of organisms to mimic previously extinct species and ubsequent reintroduction or engineering of extant species to mimic commercially valuable strains/varieties of the same could have impacts equivalent to introduction of foreign species.

d) SynBio sensors and bioremediation - use of synthetic organisms as an environmental sensing or monitoring platforms or release of synthetic biology organisms for cleaning/extracting contaminants.

Despite its intended benefits, there is an inadequate basis on which to assess risks associated with synthetic biology at the moment. For example, there is always a lack of suitable comparator to do an assessment in synthetic biology when synthetic cells are used. In line with the precautionary principle under the CBD, (which is the key when dealing with new and emerging scientific and technological issues, components, organisms and products resulting from synthetic biology techniques) efforts are underway to develop an adequate scientific basis for assessment of such activities and due consideration is to be given to the associated risks for biological diversity, including bioethics, socio-economic risks and risks to the environment and human and animal health.

In Malaysia, techniques that can be used to produce genetically modified organisms (GMOs), such as synthetic biology are regulated under Biosafety Act 2007. Any release (e.g. commercial use, planting, field trial and disposal) or research work in a contained facility involving GMOs are subjected to National Biosafety Board approval under this law. Risk assessment is a fundamental component in making decisions for activities related to GMOs under this law. The current risk assessment framework needs to be reviewed and/or adaptation made and/or a new framework provided if necessary as a guidance to assess organisms produced via synthetic biology.

The assessment should be robust enough to assess not only work that involves incorporation of genes but also work of building organisms where there are no parent organisms as comparators. As cited in a report from Australia, these novel synthetic organisms have no history of safety; in fact, they have no history at all. Synthetic biology allows synthesis of LMOs, components or products without the need of any biological system, and therefore may fall out of the scope of LMOs as technology advances.

A stepwise approach is proposed whereby safety data and characteristics of the organisms produced through synthetic biology should be more properly understood, for example the potential interaction with other organisms, impact of horizontal transfer, unforeseen evolution so that these data can be used for risk assessment and a basis of dealing with synthetic biology.

References:
1. Andrianontoandro E., Basu, S., Karig, D.K. and Weiss R. 2006. Synthetic biology: new engineering rules for an emerging discipline. Molecular Systems Biology 2006.
2. CBD Technical Series No. 82
3. Forum on synthetic biology: challenges and opportunities for Australia Forum report
4. Open-ended Online Forum on Synthetic Biology organized by the Cartagena Protocol on Biosafety Secretariat.
5. Pflegar lab. http://pflegerlab.che.wisc.edu generalresearch.html
6. Wikipedia Definition of Synthetic Biology. https://en.wikipedia.org/wiki/Synthetic_biology (Accessed July 2015)

# DETECTION OF GENETICALLY MODIFIED ORGANISM

BY DEPARTMENT OF BIOSAFETY

A diversity of methods and strategies has been brought to bear on the issue of Genetically Modified Organism (GMO) detection. Most current detection methods rely either on the polymerase chain reaction (PCR) to amplify transgene sequence(s), or on immunological methods (primarily ELISA, the enzyme-linked immunosorbent assay) to bind to a transgene product(s). Although specific DNA sequences can be detected by hybridization, it is PCR in its various formats (qualitative PCR, end-point quantitative PCR, and quantitative real-time PCR) either simplex or multiplex, with some using a real-time format, which has been generally accepted by the regulatory authorities.

Much of the debate over the labelling of GMO-derived or GMO-containing products, in both the legislative and the scientific arenas, concerns the accuracy of analytical methods. In order to be specific, a method must target a unique feature of the GM event, and must be able to detect all known authorized and unauthorized events. The Community Reference Laboratory for GM Food and Feed (CRL-GMFF) publishes validated protocols for the analysis of authorized GM crops.

Several issues still remain unresolved, specially;

- The definition and identification of endogenous genes for quantification.
- Assays for non-authorized GM events,usually because relevant DNA sequence information is lacking.
- Assays for GM crops carrying stacked transgenes, specially how to differentiate these from mixtures of single events.
- The quantification of GM material, considering variation in genome size and tissue ploidy level.
- Optimizing methods for DNA extraction from different food matrices.
- Sampling and statistical analysis.
- The development of field-based analyses, using portable instrumentation.

> *"DEPARTMENT OF CHEMISTRY IS THE APPOINTED ANALYST"*

In regulating the Biosafety Act 2007, the National Biosafety Board (NBB) has appointed the qualified officers from the Department of Chemistry Malaysia to be an analyst for the purposes of carrying out an analysis for GMO detection. The Department of Chemistry Malaysia is also the ASEAN Reference Laboratories (ARLs) for GMO.

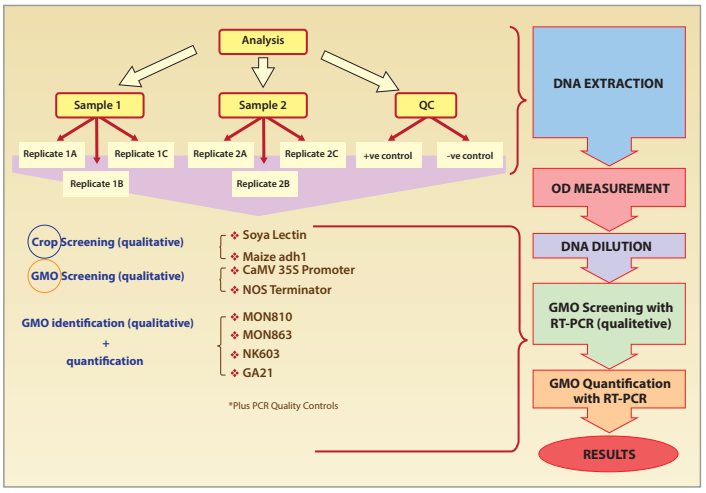



*Photo 1: Flowchart for GMO screening by Department of Chemistry Malaysia (http://www.mift.org.my/files/JasbeerKaur_MOSTI.pdf)*

# SETTLING UNFOUNDED FEARS IN GENETICALLY MODIFIED ORGANISMS (GMOs)

BY TAN SWEE LIAN, PHD, FASC, KMN[1]

Surprisingly, it is the more educated sector of the Malaysian population that appears to have the most worries about GMOs (genetically modified organisms) and their products. Perhaps, it is because they read more widely and are influenced by many Non-government Organizations (NGOs) with anti-GMO sentiments. These bodies certainly pose more sensational stories of "terminator genes", "franken foods" and "cancer-causing effects" of eating genetically modified (GM) foods. Certainly these scandalous stories are more exciting than the papers giving cold scientific facts proving the contrary.

> "How much of these "stories" (more accurately, "tall tales") are true? Let us not confuse negative attitudes towards giant corporations (such as Monsanto) with actual scientific proof of harm arising from consuming GM products.
>
> Consider: Despite GM crops and foods having been in the marketplace for more than 30 years, there has not been a single credible report of undesirable or ill effects from eating them (think cornflakes and soy products which are in all likelihood from GM crops)."

Consider, also: The planting of insect-resistant GM crops, such as "bt crops". The bt gene that has been incorporated into the plant enables it to produce a toxin which is the same as the one from Bacillus thuriengensis (bt), a bacterium accepted even by organic farming community to manage lepidopteran pests (i.e. caterpillars). The use of these bt crops translates to eliminating the need to spray crops with insecticide to protect them from caterpillars. For example, in the Philippines, it has been reported that farmers spray their brinjal crops up to 80 times, whereas bt brinjal does not require such blanket spraying of insecticides to stop these pests.

Doesn't the spraying of chemical pesticides (especially in such large quantity) bring untold harm to ALL insects - both harmful and beneficial- as well as leave residues which are likely to be injurious to the consumer of the produce as well as the environment? Remember, that the toxin produced by the bt gene only kills caterpillars - specifically affecting moth and butterfly without harming other insects, and certainly not other life forms.

There is, in recent years, a lot of controversy surrounding herbicide-tolerant GM crops, particularly Roundup Ready corn and Roundup Ready soybean, and purported evidence of their negative effects when fed to laboratory mice and rats. Roundup is the brand name of glyphosate, an herbicide patented by Monsanto in the 1970s.

No doubt, Monsanto developed the GM soybean and corn to boost sales of this Roundup herbicide because these crops will not be harmed when their herbicide is used to manage weeds. Here, we have to make a distinction whether the claim of undesirable effects from eating Roundup Ready corn or soybean are due to the GM crop itself, or due to the residual effects of glyphosate. Stringent science-based protocols are adopted when testing GM crops to ensure that they do not cause harm to humans, animals and the environment, before they are approved for sale to the general public.

However, it is undeniable that consuming a large amount of any chemical pesticide or herbicide (basically, poisons) will not be good for us. Thus, it is probably the over-use of glyphosate we must look out for (and probably monitor), and not any intrinsic harmful factors in the herbicide-tolerant GM crops, which may cause ill effects. Unfortunately, when found to be effective, farmers are known to use the pesticides/herbicides at a dose higher than the recommended rate. It addition, the farmers spray right up to the time of harvest - instead of observing the recommended abstention period of pesticide/herbicide use of two weeks before harvesting a crop.

1 Fellow of the Academy of Sciences Malaysia; a retired plant breeder, formerly from the Malaysian Agricultural Research & Development Institute (MARDI). She also a former member of the Genetic Modification Advisory Committee (GMAC). During her tenure as a GMAC member, she has played a vital role in contributing to the mandatory risk assessments done for applications of GMOs and its products in Malaysia.

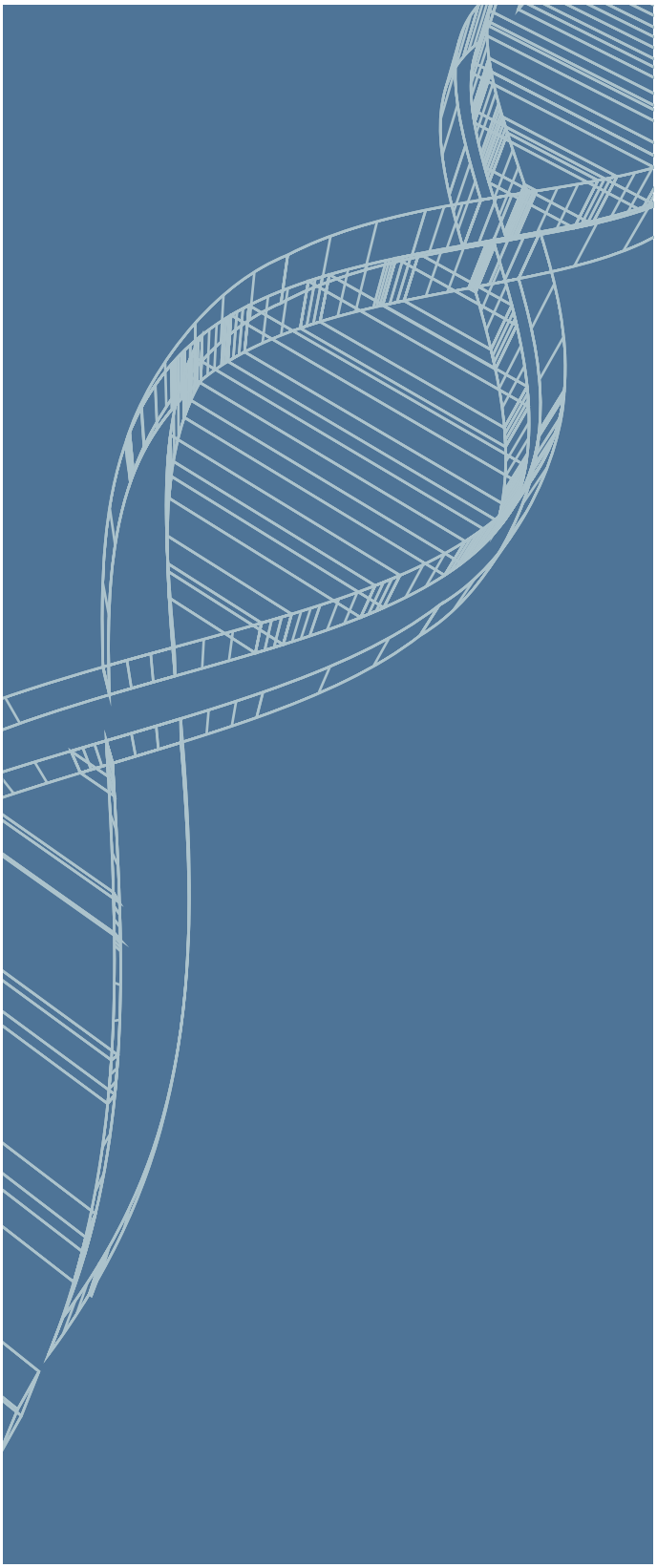
Finally, consider: Farmers are by and large receptive of any technology which improves their farming activities, brings in higher yields, and ultimately raises their income. GM crops can bring all of these benefits. The only obstacles standing in the way are:

- misinformed consumers with unfounded fears - which of course affects the marketability of GM produce

- so-called green NGOs who spread unsubstantiated information against GMOs. Some of these are no better than environmental terrorists who go around destroying expensive confined field trials of GM crops which are designed also to test for any harmful or undesirable effects of these crops

And what about the people who are facing a shortage of food and proper nutrition? Is it ethical to preach a tale of doom, warning (and indeed preventing) people who are starving or suffering from malnutrition from eating nutritious GM food? A case in point is Golden rice, so named for the high carotene content in the GM rice, which can solve the problem of blindness arising from vitamin A deficiency.

Thus, when deliberating on whether or not to eat GM food, let the scientific evidence prevail. Do not be unduly overwhelmed and swayed by nay-sayers without strong facts and scientifically sound data to back them up.



# List Of Approved Release Activities

(as of 31 July 2015)

| 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) MON 89788 glyphosate tolerant Soybean (Roundup Ready 2 Yield™) | Food, Feed & Processing | Monsanto |
| 6) MON 89034 *Lepidopteran*-protected corn | Food, Feed & Processing | Monsanto |
| 7) MON 88017 *Rootwormprotected* and *glyphosate* tolerant corn | Food, Feed & Processing | Monsanto |
| 8) ACS-GM5-3 - Herbicide-tolerant Soybean (A2704-12) | Food, Feed & Processing | Bayer |
| 9) T25 Herbicide-tolerant Maize | Food, Feed & Processing | Bayer |
| 10) A5547-127 LibertyLink® (*Herbicides-tolerant*) soybean | Food, Feed & Processing | Bayer |
| 11) FG72 (Herbicides-tolerant) soybean | Food, Feed & Processing | Bayer |
| 12) TC1507 Herbicide tolerant and insect resistance Maize | Food, Feed & Processing | Du Pont |
| 13) CV 127 (*Imidazolinone-Tolerant*) soybean | Food, Feed & Processing | BASF |
| 14) SYN-Bt11-1 - YieldGard™ Maize | Food, Feed & Processing | Syngenta |
| 15) Ice-Structuring Protein (ISP) | Food | Unilever |
| 16) Genetically modified carnation, Dianthus caryophyllus L. | Placing on the market | Suntory Holdings Ltd. |
| 17) GM Mosquito OX513A (My1) | Field Trial | Institute of Medical Research |
| 18) Confined field evaluation of delayed ripening transgenic Eksotika papaya | Field Trial | MARDI |
| 19) Transgenic rubber (*Hevea brasiliensis*) trees for confined field trial for research and development purpose | Field Trial | Malaysian Rubber Board |
| 20) TMOF Yeast – Mousticide Rice Husk and Mousticide Wettable Powder | Release to environment | EntoGenex Industries Sdn. Bhd. |
| 21) Importation of TMOF Yeast to Produce Mousticide RH and Mousticide WP and Importation of Mousticide WP | Release to environment | EntoGenex Industries Sdn. Bhd. |
| 22) 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. |

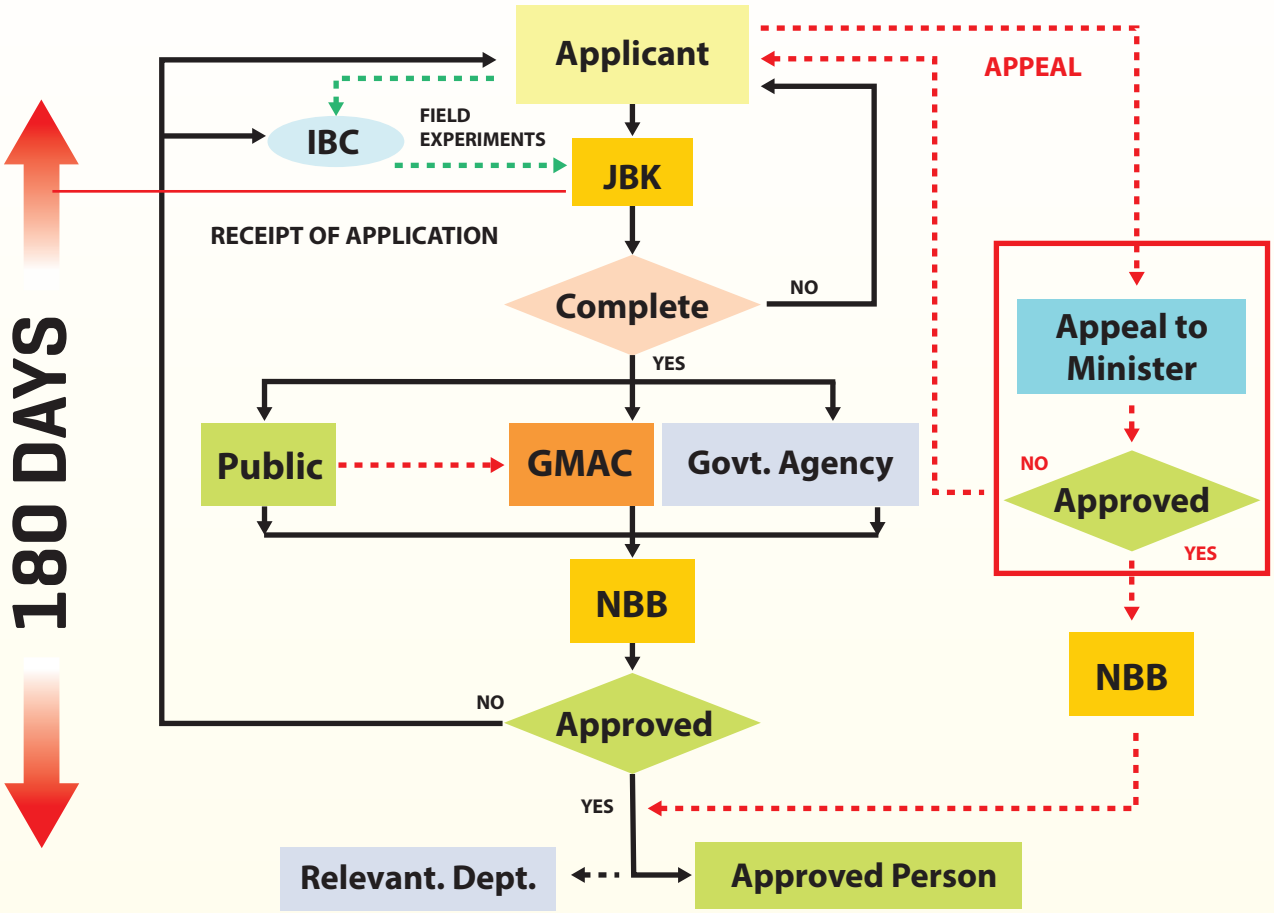
# List of registered IBCs

(as of 31 July 2015)

**Note:** In compliance with the Biosafety Act 2007 and other related regulations, any organization, which undertakes modern biotechnology research and development, shall establish an Institutional Biosafety Committee (IBC)

| NO. | INSTITUTIONS |
|---|---|
| 1. | Sime Darby Technology Centre Sdn. Bhd. |
| 2. | Institute for Medical Research (IMR) |
| 3. | Malaysian Agriculture Research Development Institute (MARDI) |
| 4. | Cerca Insights Sdn. Bhd. |
| 5. | Universiti Kebangsaan Malaysia |
| 6. | Malaysian Palm Oil Board (MPOB) |
| 7. | Universiti Sains Malaysia |
| 8. | Universiti Malaya |
| 9. | Cancer Research Initiatives Foundation |
| 10. | International Medical University |
| 11. | Universiti Malaysia Kelantan |
| 12. | Craun Research Sdn. Bhd |
| 13. | Agensi Nuklear Malaysia |
| 14. | The University of Nottingham Malaysia Campus |
| 15. | Universiti Malaysia Sabah |
| 16. | Forest Research Institute Malaysia (FRIM) |
| 17. | Universiti Putra Malaysia |
| 18. | Universiti Teknologi Malaysia |
| 19. | Universiti Malaysia Sarawak |
| 20. | ACGT Sdn. Bhd. |
| 21. | Institut Farmaseutikal dan Nutraseutikal Malaysia (IPharm) |
| 22. | Universiti Teknologi MARA (UiTM) |
| 23. | BioValence Sdn. Bhd. |
| 24. | Agro-Biotechnology Institute, Malaysia |
| 25. | GlycosBio Asia Sdn. Bhd. |
| 26. | Monash University Sunway Campus |
| 27. | Malaysia Genome Institute |
| 28. | Universiti Malaysia Terengganu |
| 29. | Universiti Tunku Abdul Rahman |
| 30. | Lembaga Koko Malaysia |
| 31. | Lembaga Getah Malaysia |
| 32. | CJ Bio Malaysia Sdn. Bhd. |
| 33. | AIMST University |
| 34. | Biocon Sdn. Bhd. |
| 35. | Sunway Education Group Sdn. Bhd. |
| 36. | UCSI University |
| 37. | Taylor's University |
| 38. | Universiti Tun Hussein Onn Malaysia |
| 39. | Sirim Berhad |
| 40. | Manipal International University |
| 41. | Verdezyne Sdn. Bhd. |

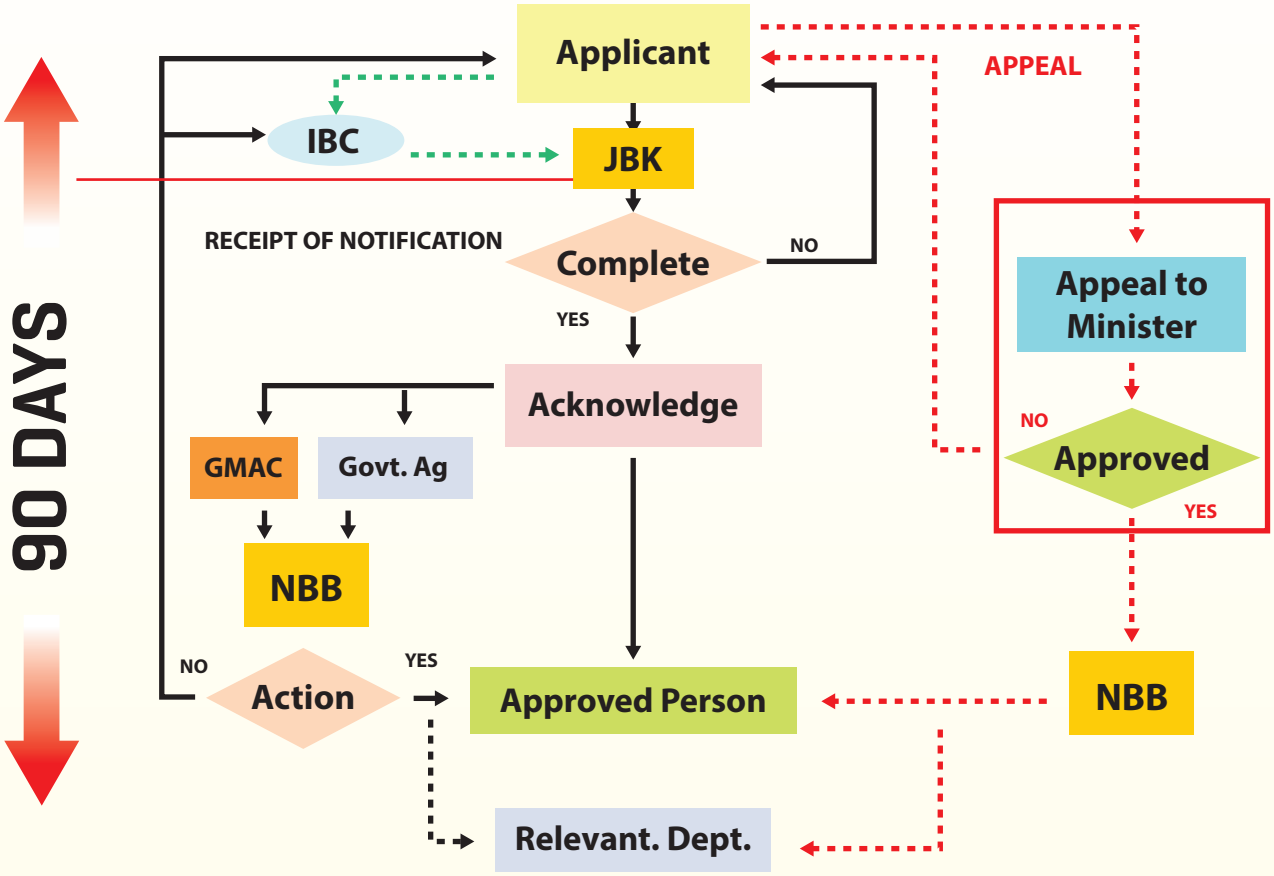
# APPROVAL PROCESS




## APPROVAL

- NBB will make a decision within **180 days**
- Decisions may vary
  - i) Approved
  - ii) Approved with Terms and Conditions
  - iii) Rejected
- Activity can start only after getting **Certificate of Approval**
- An approved person shall not undertake any release activity or any importation of LMO other than for which the certificate has been issued
- Approval Decision can be reviewed
- Offense punishable
- Appeal to Minister

# NOTIFICATION PROCESS




## NOTIFICATION

- Activity can start after receiving **ACKNOWLEDGEMENT** from JBK
- In parallel, GMAC & NBB will assess Notification and a decision will be made known within **90 days**
- Assessment of NBB may result in
  - i) No Order
  - ii) Order Cessation
  - iii) Impose Terms & Conditions
  - iv) Order Rectifications
  - v) Other Orders
- Notification Decision can be reviewed
- Offense punishable
- Appeal to Minister

NEWSLETTER

# BIOSAFETY

**DEPARTMENT OF BIOSAFETY**

Kementerian Sumber Asli dan Alam Sekitar, Aras 1, Podium 2, Wisma Sumber Asli, Presint 4, 62574 Putrajaya, Malaysia

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