BIOSAFETY ACT 2007 & BIOSAFETY REGULATIONS (APPROVAL & NOTIFICATION) 2010

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SEMINAR KESEDARAN GMO KEBANGSAAN, 2 NOV. 2016, HOTEL ARMADA, PETALING JAYA
• Introduction to Biosafety in Malaysia

• Biosafety Act 2007

• Regulatory mechanisms under the Act

• Exemptions
BIOSAFETY

• BIOSAFETY

Prevention of large-scale loss of biological integrity, focusing both on ecology and human health. These prevention mechanisms include conduction of regular reviews of the biosafety in laboratory settings, as well as strict guidelines to follow. Biosafety is used to protect us from harmful incidents.

• BIOSAFETY IN THE CONTEXT OF THE BIOSAFETY ACT 2007

Biosafety is used to describe efforts to reduce and eliminate the potential risks resulting from modern biotechnology and its products. The concept of biosafety encompasses a range of measures, policies and procedures for minimizing potential risks that modern biotechnology may pose to human, plant and animal health, the environment and biological diversity.
WHY BIOSAFETY

- WHY? to reduce and eliminate the potential risks resulting from (modern) biotechnology and its products so that it is safe for human, plant and animal health, and the environment

- Important to ensure sustainable development
WHAT ARE THE CONCERNS?

- Impact to the environment – gene flow, weediness
- Impact on non target organism or indirect effects
- Evolution of resistance (resistant pests)
- Allergenicity & toxicity
- Source of the gene – can cause disease, toxic, other negative impact
- Herbicide/Insecticide tolerance
EVOLUTION OF BIOSAFETY

1996  Administrative GMAC formed (MOSTE)
1998  Strategy XI - National Policy on Biological Diversity
2000  Signed the Cartagena Protocol on Biosafety
2003  Ratified – Protocol in force
2005  Policy Thrust 7 National Policy on Biotechnology
2006/07  Biosafety Bill in Parliament
2007  Biosafety Act passed in Parliament
2008  Biosafety Core Team formed (April)
2009  **Biosafety Act enforced (1st December)**
2010  NBB formed (March)/GMAC appointment (May)
2010  **Department of Biosafety formed (24th May)**
2010  Biosafety Regulations enforced (1st Nov)
2010  Nagoya-Kuala Lumpur Supplementary Protocol on Liability & Redress adopted (Oct)
CARTAGENA PROTOCOL ON BIOSAFETY AND BIOSAFETY ACT - COMPLIMENTARY LEGAL INSTRUMENTS

Country A
Transboundary movement - CPB

Country B
Transboundary movement - CPB

Malaysia
Domestic Law Biosafety Act
Complement the implementation of the National Policy on Biotechnology and also the National Policy on Biological Diversity.

National law that is applicable to all states in Malaysia (including Sabah and Sarawak).

Not intended to disrupt R&D.

Implementing agency is the Department of Biosafety under the Ministry of Natural Resources and Environment.

Based in Putrajaya.
MINISTER OF NATURAL RESOURCES AND ENVIRONMENT (NRE)

CHAIRMAN OF NATIONAL BIOSAFETY BOARD (NBB)
Secretary General of NRE

NBB MEMBERS

DIRECTOR GENERAL
Department of Biosafety

DEPARTMENT OF BIOSAFETY

Corporate & Management Section
Research & Evaluation Section
Enforcement & Monitoring Section

COMMITTEES ESTABLISHED UNDER NBB

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

SUB-COMMITTEES
OBJECTIVE OF THE ACT
To establish the National Biosafety Board; to regulate the release, importation, exportation and contained use of living modified organisms (LMO*) & the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity.

*The term LMO is used interchangeably with GMO
BIOSAFETY BOARD MEMBERS

Secretary General of NRE (Chairman)

DG JBK (Secretary)

National Biosafety Board Members

Ministry of Health Malaysia

Ministry of Plantation Industries and Commodities

Ministry of Domestic Trade, Co-operatives & Consumerism

4 experts in biosafety

ADMINISTRATIVE SUPPORT FROM DEPARTMENT OF BIOSAFETY
FUNCTIONS OF NBB

- Decides on all applications – approvals & notifications
- Monitors modern biotechnology activities
- Enforces the law
- Performs/provide for obligations from biosafety related agreements, conventions or treaties
- Establishes mechanisms to facilitate the collection, storage & dissemination of data relating to LMOs /products/ biosafety
- Promotes R &D, development, educational & training activities
- Assesses risk posed by LMOs/products
Formed in May 2010
Provides scientific assessment of applications for approval & notifications and gives recommendations to the NBB
Provides scientific, technical and other relevant advice to the NBB or the Minister
Responsible to NBB and also any general directions given by the Minister
SCOPE OF THE ACT

MODERN BIOTECHNOLOGY

LMOs

PRODUCTS OF LMOs

CONTAINED USE

IMPORT FOR CONTAINED USE

EXPORT

IMPORT FOR RELEASE

RELEASE

ALL INSTITUTES & PERSONS INVOLVED

ALL STAGES OF R&D AND RELEASE

ALL TYPES OF ORGANISM

ALL ACTIVITIES
Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
PRODUCTS

- Derived from LMOs or part of LMOs;
- Contains detectable recombinant DNA; or
- Profile, characteristic or properties of the product is or are no longer equivalent to its conventional counterpart irrespective of the presence of the recombinant DNA.
CONTAINED USE

Any operation including R&D, production or manufacturing involving LMOs, or storage of LMOs, undertaken within a facility, installation or other physical structure such as it prevents contact and impact of the LMOs on the external environment.

[Covers laboratories, Animal Unit, Growth Room, Glasshouse and Bioreactor Facility...]

RELEASE ACTIVITIES

- R&D purposes in all field experiments
- Supply or offer to supply for sale or placing on the market
- Offer as gift, prize or free item
- Disposal
- Remediation purposes
- Any other activity which does not amount to contained use
REGULATORY PROCESSES

1. NOTIFICATION – PART IV OF ACT
   - R&D
     • Contained use
     • Import for contained use
   - Commercialization
     • Direct introduction of LMO to the environment
     • Placing in the market
     • Commercial planting

2. APPROVAL - PART III OF ACT
   - R&D
     • Field Trial
   - Import LMO/product for placing in the market or release

DEVELOPING LMO - FROM BENCH TO MARKET

DIRECT COMMERCIAL USE – NO R&D
   - Export LMO
   - Contained use for industrial production
   - Import LMO/product for placing in the market or release
NOTIFICATION PROCESS

- Applicant
  - NBB/DG
    - Complete
      - Acknowledge
        - Action
          - GMAC
            - NBB
              - Govt. Ag
                - NBB
                  - Relevant Dept.

- APPEAL
  - Yes
    - Approved
      - NBB

- No
  - Appeal to Minister
    - Yes
      - Approved
        - NBB
    - No
      - NBB
APPROVAL PROCESS

180 days

RECEIPT OF APPLICATION

FIELD EXPERIMENTS

APPEAL

Appeal to Minister

Approved

NBB

NO

YES

Approved

NBB

NO

YES

Approved Person

Relevant. Dept.

Public

IBC

Dept.

Complete

YES

NO

GMAC

Govt. Agency

NO

YES

Approved
PUBLIC PARTICIPATION

- 4 national newspapers (Malay, English, Chinese & Tamil)/ 2 announcements in each newspaper
- Upload information about application to biosafety website
- Input received for a period of 30 days
- Other concerns/issues raised reviewed and given to Board to make decision

INPUT FROM RELEVANT GOVT AGENCY

- Depends on the LMO/product and proposed activity

<table>
<thead>
<tr>
<th>AGENCY</th>
<th>EXAMPLE OF ACTIVITY:</th>
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<tbody>
<tr>
<td>DEPT. OF VETERINARY SERVICES</td>
<td>Importing a GM animal – pest and disease free</td>
</tr>
<tr>
<td>MINISTRY OF HEALTH</td>
<td>Importing a GM microbe</td>
</tr>
<tr>
<td>MAQIS/DOA</td>
<td>Importing a GM plant – pest and disease free</td>
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<tr>
<td>PESTICIDE BOARD</td>
<td>Importing a GM biopesticide</td>
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RA & RM & ERP REQUIREMENT

RISK ASSESSMENT
Assessment of the risk and adverse effect that such LMOs and products of LMOs will have or are likely to have on the human, plant and animal health, the environment and biological diversity.

RISK MANAGEMENT
Proposed measures that shall be undertaken to prevent, reduce or control the risks and adverse effect that such LMOs and products of LMOs will have or are likely to have on human, plant and animal health, the environment and biological diversity.

EMERGENCY RESPONSE PLAN
Safety measures and procedures for the protection of human, plant and animal health, the environment and biological diversity against harm or damage caused directly or indirectly by LMOs or products of LMOs that will be undertaken in the event of an emergency and unintended release.

NOTIFICATION

APPROVAL
## SUMMARY OF REGULATORY PROCESSES

<table>
<thead>
<tr>
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<th>NOTIFICATION</th>
<th>APPROVAL</th>
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<tbody>
<tr>
<td><strong>PURPOSE</strong></td>
<td>Contained Use</td>
<td>Release</td>
</tr>
<tr>
<td><strong>TIME</strong></td>
<td>90 days</td>
<td>180 days</td>
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<tr>
<td><strong>CONSULT PUBLIC</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>FEES</strong></td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>START ACTIVITY</strong></td>
<td>Sufficient with JBK</td>
<td>Need certificate of approval</td>
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<td></td>
<td>acknowledgement</td>
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<tr>
<td><strong>APPEAL OR REVIEW</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
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PENALTY
non compliance to get approval from NBB for release and contained use activities involving LMO/products

Where such person is an individual:
- a fine not exceeding **RM250,000** or to imprisonment for a term not exceeding five years or to both;
- continuing offence, further fine no exceeding **RM10,000** for each day

Where such person is a body corporate:
- a fine not exceeding **RM500,000**;
- continuing offence, further fine no exceeding **RM20,000** for each day
ENFORCEMENT COORDINATION

- NBB Enforcement officer
- Police officer
- Inspecting officer DoA
- Customs officer
- Health Enforcement officer
- Port officer
- Fisheries officer
- Authorized veterinary officer
- Authorized Plant Variety Act officer
- Any other officer authorized in writing by NBB - MAQIS officers
# Integrated Enforcement Matrix

## Agenis Kerajaan

<table>
<thead>
<tr>
<th>Kementerian</th>
<th>Produk/Bioteknologi</th>
<th>Karalan/Prosedur</th>
<th>Iklim</th>
<th>Risiko dan Rakan</th>
<th>Tumbuhan, Produk Tanah, Airli, Hutan, &amp; Tumb. Liar</th>
<th>Vektor/Risiko</th>
<th>Lain-Lain</th>
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### Notes:
- \( \vee \) = Ujian Klinikal dan Jumlah
- \( \checkmark \) = Sertifikasi yang mengandung halaman terhadap sasaran halaman
- \( \times \) = MASQ biasa melarang halaman dan DVS sangat halaman tambahulah halaman
- \( \text{GM}^* \) = Ergasias terkawal dan penghidrakan
- \( \text{GM}^* \) = Dikawal oleh Aktal Judul Dudo 2562
- \( \text{(M)} \) = Mikroorganisms
- \( \text{(D)} \) = Drug
- \( \text{SP} \) = Selisih Pengukuran dalam Peraturan
- \( \text{KEMENBURDAN} \) = Jumlah Kera Kegalang Sertifikasi Mikroorganisms dalam Kala Organis
NEED APPROVAL
WHEN.....

WORKING WITH LMOs

Microbe
- Human
- Animal
- Plant

Vaccine
- Human
- Animal
- Fish

Human cell line
- MOH & JBK

Fish
- DOF & JBK

Animal
- DVS & JBK

MOH & JBK
DVS & JBK
DOA & JBK
MOH & JBK
DVS & JBK
DOF & JBK
MOH & JBK
DVS & JBK
ENFORCEMENT – GMO Analysis

• NBB has appointed qualified persons from the Chemistry Department Malaysia (MOSTI) as analyst to assist in enforcement activities.
LABELLING

• All LMOs, items containing LMOs and products of such organism - mandatory labelling (s61 of BA)

• GM Food Labelling under Food (Amendment) Regulations 2010 - MOH

• GM Food, food ingredients and source of gene to be labelled – includes import, preparation, advertise for sale or selling.

• Enforced in July 2010 – transition period of 2 years before full implementation
EXEMPTIONS

The Minister NRE may, upon recommendation of the NBB, exempt from the application of any or all of the provisions of this Act any person, class of persons, activity, category of activities, LMO or products of such organism (s68).

This list of Exemptions may be revised from time to time as necessary when more items are found to be safe and need not be regulated.
The First Schedule provides a list of exempted activities

Heavily borrowed from
- Australia Gene Technology Regulations (2001)
- UK GMO regulations (2000)
- Singapore Biosafety Guidelines for Research on Genetically Modified Organisms

Will be improved and updated periodically
FIRST SCHEDULE OF THE BIOSAFETY REGS 2010

Part I.

Techniques in relation to living modified organisms to which these regulations are not applicable.

Part II.

Contained use activities which are exempted from notification.

Part III.

Host/vector systems not regulated for contained use activities.
EXEMPTED ACTIVITIES

- Activities with LMOs that have been assessed over time as posing a very low risk.
- Contained research involving very well understood organisms and processes for creating and studying LMOs.
- Contained use activity only!
- No open release activity is exempted
SPECIFIC EXEMPTIONS

➤ When the LMO is a pharmaceutical or is for therapeutic purpose e.g. vaccine
  o regulated under other laws

➤ Exemptions by the Minister
  o Cotton used as fiber for any purpose in any form
  o Wood used for building and furniture

➤ Exempted activities may increase as more assessments prove of low risk activities
BIOSAFETY GUIDELINES

BIOSAFETY GUIDELINES: CONFINED FIELD TRIAL OF LIVING MODIFIED PLANTS IN MALAYSIA

User’s Guide to the Biosafety Act and Regulations

BIOSAFETY GUIDELINES: CONTAINED USE ACTIVITY OF LIVING MODIFIED ORGANISM

BIOSAFETY GUIDELINES: RISK ASSESSMENT OF GENETICALLY MODIFIED MICROORGANISMS

ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS IN MALAYSIA

GUIDELINES FOR INSTITUTIONAL BIOSAFETY COMMITTEES

Can be downloaded at www.biosafety.nre.gov.my
BIOSAFETY PUBLICATIONS

biosafety Q+A

35 frequently-asked questions on genetic modification
Welcome to BCH Malaysia Website

It was indeed a significant landmark event when the Malaysian Biosafety Act 2007 was passed in the Parliament on the 11th July 2007 and received the Royal Ascent on 29th August 2007. Even though it has been a rugged journey for this Act to be a reality, it is a positive and promising beginning for Malaysia to take a proactive approach towards protecting the environment and public health. The Minister of Natural Resources and Environment or National Biosafety Board (NBB) has been established to manage the implementation of the Act.

MALAYSIAN BIOSAFETY WEBSITE
http://www.biosafety.nre.gov.my

What's New

NEW Biosafety Q & A Cards

NEW Biosafety Q & A Cards Video in Youtube

ALL RELEVANT FORMS AND PUBLICATIONS MAY BE DOWNLOADED HERE
THANK YOU

www.biosafety.nre.gov.my

Email: biosafety@nre.gov.my

@DOBmy

Department of Biosafety Malaysia