



# OUTLINE

- Biotechnology & Biosafety
- Scope of Biosafety Act 2007
- Main Elements of Biosafety Act 2007
- Notification
- Approval
- Risk Assessment, Risk Management and Emergency Response Plan
- Confidential Business Information
- Exemptions
- Institutional Biosafety Committee
- Labelling
- Challenges



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- Capacity Building Needs
- Recommendations



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4

## BIOTECH LEAD AGENCY - MOSTI

- Malaysia a mega biodiverse country has huge potential for 'bio-wealth' creation through biotechnology
- ..... *biotechnology will be a new economic engine for Malaysia.....*

### BIOTECHNOLOGY POLICY 2005

- 9 Policy Thrust areas
- Thrust 7 – Legislative and Regulatory Framework Dev to ensure public safety whilst encouraging development
- Broad focus area: Agriculture, Healthcare and Industrial Biotech



MOSTI



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5

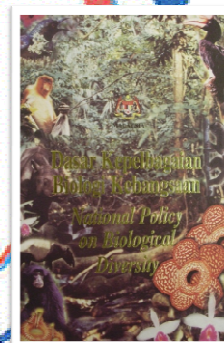
## BIOSAFETY LEAD AGENCY - NRE

- **NRE** is lead and focal agency for all matters relating to biosafety

### NATIONAL POLICY ON BIOLOGICAL DIVERSITY

1998

- Includes biosafety considerations in the development and application of biotechnology in harnessing biodiversity resources
- Strategy XI – Formulate legislation & regulation on biosafety



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6

## FOOD SAFETY LEAD AGENCY – MINISTRY OF HEALTH

### FOOD ACT 1983

To protect the public against health hazards and fraud in the preparation, sale and use of food, and for matters incidental thereto or connected therewith.



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7

## FOOD SAFETY LEAD AGENCY – MINISTRY OF HEALTH

### FOOD REGULATIONS 1985

### FOOD (AMENDMENT)

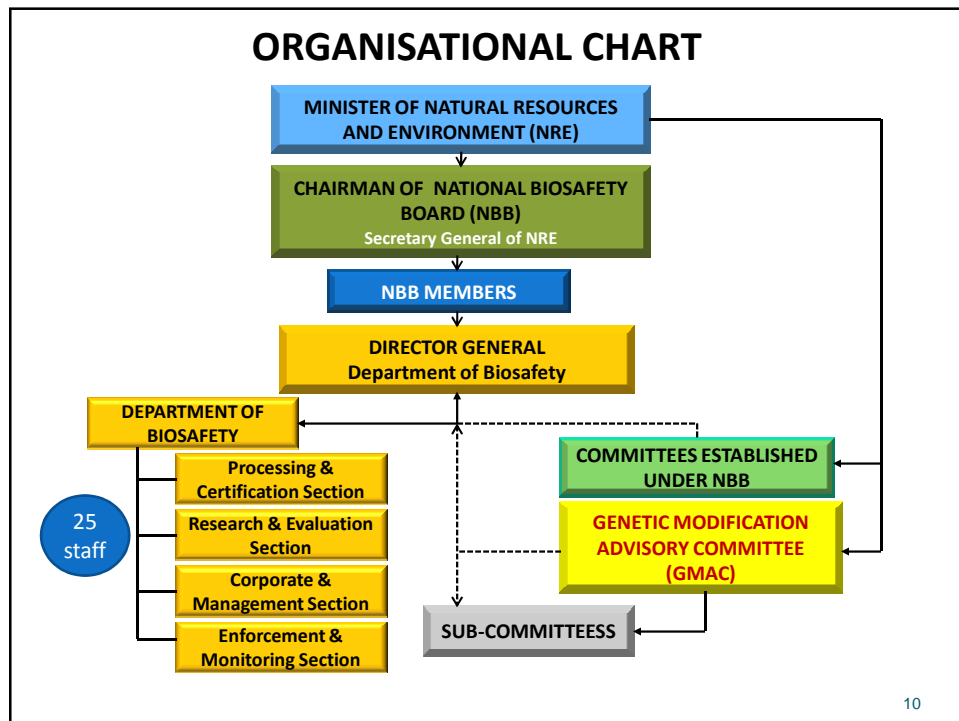
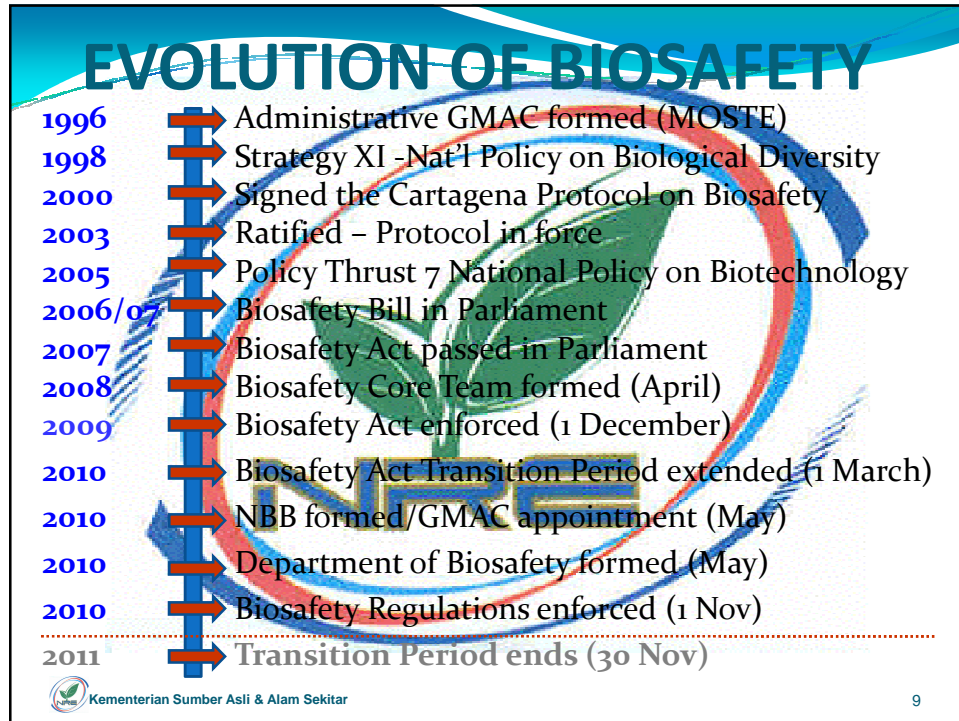
### REGULATIONS 2010

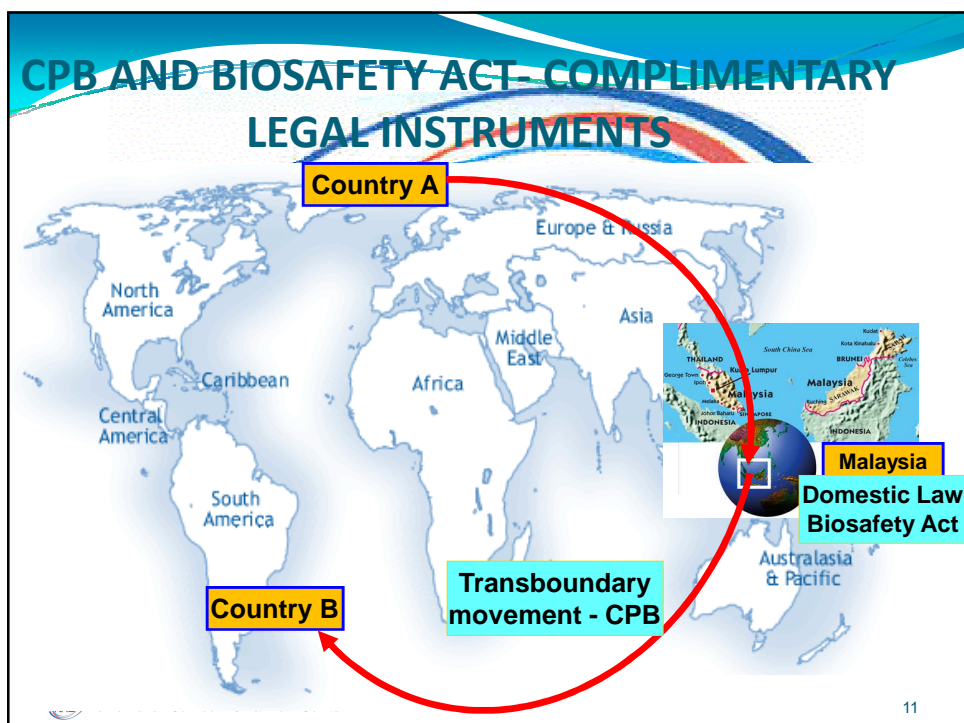
No person shall import, prepare or advertise for sale or sell any **food and food ingredients obtained through modern biotechnology** without prior written approval of the Director i.e. Deputy Director General of Health (Public Health), Ministry of Health



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8





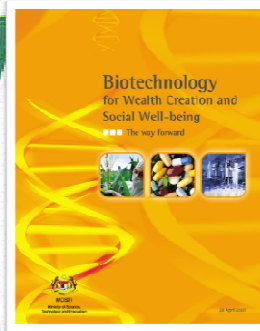
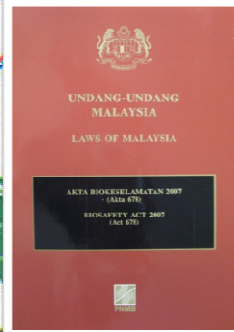
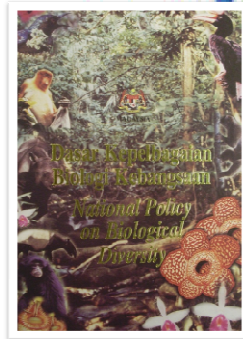
## BIOSAFETY ACT 2007

- Complement the implementation of the National Policy on Biotechnology (2005) and also the National Policy on Biological Diversity (1998) and Food Regulations .
- Fulfill Malaysia's obligation under the CPB to have a domestic regulatory framework.
- Boost the confidence of investors in biotech
- Give a clear direction on regulatory framework on modern biotechnology
- Not intended to disrupt R&D

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12

# BIOSAFETY IN MALAYSIA



Strike a balance - creating an enabling environment to gain the maximum benefit from modern biotechnology but at the same time minimizing risks to the environment and health



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13

# MALAYSIA'S PROTECTION GOAL

## OBJECTIVE OF THE ACT

To establish the National Biosafety Board; to regulate the release, importation, exportation and contained use of living modified organisms, and the release of products of such organisms, with the **objectives of protecting human, plant and animal health, the environment and biological diversity**



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14

## SCOPE OF BIOSAFETY ACT

### Federal Act

Applicable to all States in Malaysia

### Limited to Modern Biotechnology

Application of:

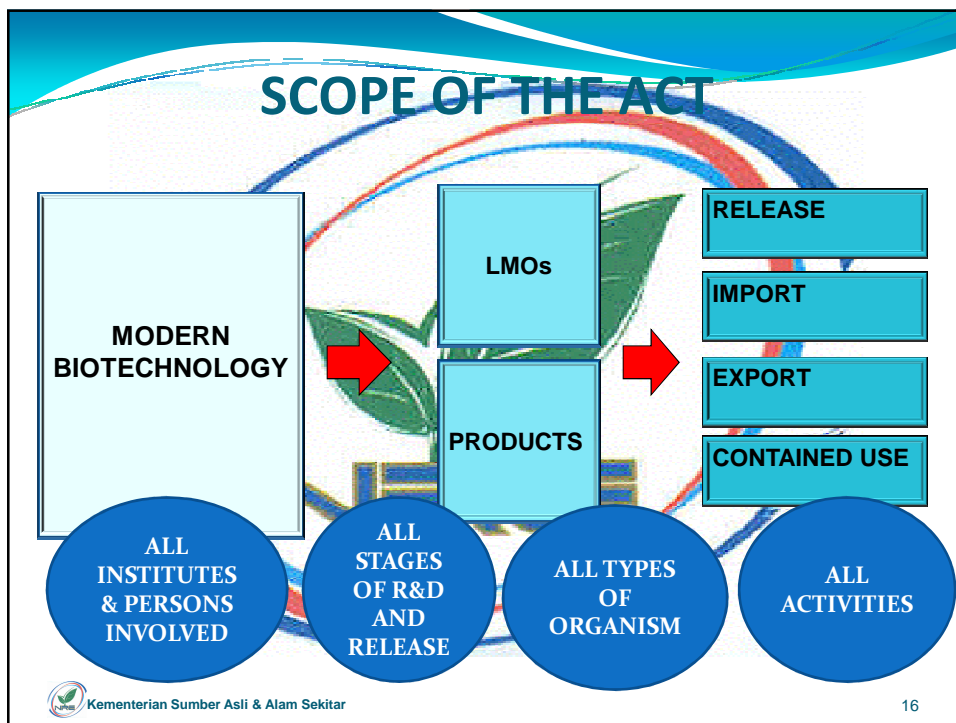
- In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (UN Cartagena Protocol on Biosafety (CPB) & the Biosafety Act)



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15

## SCOPE OF THE ACT



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16

## LMOs

Any living organism that possesses a **novel combination of genetic material** obtained through the use of modern biotechnology



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17

## 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



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18

## 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



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19

## CONTAINED USE

Any operation including **R&D**, production or manufacturing operation **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...]



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20

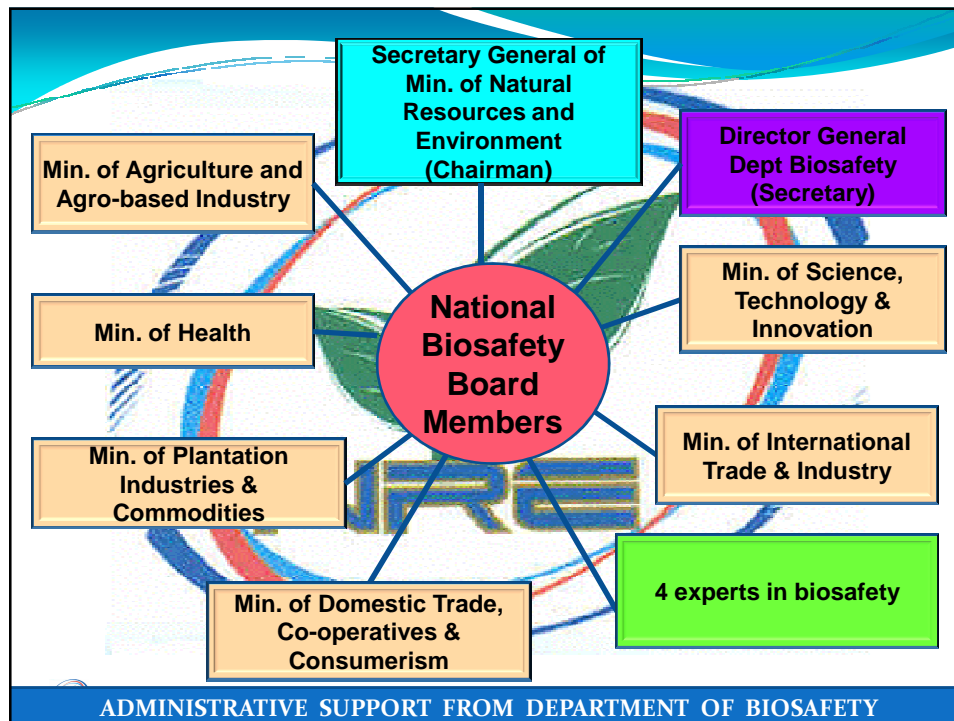
## MAIN ELEMENTS OF THE ACT

- Establish of **NBB** -key function is decision making
- Establish **GMAC** to give science based advise - to assist NBB (13 were appointed)
- Based on precautionary approach - if there are threats of irreversible damage, lack of full scientific evidence may not be used as reason not to take action to prevent such damage
- Operational issues such as application process will be spelt out in Regulations (s69)



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21



## FUNCTIONS OF NBB

- to decide on all applications to monitor activities relating to living modified organisms and products of such organisms;
- to promote research, development, educational and training activities relating to biosafety;
- to establish mechanisms to facilitate the collection, storage and dissemination of data relating to living modified organisms and products of such organisms and biosafety; and
- where so directed by the Minister, to perform or provide for the performance of the obligations arising from agreements, conventions or treaties relating to biosafety to which Malaysia is a party where such agreements, conventions or treaties relate to the purposes of this Act.



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23

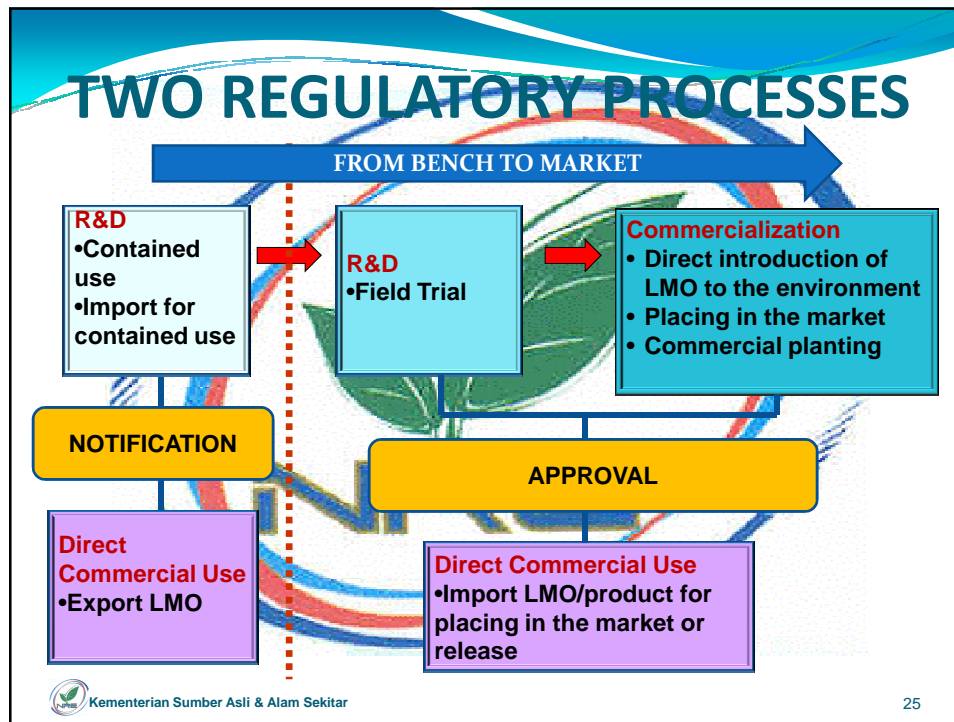
## GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

- Provides **scientific assessment** of applications for approval and 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 subject to any general directions given by the Minister.
- The Chairman of GMAC is appointed by the Minister.
- Members of GMAC are appointed by NBB and consist of **experts from various science-based and other relevant disciplines** (e.g. genetic engineering, molecular biology, microbiology, genetics)



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24



## NOTIFICATION

- Activity can start after receiving acknowledgement from Dept of Biosafety
- In parallel GMAC & NBB shall assess the activity relating to the notification and a decision will be made known within **90 days**
- Assessment of NBB may result in-
  - ☐ No order
  - ☐ Order Cessation
  - ☐ Impose Terms
  - ☐ Order Rectification
  - ☐ Other Orders



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27

## FEES FOR NOTIFICATION

Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 15. RM200

Notification of an activity involving genetic modification in class 2 under regulation 11(1), except a notification to which paragraph 4(1) or paragraph 5(1) of Schedule 10 applies. RM400

Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 2 under regulation 10(1). RM400

Notification of an activity involving genetic modification in class 3 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies. RM430

Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 3 under regulation 10(1). RM430

Notification of an activity involving genetic modification in class 4 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies. RM500

Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 4 under regulation 10(1). RM500

Notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1). RM400

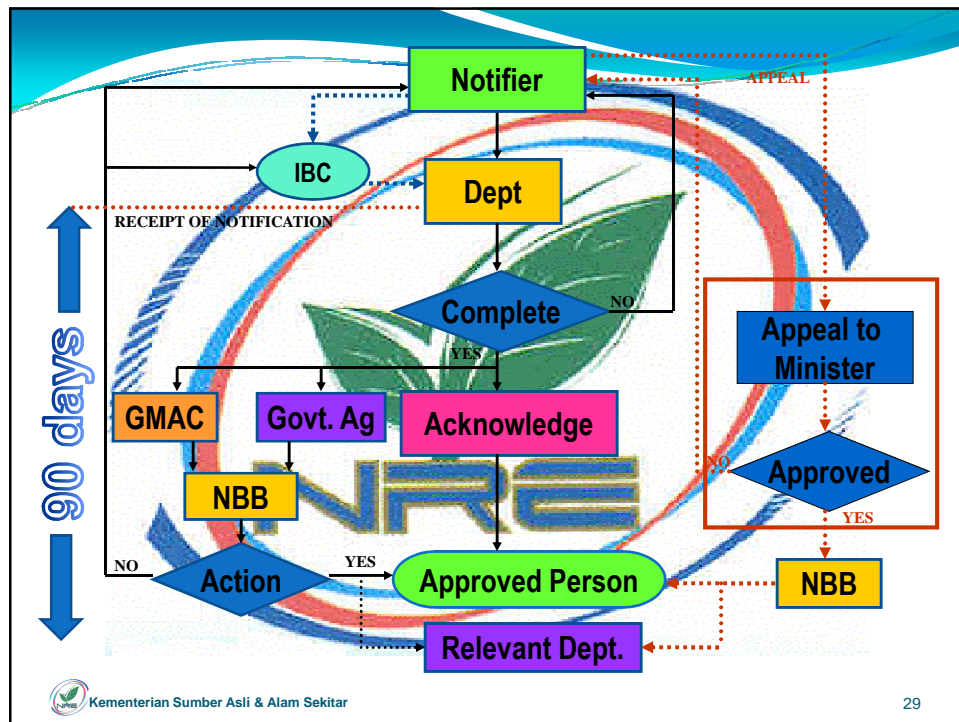
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1). RM400

Notification of additional information under regulation 15(3). RM300



Application for the written agreement of the competent authority under regulation 18(2) where the application is made after a notification has been submitted pursuant to regulation 9(1), 10(1), 11(1) or 12(1). RM300

28



## APPROVED APPLICATIONS

- Activity can start only after getting Certificate of Approval
- When application is approved, NBB will issue a certificate to the applicant
- An approved person **shall not undertake any release activity or any importation of living modified organisms other than for which the certificate has been issued**



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31

## FEES FOR APPROVAL

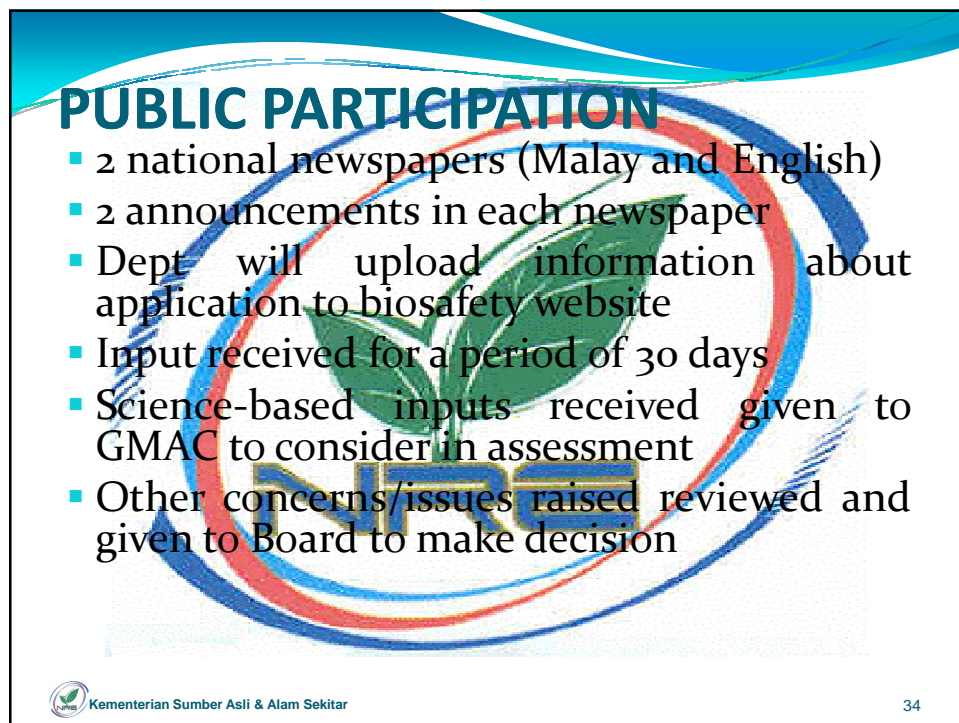
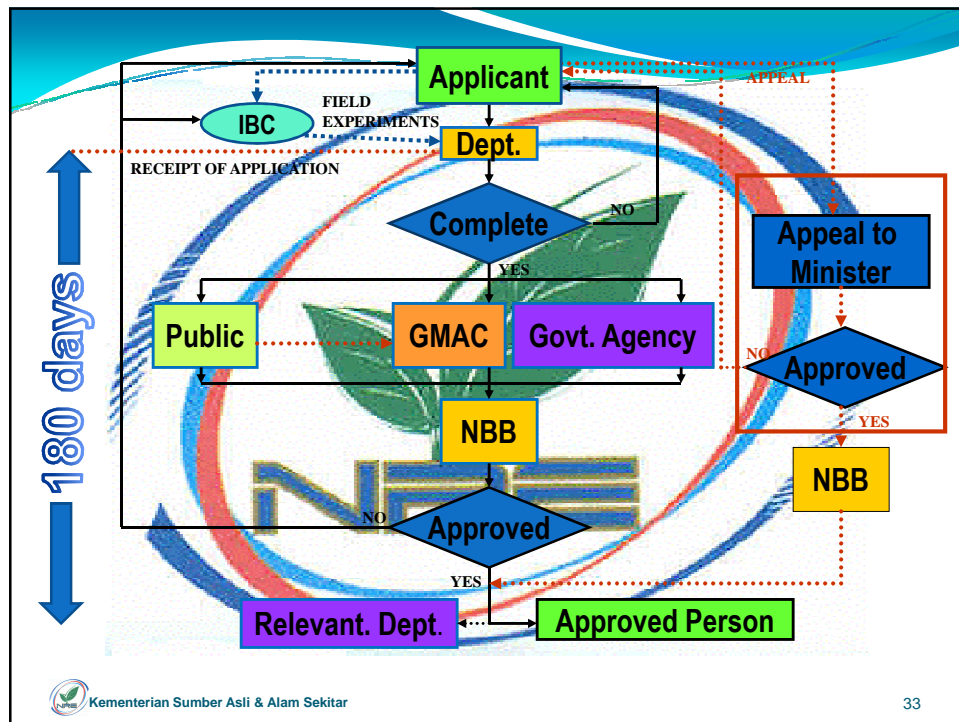
TYPE OF APPLICATION	FEES (RM)
Field Experiment below 5 hectares per location	100
Field Experiment 5 to 10 hectares per location	250
Field Experiment above 10 hectares per location	500
Commercial field release (approved LMOs)	No charge
Other Release activities (Schedule 2 of the Act)	5000

**Note - Cost of public announcement borne by applicant**



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32



## PREVIOUS APPROVALS

Former GMAC (under MOSTE and NRE) has administratively assessed and made decisions on applications before the Biosafety Act was enforced

NBB Meeting Bil 1/2010 on 25 May 2010 decided on the status of the previous applications as follows:

- all previous decisions for release activities and contained use activities issued by former GMAC will be retained
- decisions may be reviewed if there is new information on risks
- applicants are informed to submit any new information including risk on the LMOs/products that have been approved



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35

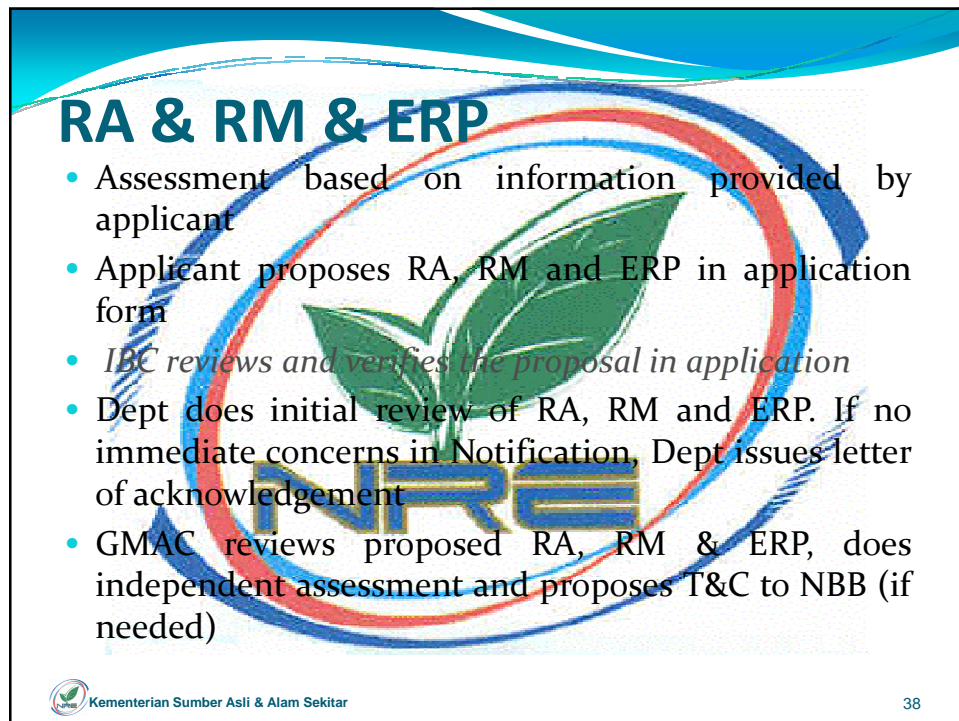
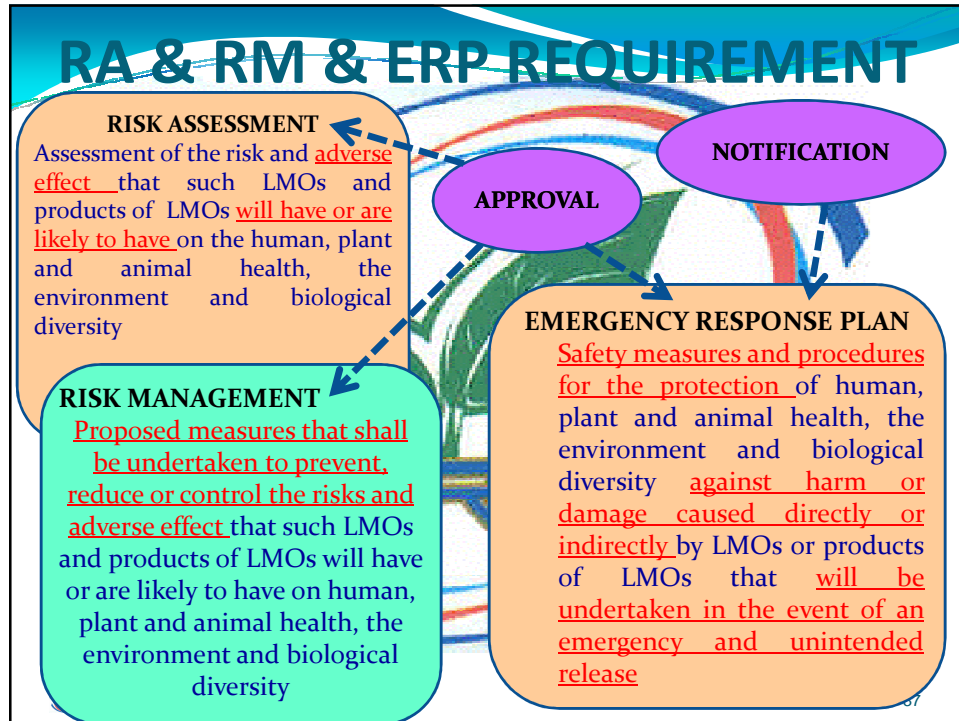
## APPROVED EVENTS/PRODUCTS

EVENT/PRODUCT	PURPOSE	APPLICANT
Roundup Ready Soybean GTS-40-3-2	Food, Feed & Processing	Monsanto
Roundup Ready Corn Event NK603	Food, Feed & Processing	Monsanto
Yieldyard Corn Borer Corn Event MON 810	Food, Feed & Processing	Monsanto
Rootworm Corn Event MON 863	Food, Feed & Processing	Monsanto
Ice-Structuring Protein (ISP)	Food	Unilever



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36



## RA & RM & ERP

- Minimum RM measures required determined by NBB with consultation from GMAC
- NBB makes decision and issues out T&C (if needed)
- Applicant to incorporate into design, construction and operation as applicable and carry out & comply these minimum RM to the satisfaction of the NBB
- Applicant to take the necessary measures in an emergency or shall on conviction be liable



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39

## ASSESSMENT OF INFORMATION

### Contained Use

- ✓ Type of activity conducted
- ✓ Facility used
- ✓ Nature of LMOs being worked on
- ✓ Proposed transport of LMOs outside stated premises and precautions taken
- ✓ Disposal of LMOs
- ✓ Decontaminating equipment
- ✓ Actions and precautions taken to minimise risks posed by proposed activities
- ✓ Etc...




### Field Trial

- ✓ Location
- ✓ LMO characteristics
- ✓ Size and scale of trial
- ✓ Survival capabilities of LMO
- ✓ Disposal of LMOs
- ✓ Decontaminating equipment
- ✓ Actions and precautions taken to minimise risks posed by proposed activities
- ✓ Etc...




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40




## CONFIDENTIAL BUSINESS INFORMATION (CBI)

- Handling of these confidential information/documents is subject to:
  - ☐ General Order (for Government officers)
  - ☐ Official Secrets Act 1972
  - ☐ Biosafety Act 2007 (s59)
- This provision is consistent with the provision in WTO
- Offence punishable



NARS

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41



## CRITERIA FOR CBI

Confidentiality can be claimed for the following:

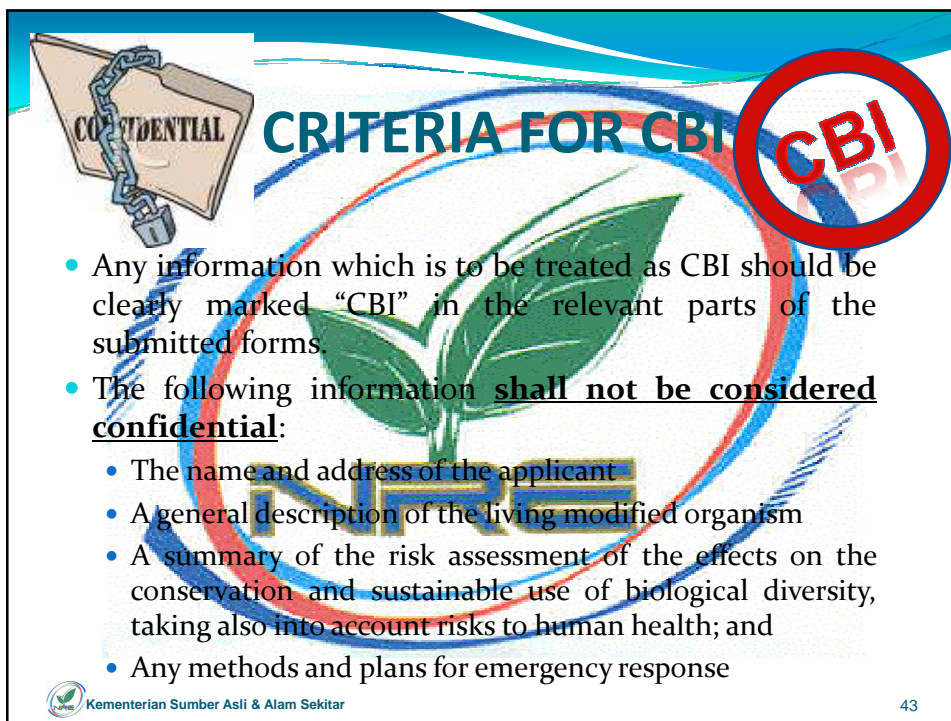
- that the information is not known generally among, or readily accessible to, any person within the circle that normally deals with the kind of information sought to be made confidential
- that the information has commercial value because it is secret and
- that reasonable steps have been taken to keep the information secret



NARS

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42




**CRITERIA FOR CBI**

**CONFIDENTIAL**

**CBI**

- Any information which is to be treated as CBI should be clearly marked “CBI” in the relevant parts of the submitted forms.
- The following information **shall not be considered confidential**:
  - The name and address of the applicant
  - A general description of the living modified organism
  - A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
  - Any methods and plans for emergency response

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43



**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

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44

## ENFORCEMENT

- NBB has appointed qualified persons from the Chemistry Department Malaysia (*Jabatan Kimia Malaysia*) as analyst to assist in enforcement activities



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## EXEMPTIONS

- The Minister 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



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46

## EXEMPTIONS

- Pharmaceuticals produced by LMOs including LMOs that are pharmaceuticals are exempted
- A list of techniques and activities normally used in modern biotechnology research (on condition that the safety measures are met), which have been proven safe are not regulated and have been listed under the Non-application provision of the Regulations.



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47

## EXEMPTIONS

- LMO which have been approved for FFP (food, feed and processing) will be exempted from applications for subsequent use for FFP. Only one time approval is needed, for the first time use.
- Products of LMOs that are non-viable such as processed wood and cotton are exempted
- Notification for export – same LMO to same country for same purpose, exempt from any subsequent Notification



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48

## APPROVAL OF GM FOOD - MOH

- All food products must get approval from MoH (even though it is from approved event)

### *Tentative processing mechanism*

- Form – available at <http://fsq.moh.gov.my>
- Submit via email/post/fax
- 1 month processing time
- No fees
- Further information, please email Pn. Shazlina – [shazlina@moh.gov.my](mailto:shazlina@moh.gov.my)

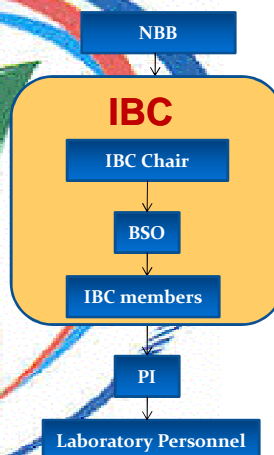


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49

## INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Formal expert committee of an organization undertaking MB R&D which involves use of any LMO/rDNA materials – to monitor & ensure compliance to the Biosafety Act 2007 at the institutional level and safe handling of MB activities



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REGISTERED WITH NBB – FORM G, NO FEES!

## LABELLING

- All LMOs, items containing LMOs and products of such organism - mandatory labelling (s61 of BA)
- GM Food Labelling under Food (Amendment) Regulations 2010
- 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 for full implementation




51


## LABELLING

- **Origin** of food/food ingredients obtained through MB  
 “**gene derived from (XX)**”
- Food/food ingredients **composed of/ contains** GMO  
 “**genetically modified (XXX)**”
- Food/food ingredients **produced from**, but does not contain GMO  
 “**produced from genetically modified (XXX)**”






52



## CHALLENGES

- Awareness
- Training
- Sampling
- Declaration
- Enforcement
- Other related legislatures

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53



## CAPACITY BUILDING NEEDS

- Resources
- Training Materials
- Technical Guidance
- Infrastructure

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54



# RECOMMENDATIONS

- Information Sharing
- Capacity Building
- Standard Operating Procedures
- Delegation of Powers
- Outreach and cooperation

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55



**NATIONAL BIOSAFETY CLEARING HOUSE - MALAYSIA**  
Department of Biosafety  
Ministry of Natural Resources and Environment

**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 Assent 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 human health and the environment from the possible adverse effects of the products of modern biotechnology as well as to fulfill Malaysia's obligation under the Cartagena Protocol on Biosafety.


After a series of consultation with the industry and other stakeholders, the Biosafety Act is in force effective **1st December 2009**. Under the Act, Ministry of Natural Resources and Environment (NRE) has been given the mandate to set up a National Biosafety Board (NBB) that will be responsible to regulate the release, importation, exportation and contained use of any living modified organism derived from modern biotechnology and products of such organisms. The Chairman of the Board is the Secretary General of NRE, representatives from Ministry of Agriculture and Agro-based Industry, Ministry of Health, Ministry of Plantation Industry and Commodities, Ministry of Domestic Trade, Co-operatives and Consumers, Ministry of International Trade and Industry, Ministry of Science, Technology and Innovation, and not more than four other persons with knowledge and/or experience in any disciplines or matters relevant to this Act. The Genetic Modification Advisory Committee (GMAC) will also be established to provide scientific, technical and other relevant advice to the Minister of Natural Resources and Environment or NBB. Members of GMAC consist of experts from various science-based and other relevant disciplines.

**What's New**

- NEW** Biosafety Regulations 2010
- NEW** Approved Field Experiment


**http://www.biosafety.nre.gov.my**

Convention on Biological Diversity / Central Portal of the Biosafety Clearing-House



**THANK YOU**

[www.biosafety.nre.gov.my](http://www.biosafety.nre.gov.my)  
[biosafety@nre.gov.my](mailto:biosafety@nre.gov.my)

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57