Biosafety and Biosecurity in UPM

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Outline of the presentation

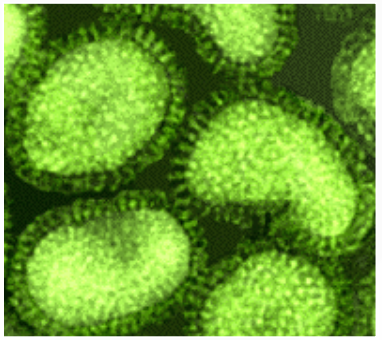
- Biohazard and Risk Group Classification
- Biosafety versus Biosecurity
- Bioethics in Research – animal, human and LMO/GMO, biological agents
- Are we ready to address biosafety and biosecurity requirements

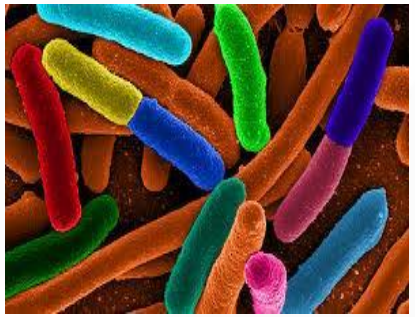
Hazard

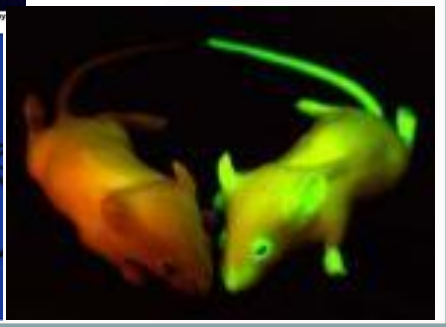
- Something that is intrinsically dangerous - an object, a chemical, an infectious agent or a situation.
- Hazards are categorized into three groups:
  - ***Physical*** **hazards** – electrical, compressed cylinder, etc.
  - ***Chemical*** **hazards**
  - ***Biological*** **hazards @ Biohazard are infectious agents [wild type or genetically modified (LMO, GMO)], infected tissues/secretions, recombinant DNA**

Biohazard Materials

- Viruses
- Bacteria
- Fungi
- Chlamydiae/Rickettsiae
- Prions
- Recombinant DNA
- Transgenic Plants, Animals & Insects
- Human and Primate Cells, Tissues, and Body Fluids
- Brain Tissue from Demented Patients
- Viral Vectors
  - Replication deficient viruses





Biosafety in Academic Research

- promoting safe lab practices & procedures;
- proper use of containment equipment and facilities
- provides advice on lab design and
- risk assessment of experiments involving infectious agents, recombinant DNA in-vitro and in-vivo.

All of us need to play our part

- Principal investigator
- Lab manager
- Biosafety Officer
- Safety Health Officer
- Veterinarian
- Science Officers
- Students
- Lab technician
- Animal Handlers
- Cleaner

Biological Hazard - Risk Group Classification (level 1 to level 4)

- Agent Risk Group Classification
  - Based upon microbiology
  - Pathogenicity of the organism
  - Mode of transmission
  - Host range
  - Availability of effective preventive and treatment measures (e.g. vaccines, antibiotics)
  - Geographic considerations (endemic ?)

WHO Lab Biosafety Manual 3rd Edition

Risk Group Classifications

- Risk Group 1 - managed at Biosafety Level 1 (BSL1)
  - Agents are not associated with disease in healthy humans. eg. *E. coli* K12 strains, *B. subtilis, S. cerevisiae*

- Risk Group 2 - managed at Biosafety Level 2 (BSL2)
  - Agents are associated with human disease of varying severity (rarely serious) and for which preventative or therapeutic interventions are often available. eg. *Salmonella,* Vibrio, Malaria, Hepatitis B Virus, *Cryptococcus neoformans, E. coli* 0157:H7

Majority of labs at UPM fullfill BSL-1 and BSL-2 requirement

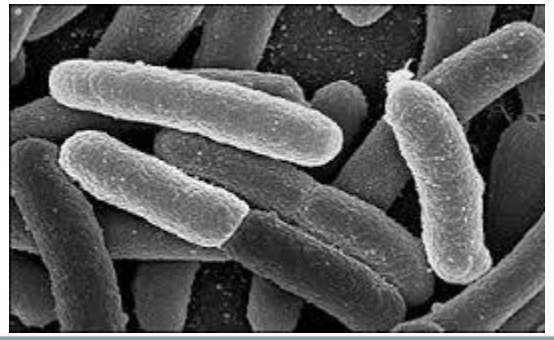
Biosafety Level 1 (BSL-1)

Standard Work Practices

- Use mechanical pipetting devices
- Wash hands frequently
- Minimize splashes and aerosols
- Decontaminate work surfaces daily
- Handle wastes properly

Personal Protective Equipment (PPE)

- Lab coat or apron
- Safety glasses or goggles
- Gloves as needed



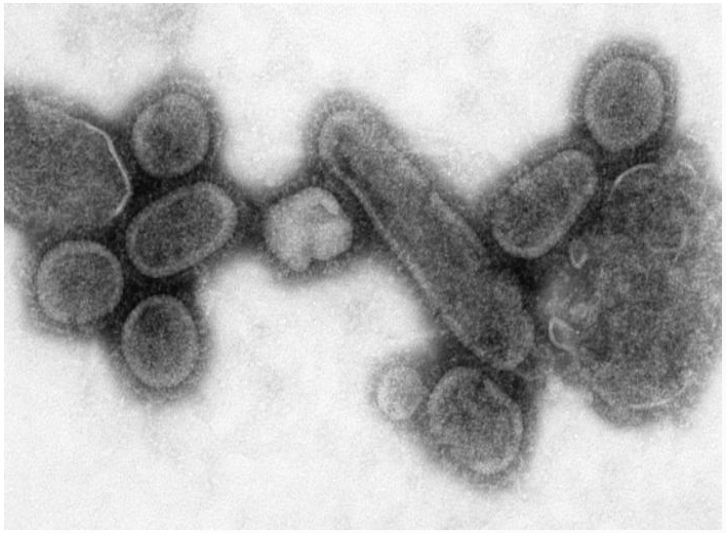
Biosafety Level 2 (BSL-2)

Use BL-2 practices when working with:

- Agents of moderate potential hazard to personnel and the environment

Examples of BL-2 agents:

- Human blood or body fluids
- Numerous viruses
- *Clostridium botulinum*
- Retroviral vectors
- Human cells in cell culture



Biosafety Level 2 (BSL-2)

Standard Work Practices

- As in BSL-1
- Additional practice
  - Restricted access
  - Place used slides/coverslips in sharps containers
  - Adequate training

Personal Protective Equipment (PPE)

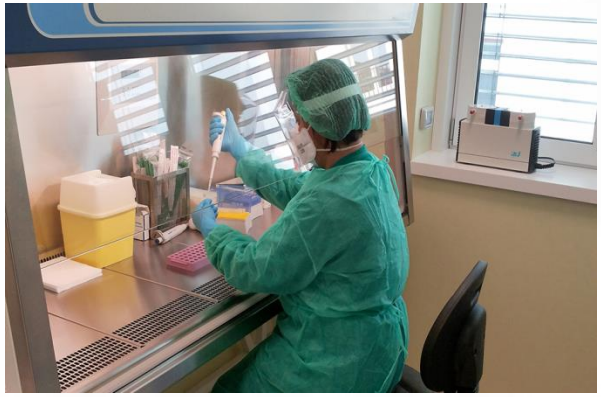
- Lab coat or apron
- Safety glasses or goggles
- Gloves
- Biosafety cabinet

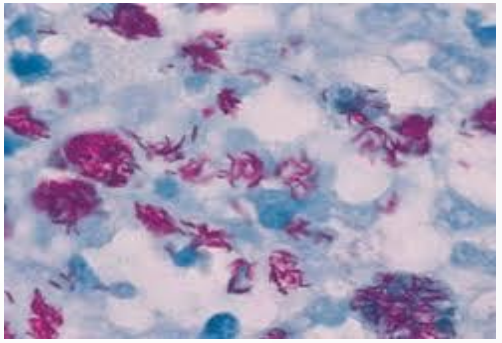
Biosafety Level 2 (BSL-2)

- Adequate illumination
- Eyewash facility (chemical versus biological)
- Autoclave available
- Biological safety cabinet (various types/class)
- Lab must be separated from public areas
- Hand-free sink

Biosafety Level 3 (BSL-3)

- Agents are associated with serious/lethal human disease for which preventative or therapeutic interventions *may* be available eg. *Brucella abortus, Mycobacterium tuberculosis, H5N1, HIV, anthrax*
- Specialized facility; double-door entry, dedicated HVAC (HEPA filtration optional), on-site decontamination, all activities performed in BSC



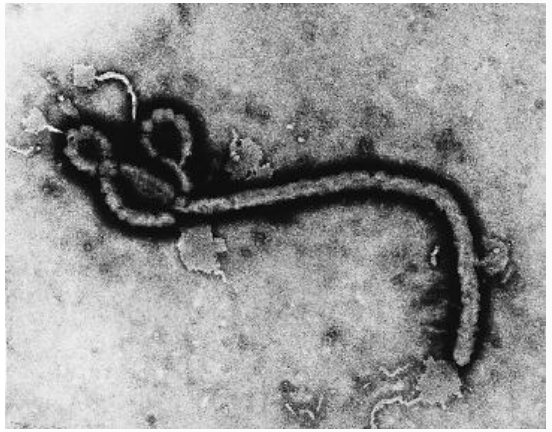


Not widely available at UPM

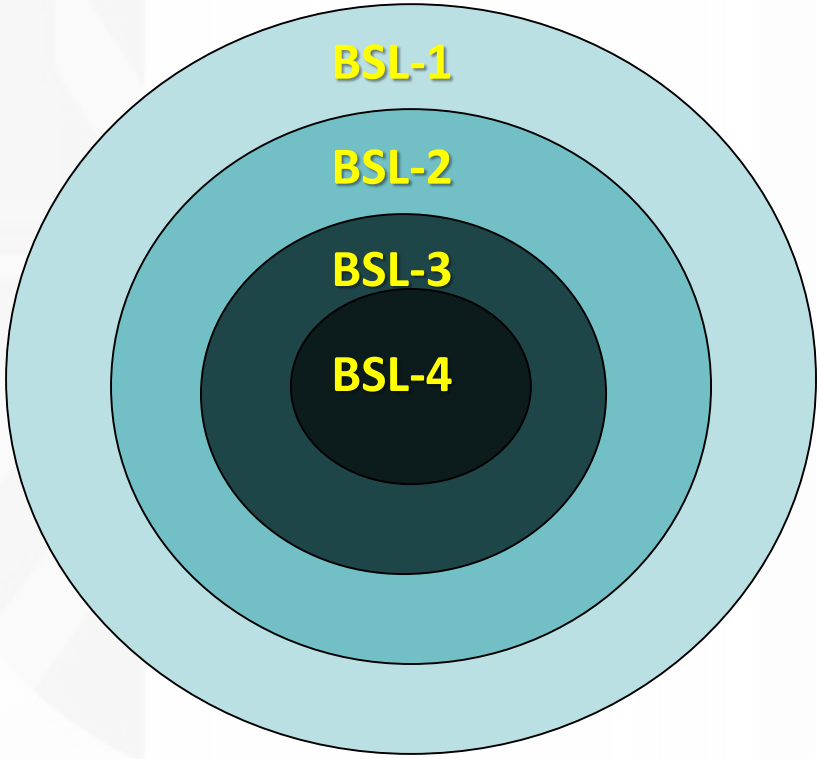
Biosafety Level 4 (BSL-4)

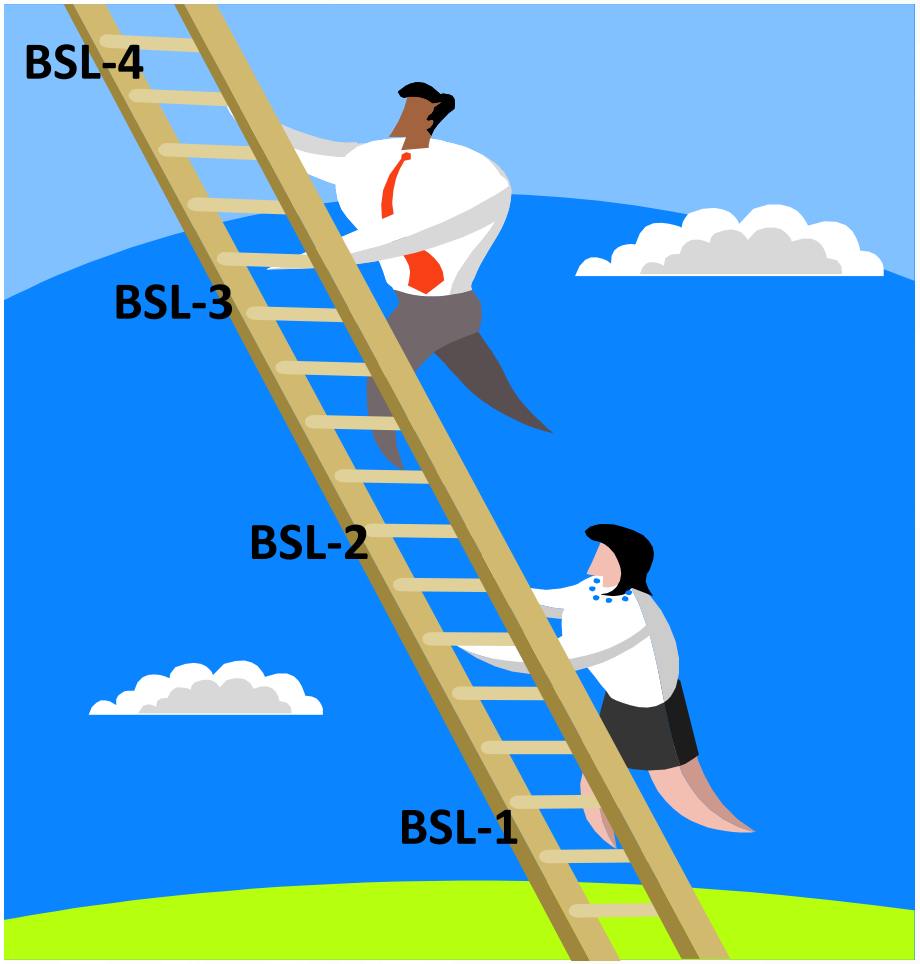
- Agents are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are *not usually* available (high individual risk and high community risk). eg. *Ebola,*
- Highly specialized facilities; air locks, HEPA filtration, kill tanks, moon suits, glove boxes, etc.

Not available at UPM



Biosafety levels build on each other

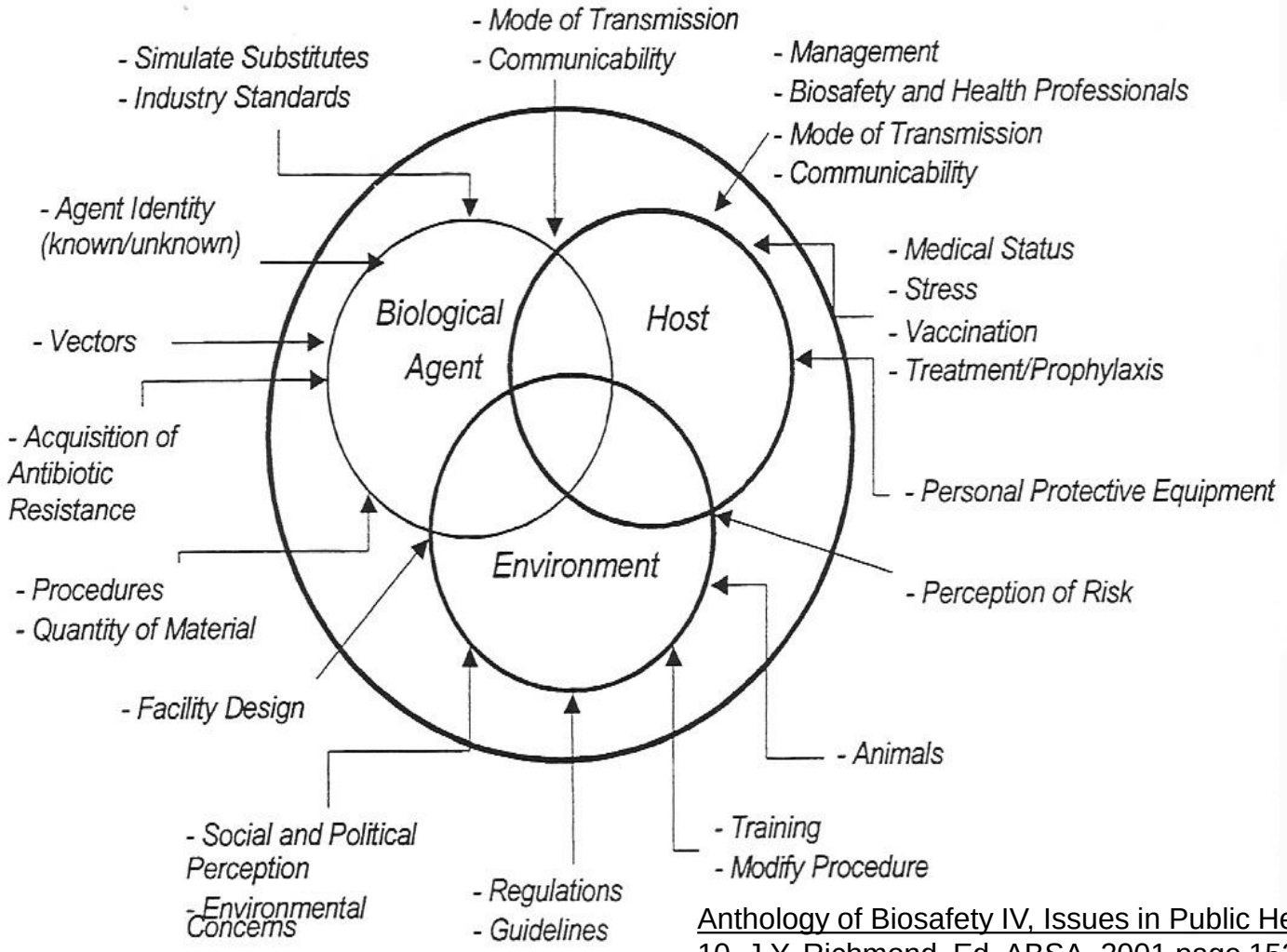




Biosafety Containment Levels

- Reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents.
  - **Primary containment**, the protection of personnel and the immediate laboratory environment
  - **Secondary containment**, the protection of the environment external to the laboratory
  - The **risk assessment** of the work to be done with a specific agent will determine the appropriate combination of these elements.

Risk Assessment Factors



Anthology of Biosafety IV, Issues in Public Health, Chapter 10. J.Y. Richmond, Ed. ABSA, 2001 page 152

Biohazard Risk Assessment: When

- Regular intervals-annually
- Whenever a change in research program occurs
  - Move or renovation
  - New employee/students
  - New pathogen or reagent
  - New equipment
  - New technique or procedure

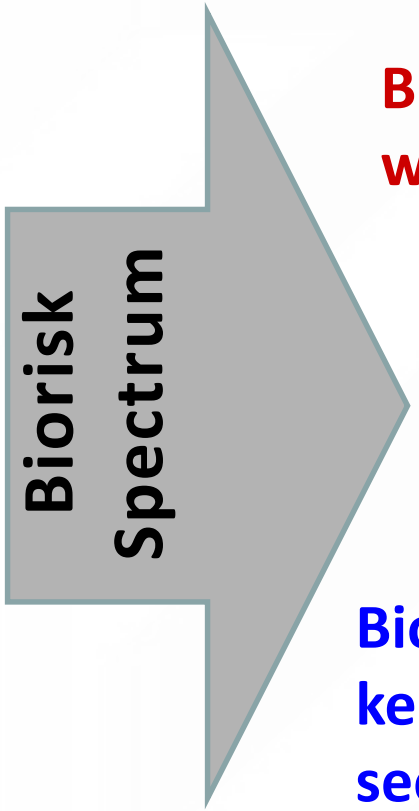
Biorisk Spectrum

Naturally occurring :

- Outbreaks on infectious diseases
- Communicable diseases
- Lab acquired infections – lack awareness, negligence
- Importation, ie. migrant labour, travel, etc

Perceived Risk :

- Modern Biotechnology –genomics, synthetic biology, nanotechnology
- Dual use / Misuse
- Bioterrorism



Biosafety – working safety

Biosecurity – keeping the work secure

Legal Frameworks

- ✓ International obligations – WHO, NIH, Cartagena, BWC, IHR, UNDO, WMA- Helsinki 1964, ICH-GCP, 1997, CIOMS and various other related documents

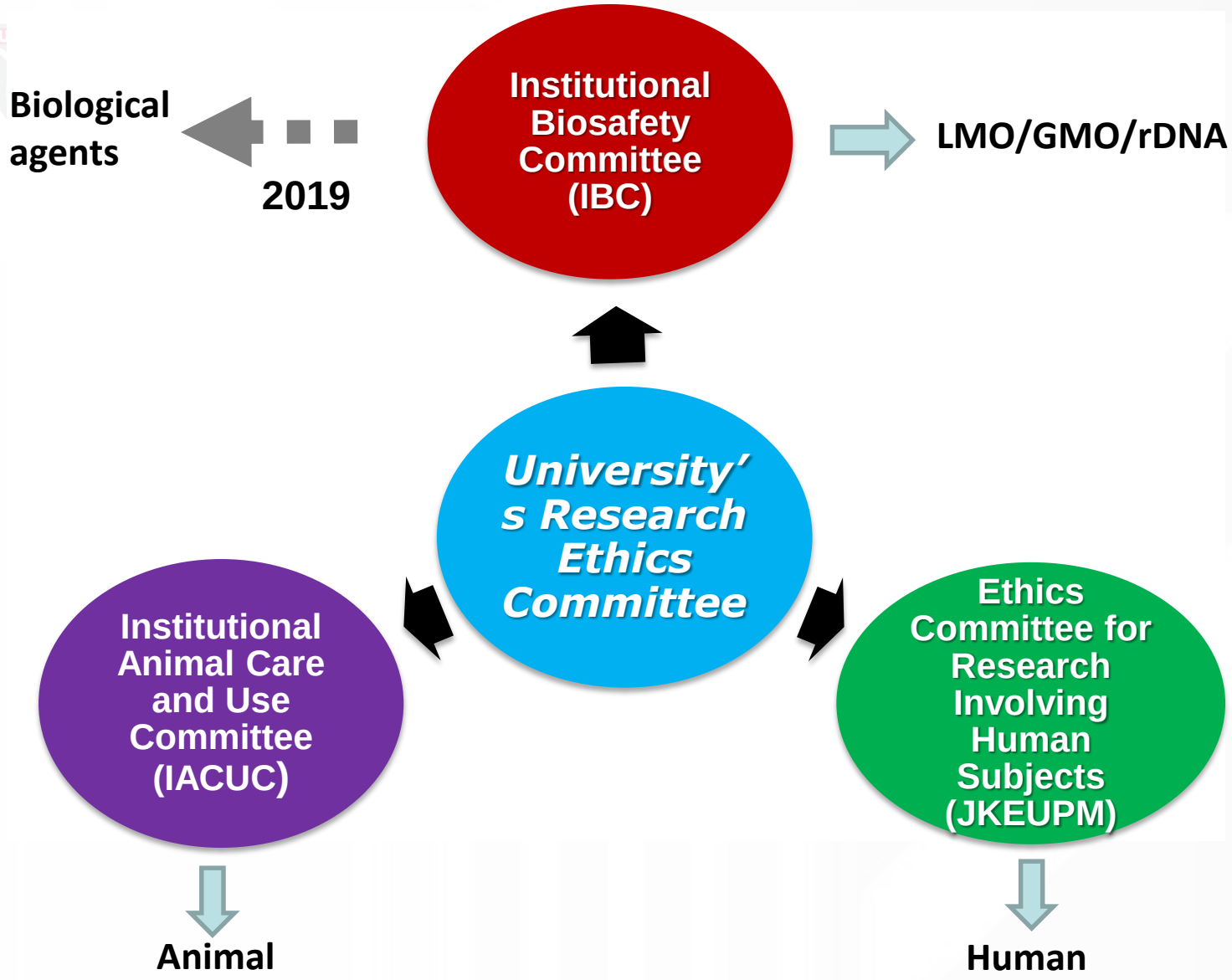
- ✓ National obligations – Biosafety Act, Malaysia Lab Biosafety and Biosecurity policy, Malaysian Guideline for GCP, MREC, Animal Welfare Act, and various legislations related to biological safety and security.

Universiti Putra Malaysia (Research) Rules 2012

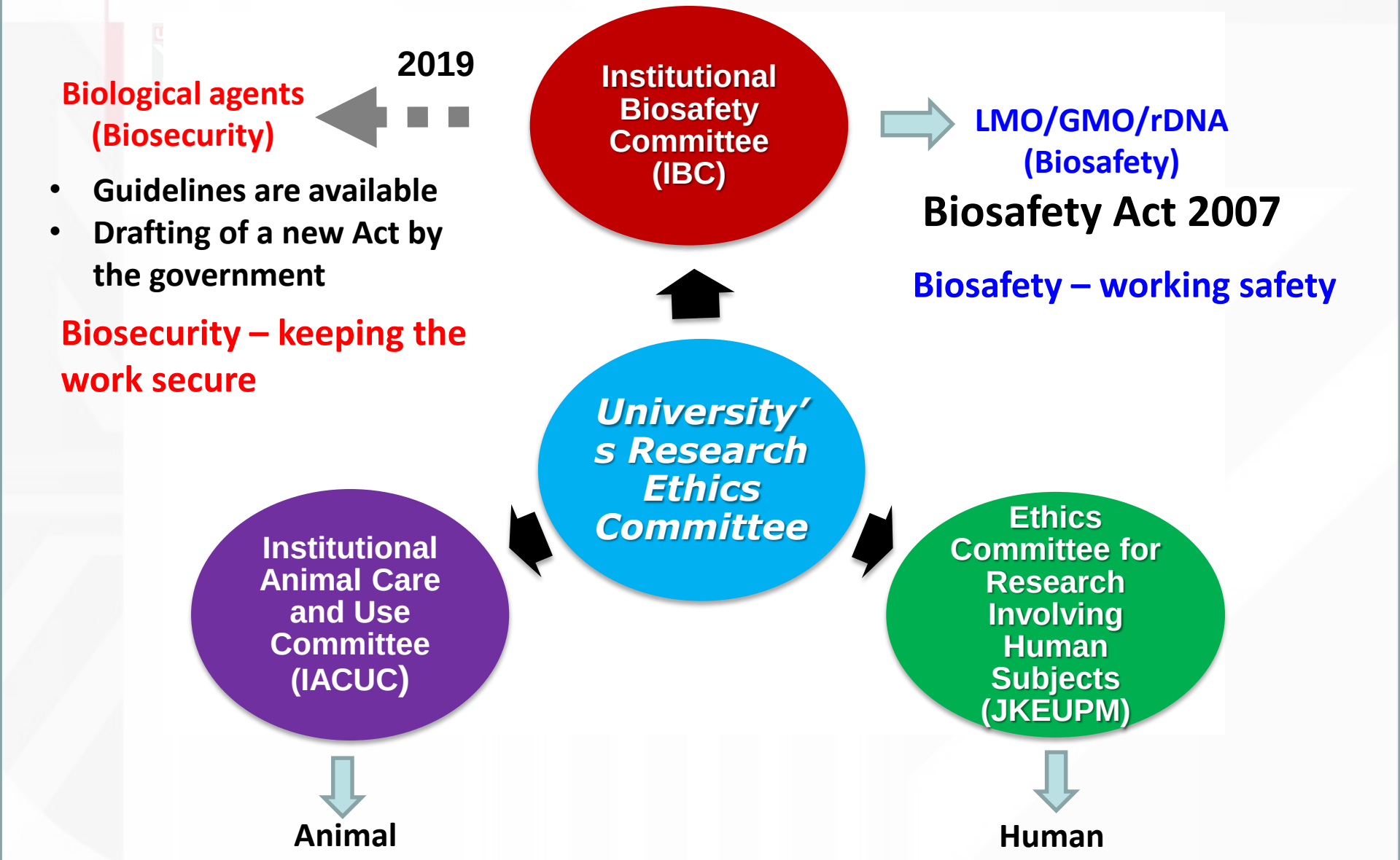
Part C : Ethics and Disciplines in Research (page 12-15)

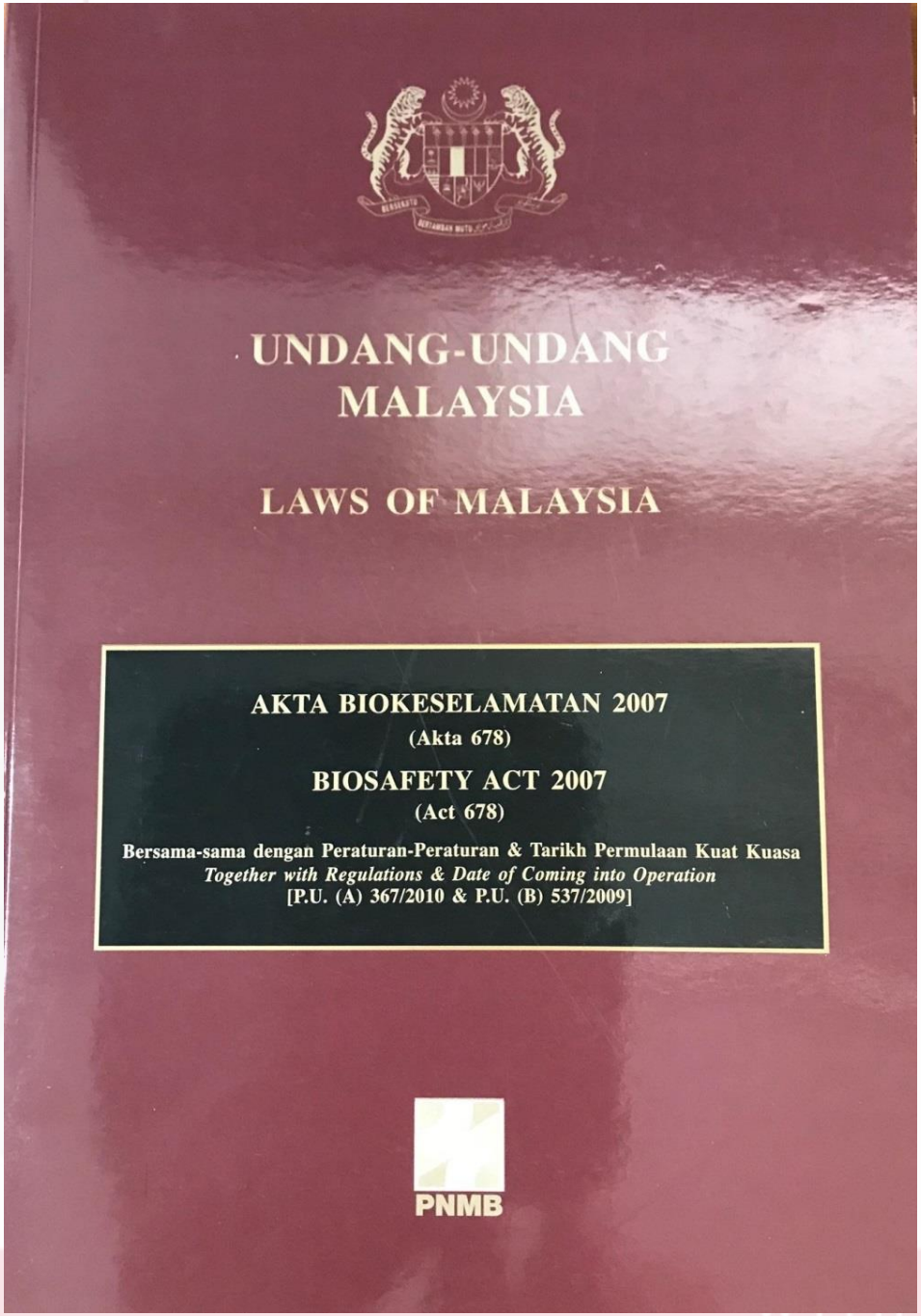
http://www.rmc.upm.edu.my/dokumen/PTPPY1_kaedahupmbi.pdf

UPM Research Ethics Committee



UPM Research Ethics Committee



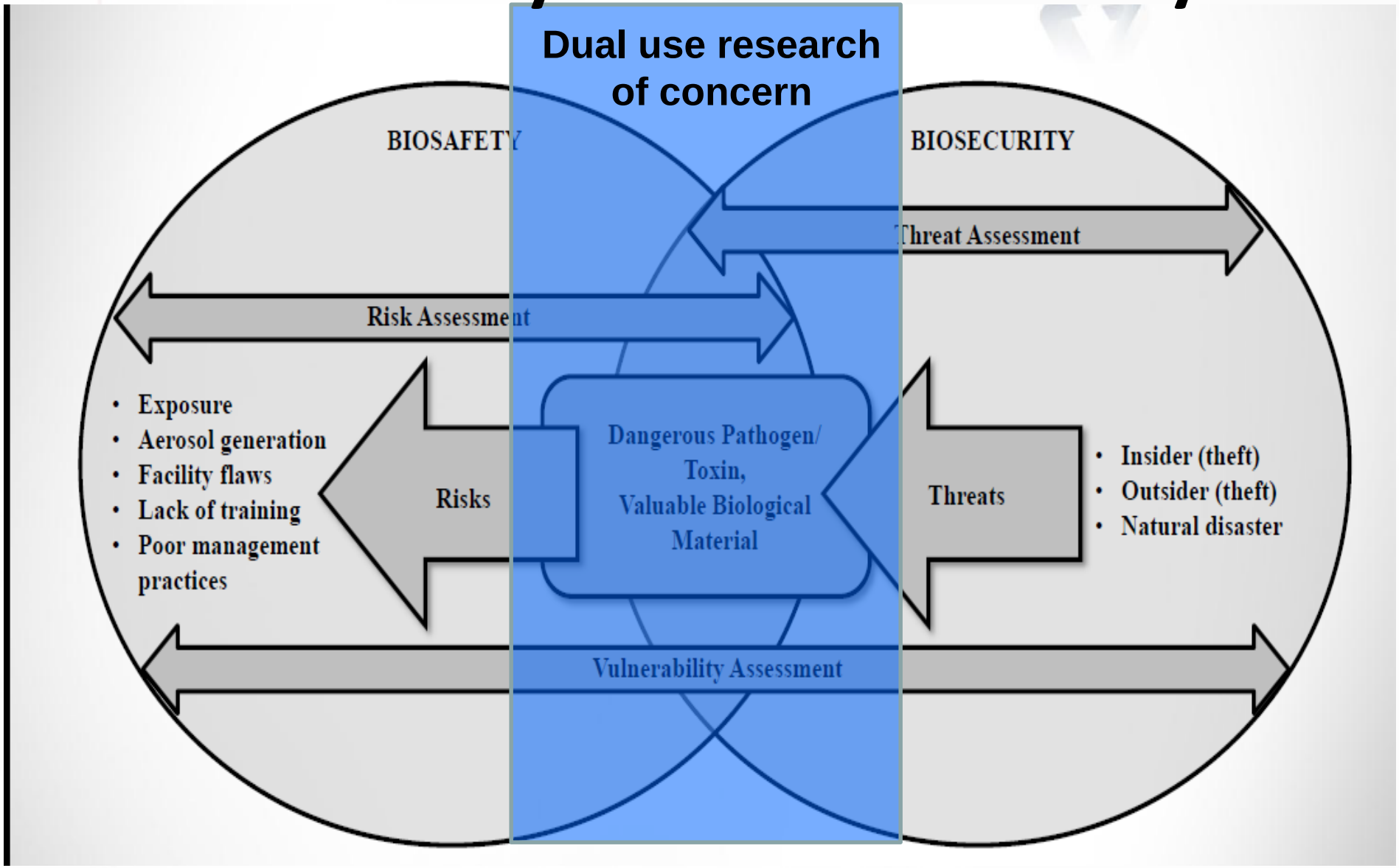


Biosafety Act 2007

Biosafety versus Biosecurity

- Biosafety is defined as laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release. Therefore, biosafety protects people from harmful germs and efforts to ensure biological safe and clean environment
- Biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release. Therefore, biosecurity protects such materials from people.

Biosafety versus Biosecurity



Source : Biosecurity : Understanding, Assessing & Preventing the Threat. John Wiley & Sons, Inc. Ch. 4, July 2013. R.N. Burnette (ed.)

Biosafety versus Biosecurity at UPM

- The handling of LMO, GMO and rDNA related activities such as contained use (in vitro & in vivo), import, export and release are been monitored by UPM and reported to Dept. of Biosafety, Ministry of Water, Land and Natural Resources
- The handling of non GMO biological agents and toxins are monitored at respectively faculties and research management office.
- Implementation of an integrated biorisk management to establish the best practise in meeting the requirement of biosafety and biosecurity is currently underway.

Laboratory Biorisk Management

Best Practices start in the laboratory…

- **Establish a sustainable laboratory biosafety & biosecurity culture**
- **Implement effective biorisk training programs, core competencies and awareness-raising of lab managers**
- **Development of Malaysian standards for biosafety and Biosecurity**

Are we ready to address biosafety and biosecurity

- Do you know the lists of biological agents that been used and stored in your workplace ?
- Do you know the scope of the activities and the research team involved in biological related projects ?
- Are the labs setup and equipment able to meet the requirements of the projects ?
- Are the staff and students of the projects well trained and competent in handling the projects ?
- Do you have a set of SOPs to address the requirements?
- Are the labs been inspected regularly ?

AGRICULTURE • INNOVATION • LIFE

UPM
UNIVERSITI PUTRA MALAYSIA
BERILMU BERBAKTI

INSTITUT BIOSAINS

Institutionalising Biosafety in UPM

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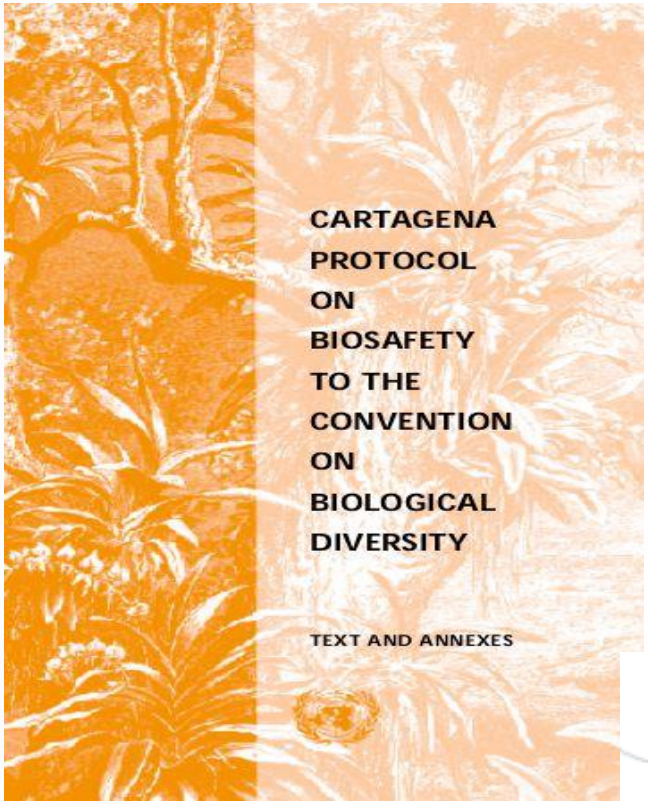
Outline of the presentation

- Biohazard and Biosafety
- Institutional biosafety committee (IBC) requirement
- Scope of the Biosafety Act 2007
- Application Procedures

Biosafety and Biosecurity Legal Framework

- **International obligations**

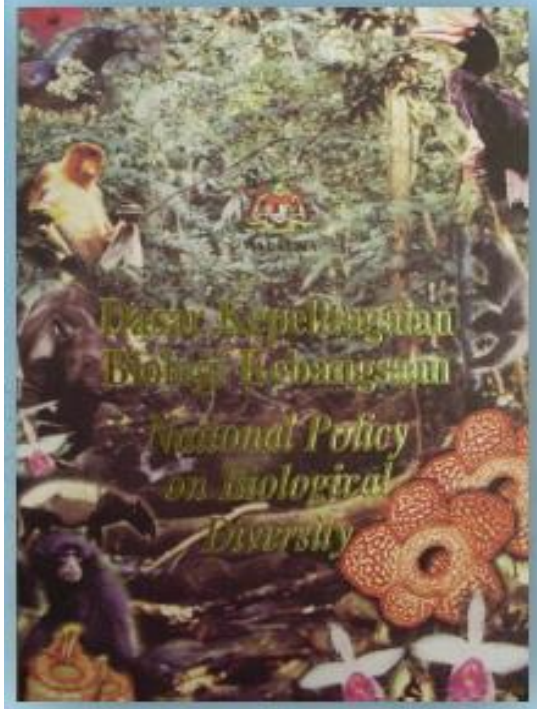


BIOLOGICAL WEAPONS CONVENTION

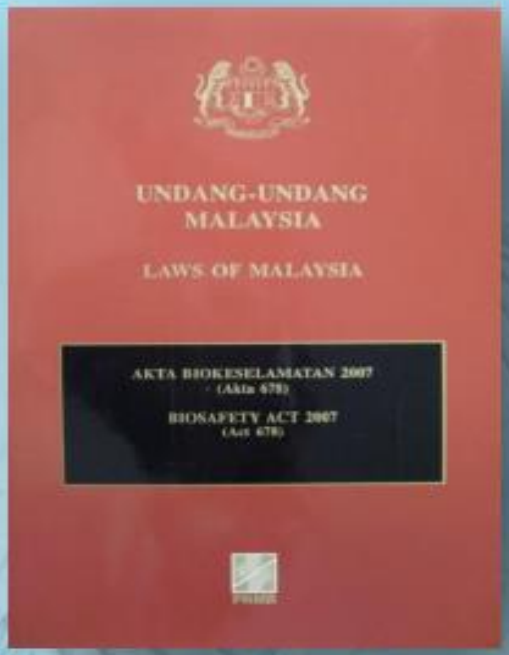
UNODA

UNITED NATIONS OFFICE FOR DISARMAMENT AFFAIRS

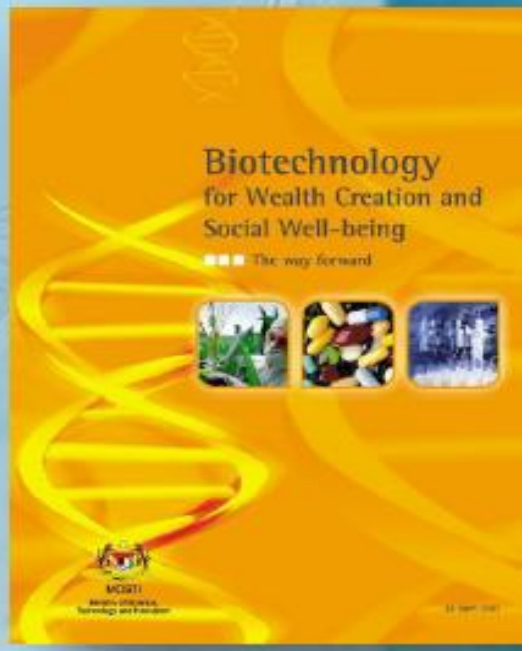
National obligations



National Policy on Biological Diversity 1998

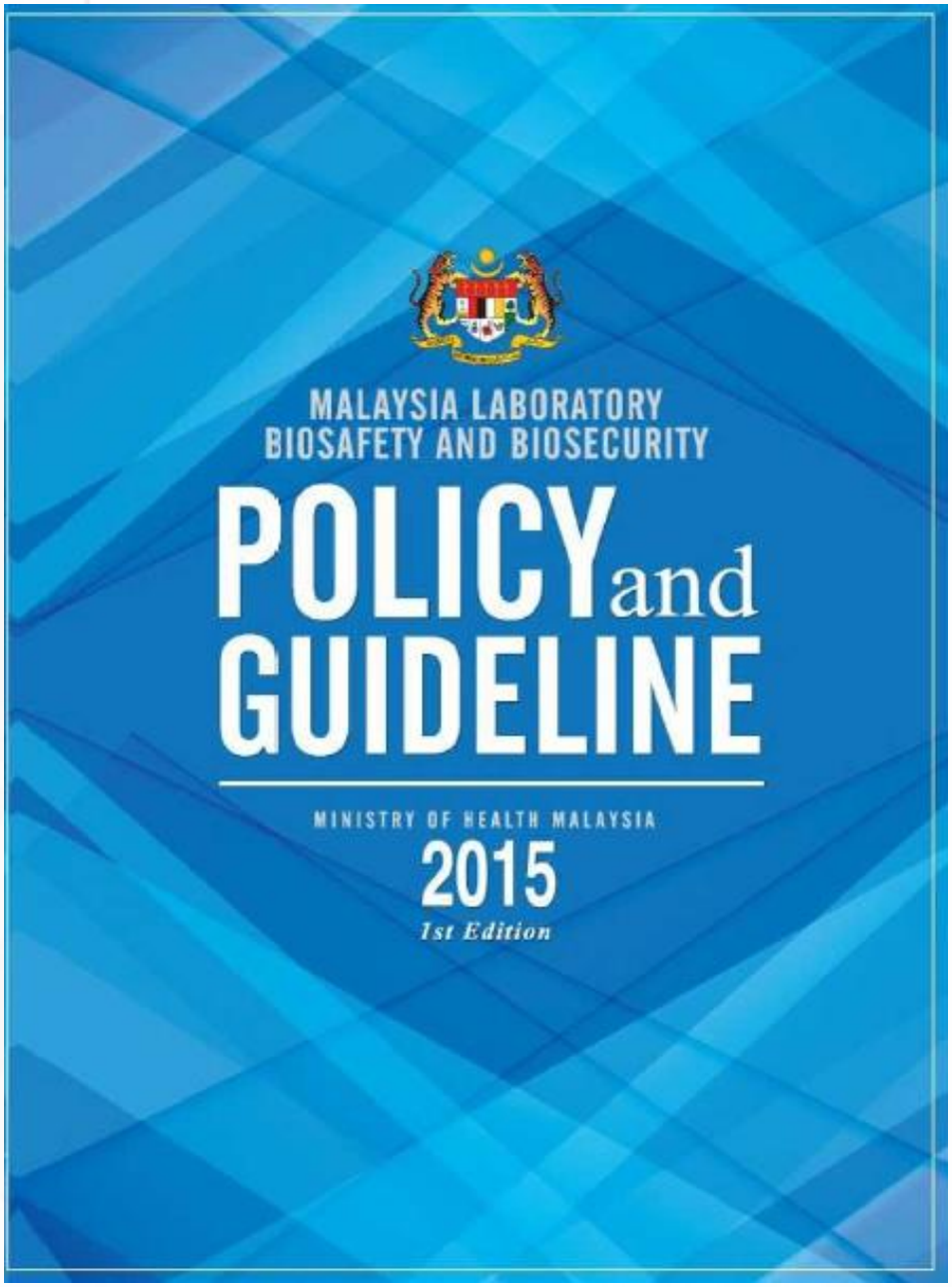


Biosafety Act 2007



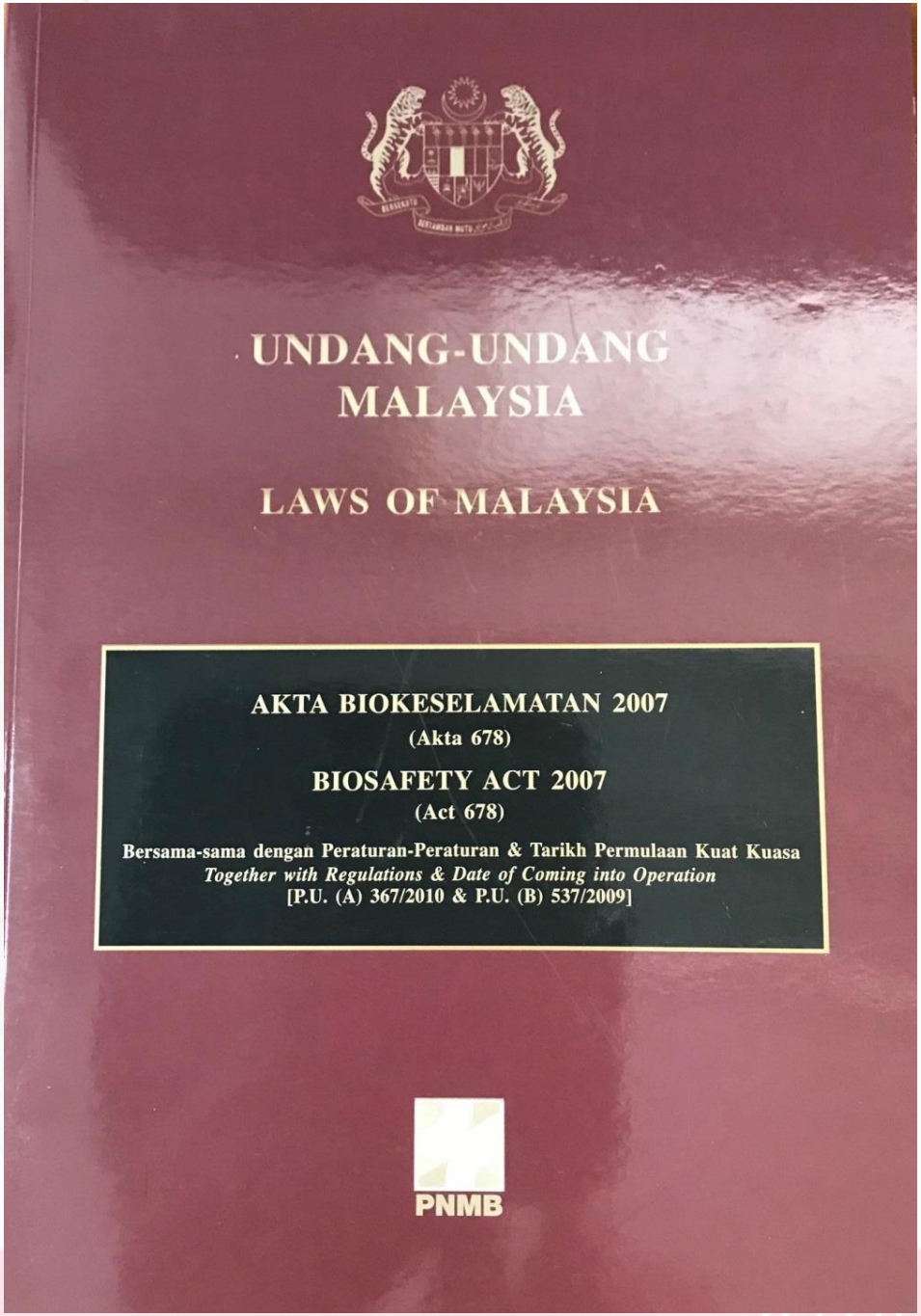
National Biotechnology Policy 2005

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



MALAYSIA LABORATORY BIOSAFETY AND BIOSECURITY POLICY AND GUIDELINE.

http://mkak.moh.gov.my/download/Biosafety_Policy_and_Guideline_2015.pdf



Biosafety Act 2007

LAWS OF MALAYSIA

ACT 678
BIOSAFETY ACT 2007

Date of Royal Assent : 28 August 2007
Date of publication in the Gazette : 29 August 2007

An 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, and where there are threats of irreversible damage, lack of full scientific evidence may not be used as a reason not to take action to prevent such damage; and to provide for matters connected therewith.

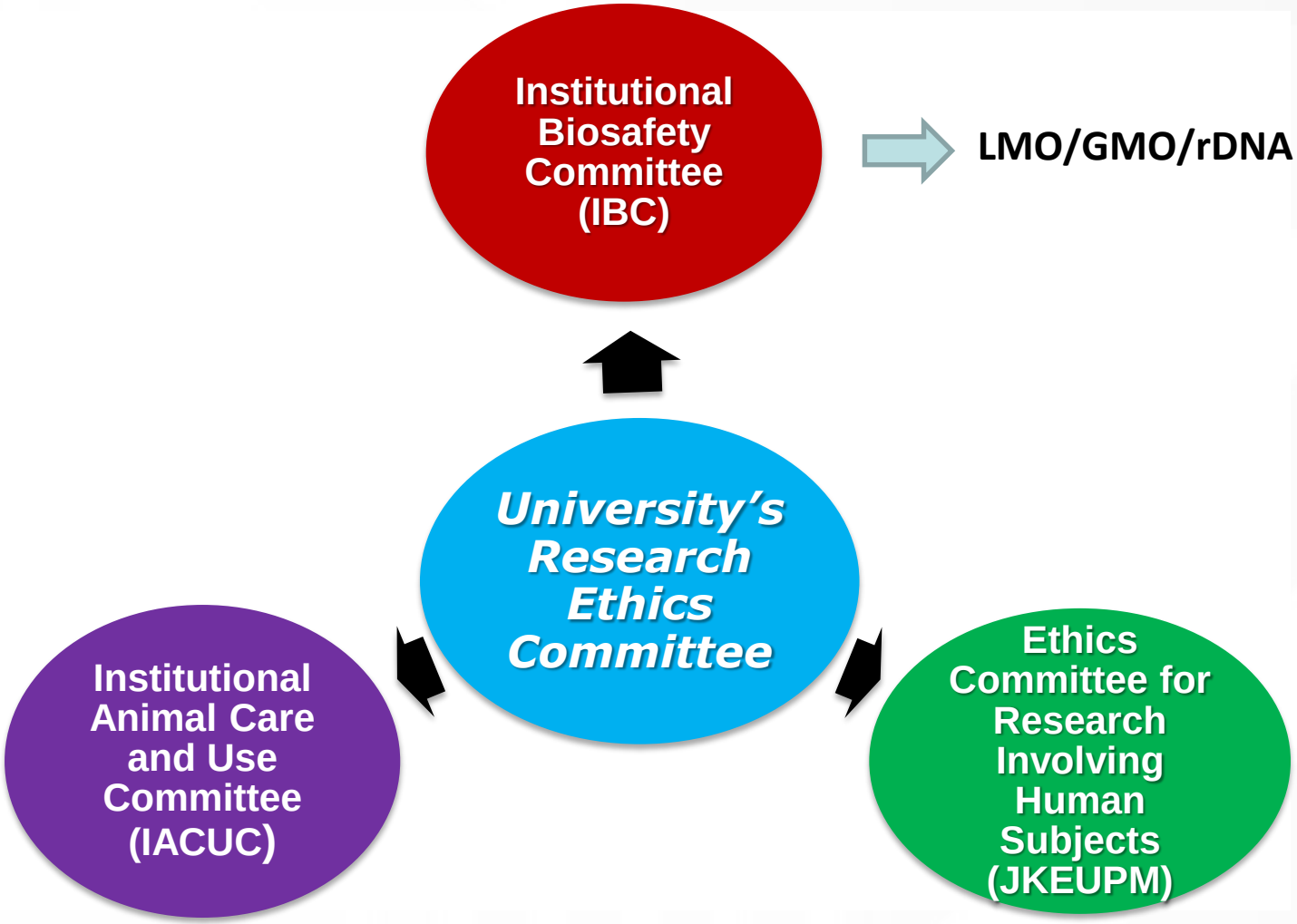
ENACTED by the Parliament of Malaysia as follows:

Biohazard Materials

Scope of Biosafety Act 2007

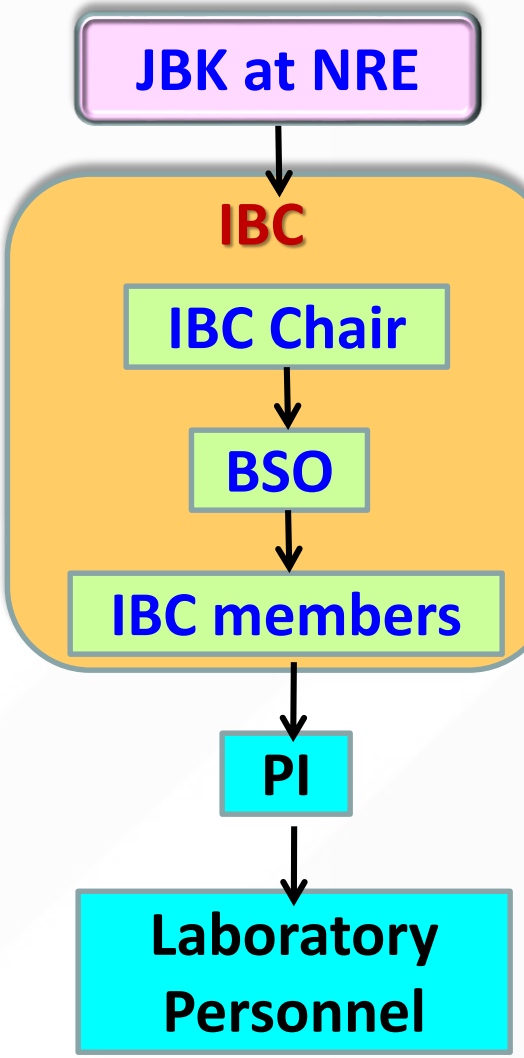
- LMO
- GMO
- rDNA

UPM Research Ethics Committee



Institutional Biosafety Committee (IBC)

Formal expert committee of an organization that undertaking modern biotechnology which involves use of any LMO, GMO and recombinant DNA materials – **to monitor & ensure compliance to the Biosafety Act 2007 at the institutional level and safe handling of modern biotechnology activities**



UPM IBC Web site : http://www.rmc.upm.edu.my/ibcbm#ibcbm

UPM IBC members

No	Name	PTJ	Position
1	Prof. Dr. Abdul Rahman Omar	Institute of Biosciences	Chairperson
2	Prof. Dr. Ho Chai Ling	Faculty of Biotechnology & Biomolecular Sciences	Secretary
3	Prof. Dr. Son Radu	Faculty of Sciences & Food Technology	Member
4	Prof. Datin Dr. Siti Nor Akmar Abdullah	Faculty of Agriculture	Member
5	Prof. Madya Dr. Zunita Zakaria	Faculty of Veterinary Medicine	Member
6	Prof. Dr. Cheah Yoke Kqueen	Faculty of Medicine & Health Sciences	Member
7	Prof. Dr Rozi Mohamed	Faculty of Forestry	Member
8	Dr. Mohd Rafee Baharudin	Occupational Safety & Health Management	Member
9	Dr. Tan Sheau Wei	Institute of Biosciences	Member
10	Dr. Nur ain Izzati Mohd Zainuddin	Faculty of Sciences	Member
11	Mr. Muhammad Adil Ahmad Tajudin	Office of the legal advisor	Member
12	Mr. Mohd Azman Ahmad	Research Management Centre	Secretariat (BSO)

IBC coordinates biosafety activities

- Committee members of various expertise; Vet, Med, Biotech, Agriculture, Forestry, Science, OSA and Legal.
- Biosafety Officer (BSO) as secretariat (RMC)
- Identify project associated with LMO, GMO and rDNA
- Evaluate, monitor and make recommendation ;
  - Evaluate and monitor the projects/activities
  - Ensure competent staff and students
  - Evaluate and monitor the premises/lab via lab visit
  - Make recommendation to JBK, NRE for approval
- Exemption – techniques related to mutagenesis, cell fusion and natural proses such as self-cloning, conjugation, transformation, etc

MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT (NRE)

MONITORING OF RESEARCH ACTIVITIES INVOLVING LIVING MODIFIED ORGANISMS (LMO)

Section 22 (1) (b) Act 678 Biosafety Act 2007 "*No person shall undertake any contained use activity involving living modified organisms without prior notification to the National Biosafety Board*"

PENALTY

Noncompliance to get approval from NBB for Release and Contained Use Activities involving LMO/products effective **30 March 2018 onwards**

Where such person is **an individual** :

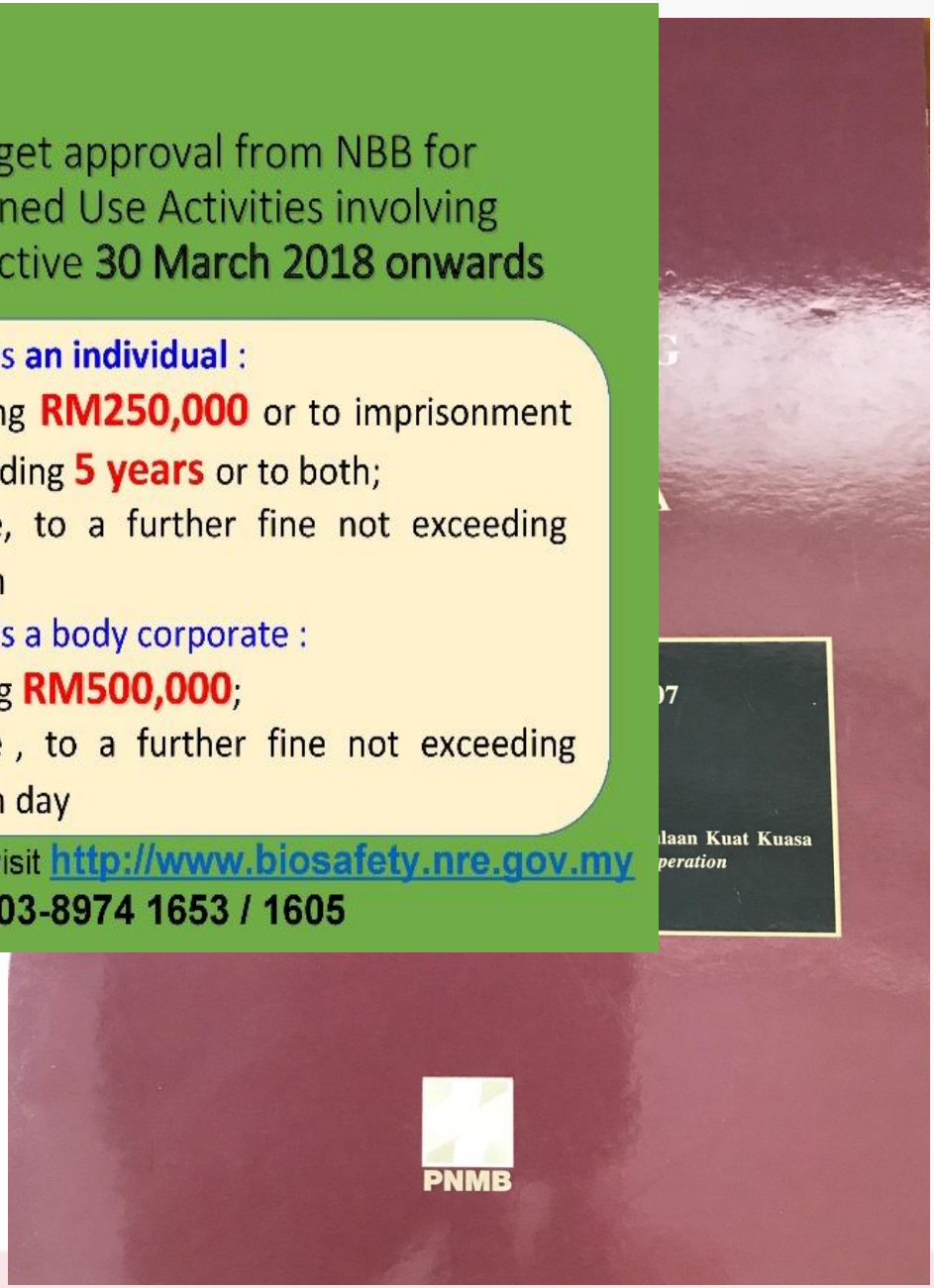
- a fine not exceeding **RM250,000** or to imprisonment for a term not exceeding **5 years** or to both;
- continuing offence, to a further fine not exceeding **RM10,000** for each

Where such person is a body corporate :

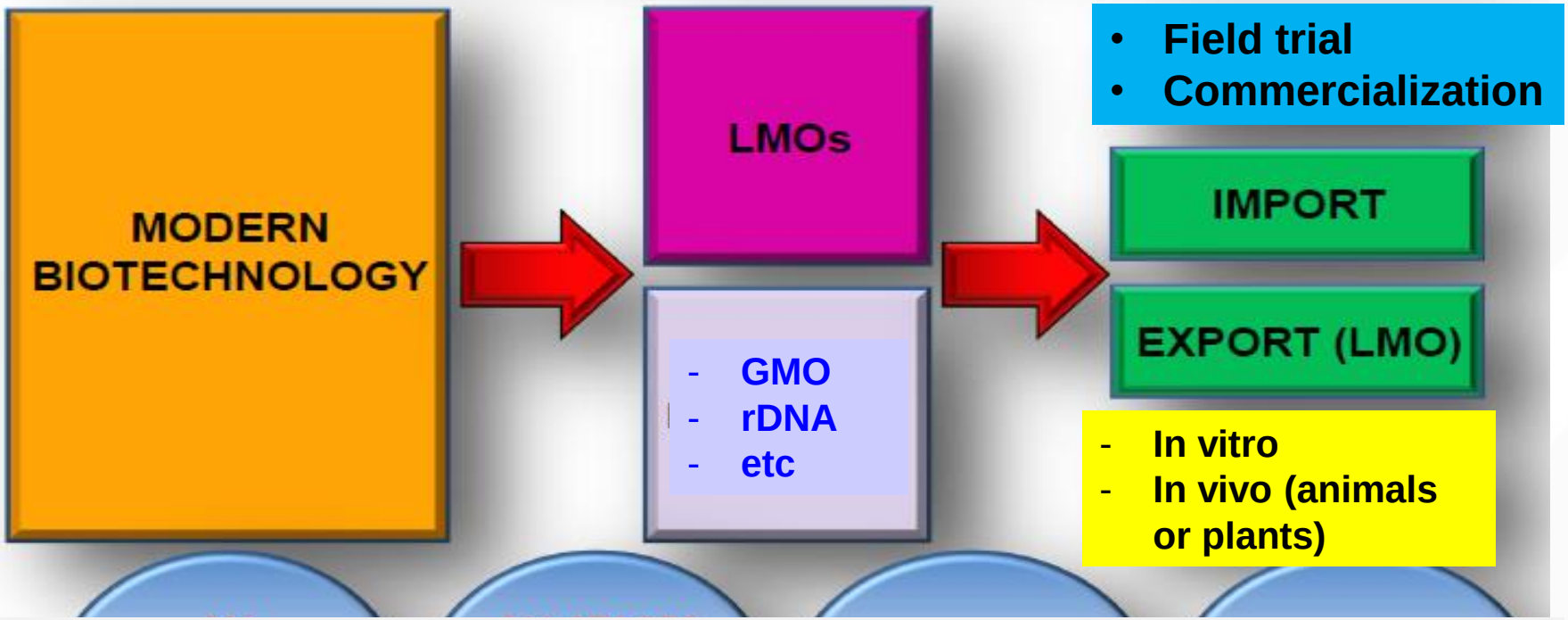
- a fine not exceeding **RM500,000**;
- continuing offence , to a further fine not exceeding **RM20,000** for each day

For further info please visit http://www.biosafety.nre.gov.my

For more information : **03-8974 1653 / 1605**



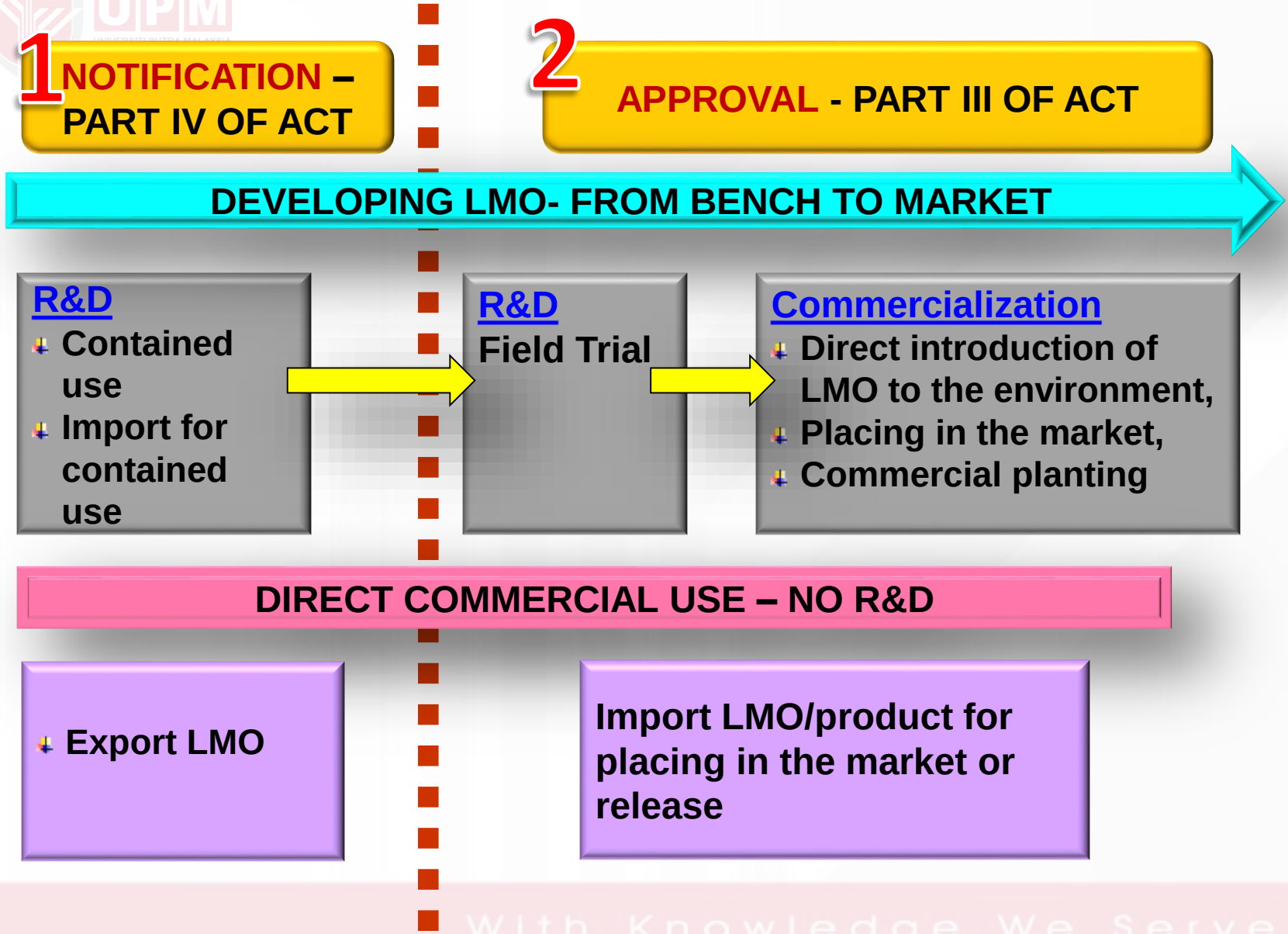
Scope of Biosafety Act 2007



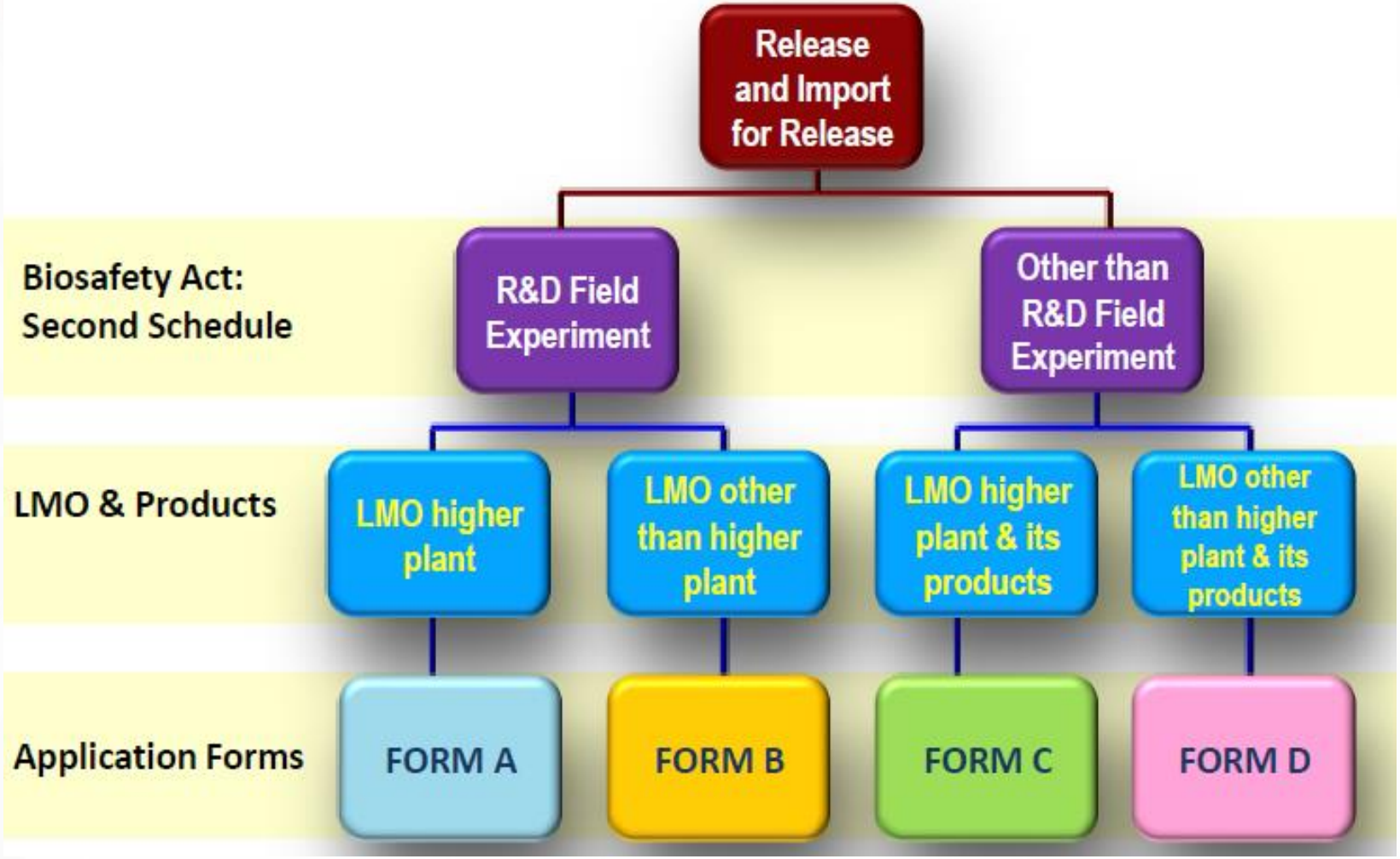
Exemptions:

A list of techniques and activities normally used in modern biotechnology research, which are proven safe, have been listed under the Non-application provision of the regulations (First schedule- Biosafety (Approval and notification) regulations 2010.

Two Regulatory Processes

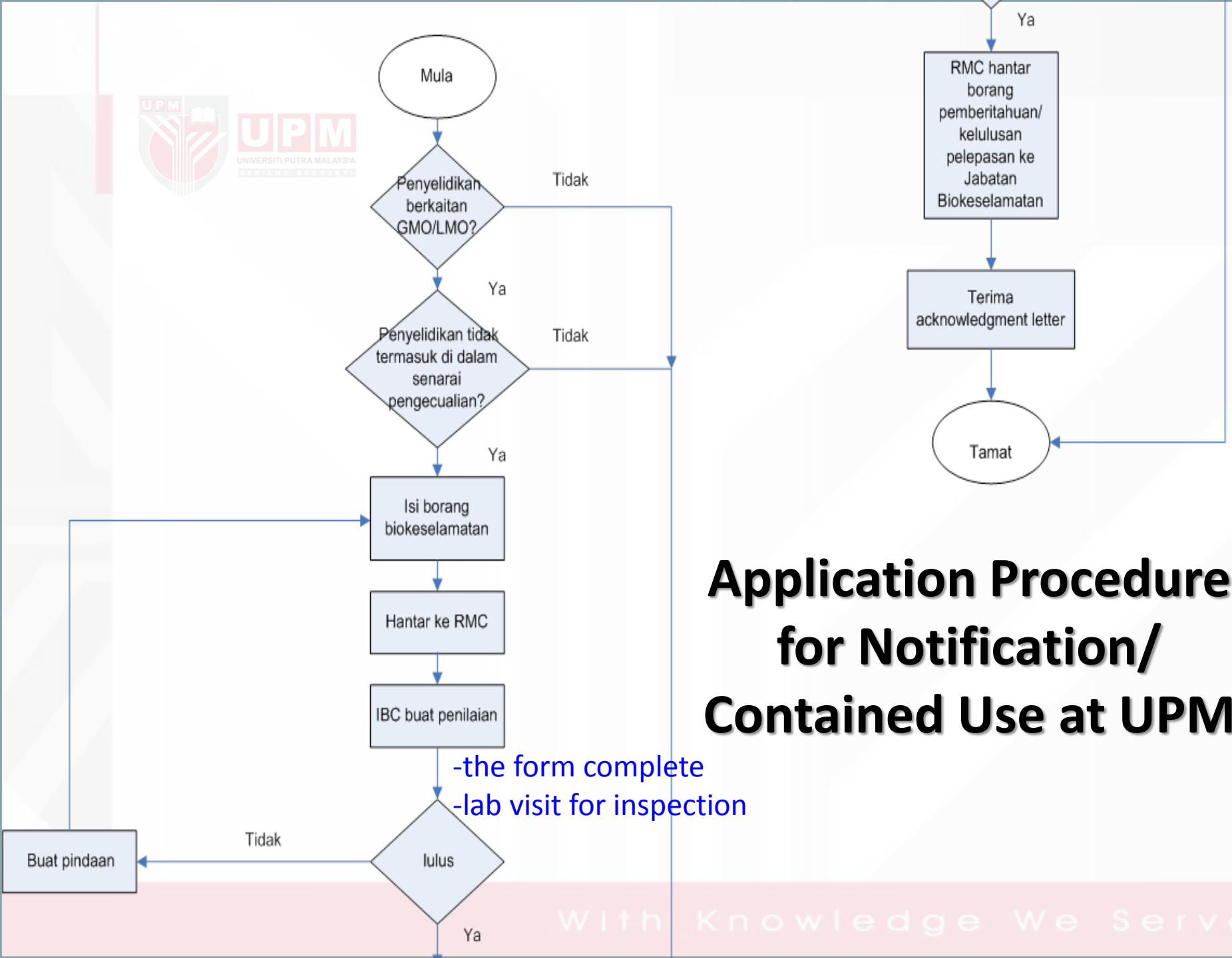


Release Approval Forms



Exemptions

- A list of techniques and activities normally used in modern biotechnology research, which are proven safe, have been listed under the Non-application provision of the regulations (First schedule- Biosafety (Approval and notification) regulations 2010.
- No need to apply for notification to Biosafety Department, Ministry of Water, Land and Natural Resources (KATS).
- Only notify IBC UPM



Application Procedure for Notification/ Contained Use at UPM

Laboratory Visit

- UPM IBC Committee/Biosafety officer will visit the laboratory within 30 days after receiving the application form
- Biosafety Committee may also visit the laboratory during the period of application
- Only the designed Laboratory that carried out the research will be visited, both the in vitro study and in vivo part in animals or plants.
- Laboratory visit based on Biosafety level 1, 2, 3 or 4 guidelines and check list prepared by KATS
- Researcher (PI and/or co-PI) are required to be there during the visit.

Laboratory Visit

Submission of Documents

- ✓ Complete the form depending on applications ;
  - Notification/Contained Use (Form E)
  - Approval for Release (Form A, B, C, D)
  - Export (Form F)

  - ✓ **Filled the Form according to the application**
  - ✓ **Research Proposal**
  - ✓ **Standard Operating Procedure** } Template given
  - ✓ **Risk Assessment Matrix** } Template given
  - ✓ **Supporting document (grant offer letter)**
  - ✓ **Brief CVs of research participants**

http://www.rmc.upm.edu.my/documentfile?L=bm

Forms

Forms	Explanation
Form E	Notification Form – Contained Use
Form F	Notification Form - Export
	Notification Form – SOP Template
	Notification Form - Risk Assessment Matrix Template
Form A, B, C, D	Approval Form
Annex 2	IBC Assessment
Annex 3	Incident Reporting
Annex 4	Occupational Disease / Exposure Investigation Form
Annex 5	Project Extension & Notice Of Termination
Form IBC (E1)	Exempted Form

Notification/Contained Use Process

Notification

- In parallel, GMAC & NBB will assess 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
- Notification Decision can be reviewed
- Offense punishable
- Appeal to Minister

Approval Application Process

Approval Decision

- NBB will make a decision within 180 days;
- Decisions may vary
  - Approved,
  - Approved with Terms and Conditions, or
  - 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.

Duration of Procedures

No.	Items	Period
1.	IBC evaluation	Evaluation carried out in 3 working days after receiving the forms
2.	Evaluation of application	14 working days
3.	Amendments of the application by the researchers	14 working days
4.	For notification/contained use : Receive ***acknowledgment letter*** from Biosafety Department	Maximum 90 working days after receiving complete documents
5.	For release : Receive ***approval letter*** from Biosafety Department	180 working days

Summary of regulatory process

	NOTIFICATION	APPROVAL
PURPOSE	Contained Use in Lab, Growth facility, Animal facility, Glasshouse, Bioreactor	Release
TIME	Maximum 90 days	180 days
FEE	No	Yes
START ACTIVITY	Sufficient with Biosafety Department Acknowledgment (normally within 14 days)	Need Certificate of Approval
APPEAL OF REVIEW	Yes	Yes

For further details

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Questions ?

Thank You