



Introduction to Biosafety



Learning outcomes

At the end of the training, participants are able to

- ▶ Explain the concepts and principles of biosafety
- ▶ Identify relevant biosafety practices according to designated situations
- ▶ Recognize the importance of biosafety measures

Module outline:

Activity
Definition of Biosafety
Introduction to biohazard groups
Route of exposure
Salient Provision of Biosafety Act & Regulations

What are you thinking of when you hear the word “Biosafety”?

How is biosafety relevant to you/your project?



<https://www.menti.com/alv5jfzmsgfb>



What is Biosafety?

Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release

(Source: WHO Laboratory Biosafety Manual, Fourth Edition)

What is Biosafety? (Cont.)

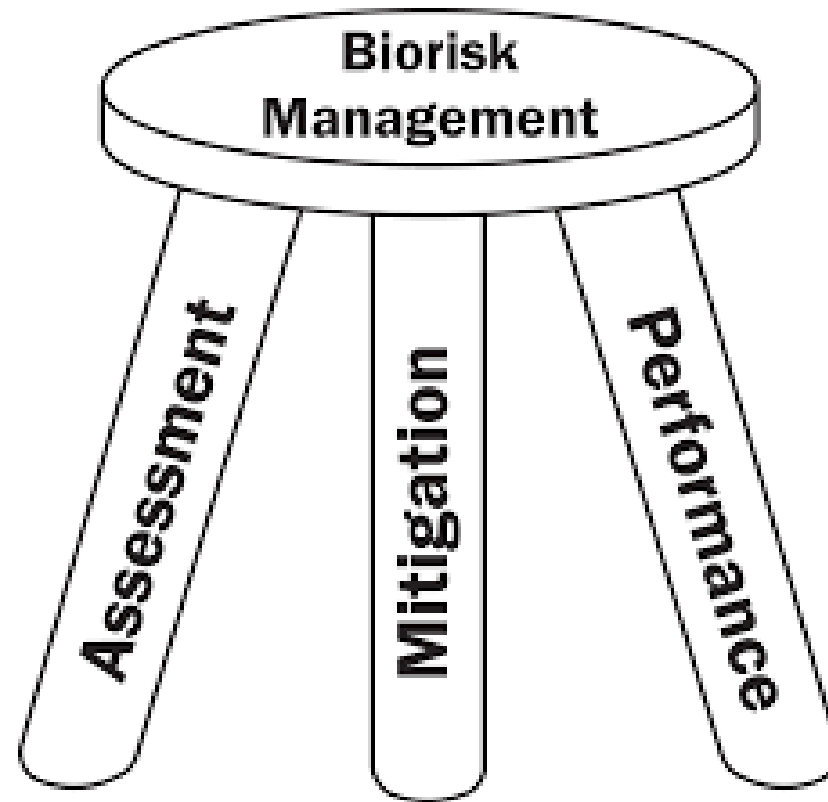
► Biological agents:

- ❖ Microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) and parasites
- ❖ Vectors
- ❖ Cell cultures
- ❖ Biological toxins, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance

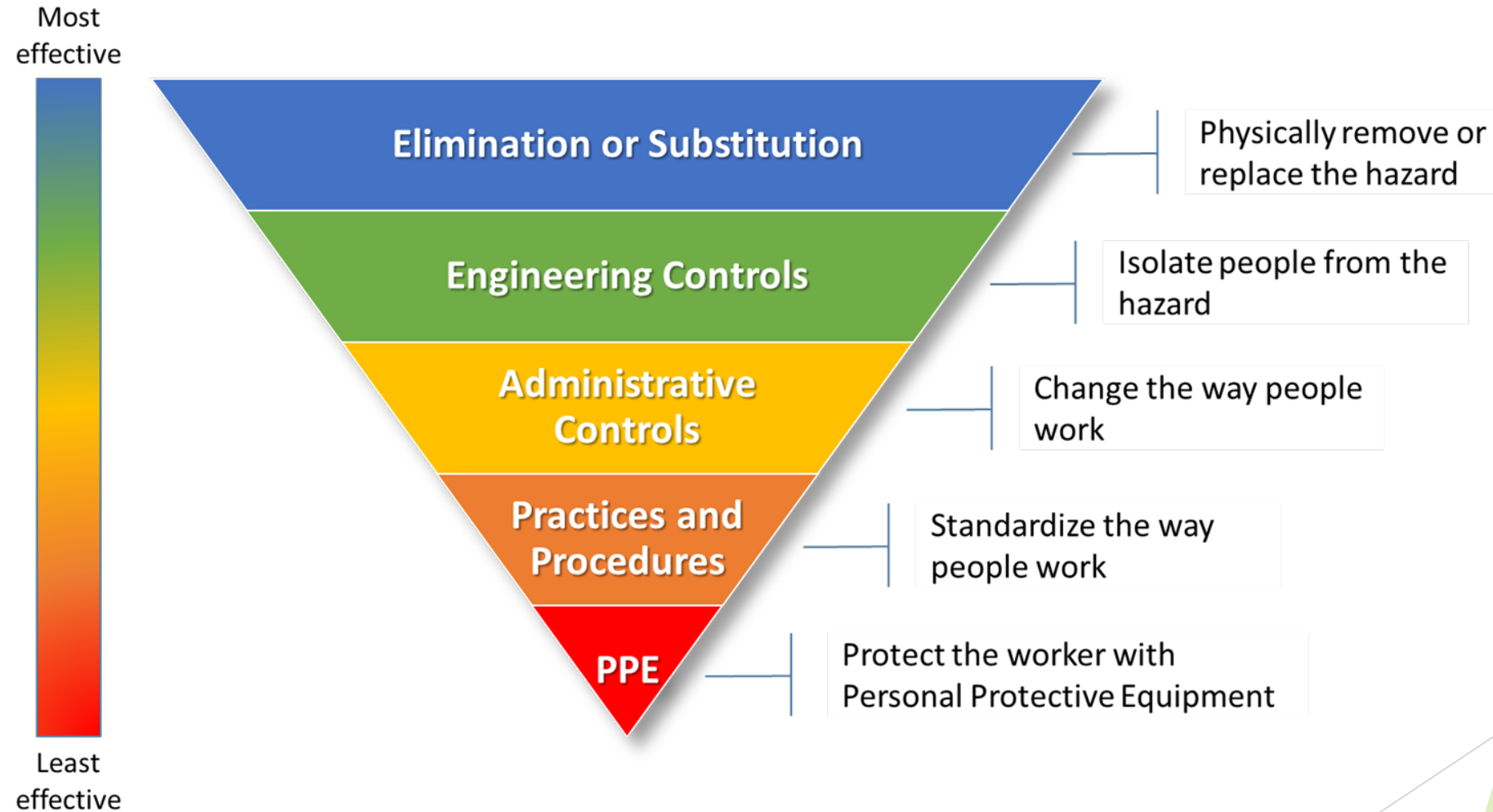
What is Biosafety? (Cont.)

- ▶ Biological agents can cause:
 - ❖ Death, disease, or other biological malfunction in humans, animals, plants, or other living organisms
 - ❖ Deleterious alteration of the environment
 - ❖ Adverse effects on commerce and trade

The “AMP” Model of Biorisk Management



Hierarchy of Control (Mitigation)



Risk groups: associated with the biosafety levels of specific pathogens handled in laboratory procedure

Risk Group	Characteristics	Examples
I	Includes viruses and bacteria and many non-infectious bacteria. The level of precaution at this level is minimal and usually involves wearing a face mask and no close contact	<i>Escherichia coli</i> and chickenpox
II	Involves microorganisms that are responsible for mild infections in humans and are often difficult to contract via aerosolized particles	Hepatitis A, B, and C, Lyme disease, <i>Salmonella</i> , measles, mumps, HIV, and dengue
III	Includes microorganisms that can be fatal to humans but for which vaccines and other treatments are available	<i>Mycobacterium tuberculosis</i> , anthrax, many types of viral encephalitis, hantavirus, Rift valley fever, malaria, Rocky Mountain spotted fever, and yellow fever
IV	Includes viruses that cause severe to fatal disease in humans, and for which vaccines or other treatments are not available	Bolivian hemorrhagic fever, Marburg virus, Ebola virus, Lassa fever virus, Crimean-Congo hemorrhagic fever and other hemorrhagic diseases, and Nipah virus

Reference: Biosafety Guidelines: Risk Assessment of Genetically Modified Microorganisms, p.204-212.

Biosafety Level (BSL) vs Risk Group

Agent Risk Group

RG4 - Agents likely to cause serious or lethal human diseases for which preventive or therapeutic interventions are usually not available.
e.g. Ebola virus, Variola virus (smallpox)

RG3 - Agents associated with serious or lethal human diseases for which preventive or therapeutic interventions may be available.
e.g. Coronavirus, Mycobacterium tuberculosis

RG2 - Agents associated with human diseases, which are rarely serious and for which preventive or therapeutic interventions are often available.
e.g. Influenza, Salmonella

RG1 - Agents not associated with disease in healthy adult humans.
e.g. E.coli

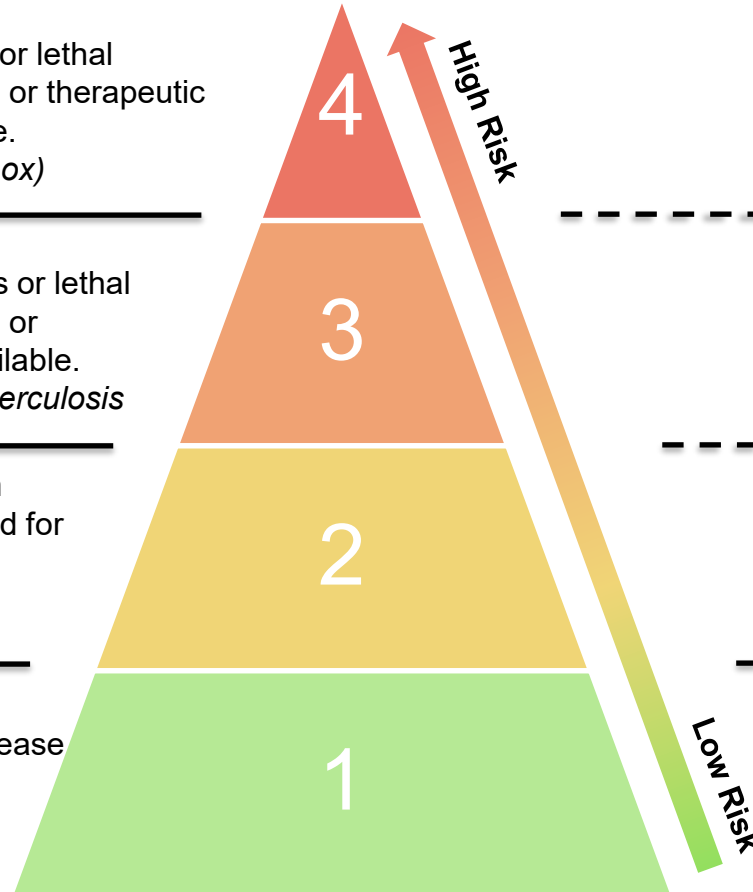
Laboratory Biosafety Level

BSL-4
Maximum containment

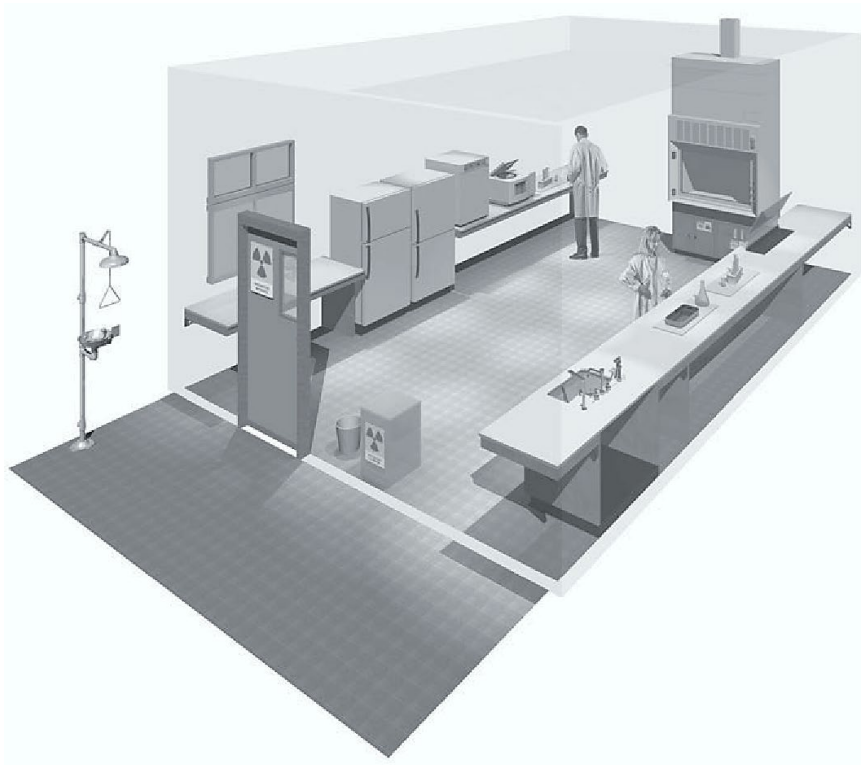
BSL-3
High containment

BSL-2
Containment

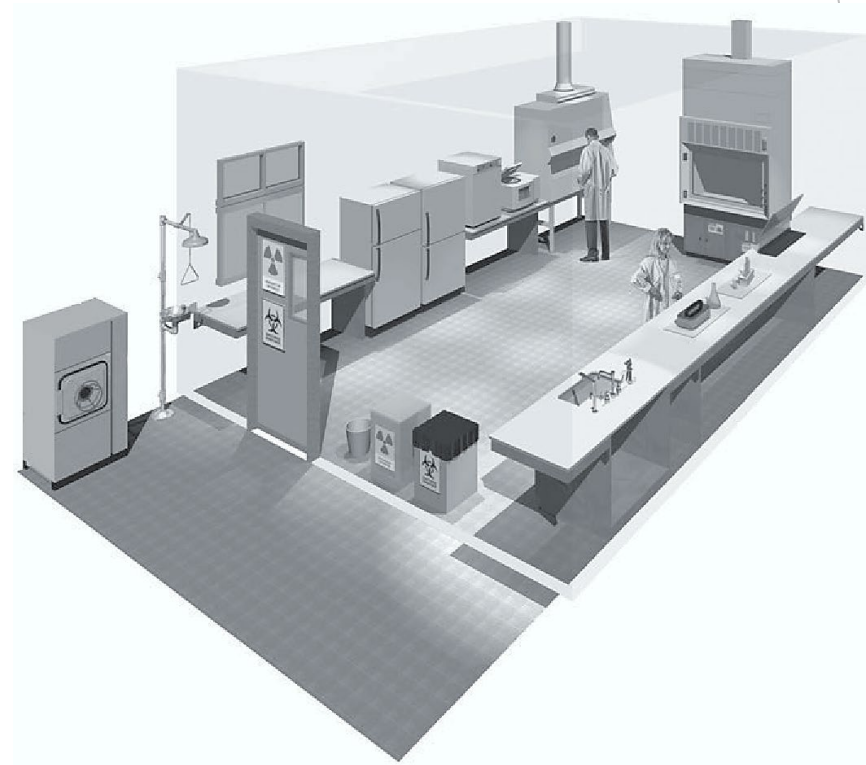
BSL-1
No containment



BSL-1 vs BSL-2 Laboratory

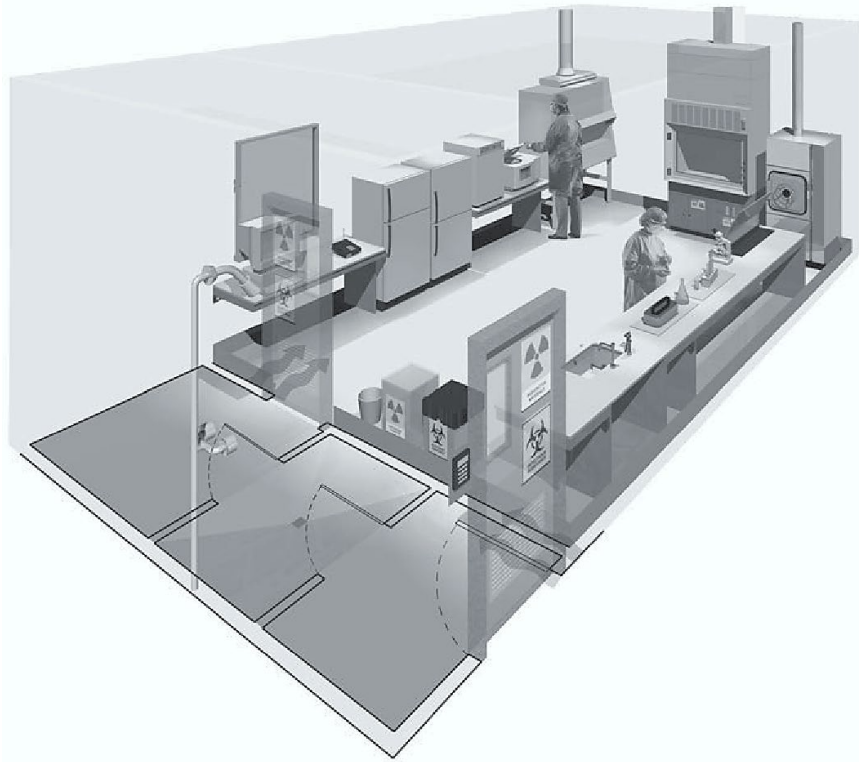


Biosafety Level 1 laboratory

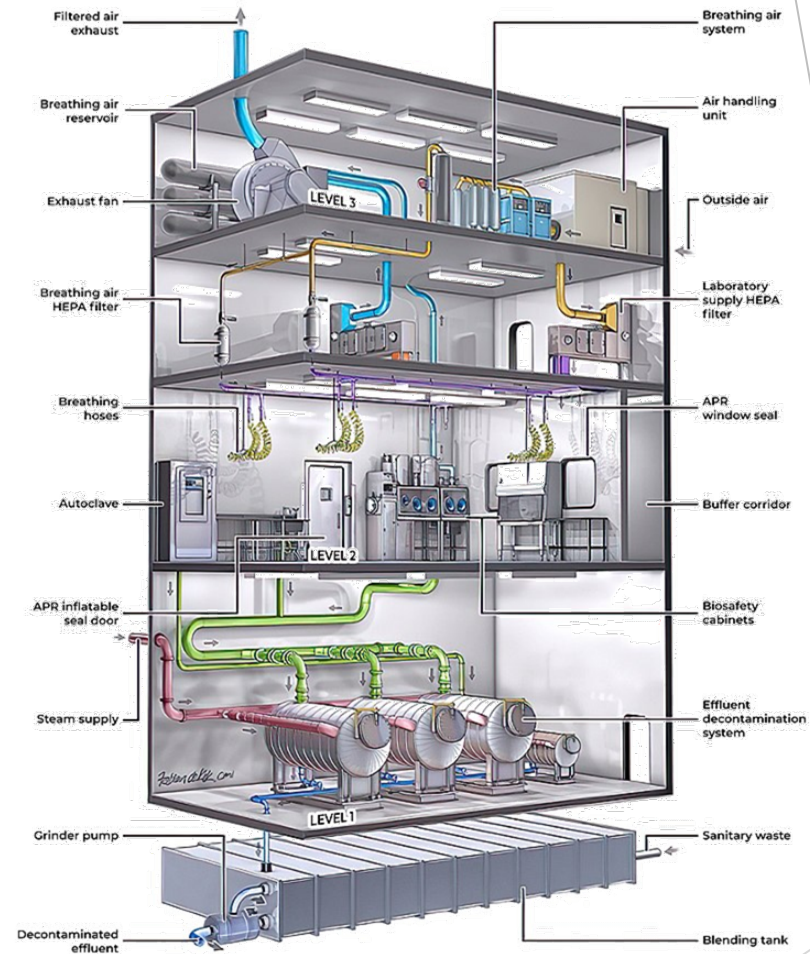


Biosafety Level 2 laboratory

BSL-3 vs BSL-4 Laboratory



Biosafety Level 3 laboratory



Biosafety Level 4 laboratory

In what ways, we can become “exposed” to risky biological agents in the laboratory?

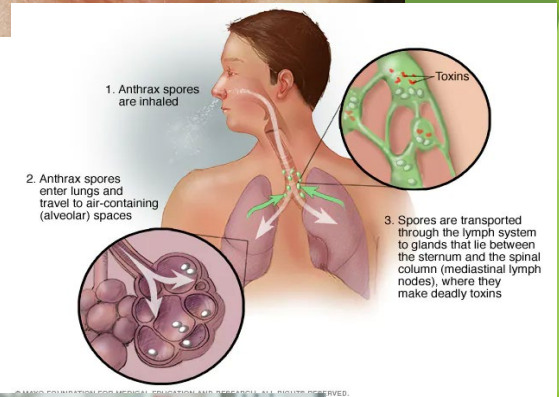
**Regardless of the previously mentioned groups*



Routes of exposure

- ▶ Percutaneous, though broken or damaged skin
- ▶ Inhalation
- ▶ Mucous membranes of the eyes, nose, and mouth
- ▶ Ingestion

Bear in mind that outcomes of infections can be severe irrespective of the route of exposure!!!



Who is responsible for and what are the consequences of laboratory biosafety incidences?

- ▶ The principal investigator or laboratory supervisor must provide appropriate training to all laboratory personnel in maintaining and sustaining a safe working environment
- ▶ Penalties for unauthorized activities
 - ❖ Individual
 - ❖ Corporate body

(Malaysian Biosafety Act 2007)



To ensure laboratory biosafety when handling biohazards, the following must be done:

1

Risk assessment

Identify biohazards, route of exposure and the likelihood of becoming infected after exposure, and the post-exposure consequences. Report the incident.

2

Laboratory safety management

Behavioral change, PPE, SOP and guidelines, laboratory engineering controls and containments. Decontamination and waste management.

Legislation on biosafety issues

- ▶ In Malaysia, we have the
 - ❖ Malaysian Biosafety Act 2007
 - ❖ other safety-related regulations

Malaysian Biosafety Act 2007

- ▶ Any organization, which undertakes modern biotechnology research and development, shall establish an **Institutional Biosafety Committee (IBC)** to ensure that any LMO/rDNA research, conducted at or sponsored by the organization, irrespective of the source of funding, shall comply with the **Malaysian Biosafety Act 2007**, any other related regulations and Malaysian laws relating to import and export, human, plant and animal health, environment, and biological diversity. The IBC shall be registered with the Board by submitting Form G (NBB/IBC/10/FORM G)
- ▶ Non-compliance may result in suspension, limitation, or termination of the non-compliant research project along with other enforcement orders on the organization, as dealt with in Part VI, Biosafety Act 2007

What is a LMO?

(according to *Malaysian Biosafety Act 2007*)

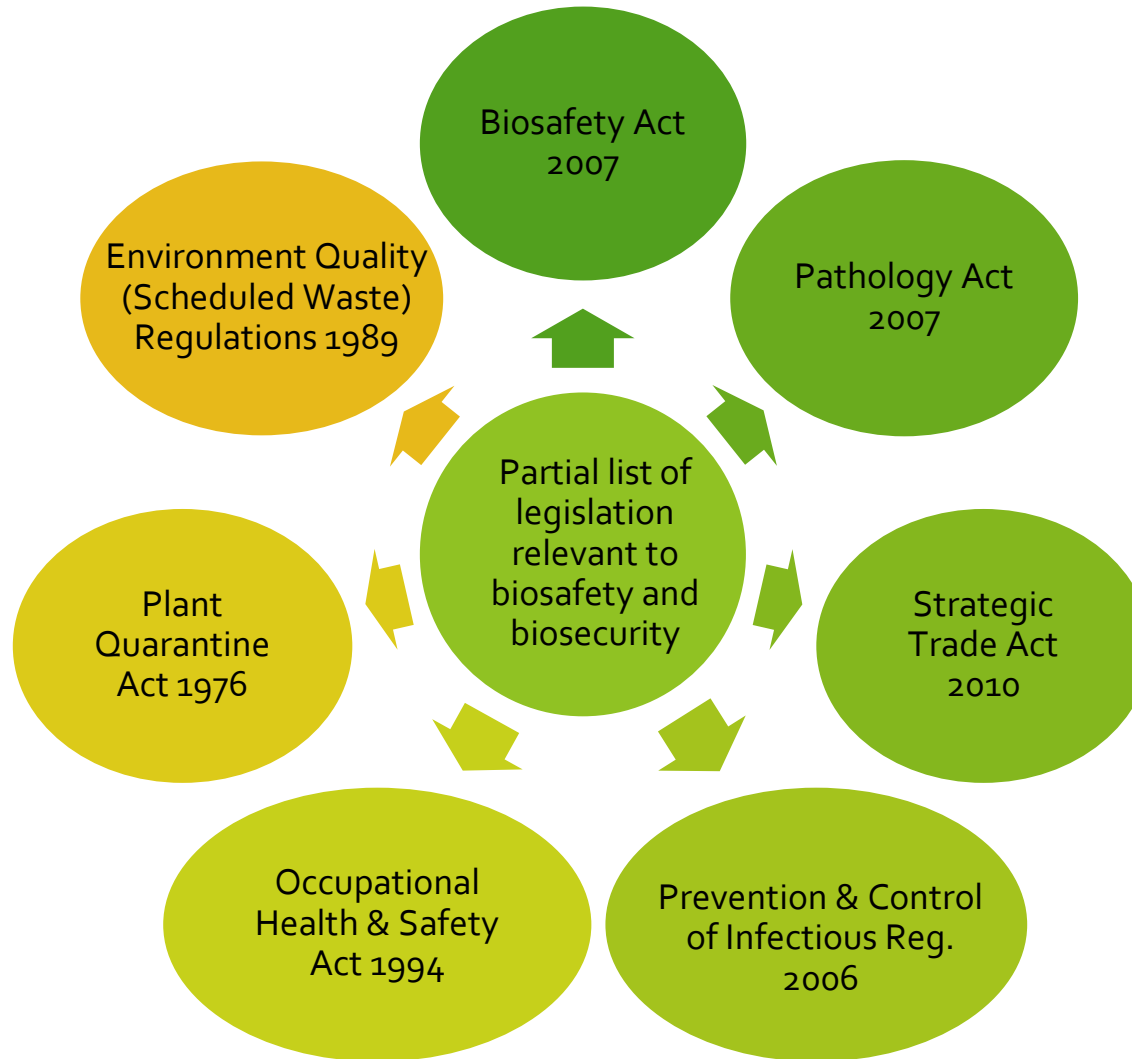
- ▶ Any living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology
- ▶ Living organisms: Any biological entity, including sterile organisms, viruses, and viroids, capable of transferring or replicating genetic materials
- ▶ Modern biotechnology:
 - ❖ *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles or
 - ❖ fusion of cells beyond the taxonomic family
(*They overcome natural physiological reproductive or recombination barriers and are not commonly used in traditional breeding and selection*)

(For more info, please visit “User’s Guide to the Biosafety Act and Regulations” by the Department of Biosafety, Ministry of Natural Resources and Environment, Malaysia)

**User’s Guide to the
Biosafety Act
and Regulations**



Related Legislation & Framework : Biosafety & Biosecurity



Credit: Zalini Yunus, PhD & Ms Kathryn Tham Bee Lim, Institut Penyelidikan Sains & Teknologi Pertahanan (STRIDE), Kementerian Pertahanan, Malaysia.

Key messages

- ▶ In laboratories, especially during the handling of biological agents exposes personnel to hazards with adverse consequences
- ▶ Exposure can occur through various means and routes
- ▶ Laboratories personnel and students must be trained to increase competency in handling biosafety issues and avoid biosafety incidences

Safe laboratory practices are part of Science!

THANK YOU



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References

- ▶ CDC, Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition.
- ▶ Malaysia Ministry of Natural Resources and Environment. 2008. The Biosafety Act of Malaysia: Dispelling the Myths.
- ▶ Malaysia Ministry of Natural Resources and Environment. 2010. Guidelines for Institutional Biosafety Committees: Use of living modified organisms and related materials.
- ▶ Malaysia Ministry of Natural Resources and Environment. 2021. User's Guide to the Biosafety Act and Regulations.
- ▶ Prakash, S.B. and Ruchika, R. 2013. Emerging Epidemics: Management and Control, First Edition. John Wiley & Sons, Inc.
- ▶ World Health Organization, Laboratory Biosafety Manual, 4th Edition.

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