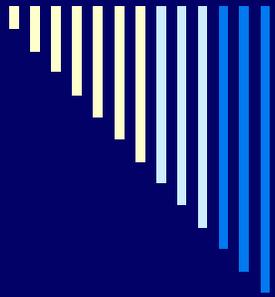


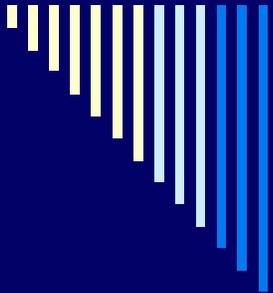
International Biosafety and Biosecurity

Ministry of Health Malaysia





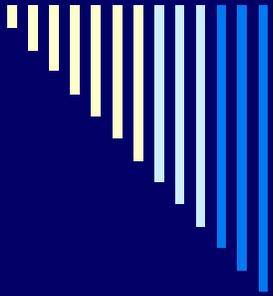
Current Status



Ministry of Health

- ❑ Disease surveillance
- ❑ Syndromic approach
- ❑ Nipah Virus surveillance
- ❑ ILI surveillance
- ❑ SARS Virus surveillance
- ❑ Avian Influenza surveillance

- ❑ Global Polio Eradication Programme
- ❑ AFP surveillance
- ❑ Polio biocontainment
- ❑ Biomedical Research
- ❑ Dengue
- ❑ Nipah
- ❑ HIV
- ❑ TB
- ❑ Malaria



- Ministry of Higher Education

- Diagnostics
- Surveillance

- Research

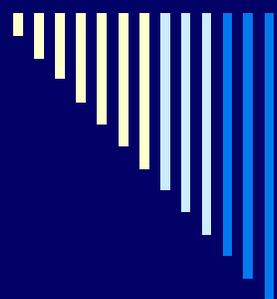
- Nipah
- HIV
- TB

- Ministry of Agriculture

- Diagnostics
- Surveillance
- - Nipah
- - Avian Flu

- Research

- Nipah
- Avian Flu
- NDV



Capabilities

□ Diagnostics

□ Routine cultures for Bacterial, viral, fungal

□ BSL-2 ,BSL-3 laboratories

□ Formulation & fill plant

□ cGMP pilot and production plant

□ Research

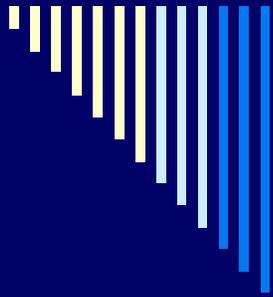
□ Vaccines

□ Diagnostics

□ Recombinant DNA Technology

□ Animal house for toxicology and invivo studies

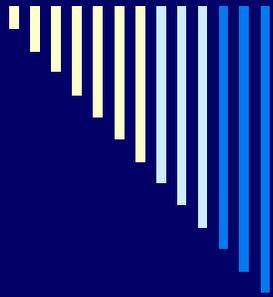
□ Insectarium



Ministry of Defence

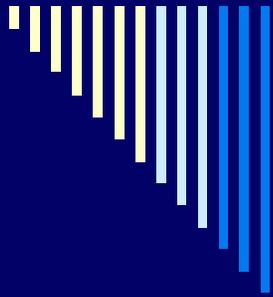
- Medical Services
 - Diagnostics
 - Occupational Health

 - Special Unit for Bioweapon/Biosecurity
 - Overlapping roles with medical services
-



Provisions for Biosafety / Biosecurity

- ❑ MOH : Biosafety Committee (IBC) under research arm
- ❑ Regional & Hospital labs : awaiting instructions from Central Agency
- ❑ MOA : IBC (Veterinary Research Institute)
- ❑ MOE: not available in all universities
- ❑ MOD: intra-agency discussions
- ❑ All facilities have laboratory manuals, GLP ,ISO 17025/15189 accreditation



- Physical Security

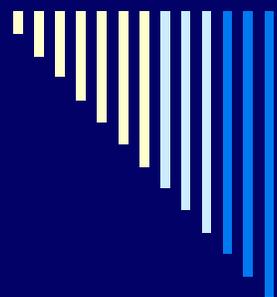
- Access control
- Card system
- CCTV

- Personnel security

- Visitor Control
- Security guards
- Badges

- Screening

- Medical Screening
- Background
- Experience



- **Material Control**

- Containment

- Dedicated
freezers/nitrogen tanks

- Card access

- Electronic and
written Inventory
data

- **Chain of Custody**

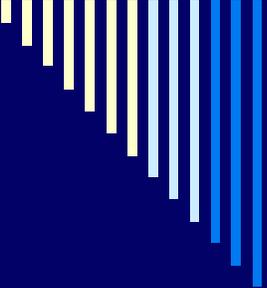
- Log book

- Material transport
security

- Receipt of material

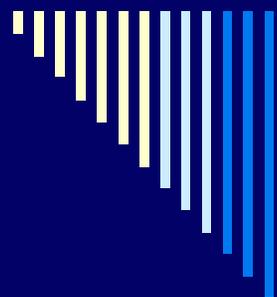
- Location

- Inventory



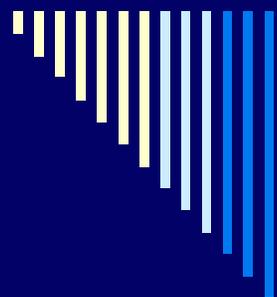
Import and Transfer Control

- ❑ **Permit** required for biological materials
 - ❑ Customs **declaration** form
 - ❑ Approval prior to importation
 - ❑ Issued per consignment
 - ❑ Upon arrival, **special clearance** and forwarding agents to be onsite
 - ❑ Packaging and labeling **consistent with IATA requirements**
 - ❑ Receipt to be **documented**
-



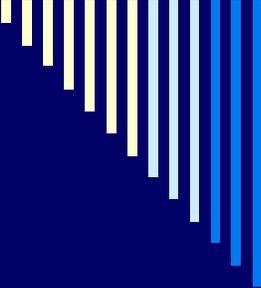
Current Status

- Biosafety Bill in progress
 - Biosafety Board to be formed
 - Institutional Biosafety Committees
formative stages
-



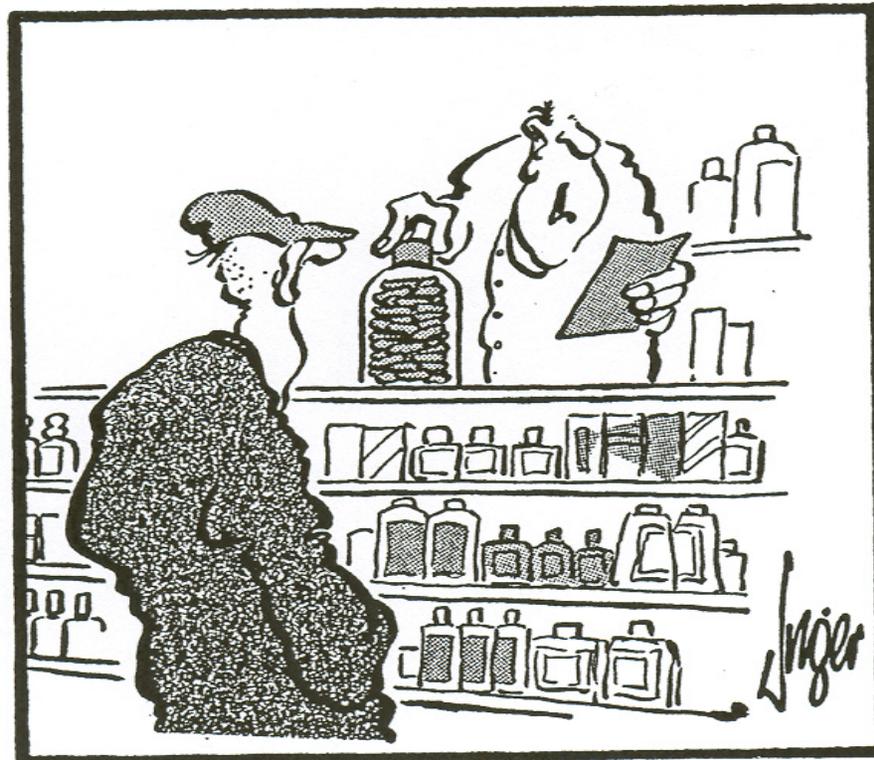
Concerns

- Lack of awareness
- Terminology and definitions:
 - **Biosafety** or **Biosecurity**
- Recombinant DNA technology
- Genetically modified organisms



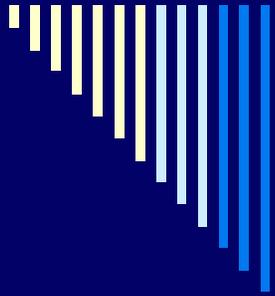
Next steps for MOH

- Spearhead formation of a National Biosafety /Biosecurity (Biological agents & Toxins) Committee
 - **Formulation of a National Biosafety Policy**
 - Revisit proposed Biosafety Bill
 - **Increase awareness and commitment to Biosafety/Biosecurity**
 - Allay anxiety among researchers through various consultative efforts, training and education
 - **Get buy in from all stakeholders**
-



“Take one capsule tonight, and if there’s no improvement by tomorrow morning, take the whole bottle.”

**Should a prescriptive approach
Be considered ?**



Critical success factors

- National agenda, Cabinet decision
- Clear responsibilities
- Interagency : MOH,MOE,MOD,MOA
- Regional Linkages

We all need to be in this together!

Researchers



WHO
WHO

ABSA
EBSA
APBSA

Regulators

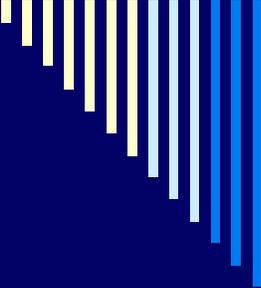
Public Health

Collaborating
centres

Top down, bottom up approach
Awareness, acceptance &
Commitment, Training & Training
Appropriate regulation and policies



Biological Risk
Management



Regional Approach

- ❑ Establish **focal points** at country level
 - ❑ REDI centre coordinator
 - ❑ **Take stock** of capabilities and deficiencies..to be documented. Share best practices
 - ❑ **Criteria for assessment** set with country inputs
 - ❑ Programme **planning** for awareness, education & training
 - ❑ **Working with partners:** WHO, Sandia, Biosafety associations, CDC
-



REGIONAL Networking Proposal



- Management support
- Biosafety infrastructure
- Guides, Policies, Bills
- Political Will & Clout

WHO ,CDC, Biosafety assoc, etc

- Advocacy
- Best practices
- Train the trainers
- Inspection/ certification criteria



MENTOR

Category A countries

**Focal point:
REDI Centre**
•Coordination and collation

- Advocacy (Bilaterals, ASEAN)
- Guidelines for biosafety
- Regional training
- Best practices
- Inspection/certification

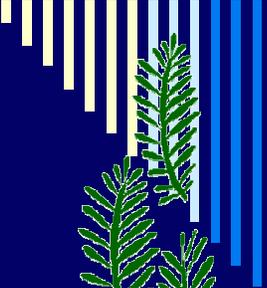


Category B countries

MENTEE

**INCREMENTAL
SUPPORTIVE
COLLABORATIVE**

- Take stock based on criteria
- Capabilities to create Biosafety culture
- Management and Stakeholders support



Thank you