

Singapore's Perspectives on Biosafety & Biosecurity

Koh Peng Keng
Senior Director (Operations)
Ministry of Health
Singapore



Our Concerns

- **Singapore's development as a regional Biomedical Science Hub**
- **Lab-acquired SARS infection in Singapore, Taiwan & China**
- **Potential use of some biological agents as weapons of bioterrorism**



Our Solution

A framework to promote biosafety culture:

- **Transparent and follows internationally-recognized standards**
- **Comprehensive but not prescriptive**
- **Balanced between safety and research freedom**



Our Approach

- **Formation of the multi-disciplinary National Biosafety Committee (NBC) to implement the Biosafety Framework in March 2003**



Our Approach

- **Three Technical Working Committees (TWCs) appointed by the NBC with specific tasks to:**
 - Draw up and update the biological agent list
 - Formulate and update the biosafety standards
 - Define the training requirements
- **Legislation to promote biosafety and enhance biosecurity**



Legislation

Biological Agents and Toxins Bill

- **Regulates the possession, use, import, transfer, transportation of biological agents and toxins**
- **Provides for safe practices in handling of such biological agents and toxins**



Biosafety versus Biosecurity

- **Biosafety based on principles and techniques that protect workers from exposure***
- **Biosecurity based on security measures designed to reduce risk of loss, theft or diversion***
- **Foundation of a biosecurity program is a strong biosafety program**

* Source: WHO Laboratory Biosafety Manual (3rd Ed)

Components in the Legislation

- **Biological agent and toxin lists**
- **Agent tracking system**
- **Transport requirements**
- **Facility requirements**
- **Other controls**



High-risk biological agents & toxins



Biological Agent & Toxin Lists

- **Five separate schedules with different degree of control based on risk assessment**
- **38 biological agents and 5 toxins with biosecurity concerns were considered to have potential to be weaponised**
- **These agents will require maximum control involving all components in the framework.**

Agent Tracking System

- **Import control**
- **Possession control**
- **Transfer control**



Import Control

- **Permit to import required for all scheduled biological agents and toxins.**
- **Approval to possess required before permit to import can be granted.**
- **Agent-specific and issued on per consignment.**
- **Importers have to notify MOH of any failure to receive.**

Possession Control

- Approval to possess high risk biological agents/toxins

- Linked to certified facilities

- Approval to possess:

- Agent-specific

- Approvals required for first-time use

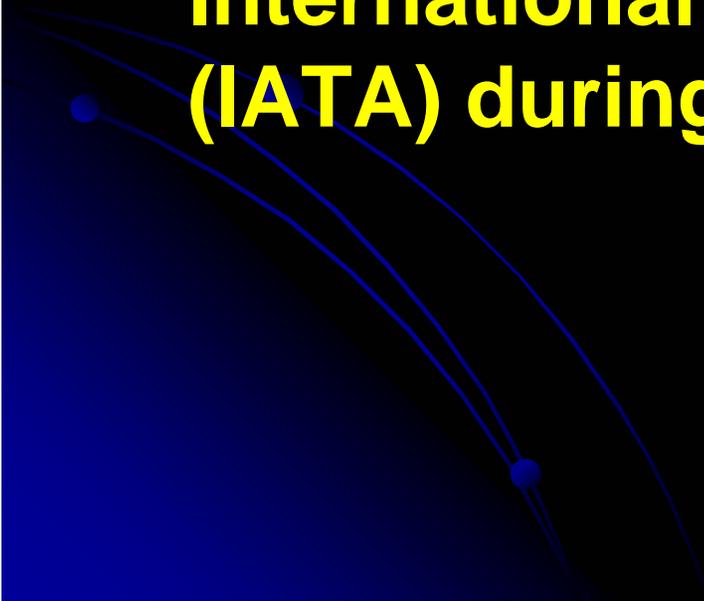
Transfer Control (1)

- **Both transferor and transferee of scheduled BA and toxins must hold valid approval to possess**
- **Transferor to notify:**
 - **MOH of the proposed transfer**
 - **transferee of the estimated time of receipt**
 - **carrier of a 24-hr emergency contact number**

Transfer Control (2)

- **Transferee has to notify MOH of any failure to receive BA.**
 - **Transfer notification**
 - **transferee of the estimated time**
Agent-specific
 - **Issued on per consignment**
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Transport Requirements (1)

- **Transport by postal mail or public transportation is strictly prohibited**
 - **Packaging and labeling to follow the principles as stipulated by the International Air Transport Association (IATA) during transportation**
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Transport Requirements (2)

● **Couriers to ensure that:**

- no unreasonable delays
- drivers for must undergo training in the management of accidents involving biohazardous materials
- conveyance used for transport must be affixed with biohazard labels
- an appropriate security plan is developed and implemented.

Facility Requirements (1)

Facilities must :

- Be certified by MOH-approved certification bodies
- Meet mandatory criteria for certification
- Undergo annual re-certification
- Notify MOH of major lapses during certification/recertification process.

Facility Requirements (2)

- **Certified facilities must**

- maintain inventory records of all scheduled BA and toxins

- notify MOH of all lab-acquired infections and accidents involving scheduled BA and toxins

- **Certified facility must also be gazetted as a 'Protected Place'**

Other Controls

- **Inactivated samples**
- **Large-scale production**
- **Management responsibilities to**
 - appoint a biosafety committee & coordinator
 - ensure staff are adequately trained in biosafety
 - maintain facility and equipments in good working conditions
 - ensure safety of activities, staff and visitors to facilities
 - established health surveillance and reporting system

Exemptions

- **Disposal by hazardous waste contractor**
 - **Handling of BAs in diagnostic work & autopsies**
 - **Collection of food/environmental samples for public health purposes**
 - **Use/possession of toxins in finished medicinal or cosmetic products**
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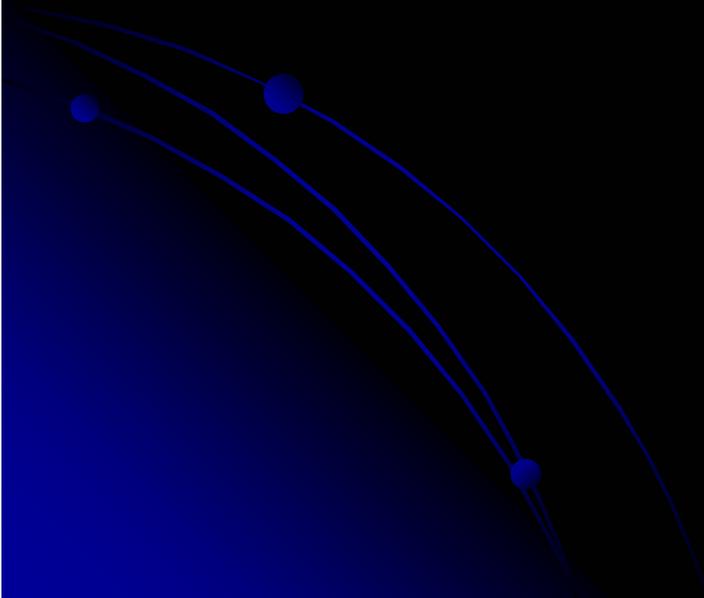
Export Control

Strategic Goods (Control) Act

- Singapore is a party to the Biological Weapons Convention, which is linked to the UN Security Council Disarmament initiative
- Regime of export control for a list of biological agents/toxins

Way Ahead

- **Engage the industry for the implementation of BATA**
- **Build capacity in MOH to more effectively promote biosafety**



Contact

**Biosafety Office
Operation Group
Ministry of Health
College of Medicine Building
16, College Road,
Singapore 169854**

Fax: 65-6325 4679

E-mail: MOH_Biosafety@moh.gov.sg