# Singapore's response to biorisk events at home and abroad

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# Introduction

- Background : History and Events shaping biosafety/biosecurity measures in Singapore
- Critical Legislation:  Tradenet and BATA
- Institutional Biosafety Committees
- Biosafety/Biorisk Associations

# Historical Background

**2003**
**BSL3 MOH Lab Commissioned**
**SARS Outbreak**
**SARS Lab Acquired Infection**

**2009**
**Code of Ethical Practice**

**2009**
**H1N1 Outbreak (lab guidelines)**

**1997**
**Nipah Outbreak**

**2008**
**Guidelines on Animal Transport and Use in Clinical and Public Areas (IACUC)**

**2006**
**Genetically Modified Organisms (GMO's) Guidelines**

**2005**
**Biological Agents and Toxins Act (BATA)**

**2002**
**Strategic Goods (Control) Act**

**1976**
**Infectious Diseases Act**

**1965**
**Animals and Plants Act**

# Events leading to biosafety & biosecurity legislation: a historical perspective

- **First event (1998)**
  Nipah virus - Malaysia & Singapore
- **Second event (2001)**
  US anthrax letters
- **Singapore Economic Development Board's drive (2001)***
  to develop biomedical industry

# Strategic Goods (Control) Act, 2002 (Tradenet)

An Act to control the transfer and brokering of strategic goods, strategic goods technology, goods and technology capable of being used to develop, produce, operate, stockpile or acquire weapons capable of causing mass destruction, and missiles capable of delivering such weapons; and for purposes connected therewith.

An important tool it controls is Tradenet. Approval to import biological agents done on line. Used by AVA, MOH. Approval must be obtained prior to importation by these agencies.

# Biosafety Building Blocks

## 2002 – 2 study trips

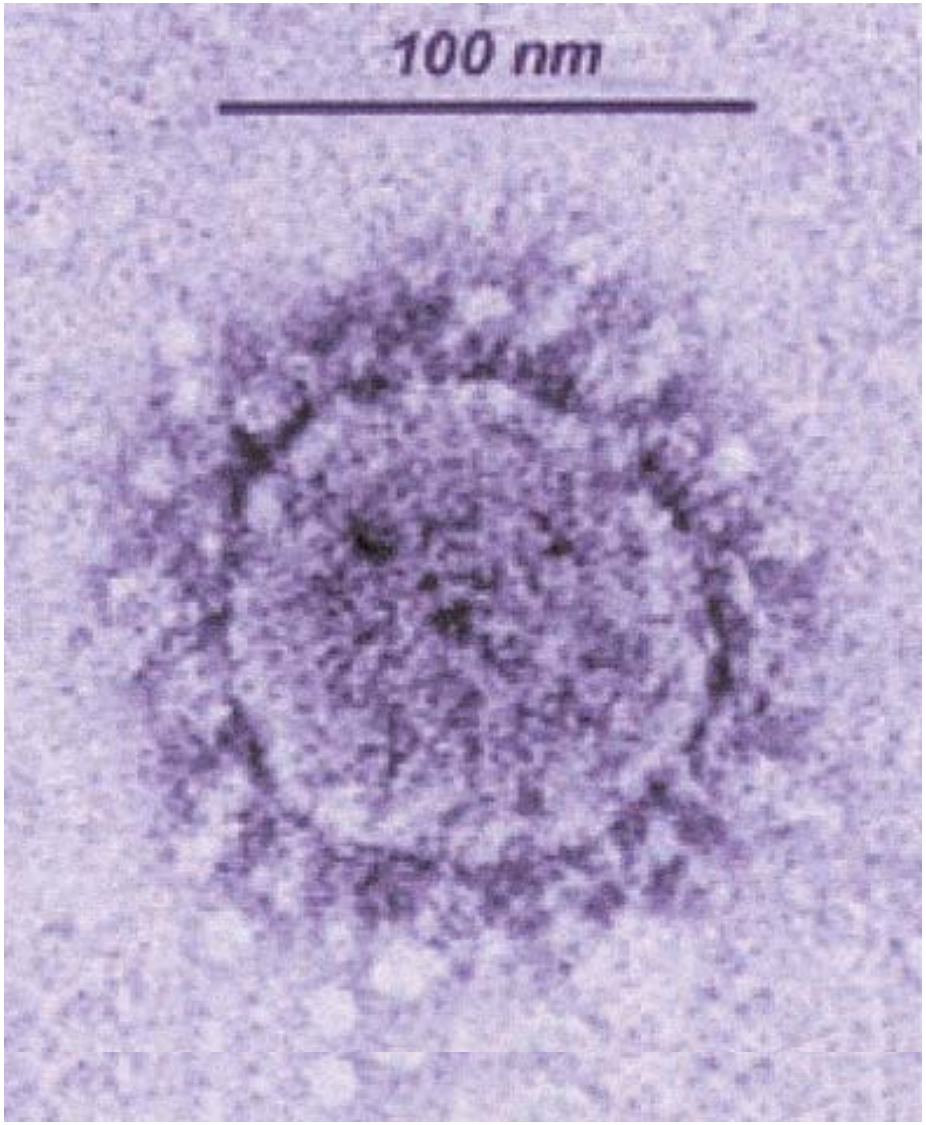
- April: USA – Centers for Disease Control & Prevention
- November: Canada – Biosafety Office & Office of Laboratory Security

## 2003 – Formation of National Biosafety Committee and

3 Technical Working Groups on

- National Biosafety Standards
- Select Agents
- Biosafety Training

SARS Coronavirus – Laboratory Acquired infection, 2003



# Findings & Recommendations from the Lab-Acquired SARS Infection

## Findings

- Lab Structural problems
- Insufficient staff training
- Limited space & crowding
- Lack of inventory and tracking of infectious samples
- Lack of structural regulatory framework and National Standards for Biosafety

## Recommendations

- The need for a national legislative basis for standards in biosafety
- A structure should be created for lab certification covering both structural integrity & operating procedures
- A tracking system for importation, exportation to and from Singapore and movement or transfer between local labs

# Components of the BATA

- Regulation of **biological agents and toxins**
- **Duties and obligations** of facility operators and carriers
- **Enforcement**

The BATA was passed by the Parliament in Oct 2005 and enacted in Jan 2006 and is administered by the Biosafety Legislative Branch of the Ministry of Health, Singapore

# Regulation of biological agents & toxins

## *(Relationship between schedules & risk groups)*

- Schedule 1 Part I (RG3)
- Schedule 1 Part II (RG3 with BT potential)
- Schedule 2 (RG4 with BT potential)
- Schedule 3 (Large scale production of RG2)
- Schedule 4 (RG2)
- Schedule 5 (Microbial toxins with BT potential)

# BATA Regulations

1. Possession of agents of high biosafety risk levels (RG3 & RG4) and biosecurity agents (RG3, RG4 and toxins with BT potential)

   - *High biosafety risk – certified BSL3 facility*
   - *High biosecurity risk – protected place*

   Diagnostic activity is exempted

2. Special transportation for high level biosafety and/or biosecurity risk agents, or high volume of RG2 (≥10 litres) agents

3. Import permit needed for RG2-RG4 microorganisms and the listed toxins

# Duties and Obligations of Facility Operators and Carriers

**Facility operator**
*(manager of the facility)*

- Ensure all activities in the facility is carried out safely by trained and competent personnel
- Ensure all requirements of the BATA are fulfilled

**Carriers**
*(persons who transport agents in Schedule 1,2,3 and 5)*

- Must attend Hazmat training course, with Hazmat (Hazardous materials transport) permit

# Enforcement

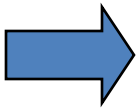
**Director of Medical Services (MOH) has the following powers:**

- Entry, search & seizure
- Orders for cessation of activity & closure of facility
- Obligatory medical examination/treatment
- Impose penalties

# BATA Offences

**Use of BA or toxins for non peaceful purpose**

- Possession of BA or toxins without approval
- Large scale production of BA without approval
- Importation/transshipment of BA or toxins without permit
- Transportation of BA or toxins by mail/public transport
- Failure to perform duties and obligations



**Life imprisonment and/or S$1 million**

10-years imprisonment and/or S$100K

1 year imprisonment and/or S$10K

½ year imprisonment and/or S$5K

(Severity of punishment depends on degree of offence)

# System In-place to Facilitate the Administration of the BATA

- Gazetting of facilities as protected place by the *Ministry of Home Affairs*

- Vetting of personnel accessing protected facilities by the *Internal Security Department, MHA*

- Involving *Singapore Civil Defense Force, MHA* in emergency response of Labs

- Collaborating with other ministries & agencies (*esp. the Singapore Police Force, MHA*) on sensitive materials

# System In-place to Facilitate the Administration of the BATA

- Annual certification of BSL3 facilities by *MOH-Approved Facility Certifiers*
- Training of biosafety training courses by *MOH-Approved Training Providers*
- On-line application for approval & permit using IT system *(MOH & Singapore Customs)*

# The Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs), 2006

Established to ensure the safe containment, handling and transport of GMOs used in research and to provide a common framework for assessment and notification of research on GMOs. The scope covers experiments that involve the construction and/or propagation of all biological entitites (cells, organisms, prions, viroids or viruses) which have been made by genetic manipulation and are of a novel genotype and which are unlikely to occur naturally or which could cause public health or environmental hazards.

**It covers**

- summary of procedures dividing them into 3 categories for assessment and notification of research work,
- roles and responsibilities of Institutions, IBCs and PIs,
- transport and import of transgenic animals, insects and their pathogens, transgenic plants
- supply of genetically manipulated material to other research workers,
- Import of genetically manipulated organisms or materials

# H1N1 Outbreak, 2009

**Initial Response**

- Laboratory Advisory, MOH, May 2009

  Virus considered RG3; culture done at BSL3 laboratories

  Diagnostic work handled inBSL-2 lab with BSL3 practices

- Audit of all laboratories dealing with influenza diagnosis and research . Advise given to close gaps identified to ensure safe handling of the influenza samples

- Revised Advisory released on Sep 18, 2009

  H1N1 considered same risk group as usual epidemic strains. Virus handled at BSL-2, in class 2 biosafety cabinet

# Institutional Biosafety Committees

- National University of Singapore (2002)
- Singapore General Hospital
  - Animal Facility Biosafety Committee (2006)
  - SGH Institutional Biosafety Committee (IBC) (2007)
- SingHealth IBC (2010) – overarching oversight of 9 national institutes using common structure, common risk assessment template, expert panel. Provide interagency liaison, compliance with BATA, secretarial assistance (annual reports, etc)

# Biosafety Associations

- **Asia Pacific Biosafety Association (2005)**

  MOH approved training provider

- **Biorisk Association of Singapore (2010)**

  At present in consultation with the MOH, Education institutions and the Ministry of Manpower to develop a framework for formalised and nationally recognized biosafety training

# Acknowledgements


- Se Thoe Su Yun (MOH)
- Sim Phoi Sang (SingHealth IBC office)