



Laboratory Oversight: Examples from Around the World

Biosecurity Inspector Training

**Staten Serums Institut
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www.biosecurity.sandia.gov

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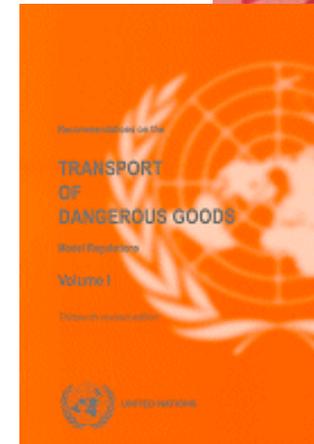
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International Guidelines

- **Laboratory Biosafety**
 - World Health Organization (WHO) – Laboratory Biosafety Manual (LBM) 3rd Edition
- **Laboratory Biosecurity**
 - WHO – LBM 3rd Edition
 - WHO – Biorisk Management: Laboratory Biosecurity
 - OECD – has security requirements for their Biological Resource Centers
- **Transport of Infectious Substances**
 - UN Recommendations on the Transport of Dangerous Goods. Model Regulations
 - ICAO requirements / IATA standards





National Measures

- **BWC Implementing Legislation**
 - Bans development, production, and stockpiling
- **National Legislation and Regulations for Laboratory and Transportation Biosecurity and Biosafety**
 - Control use, storage, and transport of dangerous pathogens domestically
- **Export Controls**
 - Control transport of dangerous pathogens and technology internationally
- **Implementation Standards or Guidelines**
 - Provide assistance to those who handle, store, or transport dangerous pathogens so that they can comply with legislation while still meeting their biomedical and bioscience research and diagnostic duties



Canada



- **BWC Implementing Legislation**
 - Biological and Toxin Weapons Convention Implementation Act – 2004
- **National Legislation and Regulations**
 - Human Pathogens Importation Regulations Act
 - Overseen by Office of Laboratory Security (within Health Canada)
 - Controls and tracks use of imported dangerous pathogens
- **Export Controls**
 - Export and Import Permits Act
- **Implementation Standards or Guidelines**
 - Laboratory Biosafety Guidelines
 - Addresses biosafety and biosecurity
 - Office of Laboratory Security certifies BSL3 and BSL4 facilities



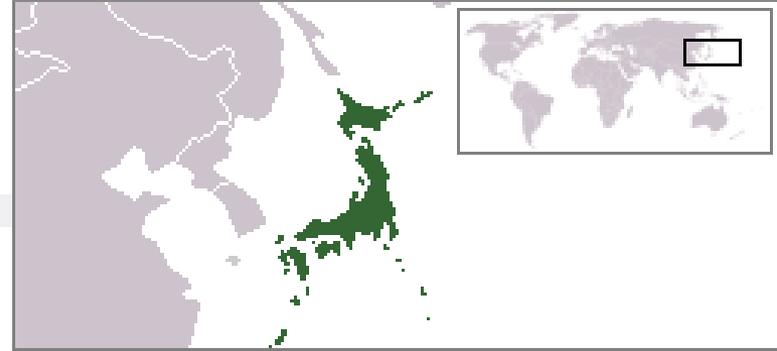
India



- **BWC Implementing Legislation**
 - Prevention of Terrorism Act 2002
 - Bans possession of biological substances of warfare
- **National Legislation and Regulations**
 - The Weapons of Mass Destruction and Their Delivery Systems (Prohibition of Unlawful Activities) Bill
 - Prohibits all unlawful activity related to WMD including their means of delivery and dual-use materials, equipment, and technology
 - Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms, Genetically-engineered Organisms, or Cells
 - Regulates use, import, and export of listed microorganisms
 - Research with regulated microorganisms may only take place in government-approved laboratories
- **Export Controls**
 - Within other regulations
- **Implementation Standards or Guidelines**
 - Recombinant DNA Guidelines



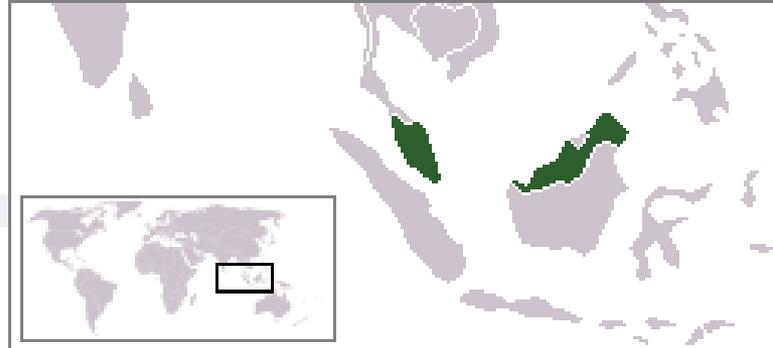
Japan



- **BWC Implementing Legislation**
 - 1982
- **National Legislation and Regulations**
 - Infectious Disease Law Amendment (2007)
 - Prohibits possession of some pathogens; biosecurity requirements
- **Export Controls**
 - Foreign Exchange and Foreign Trade Control Law
 - Regulates WMD-related materials and dual-use technologies
- **Implementation Standards or Guidelines**
 - NIID has biosafety guidance but many rely on WHO LBM3 or BMBL
 - Guidelines for Recombinant DNA Experimentation



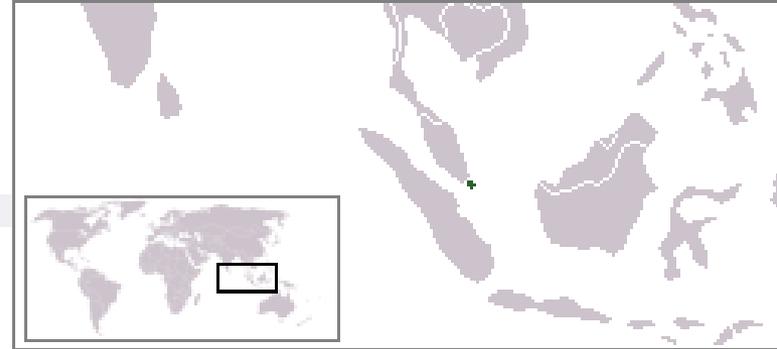
Malaysia



- **BWC Implementing Legislation**
 - Obligations covered under multitude of registration
- **National Legislation and Regulations**
 - Biosafety Act of 2007 and Pathology Act of 2007
 - Drafting a Biological Weapons Act that will address pathogens
- **Export Controls**
 - Import controls for pathogens but lacks substantive export control laws (currently under revision to address gap)
- **Implementation Standards or Guidelines**
 - BW Act will lead to development of:
 - Biosafety and biosecurity standards,
 - Minimum professional qualification requirements, and
 - Biosafety/biosecurity officers



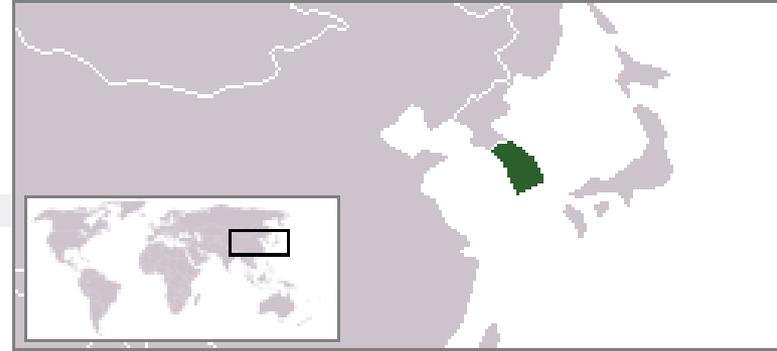
Singapore



- **BWC Implementing Legislation**
 - No specific legislation identified
- **National Legislation and Regulations**
 - Biological Agents and Toxins Act (BATA; 2005)
 - Framework for regulating biological activities in Singapore
 - Addresses: Possession, Use, Import/Export, Transfer, Transport, Biosafety
 - Up to \$1 million fine and life imprisonment
- **Export Controls**
 - Establishing “enhanced export control regime” to
 - Control strategic goods movement
 - Prevent WMD proliferation
- **Implementation Standards or Guidelines**
 - Have adopted the WHO LBM as the Singapore standard



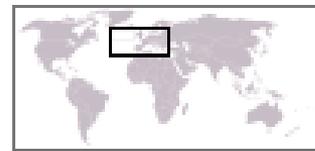
South Korea



- **BWC Implementing Legislation**
 - Part of CWC implementing legislation
- **National Legislation and Regulations**
 - Counter-Terrorism Act of 2001
 - Increased penalties for offenses for using biological materials
- **Export Controls**
 - Foreign Trade Act
 - Comprehensive system of export controls, including a focus on nonproliferation of biological items
- **Implementation Standards or Guidelines**
 - Korean Center for Disease Control (KCDC) Division of Biosafety Evaluation and Control responsible for
 - Issued national biosafety guidelines (which include biosecurity)
 - Certifies BSL3 and BSL4 facilities throughout Korea



United Kingdom



- **BWC Implementing Legislation**
 - Biological Weapons Act (1974)
- **National Legislation and Regulations**
 - Anti-Terrorism, Crime, and Security Act of 2001
 - Part 6 amends Biological Weapons Act to address transfer of biological materials
 - Part 7 requires Security of Pathogens and Toxins
- **Export Controls**
 - Export of Goods (Control) Order
 - Export Control Act 2002 adds provisions to regulate transfer of intangible technologies
- **Implementation Standards or Guidelines**
 - Guidance developed by Advisory Committee on Dangerous Pathogens



United States



- **BWC Implementing Legislation**
 - Biological Weapons Anti-Terrorism Act – 1989
- **National Legislation and Regulations**
 - Select Agent rules
 - HHS and USDA
 - Hazardous Materials Transport regulations
 - DOT
- **Export Controls**
 - Export Administration Act
- **Implementation Standards or Guidelines**
 - Biosafety in Microbiological and Biomedical Laboratories (BMBL) – 5th edition includes biosecurity
 - NIH Guidelines for Recombinant DNA
 - Requires Institutional Biosafety Committee if receive any NIH funding for rDNA work



Biosecurity Regulations – More In-depth Examples

Only a few countries have regulations requiring security of dangerous pathogens in laboratories:

- Australia
- Canada
- Czech Republic
- Denmark
- France
- Japan
- Singapore
- South Korea
- United Kingdom
- United States



Australia

- **National Health Security Act (2007)**
 - Drafting amendment now (2009)
- **“Security Sensitive Biological Agents” (SSBAs)**
 - Human, zoonotic, and animal pathogens and toxins
 - 2 Tiers
- **Requirements**
 - Facility registration
 - Responsible official and deputy RO at each facility
 - Minimum standards for risk assessment
 - Vulnerability assessment for Tier 1 only
 - In process of establishing background check requirements
 - Physical security to limit access based on risk assessment and Tier
 - Specific inventory requirements
 - Written plans required and mandatory intervals for internal inspections



Japan

- **Infectious Disease Control Law (2006)**
- **Infectious agents and toxins regulated**
 - Human and zoonotic pathogens and toxins
 - 4 Tiers
- **Requirements**
 - Tier1 pathogens: prohibited unless designated by Minister of Health
 - Tier 2 pathogens: require prior permission for possession or use
 - Tier 3 pathogens: facilities must register
 - Tier 4 pathogens: facilities must report loss, theft, or release
 - Must implement minimum biosafety and biosecurity standards for all levels based on risk assessment but minimum standards not defined
 - Inspections



United States

- **Bioterrorism Preparedness Act of 2002 – US Public Law 107-188**
 - New legislation pending that will revise regulations
- **“Select Agents”**
 - Human, zoonotic, and animal pathogens and toxins (~80)
 - List reviewed biennially or as needed
- **Requirements**
 - Facility registration
 - Responsible official and alternate RO at each facility
 - Facility risk assessments
 - Background check requirements for anyone with access
 - Physical security to limit access
 - Specific inventory requirements
 - Written plans required
 - Training requirements for everyone
 - Inspections prior to approval



Conclusions

- **Countries use a mixture of regulations and guidance**
- **Many models for regulation**
- **Laboratory biosafety standards and practices generally more advanced than laboratory biosecurity**
- **Many countries just beginning to address these issues at a national level**

- **Resources:**
 - **Interpol**
 - <http://www.interpol.int/Public/BioTerrorism/NationalLaws/>
 - **OECD**
 - <http://www.biosecuritycodes.org/leg.htm>