
Laboratory Oversight: Examples from Around the World

Laboratory Biosafety and Biosecurity Workshop

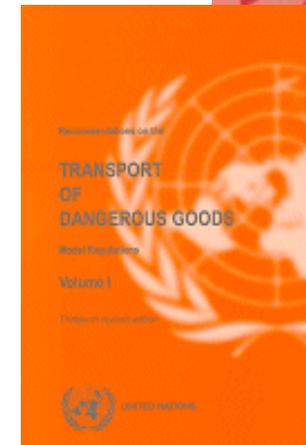
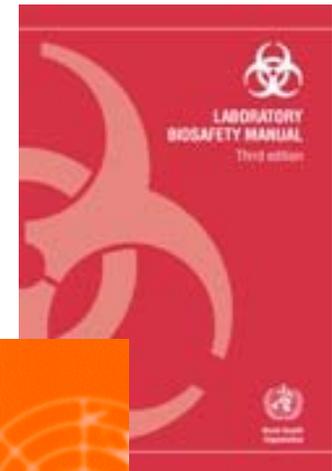
**Cairo, Egypt
3-5 April 2007**

www.biosecurity.sandia.gov

SAND No. 2006-2017C
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
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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**
 - To be published in 2006
 - **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



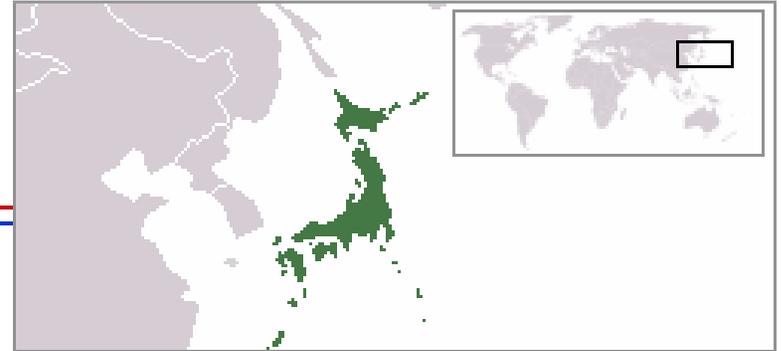
- **BWC Implementing Legislation**
 - **Biological and Toxin Weapons Convention Implementation Act – 2004**
- **National Legislation and Regulations**
 - **Human Pathogens Importation Regulations Act**
 - Overseen by Office of Laboratory Security (within Health Canada)
 - Controls and tracks use of imported dangerous pathogens
 - Regulates biosecurity and biological weapons nonproliferation
- **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



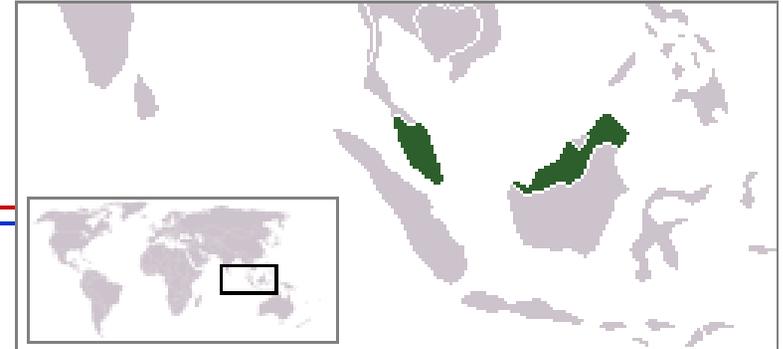
- **BWC Implementing Legislation**
 - **Prevention of Terrorism Act 2002**
 - Bans possession of biological substances of warfare
- **National Legislation and Regulations**
 - **The Weapons of Mass Destruction and Their Delivery Systems (Prohibition of Unlawful Activities) Bill**
 - Prohibits all unlawful 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**
 - Department of Biotechnology under Ministry of Science and Technology
 - 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



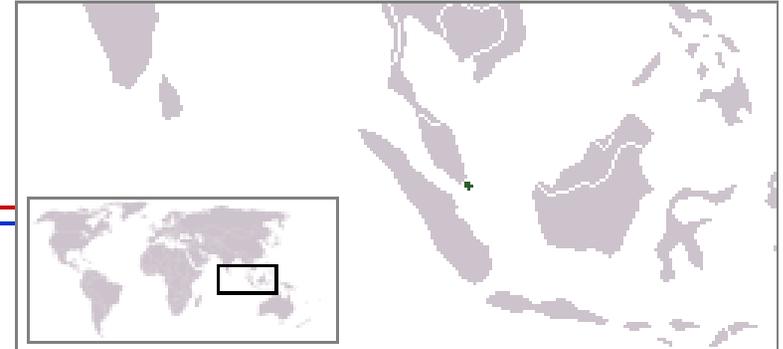
- **BWC Implementing Legislation**
 - 1982
- **National Legislation and Regulations**
 - **Infectious Disease Law Amendment (2007)**
 - Will prohibit possession and production of pathogens
- **Export Controls**
 - **Foreign Exchange and Foreign Trade Control Law**
 - Regulates WMD-related materials and dual-use technologies
- **Implementation Standards or Guidelines**
 - **National Institute of Infectious Diseases has biosafety guidance but many rely on WHO LBM3 or BMBL**
 - **Guidelines for Recombinant DNA Experimentation**
 - **Ministerial Notice on Laboratory Safeguards- October, 2001 (Ministry of Health, Labour, & Welfare)**
 - Requests labs to establish safeguard systems for dangerous pathogens, to ensure adequate security measures, to keep a register of dangerous pathogens and to maintain records of the possession of select agents as well as their stated purpose

Malaysia



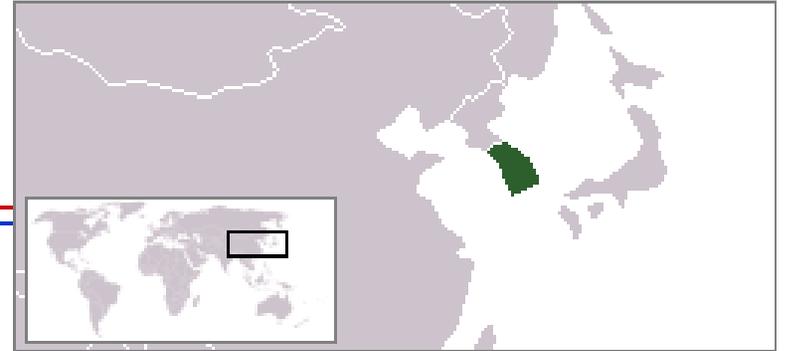
- **BWC Implementing Legislation**
 - **Obligations covered under multitude of legislation**
 - Penal Code, the Corrosive and Explosive Substances and Offensive Weapons Act 1958, the Arms Act 1960, the Customs Act 1967, the Prevention and Control of Infectious Diseases Act 1988 and the Plant Quarantine Act 1976
- **National Legislation and Regulations**
 - **National Biosafety Committee established in 2005 is tasked with writing a Biological Agents and Toxins Act**
 - **Planning to write a National Laboratory Biosafety and Biosecurity Policy – Interagency, cabinet level document**
- **Export Controls**
 - **Import controls for pathogens but lacks substantive export control laws**
- **Implementation Standards or Guidelines**
 - **Under development**
 - **Institutional Biosafety Committees in formative stages**
 - **Conducting a nationwide survey to determine capabilities, activities, types of agents, biosafety levels to determine baseline**

Singapore



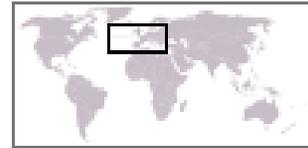
- **BWC Implementing Legislation**
 - No specific legislation identified
- **National Legislation and Regulations**
 - **Biological Agents and Toxins Act (BATA; 2005)**
 - Framework for regulating biological activities in Singapore
 - Addresses: Possession, Use, Import/Export, Transfer, Transport, Biosafety
 - 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**
 - **Planning to revise CWC to include biological weapons and toxins**
- **National Legislation and Regulations**
 - **Counter-Terrorism Act of 2001**
 - Increased penalties for offenses for using biological materials
 - **New legislation to address manufacture, transportation and use of hazardous 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**
 - Establishing national biosafety guidelines
 - Certifying BSL3 and BSL4 facilities

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 – implementation requires close coordination of laboratories and local police
- **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**
 - **Need to notify Health & Safety Executive first time hazard group 2, 3, or 4 pathogens are used on premises; notification is also required of the subsequent use of certain agents**

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)**
 - **NIH Guidelines for Recombinant DNA**
 - Requires Institutional Biosafety Committee if receive any NIH funding for rDNA work

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>