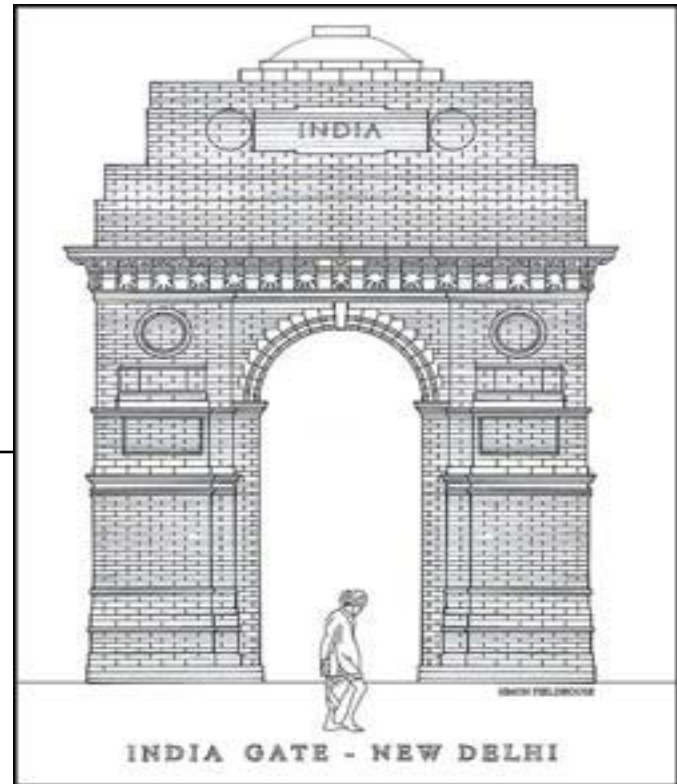


# Presentation

by

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# Oversight of Dual-use Research

*An Asian Perspective*



# Presentation Layout

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- **Defining the Problem**
- **Compare & Contrast: Fink Report**
- **Epidemics and Asia**
- **Biotech Industry and Asia**
- **Safety & Security: Few Asian Cases**
- **Asian View**



# “Dual-use” Dilemma

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- **Civilian facilities could be used for military purposes**
- **Equipment and agents could be misused**
- **Terrorists could take advantage of existing BT infrastructure without state knowing it**
- **Scientific knowledge could reach wrong hands**
- **Accidental release of ‘germs’**



## The Issue

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**Modern biological research offers enormous potential to benefit society**

**The synergy created by increasing knowledge and open exchange of ideas and information is accelerating the advance of medicine, industry, and agriculture**

- **The growing risk: New advances could help making novel biological weapons or could be misused by careless groups and individuals**



# The Indicators

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- **South Korea scientists conducted experiments to enrich small amounts of uranium (2000)**
- **Done without official approval**
- **The very nature of WMD is so secretive- often governments are unaware about small scale scientific projects**
- **Experimenting on 'germs': possibility exists**



# The Difficulty

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- The open exchange of scientific data and concepts is need of the hour
- **Results of fundamental research should remain unrestricted**
- Vaccine development, for example, depends on cutting-edge biomedical research
- **Censorship is complicated in 'Web era'**
- **Publish or Perish???**



# The Requirement

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- **21<sup>st</sup> Century threats demand different solutions**
- **Threat could be from non-state or a 'rogue' state**
- **There is ongoing change in pattern of terror**
- **Goal of terror today is much beyond media coverage and attention**
- **To match a balance between openness in 'science' and reticence of 'security' is the challenge**





# The Need

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- **Coordinated global efforts are needed to reduce this growing risk**
- **Oversight of Dual use research-a need to create templet to resolve this issue**
- **The templet should take into consideration culture, pracitices, ethics etc. of the region into account**



# Ensuring Responsible Oversight for BT

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- **Educating the Scientific Community**
- **Review Plans for Experiments**
- **Review at Publication Stage**
- **Creation of a National Science Advisory Board for Biodefense (NSABB)**
- **Protection Against Misuse**
- **Engage Life Sciences in Security**
- **Harmonize International Oversight**



**Could Fink Model**  
be superimposed

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on **Asia-Pacific?**

***YES and NO***



# An Asian Scrutiny

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- Educating the Scientific Community- *is possible and is being done*
- Review experiments/publications- *may be*
- Protection against misuse- *country specific models exist*
- Harmonize International Oversight- *agreeable*
- Creation of a advisory board for *Biodefense-policies exist*
- Engage Life Sciences in Security-*problematic*



# Asia

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the worst sufferers from epidemics  
in recent past

***SARS***

***Bird Flu***



# SARS

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- Between the first description of the disease in November 2002 and July 2003, there were approximately **8,000 probable cases** and just fewer than **800 deaths** worldwide
- The epidemic cost Asia approximately **US\$30 b** in terms of losses in tourism and business and in other direct costs



## **SARS** contd

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- **From August 2003 to November 2004—natural course of infection over-seventeen confirmed cases of SARS**
- **Four from community-acquired ( exposures at an animal market)**
- **Six other cases were laboratory-acquired**
- **One of the laboratory-acquired infections led to seven additional infections**



## SARS contd

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- In none of these cases has it been assumed that there was a profound failure of technology or equipment
- The problem people working with those organisms lacked the training & resources
- Oversight and regulation of any activity is composed of several layers of regulatory frameworks and implementation
- The implementation of such a complex system at multiple levels is the real challenge





# Bird Flu

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- **Principal transmission of the virus occurring among poultry and other birds**
- **At the overall macroeconomic level, costs so far have been fairly limited, but could rise significantly, SE Asia worst affected region**
- **A pandemic of avian influenza among humans could cost the global economy US\$800 billion a year-** *The World Bank Study*



# BT Industry Asia-Pacific

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- Growth Rate of > 11% from 2004-06
- Expected value of market by 2006 > US\$ 39.16 b
- Japan, China, and Taiwan largest growing markets (presently has 76% market share)
- Likely to emerge as a key destination for clinical trials & stem cell research
- Major growth in agriculture sector- developing large number of GM crops



## **BT Industry Asia-Pacific** contd

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- **Biopharma industry will emerge as a major segment**
- **Industry is largely dependent on the government, little private participation in most of the countries**
- **The Contract Research industry in India could reach as high as US\$ 270 m by 2009**
- **In few cases opaque government policies and regulations**

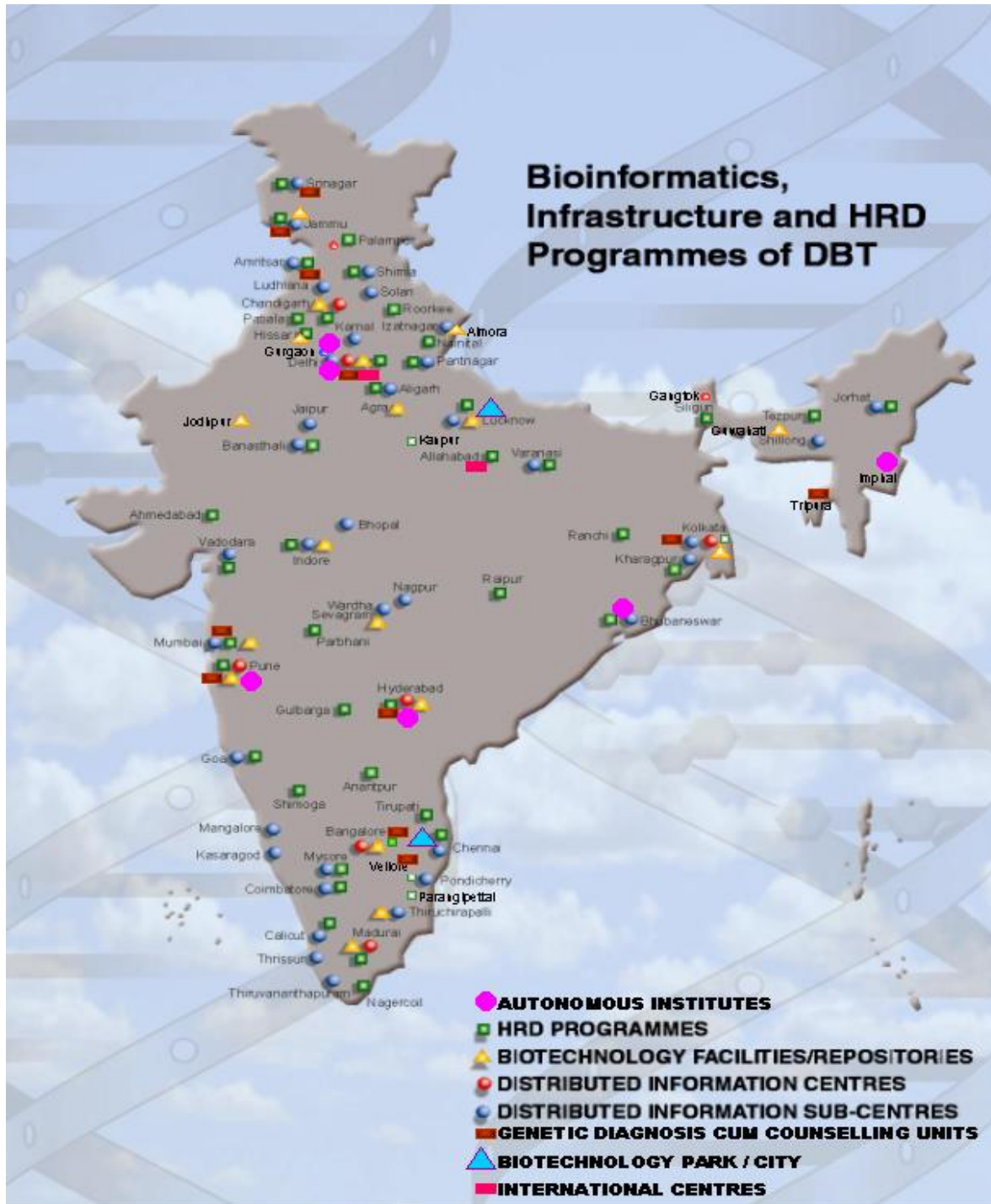


# Indian Biotech Industry

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- Growth rate of 28.09% from the year 2005
- **Expected turnover US\$ 5 b by the end of 2010**
- Key destination for clinical trials & stem cell research
- **Important role in Agriculture sector by developing large number of GM crops**
- **BioPharma industry, comprising of vaccines, therapeutics and other products, will emerge as major segment**

# Bioinformatics, Infrastructure and HRD Programmes of DBT





*Asian States*

**&**

**Oversight of Dual-use Research**



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**India's diktat**  
to fight Disease Spread

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BW Proliferation



## India has in place

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A **regulatory mechanism** for the maintenance of security and oversight of pathogens, micro-organisms, genetically modified organisms and toxins in production, import, export, use and research





# Measures Taken by India

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- **Environment (Protection) Act, 1986-Procedures and Safeguards for handling of 'Hazardous Substances'**
- **1989 Rules- hazardous microorganisms & gene tech**
- **1990 Recombinant DNA Safety Guidelines (RDAC)**
- **Need for Institute Bio-safety committee (IBSC) for any lab**



## Biosafety regulatory framework

- **1989 Rules are elaborated & revised time to time**
- **1994: Revised guidelines for safety in biotechnology**
- **1998: Guidelines for research in Transgenic Plants, Toxicity, Evaluation of Transgenic seeds, plants**



## Identifying micro-organisms...

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- *Various guidelines list micro-organisms on the basis of differential risk assessment*
- *Category 2 of SCOMET list (dual-use export control)*



# **Advisory & regulatory bodies**

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- **Review Committee on Genetic Manipulation (RCGM)**
- **Genetic Engineering Approval Committee (GEAC)**
- **Coordination is done by DoB**



# Code of Conduct

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- **ICMR has developed CoC for scientists engaged in biomedical research, 2000**
- **In consistence with the 1964 Helsinki declaration later amended in 2000 based on principles of autonomy, privacy, justice and equity**



## Recent legislations...

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- *The drug policy, 2002*
- *National Seeds Policy, 2002*
- *Ethical Policies on the Human Genome, Genetic Research and Services, 2002*



## **WMDs Bill 2005**

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- **WMD proliferation is a criminal offence**
- **Prevent manufacture, export, transfer, transit and transshipment of WMD material, equipment, technology and their means of delivery**
- **Penalties carry jail terms from five years to life imprisonment along with fines**
- **Companies are also liable for prosecution**



# Safety Rules: China

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- The Chinese regulations are drawn from the **“best practices”** of international biosafety and biosecurity regulations
- **All rules and regulations at par with global standards**





# China and BT Industry

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- China has a large and rapidly growing biotechnology and pharmaceutical industry
- More than 500 enterprises associated with life science and biotechnology with 50,000 employees



# Philippines

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- The first Philippine anti-terrorism bill was proposed on 19 January **1996** and passed its own anti-terrorism law on 06 March **2007**
- **National Committee on National Committee on Biosafety of the Philippines (NCBP) —established in 1990 *first* BIOTECH regulatory system in ASEAN Region**



# **Biosafety: Philippines**

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- **Institutional Biosafety Committee and Technical Committee and Technical Review Panel at place**
- **Draft guidelines to ensure that experiments using GMOs do not pose unacceptable risks to human health and the environment**



# Sri Lanka & Biosafety

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- **Has established a national biosafety framework but it essentially deals with genetically modified organisms**
- **15 universities and 50 research institutes deal with BT**
- **Safety guidelines are by individual laboratories**
- **Biosafety and biosecurity regulations do not exist**
- **Lack legal framework**



# Asia & Causes of Disease Spread

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- **Globalization**
- **Modern Medical Practices**
- **Urbanization**
- **Environmental Factors**
- **Change in social and behavioral patterns**



# Problem Areas

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- **The number of people who could possibly understand regulations and implement them at a policy level is probably quite small**
- **The number of people technically trained to implement them is even smaller**
- **Specific guidelines for oversight on dual use Biotech Research required in few cases**



## Is Asia Having a Separate View?

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- **Not really**
- **BT is still in a developing stage than many other countries**
- **Good practices exist but may not have reached to the grass-root level**
- **Lack Training / Infrastructure could be a problem in certain cases**



# Image Asia

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- Mixed picture
- **Traditional spread of disease represents a security challenge-states have different views**
- **Need to understand the security dimension in contemporary 'microbial era'**
- **Multilateral forums like ASEAN, ARF, APEC have started routinely focusing on BT threat**
- **Security & Intelligence establishments are inherently conservative**
- **States not ready to look beyond narrow focus on BW**





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## **We must recognize.....**

*The biotechnology safety guidelines could never be one time exercise as knowledge is ever expanding*



**THANK YOU**