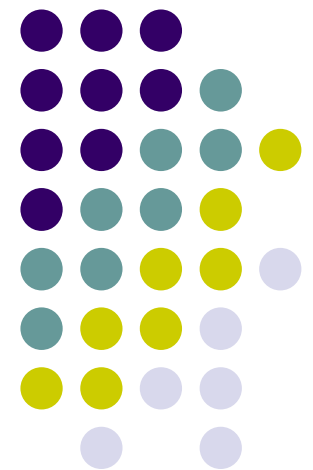


**Presentation**  
*by*

Ajey Lele

*Institute for Defence Studies & Analyses*  
(IDSA)  
New Delhi, India

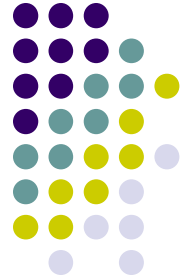






*Asian View on  
National & Regional Legislation  
Implementation*

# Presentation Layout



- Asia-past, present & future
- Threat perception
- Epidemics and Asia
- Biotech Industry and Asia
- Legislation Implementation
- Report card Asia

# Asia in the New Millennium



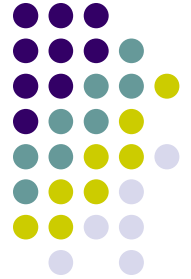
## History

- Arena for Western exploitation and dominance
- Asia functioned as the “object” rather than the “subject” of power

## 21<sup>st</sup> Century

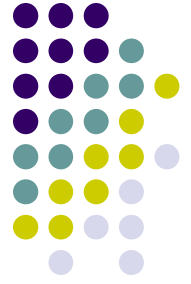
- New strategic center of gravity in international politics
- A region showing successful economic development. Rise of Asia is a reality

# Reality Check



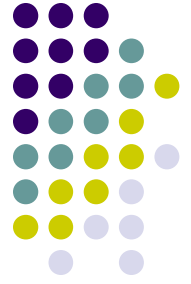
- Areas of prosperity and poverty coexist
- The region does not host the merely labor-dominant economies of yesteryear
- Areas with *advanced industrial economies* as well as states on the *threshold of emerging as major economic players* but few states are showing '*failing*' tendencies

# Reality Check *contd*



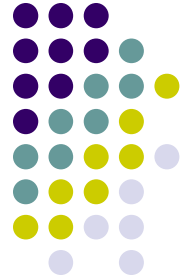
- Technology development is on the rise
- **Biotechnology: Key area of focus**
- Wealth and prosperity of the West will remain dependent on continued linkages with the Asian economies

# Asia: a Zone of Conflict?



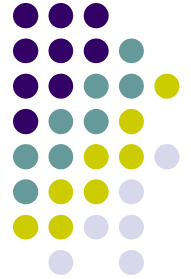
- Present State Vs State conflicts: Russia-Georgia, Iran, Thailand-Cambodia...
- “Distant wars”: India-Pakistan, China-Japan, India-China, US-China...
- Terrorism- India, Pakistan, Afghanistan, Sri Lanka, Bangladesh, Indonesia, Malaysia, Philippines...Iraq...

# Asian Concerns



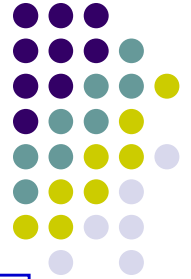
- Terrorism and religious fundamentalism
- Energy security, Food security
- Global Warming/Climate Change, Natural Disasters
- Epidemics

# The Criticism



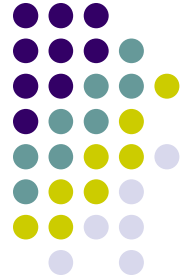
- Asian region poses a WMD threat to rest of the world
- Mature NBC programs from Russia, China to India, Pakistan to Iran to North Korea
- Sophisticated delivery systems such as ballistic and cruise missiles to spinoff technologies from space programs

# BW: Where Asia Stands?



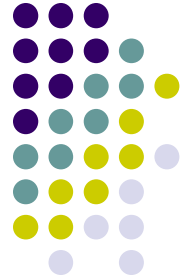
- Historical baggage of usage of BW: Japan-China
- Aum Shinrikyo cult was serious, Rajneesh Cult used it at Oregon but had Asian origins
- North Korea claims to possess Biological Weapons
- Discovered in Kabul, helium balloon armed with anthrax, attributed to a Pakistani nuclear scientist turned Taliban philanthropist

# WMD Threat & Asia *(5 years)*

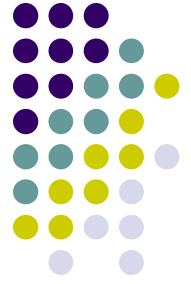


- Chances of Hoax cases are maximum
- Usage of CBR weapons - a possibility
- Radical elements may use it

# WMD Threat & Asia *(5 years)*

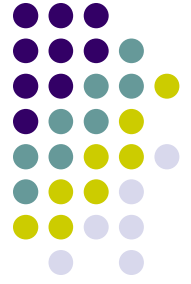


- Terrorists may procure biological weapons from 'Networks'
- LTTE may opt for biological weapons
- American troops in Afghanistan/Iraq could be targets



## WMD Threat & Asia (10-15y)

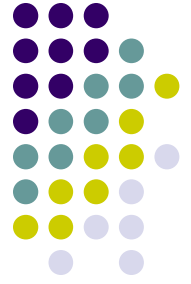
- *Scenario*: Palestine problem is resolved, Al Qaeda shifts its focus to Kashmir-desperation may force them to use biological weapons
- **Advancements in BT: Designer bio-weapons**
- Agro terrorism



# “Dual-use” Dilemma

- Civilian facilities could be used for military purposes
- Equipment and agents could be misused
- Terrorists could take advantage of BT
- Scientific knowledge could reach wrong hands
- Accidental release of ‘germs’

# Indicators: likely dangers...

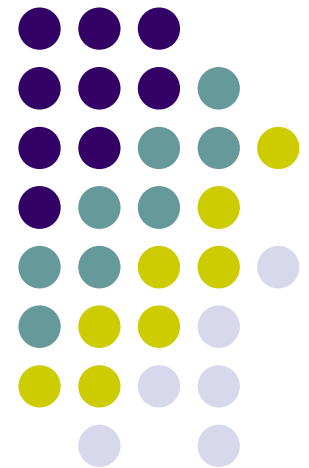


- South Korea scientists conducted experiments to enrich small amounts of uranium (2000)
- Done without official approval
- The very nature of WMD is so secretive-often governments are unaware about small scale scientific projects
- Experimenting on 'germs': possibility exists

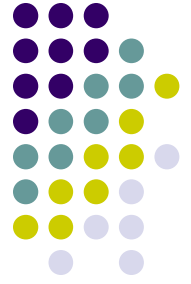
# Epidemics: Unending Story

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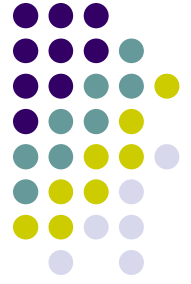
- *SARS*
- *Bird Flu*
- *Melamine-Poisoned milk*



# SARS

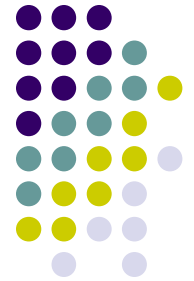


- Between the first description of the disease in November 2002 and July 2003, there were approximately *8,000 probable cases* and just fewer than *800 deaths* worldwide
- The epidemic cost Asia approximately US\$30 b in terms of losses in tourism and business and in other direct costs

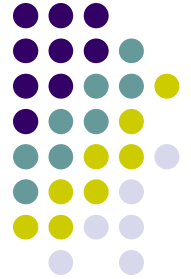


# Bird Flu

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



# **BT Industry & Asia**



# BT Industry Asian Region

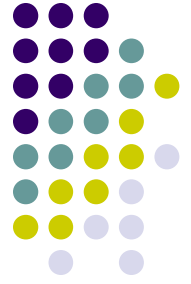
- Growth Rate of > 11% from 2004-06
- Expected value of market by 2007 > US\$ 41 b
- Japan, China, and Taiwan largest growing markets (Japan, China, Australia >79% market share)
- Future destination for clinical trials & stem cell research. Biopharma industry is the future
- Major growth in agriculture sector- GM crops

# BT Industry Asian Region *contd*



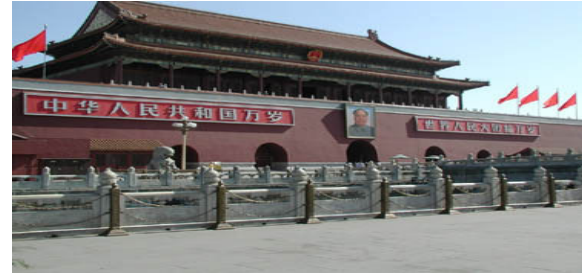
- Largely state dependent sector, private participation in less but on rise
- The Contract Research industry in India could reach as high as US\$ 270 m by 2009
- In few cases opaque government policies and regulations
- China & India: low costs, big talent pool- to emerge as most potential biotech research & manufacturing outsourcing destinations in the future

# Indian Biotech Industry



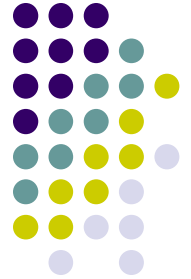
- Growth rate of 28.09% from the year 2005
- Expected turnover US\$ 5 b by the end of 2010
- Key destination for clinical trials & stem cell research
- Important role in Agriculture sector by developing large number of GM crops
- BioPharma industry, comprising of vaccines, therapeutics and other products,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

# China BT Industry

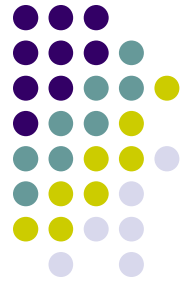


- Biotech program dates back to 1986
- Deng Xiaoping anointed genetic engineering as one of seven technologies critical to economic growth
- Aim to generate \$250 b from BT sector by 2020
- Juxtaposing other technologies on BT

# China and BT Industry

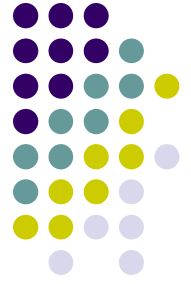


- China has a large and rapidly growing biotechnology and pharmaceutical industry
- More than 500 enterprises associated with life science and biotechnology with 50,000 employees



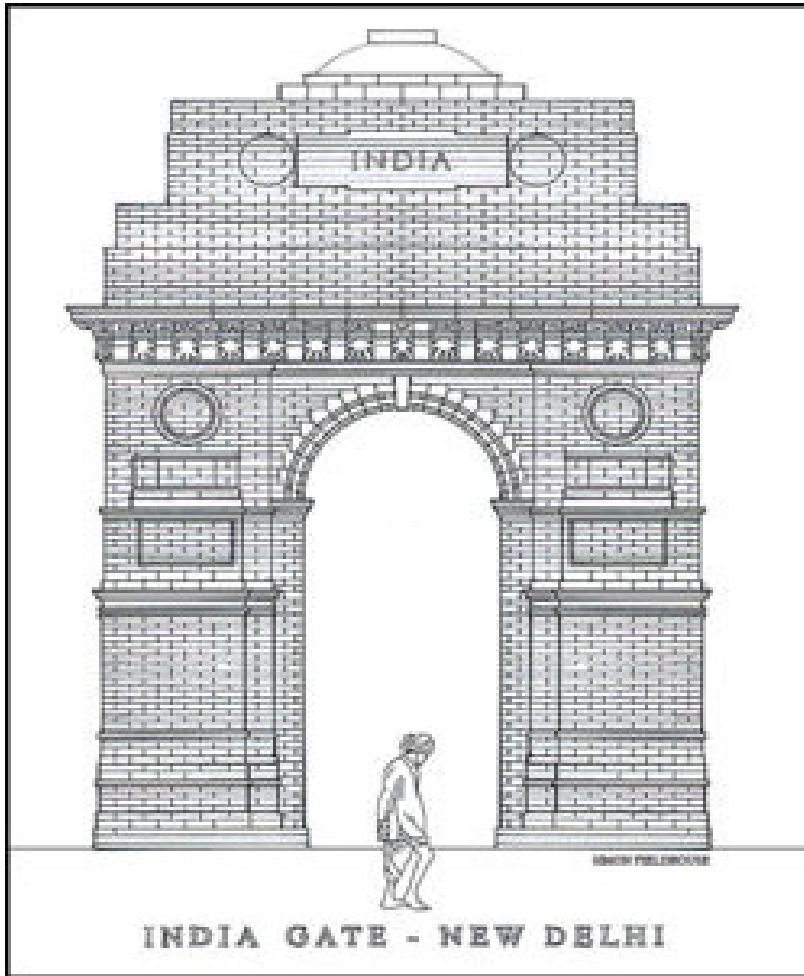
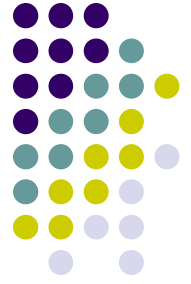
## Health Issues & Public Perception

- South Korea suspended imports of US beef five years ago amid concerns of mad cow disease, public protests after government's decision to resume imports of US beef
- China faced difficulties during toxic milk problem
- Illiteracy/Perceptions play a major role-lack of education
- States are lacking in efforts to sound out public opinion and try to seek people's understanding



Asian states are BWC signatories, many have biosafety and biosecurity measures in place and understand the need to enhance national implementation

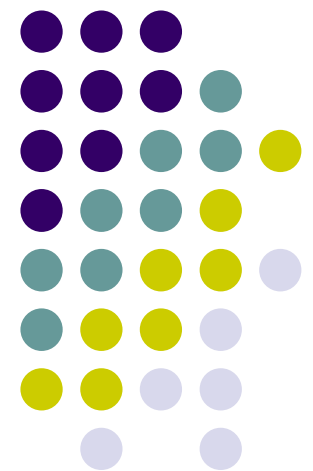
However, the *National & Regional Legislation Implementation* need to be viewed at the backdrop of their socio economic realities



India's diktat

# India has in place

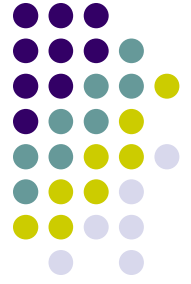
**A regulatory mechanism & legal architecture** *for the maintenance of security & oversight of pathogens, micro-organisms, GM organisms and toxins in production, import, export, use and research*





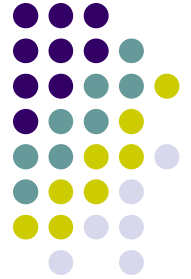
# Measures Taken by India

- 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



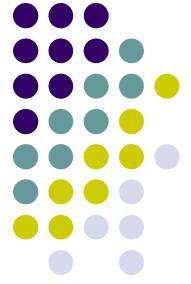
# Biosafety Regulatory Framework

- 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



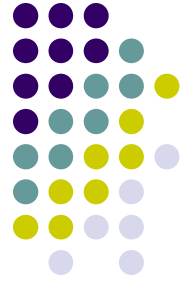
## Identifying Micro-organisms...

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



## Advisory & Regulatory Bodies

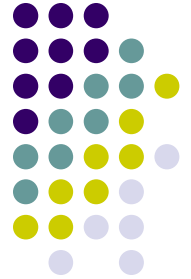
- Review Committee on Genetic Manipulation (RCGM)
- Genetic Engineering Approval Committee (GEAC)
- Coordination is done by DoB



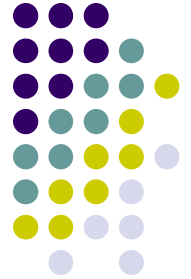
# Code of Conduct

- 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...



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



# WMDs Bill 2005

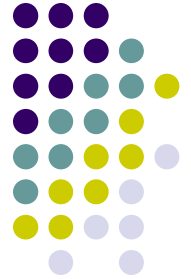
- WMD proliferation is a criminal offence
- Prevent manufacture, export, transfer, transit and transshipment of WMD material, equipment, technology and their means of delivery
- Penalties carry jail terms from five years to life imprisonment along with fines
- Companies are also liable for prosecution

# Safety Rules: China



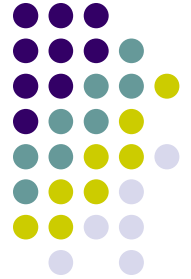
- The Chinese regulations are drawn from the “best practices” of international biosafety and biosecurity regulations
- All rules and regulations at par with global standards

# Philippines



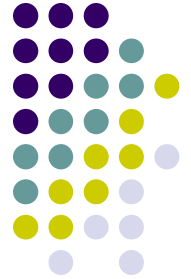
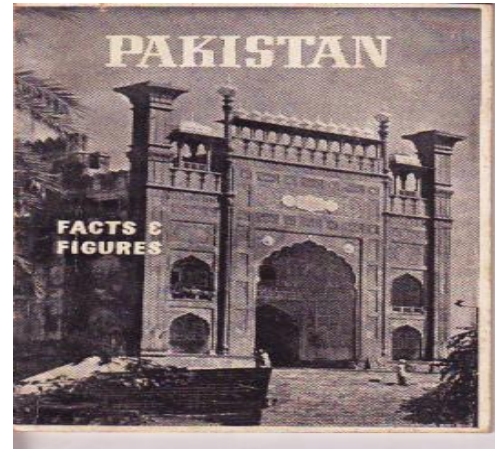
- The first Philippine anti-terrorism bill was proposed on 19 January 1996 and passed its own anti-terrorism law on 06 March 2007
- National Committee on National Committee on Biosafety of the Philippines (NCBP) — established in 1990 *first* BIOTECH regulatory system in ASEAN Region

# Philippines *contd*



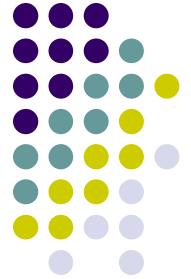
- Institutional Biosafety Committee and Technical Committee and Technical Review Panel at place
- Draft guidelines to ensure that experiments using GMOs do not pose unacceptable risks to human health and the environment

# Pakistan



- A reasonable framework in place
- *The Pakistan Biological Safety Association (PBSA), Sep 2008: a watchdog to monitor observance of biosafety standard in laboratory work on microbes, pathogens and transgenic materials*

# Sri Lanka



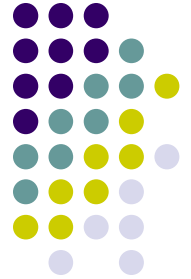
- Has established a national biosafety framework but it essentially deals with genetically modified organisms
- 15 universities & 50 research institutes deal BT
- Safety guidelines are by individual laboratories
- Biosafety and biosecurity regulations do not exist
- Lack legal framework

# Status Indonesia...

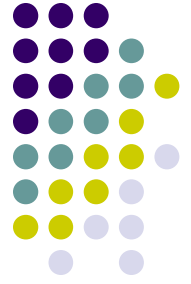


- Region with 17000+ islands
- Laws combating terrorism exist-  
1/2002,2/2002,15/2003 –are not strong enough to  
differentiate dual use nature of bio-agents
- National Legislation on implementation of BWC  
exists
- Abide by UNSC1373, 1540

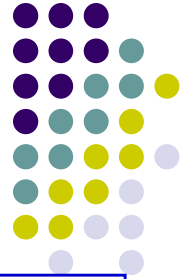
# Iran



- National Biosafety Framework (2007): Policy regarding BT, agriculture, health. Include laws, regulations etc.
- Environmental Protection and Enhancement Act (1974)
- Plants Protection Act (1967)

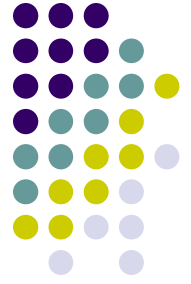


# Assessment Asia



## Through a Prism of Fink Committee

- Educating the Scientific Community- *is possible and is being done-at* places slow progress
- 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 & Process of Implementation

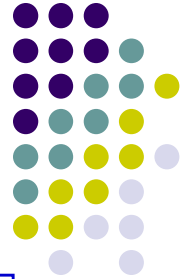
- Structures do work
- BT is still in a developing stage in regard to most parts of Asia
- Good practices exist but may not have reached to the grass-root level
- Lack Training. Infrastructure could be a problem in certain cases

# Difficulties



- Small group of people are involved, policy makers do need independent opinions which are not easily available
- The number of people technically trained to implement them is even smaller
- Specific guidelines keeping in view growth of technology and threat of terrorism need to be evolved

# Image Asia

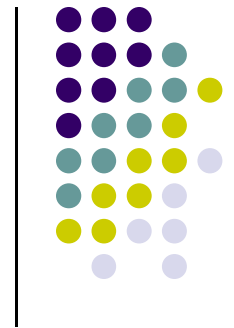


- **Mixed picture**
- **Natural spread of disease also represents a security challenge- but states have different views**
- **Need to understand the security dimension in contemporary 'microbial era'**
- **Multilateral forums like ASEAN, ARF, APEC have started routinely focusing on BT threat**
- **Security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



# Asia Need to Recognize...

- 21<sup>st</sup> Century threats demand different solutions
- Threat could be form non-state or a 'rogue' state
- There is ongoing change in pattern of terror
- Absence of BW usage till now does not guarantee zero probability
- To match a balance between openness in 'science' and reticence of 'security' is the challenge



THANK YOU