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# **International Obligations for Managing Infectious Disease Risks**

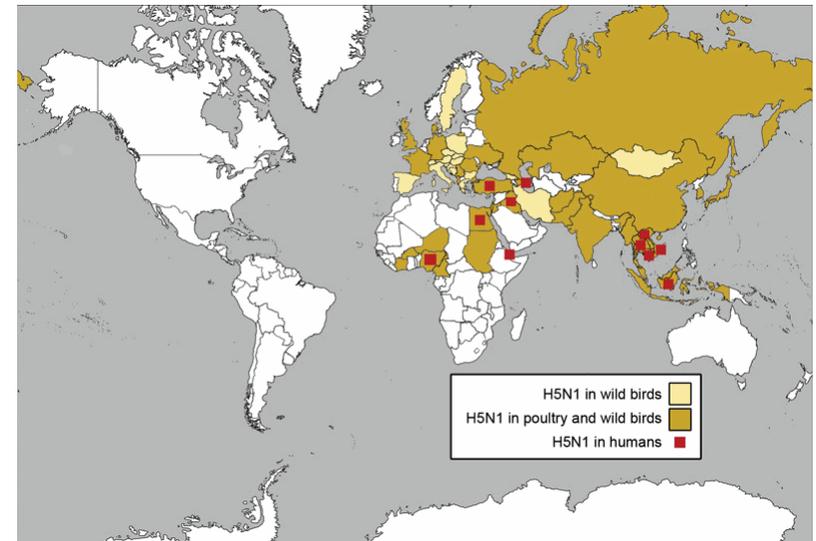
## ***Laboratory Biosafety and Biosecurity Workshop***

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

**[www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)**

# Infectious Disease

- Recent outbreaks of emerging infectious disease awakened the international community to threats to public and agricultural health
- Mitigation strategies are needed to manage outbreaks
- Measures must also be developed to *prevent* outbreaks of highly infectious disease from occurring
- Array of international obligations for both naturally-occurring and deliberate infectious disease outbreaks
  - International Health Regulations
  - Biological Weapons Convention
  - UNSCR 1540



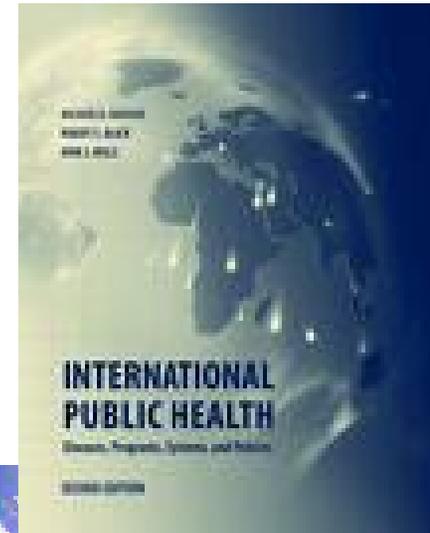
**Nations With Confirmed Cases  
H5N1 Avian Influenza (February  
2007)**

# International Health Regulations (IHR)

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- **Original IHR**
- **Adopted in 1969**
- **Purpose: ensure maximum protection against the international spread of diseases with a minimum interference with world traffic**
- **Notify and Respond**
  - Cholera
  - Plague
  - Yellow Fever



# New IHR

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- **Adopted in May 2006 by WHA and member states**
- **Enter into force on 15 June 2007**
- **Purpose**
  - **Protect against, respond to international disease spread avoiding unnecessary interference with travel and trade**



# Broader Scope for New IHR

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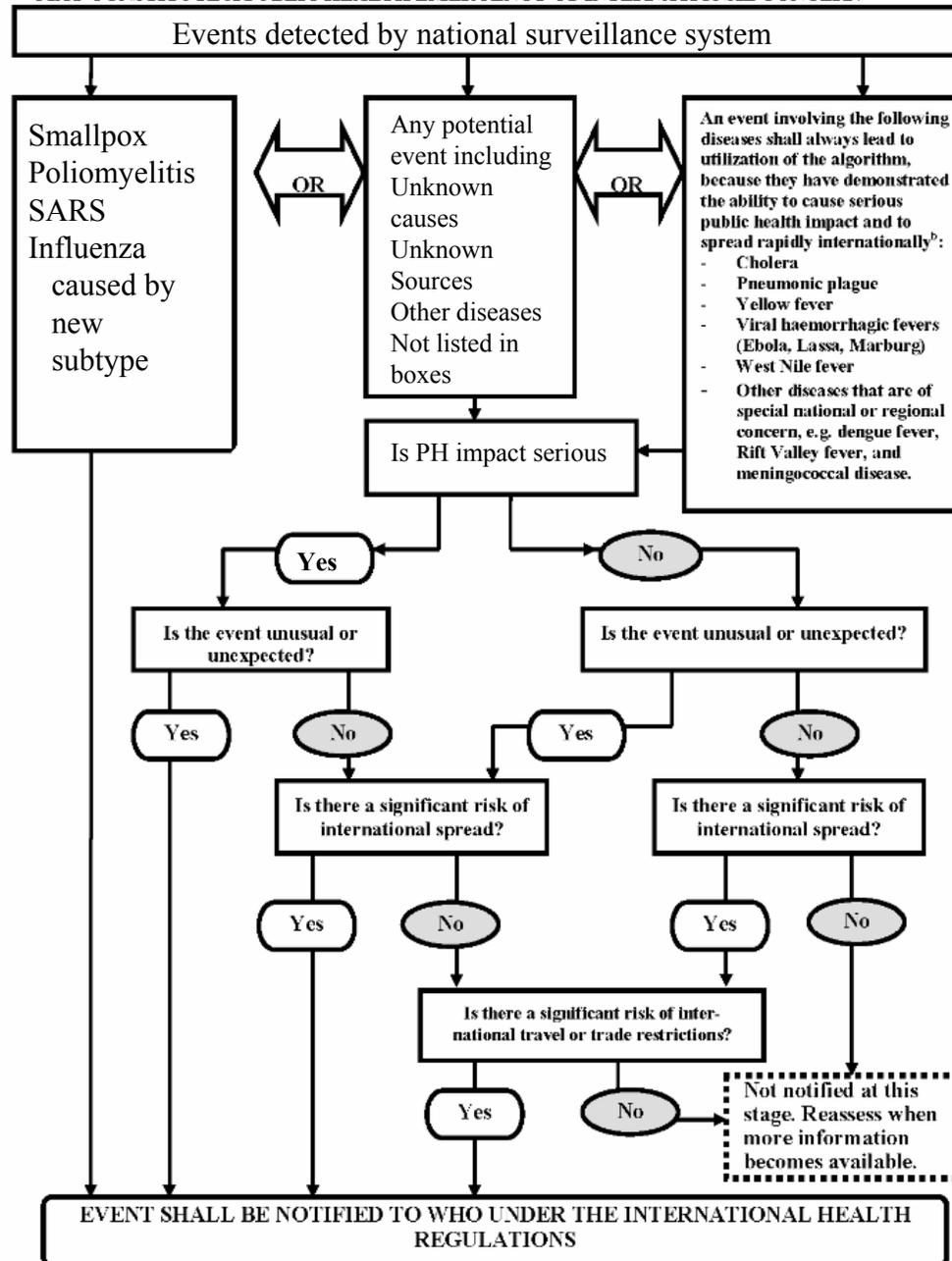
- **Notify**
  - **ALL** events that may be public health events of international concern
- **Report to WHO via Focal Point**
  - Significant PH risks **OUTSIDE** of their territory
  - State parties should identify focal point by August of 2006
- **Define public health capacities at multiple levels**
  - Local
  - State
  - National
- **Develop, strengthen, maintain capacities to**
  - **Detect, report, respond to public health emergencies**
    - International airports,
    - Ports,
    - Ground crossings

# Public Health Emergency of International Concern

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- **Extraordinary public health event which is determined to be:**
  - **Public health risk to other States through international spread of disease**
  - **Potentially requires a coordinated international response**
- **Dependant on factors**
  - **Proximity to international border**
  - **Mode of transmission**
- **Decision Instrument**
  - **Seriousness of event**
  - **Unusual or unexpected nature of event**
  - **Potential for international spread**
  - **Risk to travel and trade**

DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN



# The BWC and Biosecurity

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- **Bacteriological (Biological) and Toxin Weapons Convention (BWC) addresses three relevant issues.**
  - **National Implementing Legislation**
  - **National Pathogen Security (biosecurity)**
  - **International Cooperation**
  
- **Recent technical experts meetings to strengthen the BWC.**
  - **States Parties agree to pursue national implementation of laboratory and transportation biosecurity (2003)**
  - **States Parties agree to continue discussions on laboratory biosecurity (2006 Review Conference)**



# UNSCR 1540 and Biosecurity

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- **Urges States to take preventative measures to mitigate the threat of WMD proliferation by non-state actors**
- **UNSCR 1540 requires States to**
  - **Establish and enforce legal barriers to acquisition of WMD by terrorists and states**
  - **Submit reports to the 1540 Committee on efforts to comply**
- **Paragraph 3 is the key provision that supports biosecurity**
  - **“Take and enforce effective measures to establish domestic controls to prevent the proliferation of . . . biological weapons . . .; including by establishing appropriate controls over related materials”**
    - **Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport**
    - **Develop and maintain appropriate effective physical protection measures**



# Biosecurity Goes Global

The 2001 anthrax letters triggered a strong U.S. response. Now the rest of the world is starting to take biosecurity more seriously—but not necessarily by adopting the U.S. approach

Three years ago, the small number of life scientists using the term “biosecurity” were talking about ways to keep diseased crops and livestock from crossing national borders. Then came the fatal October 2001 anthrax letter attacks against several U.S. targets. In short order, thousands of U.S. scientists were confronted with an avalanche of new and often unpopular rules designed to keep potentially dangerous pathogens and toxins away from bioterrorists. Researchers who break those rules could face significant criminal penalties.

Despite these aggressive steps on the home front, U.S. officials readily acknowledged that unilateral action was insufficient and that the world needed to form a united front against increasingly sophisticated biotechnologies. But many nations were skeptical of the threat. They also doubted the value of what critics call “the guns, guards, and gates” approach to biosecurity. The result, says Reynolds Salerno, a biosecurity expert at Sandia National Laboratories in Albuquerque, New Mexico, has been “tremendous confusion and concern in the international life sciences community about biosecurity.”

That confusion may be giving way to cooperation, however, as an increasingly global effort to define and implement biosecurity is gaining speed. Nations are moving to pass new biosecurity laws, while public health and security experts are hammering out voluntary biosecurity guidelines and debating “codes of conduct” for life scientists. Many countries are thinking about looser rules for less risky agents than in the United States, which critics say has imposed a one-size-fits-all approach, and few are likely to require the extensive criminal background checks carried out by U.S. agencies.

The new world order may not resemble the U.S. model. But like it or not, life scientists worldwide are about to become much more familiar with the term biosecurity.

—DAVID MALAKOFF



**Spreading the word.** U.K. officials are preparing to host a Bioweapons Convention-related summit in October 2005 on “codes of conduct” for life scientists who work with potentially dangerous pathogens and biotechnologies. Although few believe that such codes will deter evildoers, advocates say they can play an important role in raising awareness of biosecurity. This winter, academic and industrial scientists will gather in Washington, D.C., to sign a pledge to help prevent the misuse of biological research—a theme also stressed in a new public relations campaign (left) by the International Committee of the Red Cross (www.icrc.org). Such efforts are “a way to encourage dialogue,” says Michael Moodie of the Chemical and Biological Arms Control Institute, an organizer of the Washington meeting. In the meantime, the Federation of American Scientists and other groups are preparing biosecurity course materials for undergraduate and graduate students.

**Self-help book.** Early next year, the 192-member World Health Organization (WHO) plans to unveil its first-ever set of international biosecurity guidelines. The consensus how-to guide, currently in draft form, should help “clear up a lot of confusion ... by clarifying best practices and minimum standards for keeping pathogens secure,” says Brad Kay, a WHO biosafety expert in Lyon, France. But implementing the voluntary standards is another story. Many poorer nations won’t want to divert precious public health funds to security, and WHO has meager resources to help out. It also isn’t clear what would happen to labs that don’t meet the standards. “WHO has no mandate to become a global enforcer,” says Kay. In the United States, meanwhile, a team of government and academic researchers is writing a new biosecurity chapter for the “bible” of lab safety, *Biosafety in Microbiological and Biomedical Laboratories*.



**Center of expertise.** The United States and Europe are spending more than \$90 million annually to help Russia secure its sprawling former bioweapons complex and employ an estimated 6000 former bioweapons scientists. But efforts to attract investment from foreign biotech and drug firms have had mixed results, and some critics say more needs to be done to prevent ex-Soviet pathogens and weapons experts from leaking into the black market. “Biosecurity is about limiting the spread of expertise, too,” says Amy Smithson, a nonproliferation specialist at the Center for Strategic and International Studies in Washington, D.C.



**Whose resolve?** Last April, the United Nations Security Council adopted Resolution 1540, which expresses “grave concern” about bioterrorism and directs UN members to enact tough controls on potential bioweapons. The resolution is intended to help close legal loopholes in dozens of nations—including some with growing biotech industries—with laws that don’t cover all the bases. “They are now obligated to build the legal framework needed for effective biosecurity,” says Barry Kallman, a law professor at DePaul University in Chicago, Illinois. Critics, however, see the measure as a U.S.-backed gambit to sidestep efforts to strengthen the Biological and Toxin Weapons Convention, which is in limbo until at least 2006.

**Bioterror fighters.** Interpol, the International Criminal Police Organization, has launched a 2-year effort to train police in its 181-member countries on biosecurity and fighting bioterrorism. “You’d be amazed at how little the average police chief knows about the subject,” says Barry Kallman of DePaul University, who is involved in the project, which is funded by the Alfred P. Sloan Foundation. One goal: to teach investigators how to avoid lumping legitimate researchers in with the bioterrorists.



**Lessons learned.** The Republic of Georgia is on the verge of adopting biosecurity rules modeled on the U.S. approach—but with some important differences. For instance, the same agency will regulate both biomedical and agricultural scientists in the United States that job is split between the Centers for Disease Control and Prevention and the U.S. Department of Agriculture. “We’re telling people that our model is often far more complicated than what they need,” says a U.S. State Department official who advises other governments on biosecurity.

**Building boom.** Kazakhstan is the first of several nations getting new, secure laboratories to store and study dangerous pathogens. The facilities are courtesy of a U.S.-funded effort to reduce the bioterror threat in the former Soviet Union. Construction of the new Human Health Central Reference Lab and Repository in Almaty is set to begin in mid-2005, with Uzbekistan and Georgia next on the list. Meanwhile, talks are under way on long-term strategies for consolidating the 500 or more culture collections around the world that stock dangerous pathogens, with a goal of fewer, more secure facilities.



**Asia alert.** Asian Pacific leaders pledged last year to get tough on biosecurity—in part due to fears that their rapidly growing biotech industries could attract regional terrorist groups along with investors. “Singapore views this threat with grave concern,” Deputy Prime Minister Tan Keng Yam said at a biosecurity conference held in the city-state earlier this year. China, meanwhile, has ratcheted up export controls and is examining both its biosafety and biosecurity rules in the wake of the SARS epidemic and several lab accidents.

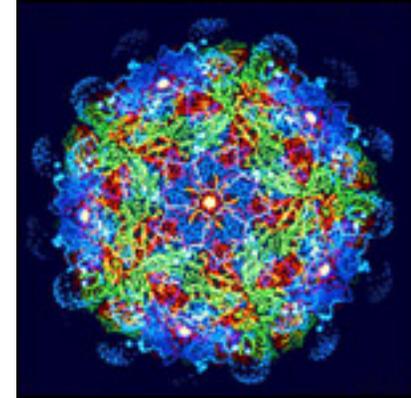


# A Need for Global Laboratory Biosecurity

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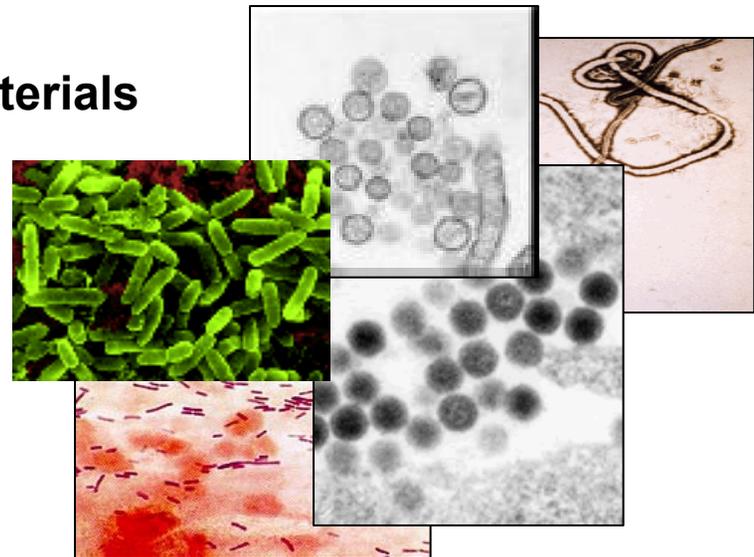
- **The International Committee on the Red Cross:**
  - “Alarmed by the hostile uses of biotechnology the ... ICRC appeals ...to all political and military authorities ... to enact effective controls on biological agents with potential for abuse”
- **United Kingdom Legislation:**
  - “There is a need to ensure that terrorists do not have access to premises, which hold substances that may be used in a potentially devastating manner such as pathogens dangerous to human, plant, or animal health”
- **Singapore Ministry of Health:**
  - “Certain biological agents and toxins may be used as weapons of terror and thus pose a threat . . . . there is a need for a regulatory framework to provide for proper security of such agents and prevent possible misuse”



# A Materials Approach to BWNP

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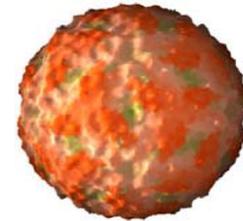
- **Determining which materials are of concern**
  - Biological agent prioritization
- **Securing high risk materials for legitimate use**
  - Facility biosecurity
  - Transport biosecurity
- **Controlling and tracking high risk materials**
  - Facility biosecurity
  - Transport biosecurity
  - Export controls



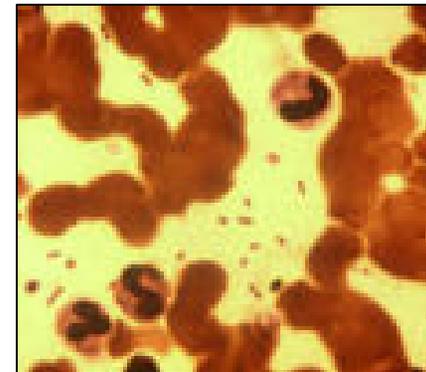
# Biological Agent Prioritization

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- Identifies *high risk agents* through scientific analysis that evaluates weaponization potential and consequences of use.
  - How attractive or valuable the agent would be to an adversary
- Allows policymakers to focus on securing the *highest risk agents*.
  - Optimizes allocation of resources



*FMD virus*



*Yersinia pestis*

# Facility Biosecurity

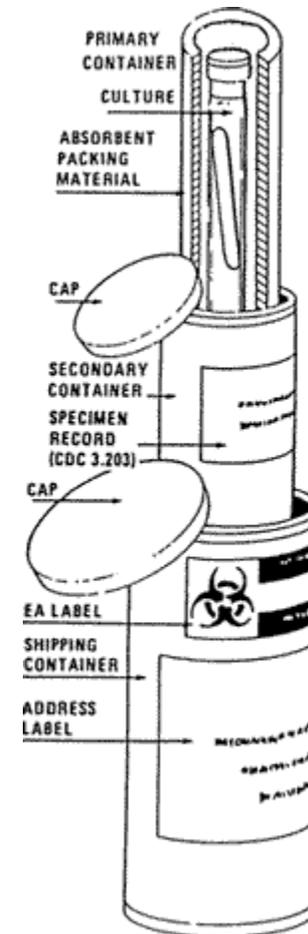
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- Secures *high risk agents* in facilities where they are used and stored.
  - Aims to prevent terrorists or proliferant states from acquiring biological agents through theft
  - Relies on physical security, personnel security, and material control & accountability
- *High risk agents* are housed in thousands of legitimate facilities worldwide, and the biotechnology industry continues to expand.
- Imperative to develop systems that balance security, safety, and research
- Imperative to develop global biosecurity standards for facilities



# Transport Biosecurity

- Secures *high risk agents* during transport between facilities
  - Aims to prevent terrorists or proliferant states from acquiring biological agents through theft
  - Relies on chain of custody principles and end-user agreements
- *High risk agents* are routinely shipped worldwide for diagnostic and research activities
  - A local, national, and international concern
- Need to develop a common standard, harmonize regulations for security



# Export Controls

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- Controls the transfer of *high risk* agents and technology
  - Applies to both tangible (e.g. biological agents, equipment) and intangible (e.g. technical data) items
- Export control licenses are a process to validate the end-user and allow for legitimate exchanges while countering proliferation
  - Public health requires sharing
    - Research
    - Diagnosis
    - Outbreak response
  - Materials and information are inherently “dual-use”
    - Valuable for many legitimate, defensive, and peaceful commercial, medical, and research applications



# Strengthening Biological Risk Management

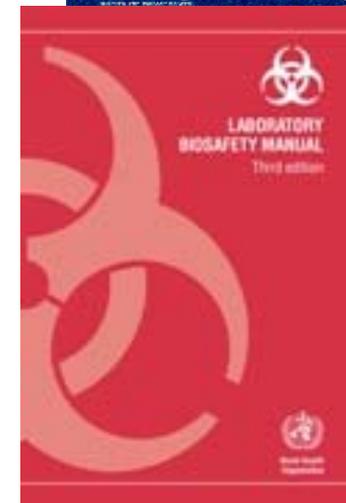
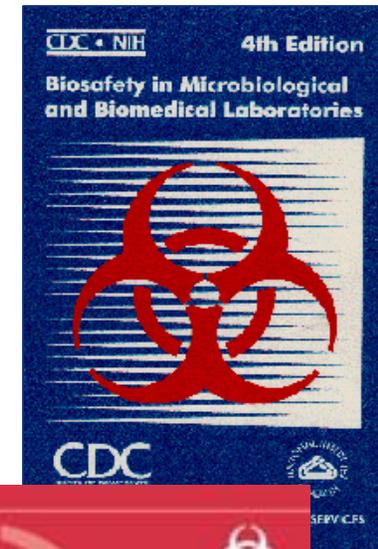
## *Vision for Integrated BioRisk Management:*

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"



# New Developments

- **New edition of CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* includes extensive recommendations on biosecurity**
- **WHO/FAO/OIE developed joint international biosecurity guidelines: Biorisk Management: Laboratory Biosecurity Guidance**
- **Organisation for Economic Co-operation and Development (OECD) is establishing biosecurity guidelines**
- **Hopefully, these initiatives will**
  - **Avoid conflicting recommendations**
  - **Promote the concept of integrated biosafety and biosecurity**
  - **Introduce a tiered system of protection based on risk assessment and management methodologies**



# Conclusions

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- **Infectious disease threat is changing**
  - **International Health Regulations**
  - **National Legislation for Laboratory and Transportation Biosecurity**
    - **Control use, storage, and transport of dangerous pathogens domestically**
  - **Export Controls**
    - **Control transport of dangerous pathogens and technology internationally**
  - **Biosecurity 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**
  - **Requires cooperation and coordinate of scientific, public health, and security communities**

**“Infectious diseases make no distinctions among people and recognize no borders”  
President George Bush, November 2001**