



International Nonproliferation Regimes to Counter the BW Threat

Sandia National Laboratories
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Challenges for the Development of Preventive Solutions

- **Terrorists no longer need sophisticated processing and dissemination systems to threaten international security**
- **Materials, technologies, and expertise are distributed among thousands of legitimate bioscience facilities worldwide**
- **Excessive controls on the biotechnology industry will jeopardize critical research without providing tangible security benefits**



Strategies to Counter the Bioterrorist Threat

- **Biodefense**
 - Enhance the ability of a country to respond to the next bioterrorist attack
 - A *domestic* strategy designed to reduce the consequences of bioterrorism
- **Biological Weapons Nonproliferation**
 - Reduce the risk that bioscience and biotechnology could be used maliciously
 - An *international* strategy designed to prevent the acquisition, use, and spread of biological weapons



Development of US Policies to Mitigate the Bioterrorist Threat

- Recently, US policymakers have focused on biodefense
 - Aims to improve the ability of the US to respond domestically to an outbreak of infectious disease after it has occurred
 - \$10 billion invested since 2001; \$7 billion requested in FY05

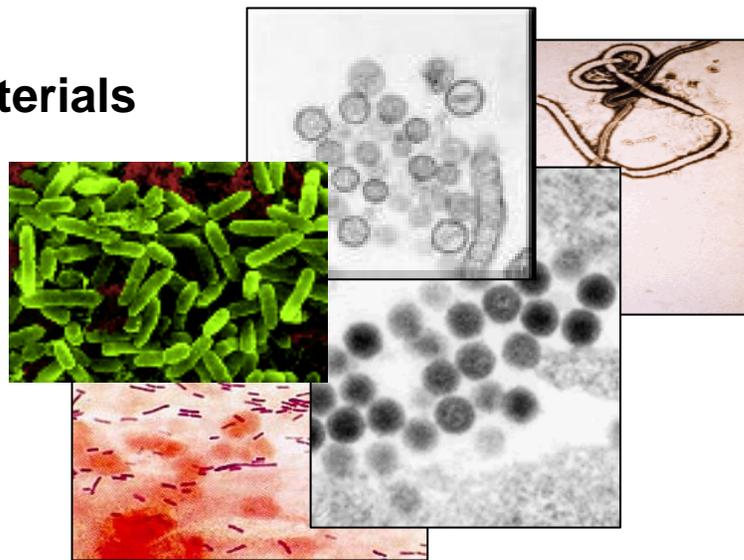
- Biodefense activities include
 - Improving diagnostics and disease surveillance
 - Developing detection technologies
 - Strengthening emergency response capabilities
 - Enhancing decontamination and remediation technologies
 - Building public and agricultural health capacities
 - Increasing the effectiveness and availability of vaccines and therapies

- Recently, the need to develop preventive measures has also been raised:
 - *“Preventing biological weapons attacks is by far the most cost effective form of biodefense. Prevention requires the continuation and expansion of current multilateral initiatives to limit the access of agents, technology, and know-how to countries, groups, or individuals seeking to develop, produce and use these agents.”*

- Homeland Security Presidential Directive 10

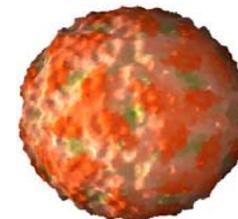
A Materials Approach to BWNP

- **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

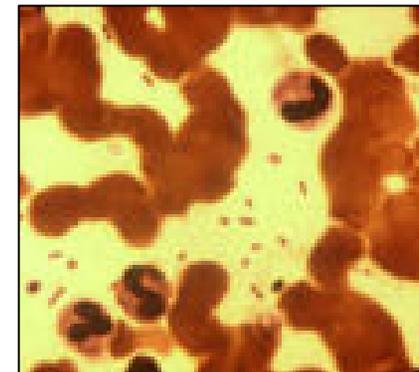


Biological Agent Prioritization

- 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

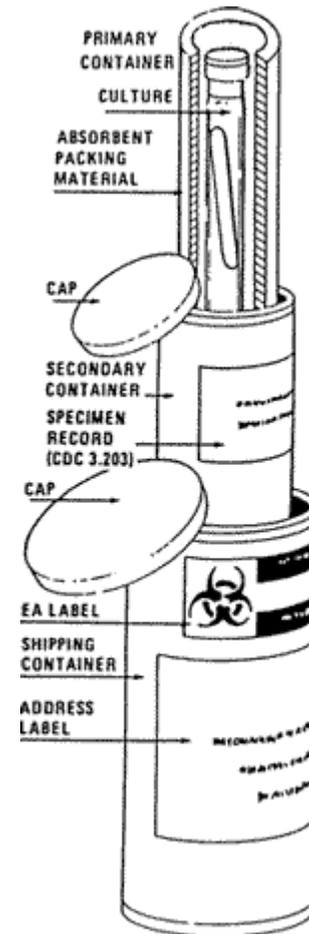
Facility Biosecurity

- 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



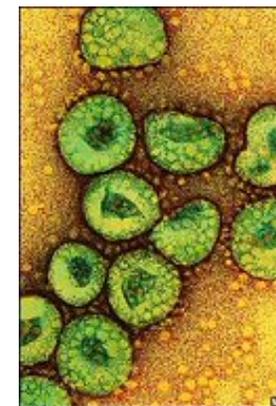
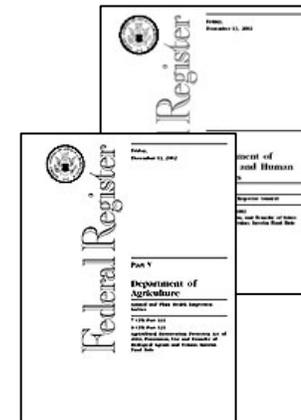
Export Controls

- 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



Mitigating the Threat through Protection of Source Materials

- In response to the anthrax attacks of 2001, the U.S. has imposed new rules that are designed to improve the security and agent accountability of legitimate bioscience research laboratories
 - US Select Agent Rule
- However, it is critical to secure dangerous pathogens and toxins globally. Current international requirements include:
 - Biological Weapons Convention (BWC)
 - United Nations Security Council Resolution (UNSCR) 1540
- Imperative to promote the development of laboratory biosecurity systems and practices that are appropriate to the needs of international community



SARS virus

The BWC and Biosecurity

- **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).**



UNSCR 1540 and Biosecurity

- **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 Moode 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.



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 Kellman, a law professor at DePaul University in Chicago. Critics, however, see the measure as a U.S.-backed ploy to sidestep efforts to strengthen the Biological and Toxin Weapons Convention, which is in limbo until at least 2006.

Biocrime 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 Kellman 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.



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 biosecurity 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, *Biosecurity 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.



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 biosecurity and biosecurity rules in the wake of the SARS epidemic and several lab accidents.

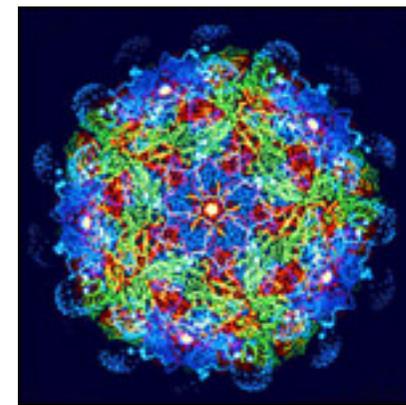
Lessons learned. The Republic of Georgia is on the verge of adopting biosecurity rules modeled on the U.S. approach—but with some important differences. For instance, the same agency will regulate both biomedical and agricultural scientists in the United States that job is split between the Centers for 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.



A Need for Global Laboratory Biosecurity

- **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”



Strengthening Biological Risk Management

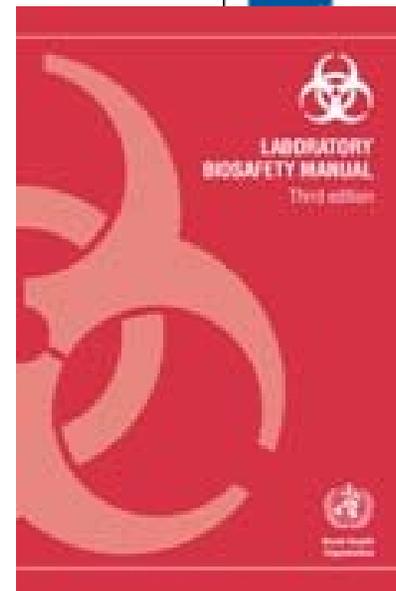


Vision for Integrated BioRisk Management:

- ✓ 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"

Laboratory Biosecurity Supports Laboratory Biosafety

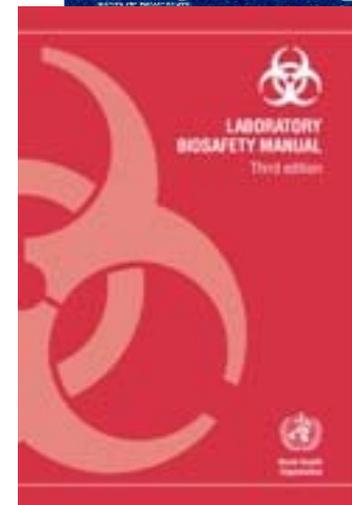
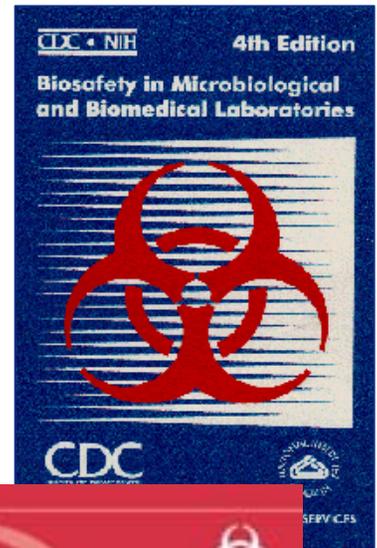
- **Laboratory biosecurity supports the laboratory biosafety agenda of preventing disease in people, animals, and plants and minimizing the risk of worker injury**
- **Safe and secure laboratories help**
 - **Ensure the containment of hazardous infectious substances in laboratories**
 - **Maintain citizens' confidence in the activities of the bioscience research community**
 - **Increase transparency to investors in the biomedical and biotechnology industries**
 - **Protect valuable research and commercial assets**
 - **Reduce the risks of crime and bioterrorism**



Anticipated Developments

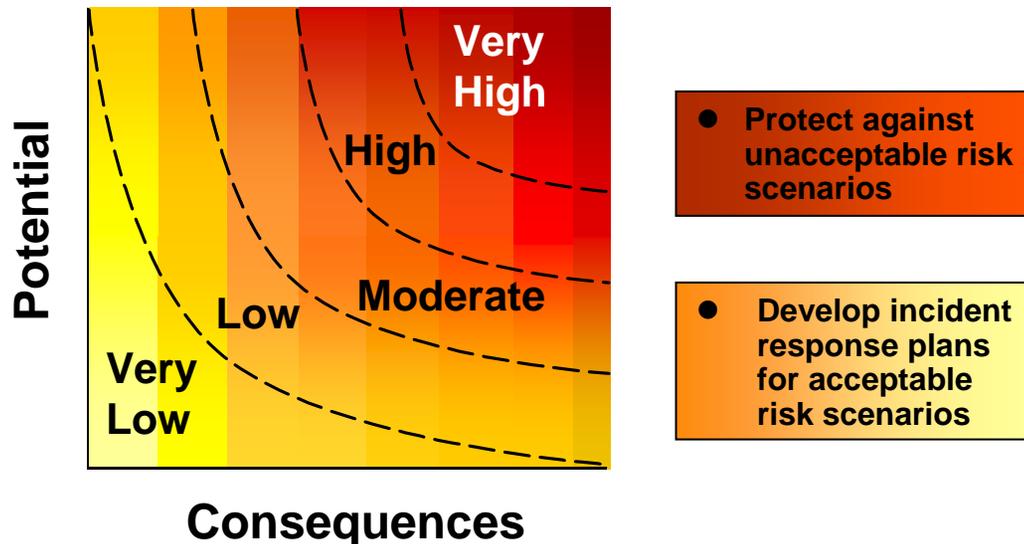
- Next edition of CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* will include extensive recommendations on biosecurity
- Canada's Laboratory Biosafety Guidelines includes biosecurity
- WHO Laboratory Biosafety Manual (Ch 9 is Laboratory Biosecurity)
- WHO/FAO/OIE developing joint international biosecurity guidelines: Biorisk Management: Laboratory Biosecurity
- 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



Biosecurity and Biosafety Based on Risk Management

- Laboratory work with pathogens will always involve some level of safety and security risk
- Most biological materials occur in nature and can be isolated from nature
- Critical not to compromise legitimate bioscience operations
 - Systems should be designed to address unique situations
- Resources are not infinite; existing resources should be used efficiently
- Management must distinguish between “acceptable” and “unacceptable” risks
 - Ensure that protection and the cost is proportional to the risk



Conclusions

- **BW threat is changing and requires new approaches to mitigate**

- **Recommended steps include:**
 - **BWC Implementing Legislation**
 - Bans development, production, and stockpiling
 - **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 and security communities**

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