Laboratory Biosecurity
United States Regulatory Approach

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US Policy Response to the Bioterrorist Threat

• Emerging US security regime has two sets of objectives
  ▪ Enhance ability to respond to public and agricultural health emergencies
  ▪ Reduce the risk that bioscience and biotechnology could be used maliciously

• Realization that bioscience facilities are potential sources of biological weapons material (viable and virulent pathogens)

• USA PATRIOT Act of 2001 – US Public Law 107-55
  ▪ Restricted Persons

• Bioterrorism Preparedness Act of 2002 – US Public Law 107-188
  ▪ 42 CFR 73 (Human and Overlap)
  ▪ 9 CFR 121 (Animal and Overlap)
  ▪ 7 CFR 331 (Plant)

- Facility registration if it possesses one of 82 Select Agents
- Facility must designate a Responsible Official
- Background checks for individuals with access to Select Agents
- Access controls for areas that contain Select Agents
- Detailed inventory requirements for Select Agents
- Security, safety, and emergency response plans
- Safety and security training
- Regulation of transfers of Select Agents
- Extensive documentation and recordkeeping
- Safety and security inspections
Hazardous Material Transportation Security

- Infectious substances (Class 6.2) and toxins (Class 6.1) are HazMat
  - Select Agents regulated under 42 CFR 73 require HazMat transport security measures
- HazMat regulated security requirements include:
  - Training
    - Security awareness training
    - Specific training as appropriate
  - Written security plan
    - Based on assessment of transportation security risks
    - Address personnel security, unauthorized access, en route security

Bacillus anthracis

Coccidioides immitis
Concerns About Select Agent Rule

- Top-down security regime not tailored to laboratory realities
- No need to steal a Select Agent to perpetrate bioterrorism
- Fear that security will trump biosafety, increasing the risk of accidental release or exposure
- Security requirements increasing operational impediments and compromising research funding
- Identical protection measures for the 82 agents and toxins despite their various degrees of attractiveness to adversaries
- No protection if personnel do not understand and accept security
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, at least 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 bioterrorists. 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 Slocum, 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. In the United States, which critics say has imposed a one-size-fits-all approach, and few are likely to require the expensive, cumbersome background checks carried out by U.S. agencies.

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

-David Malakoff

Science, Vol. 305, 17 September 2004
Select Agents

Heightened Security or Noncollegial Science?

New restrictions on federally funded research involving the world’s most dangerous pathogens are hemming foreign collaborations.

A pushing consensus on select agents, researchers with the U.S. Centers for Disease Control and Prevention (CDC) have seen a renewal of concern about foreign laboratories that are involved in a bioterrorist event. To address these threats, a bioterrorism specialty at the National Institutes of Health (NIH) has been set up to make sure that laboratories are prepared to handle these events. They have been successful at containing the situation, but not without controversy or cooperation with foreign counterparts. One way to solve this is to establish a network of laboratories that are prepared to handle these events. The network has been successful in containing the situation, but not without controversy or cooperation with foreign counterparts.


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Science

A Selection of Select Agents

No pathogens, American scientists have been found to harbor VE

Some Countries Are Betting That A Few Seconds Can Save Lives

At the University of Texas Medical Branch (UTMB) in Galveston, researchers are studying ways to detect and treat unstable conditions in a bioterrorist event.

Earthquake Preparedness


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International Perspectives

- Bioterrorism not perceived as a serious threat in much of the world
- Apprehension that US biosecurity methods, or international regulatory regime, would hinder advances in basic biomedical research
- Acknowledgement that dangerous pathogens have intrinsic value and need to be protected globally
- Member States to the BWC have acknowledged the importance of national implementation of laboratory biosecurity
- Ultimately, success will depend on willing implementation by the international scientific community and internationally available resources
Anticipated Developments

• Select Agent Final Rule still forthcoming
• Next edition of BMBL will include a chapter on biosecurity in addition to a revised Appendix F
• WHO/FAO/OIE developing joint international biosecurity guidelines
• OECD has expressed interest in establishing biosecurity guidelines
• Hopefully, these initiatives will
  ▪ Avoid conflicting recommendations
  ▪ Promote the concept of integrated biosafety and biosecurity
  ▪ Introduce a tiered system of protection
Biological Agent Risk Assessments

**BIOSAFETY**

- Review fundamental agent properties
  - What is known about the agent?
  - Associated with infections, toxicity, oncogenicity, or allergies?

  - Place in Safety Risk Group

  - Does planned lab activity change risk?

  - Determine appropriate biosafety measures

**BIOSECURITY**

- Review fundamental agent properties
  - What is the weaponization potential?
  - What are the potential consequences of malicious use?

  - Place in Security Risk Group

  - Does planned lab activity or threat environment change risk?

  - Determine appropriate biosecurity measures

**Defines Laboratory Operating Environment**
Sandia Biosafety/Biosecurity On-Line Survey

• 360 respondents so far
  ▪ 51% Select Agent facilities, 49% non-Select Agent facilities
  ▪ 43% universities, 18% industry, 16% clinical/diagnostic, 15% government
  ▪ 27% lab directors/managers, 22% biosafety officers, 16% PI’s, 12% technicians, 8% RO’s

A biosecurity program should be designed to incorporate both activities (biosafety and biosecurity) into a daily regime that allows for productive work as well as safety and security.”

www.biosecurity.sandia.gov
Summary

• Biosecurity regulations, guidelines, and implementation methodologies are evolving

• The “internationalization” of laboratory biosecurity practices is an important development
  ▪ Securing dangerous pathogens in one or a few countries is insufficient to mitigate the threat of bioterrorism or biological weapons proliferation

• However, the US Select Agent Rule is not universally applicable
  ▪ Laboratory biosecurity guidelines and requirements need to reflect local and national concerns and priorities