



The US Select Agent Rule and an International Opportunity to Develop Laboratory Biosecurity Guidelines

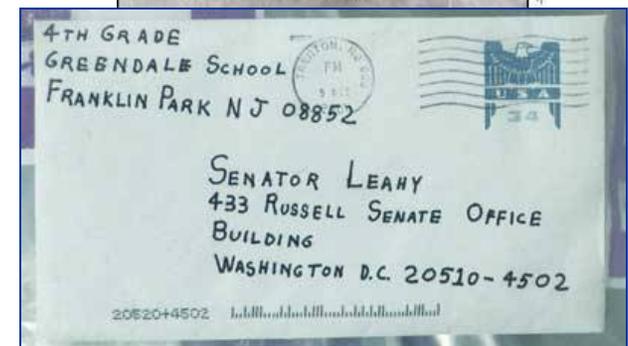
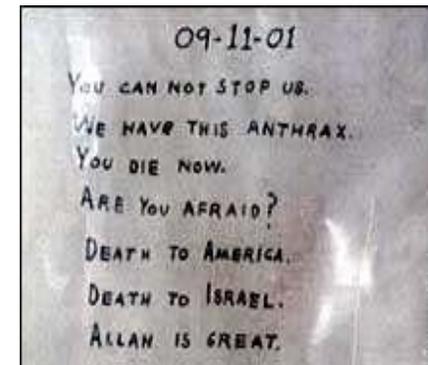
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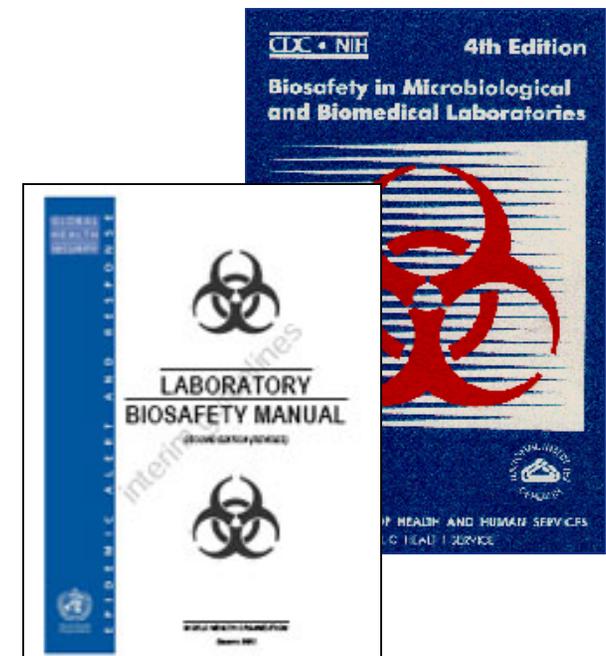
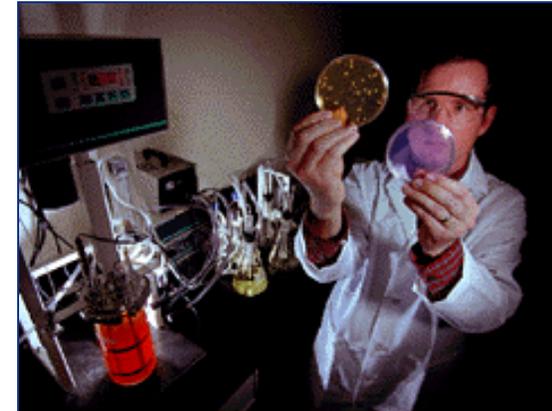
US Policy Response to the Bioterrorist Threat

- 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)
 - US Select Agent Rule, 2003
- New US regulatory “biosecurity” environment has broad international repercussions that the international community cannot ignore



Biosafety and Biosecurity

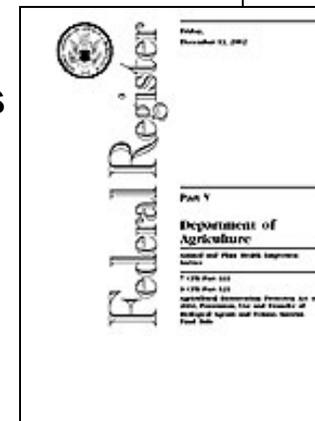
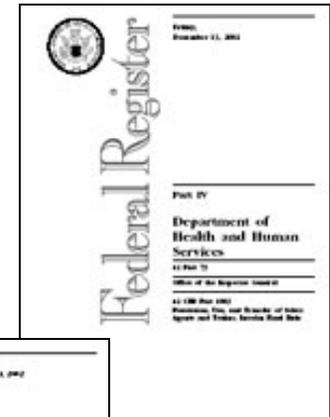
- **Biosafety**
 - **Objective:** reduce or eliminate accidental exposure to or release of potentially hazardous agents
 - **Strategy:** implement various degrees of laboratory “containment” or safe methods of managing infectious materials in a laboratory setting
- **Biosecurity**
 - **Objective:** protect biological agents against theft and sabotage
 - **Strategies:** implement graded levels of protection based on a risk management methodology
- **Control of certain biological materials is necessary, but *how* that is achieved must be carefully considered**
 - **Biosecurity and biosafety should be integrated systems, designed not to compromise necessary infectious disease research**





New US Regulatory Environment for Biosecurity

- **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)**
- **The CFR require specific measures**
 - **Registration of a facility if they possess one of the 82 Select Agents**
 - **Background checks for individuals with access to Select Agents**
 - **Facility must designate a Responsible Official**
 - **Security, safety, and emergency response plans**
 - **Safety and security training**
 - **Regulation of transfers of Select Agents**
 - **Recordkeeping**
 - **Safety and security inspections**





Human Select Agents and Toxins

- Crimean-Congo haemorrhagic fever virus
- Ebola viruses
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
- Tick-borne encephalitis complex (flavi) viruses
- Variola major virus and Variola minor virus (Alastrim)
- *Rickettsia prowazekii*
- *Rickettsia rickettsii*
- *Yersinia pestis*
- *Coccidioides posadasii*
- Abrin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Tetrodotoxin
- Shiga-like ribosome inactivating proteins



Overlap Select Agents and Toxins

- Eastern equine encephalitis virus
- Nipah and Hendra complex viruses
- Rift Valley fever virus
- Venezuelan equine encephalitis virus
- Botulinum neurotoxins
- *Clostridium perfringens* epsilon toxin
- Shigatoxin
- Staphylococcal enterotoxins
- T-2 toxin
- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Botulinum neurotoxin producing species of *Clostridium*
- *Coxiella burnetii*
- *Francisella tularensis*
- *Coccidioides immitis*



Animal Select Agents and Toxins

- African horse sickness virus
- African swine fever virus
- Akabane virus
- Avian influenza virus (highly pathogenic)
- Bluetongue virus (exotic)
- Pox viruses (camel, goat, sheep)
- Classical swine fever virus
- Foot and Mouth Disease virus
- Japanese encephalitis virus
- Lumpy skin disease virus
- Malignant catarrhal fever virus
- Newcastle disease virus
- Peste des petits ruminants virus
- Rinderpest virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (exotic)
- *Cowdria ruminantium*
- *Mycoplasma capricolum*
- *Mycoplasma mycoides*
- Bovine spongiform encephalopathy agent



Plant Select Agents and Toxins

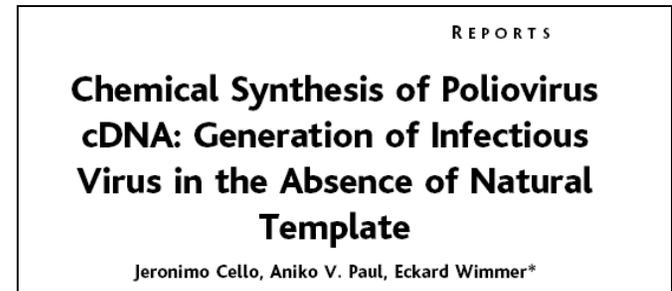
- Plum pox potyvirus
- *Liberobacter africanus*
- *Liberobacter asiaticus*
- *Ralstonia solanacearum*
- *Xanthomonas oryzae*
- *Xylella fastidiosa*

- *Peronosclerospora philippinensis*
- *Phakopsora pachyrhizi*
- *Sclerophthora rayssiae*
- *Synchytrium endobioticum*

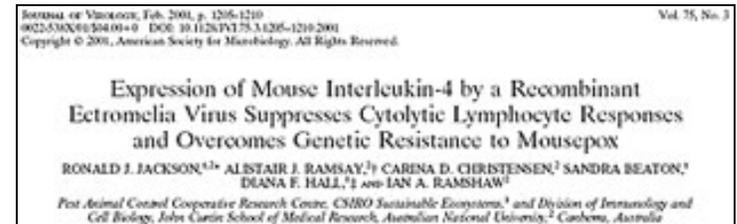


Scientific Concerns

- Top-down security regime not tailored to laboratory realities
- Need not 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
 - Withdrawal from research on Select Agents



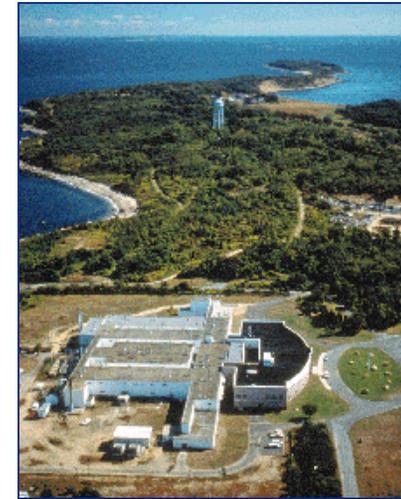
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Security Concerns

- Although some agents have the potential to cause serious harm to the health and economy of a population, all have legitimate medical, commercial, and defensive applications
 - Identification of illegitimate activities extremely difficult
- Nature of the material makes diversion extremely difficult to prevent
- Identical protection measures for the 82 agents and toxins despite their various degrees of attractiveness to adversaries
- Most likely threat to viable and virulent pathogens is from someone who has legitimate access to the facility
- No protection if personnel do not understand and accept security





International Concerns

- **Bioterrorism is generally not perceived as a serious threat in much of the world**
 - Priority is on identifying and controlling natural outbreaks of infectious disease
- **Best defense against emerging infectious disease and bioterrorism is the science that creates improved vaccines, diagnostics, and therapies**
- **Apprehension that US biosecurity methods, or international regulatory regime, would hinder advances in basic biomedical research by**
 - Increasing the cost
 - Straining international collaborations
 - Restricting information sharing
- **Acknowledgement that dangerous pathogens have intrinsic value and need to be protected globally**
 - Rapid expansion of the biotechnology industry has resulted in the global proliferation of dual use materials, technologies, and expertise





Proposal for Achieving International Biosecurity

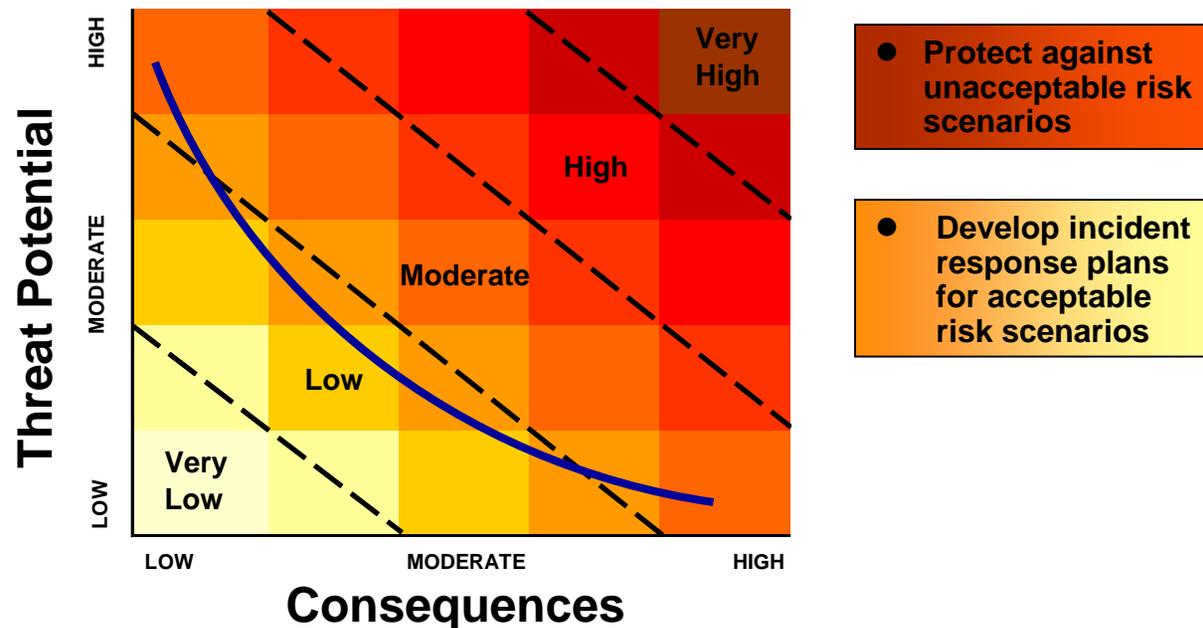
- **Securing pathogens and toxins must be an international endeavor**
 - Mitigate the risk of bioterrorism/biological weapons proliferation
 - Also mitigate the risk of accidental release of dangerous organisms
- **Success of biosecurity will depend on willing implementation by the scientific community**
 - Essential to integrate biosecurity and biosafety practices
 - Avoid compromising fundamental biomedical and microbiological research
- **International guidelines should be promulgated by a respected international technical organization in the life sciences**
 - World Health Organization
 - World Federation of Scientists

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



Biosecurity Based on Risk Management

- Security in a biological environment will never be perfect, and the consequences of loss of this material is a subject of considerable debate
- Critical for biosecurity to employ risk management strategies
 - Distinguish between “acceptable” and “unacceptable” risks
 - Ensure that protection for an asset, and the cost, is proportional to the risk of theft or sabotage of that asset



Summary

- **Necessary to take steps to reduce the likelihood that certain pathogens and toxins could be stolen from bioscience facilities**
- **Critical that these steps are designed specifically for biological materials and research**
- **Most biosecurity measures should reinforce and complement existing biosafety measures**
- **Need for a respected international technical organization to promulgate international biosecurity guidelines**
 - **Involve international scientific community in their development so that they can be widely accepted and implemented**





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