Risk Assessment and Risk Management

SNL Biosecurity Team

National Workshop on Biosecurity

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NNSA National Nuclear Security Administration

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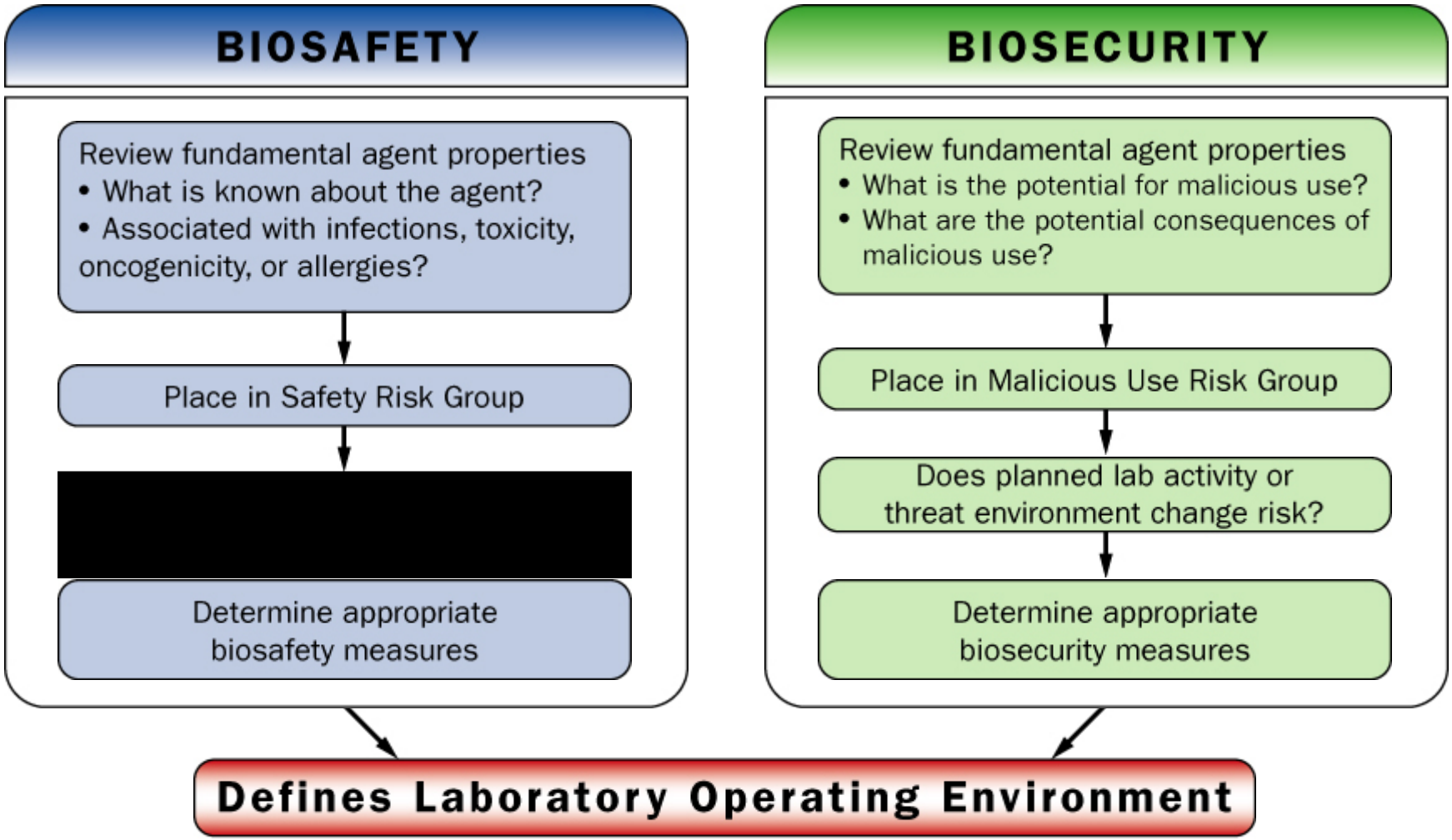
Risk Management

- Establishes which assets should be protected against which threats
  - Assets include items that are:
    - Dangerous
    - Hard to replace
    - Rare
    - Critical to operations
- Ensures that the amount of protection provided to a specific asset, and the cost for that protection, is proportional to the risk of the theft or destruction of that asset
- Begins with a risk assessment
- Proceeds with risk mitigation
- Continuously improves with monitoring and adjustment

Integrated Biosafety and Biosecurity



Biosafety Risk Assessment: Safety Risk Group Evaluation

- What is known about the agent?
  - Pathogenicity – ability to cause disease
  - Virulence – degree of pathogenicity
  - Host range – restricted or broad, human, animals, plants
  - Communicability – are there reports of epidemics? Of laboratory infections?
  - Transmission – means (e.g. direct contact, vector borne) and routes (e.g. ingestion, inhalation)
  - Environmental stability – e.g. resistance to disinfection
- Additional agent factors:
  - Toxicity
  - Is the agent associated with cancer (e.g. Hepatitis B virus associated with liver cancer)?
  - Does the agent or by-products induce allergic reactions (e.g. Penicillin)?

Biosafety Risk Assessment: Safety Risk Groups

WORLD HEALTH ORGANIZATION

- **Risk Group 1**
  - No or low individual and community risk
  - Unlikely to cause human or animal disease
- **Risk Group 2**
  - Moderate individual risk, low community risk
  - Can cause disease but unlikely to be a serious hazard. Lab exposures may cause serious infection, but effective treatment and preventative measures are available and risk of spread of infection is limited
- **Risk Group 3**
  - High individual risk, low community risk
  - Usually causes serious human or animal disease but does not ordinarily spread. Effective treatment and preventative measures are available.
- **Risk Group 4**
  - High individual and community risk
  - Usually causes serious human or animal disease and can be readily transmitted. Effective treatment and preventative measures are not usually available

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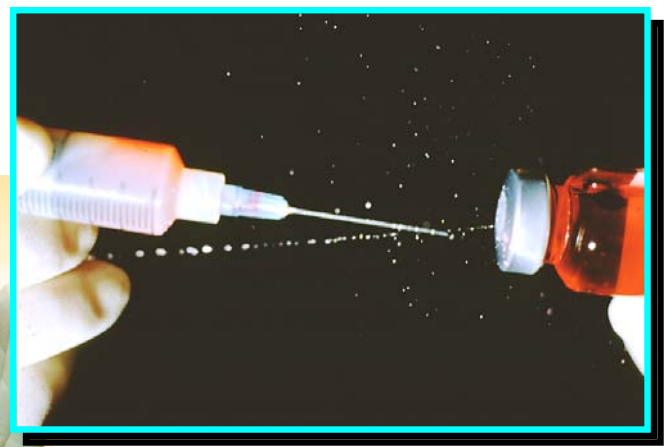
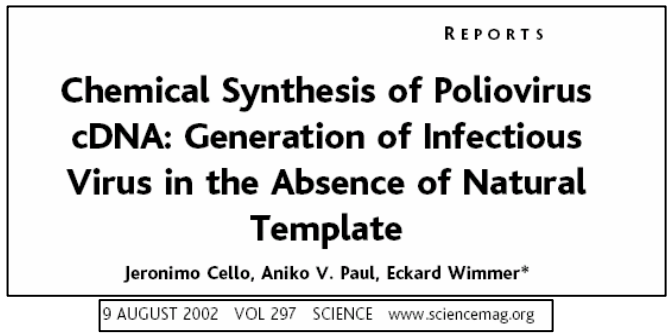
Biosafety Risk Assessment: Elements That May Modify Risk

- Risk Group is the starting point of the risk assessment
- Does the environment or activity change the risk?
  - Lab vs. field studies
  - Animal studies?
  - Procedures
    - Does planned experiment have the potential to generate aerosols?
  - Equipment
    - Needles
    - Centrifuges
    - Homogenizers
    - Pipettes



Biosecurity Risk Assessment: Malicious Use Risk Group Evaluation

- **Assess value of the agents from an adversary's perspective**
  - **Consequences**
    - Contagiousness
    - Medical effects (morbidity and mortality)
    - Potential to become endemic
    - Economic impact
  - **Weaponization potential**
    - Acquisition
    - Production
      - Ease of growth
      - Ease of processing
      - Ease of storage
    - Dissemination
      - Modes (e.g. Aerosol, Oral)
      - Environmental hardiness

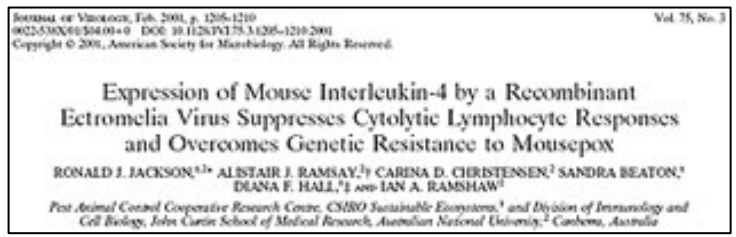


REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org



JOURNAL OF VIROLOGY, Feb. 2001, p. 1205–1210 Vol. 75, No. 3

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Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

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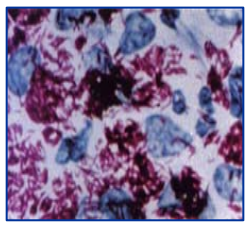
Biosecurity Risk Assessment: Malicious Use Risk Groups

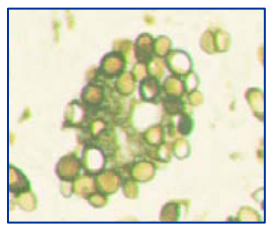
- **Nonpathogenic**
  - Malicious use would have insignificant or no consequences
- **Low Malicious Use Risk (LMUR)**
  - Difficult to deploy, and/or
  - Malicious use would have few consequences
- **Moderate Malicious Use Risk (MMUR)**
  - Relatively difficult to deploy, and
  - Malicious use would have localized consequences with low to moderate casualties and/or economic damage
- **High Malicious Use Risk (HMUR)**
  - Not particularly difficult to deploy, and
  - Malicious use could have national or international consequences, causing moderate to high casualties and/or economic damage
- **Extreme Malicious Use Risk (EMUR)**
  - Would normally be classified as HMUR, except that they are not found in nature (eradicated)
  - Could include genetically engineered agents, if they were suspected of being a HMUR

Biosecurity Risk Assessment: Agent Examples

- LMUR: *Mycobacterium leprae*
  - Consequences: Low
    - Not highly virulent, not highly contagious, and completely curable – majority recover without treatment
  - Weaponization potential: Low
    - Production is a significant challenge and not environmentally hardy
- MMUR: *Coccidioides immitis*
  - Consequences: Low to moderate
    - Usually asymptomatic, not contagious, and 5-10 out of every 1000 infected develop life-threatening infection
  - Weaponization potential: Moderate
    - Requires technical skills to handle, Easy to procure virulent strain (wide endemic area), Easy to grow colonies and produce spores



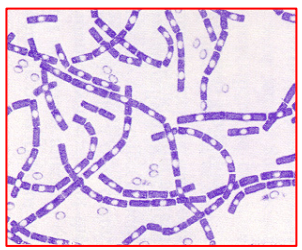
Mycobacterium leprae



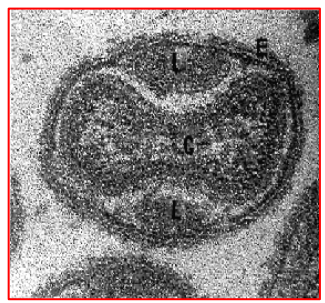
Coccidioides immitis

Biosecurity Risk Assessment: Agent Examples

- **HMUR: *Bacillus anthracis***
  - **Consequences: Moderate to high**
    - **High fatalities, not contagious, and early diagnosis is difficult**
  - **Weaponization potential: High**
    - **Wide endemic area, easy to grow, very stable**
- **EMUR: Variola major virus**
  - **Consequences: High**
    - **High fatality rate, contagious, very few vaccinated individuals**
  - **Weaponization potential: Moderate**
    - **Stable in aerosol but extremely difficult to obtain**



Bacillus anthracis



Variola major

Biosecurity Risk Assessment: Elements That May Modify Risk

- **Consider lab experiment**
  - **Does planned experiment produce an agent with higher weaponization potential or higher potential consequences?**

Biosecurity Risk Assessment: Threat Environment

- **Adversary Classes**
  - Terrorist
  - Extremist
  - Psychotic
  - Criminal
- **Insiders**
  - Authorized access to the facility, dangerous pathogens, and/or restricted information
  - Distinguish Insiders by level of authorized access
    - Site
    - Building
    - Asset
  - Facility management, site security, and local law enforcement interviews
- **Outsiders**
  - No authorized access
  - Local law enforcement, site security, and intelligence community interviews

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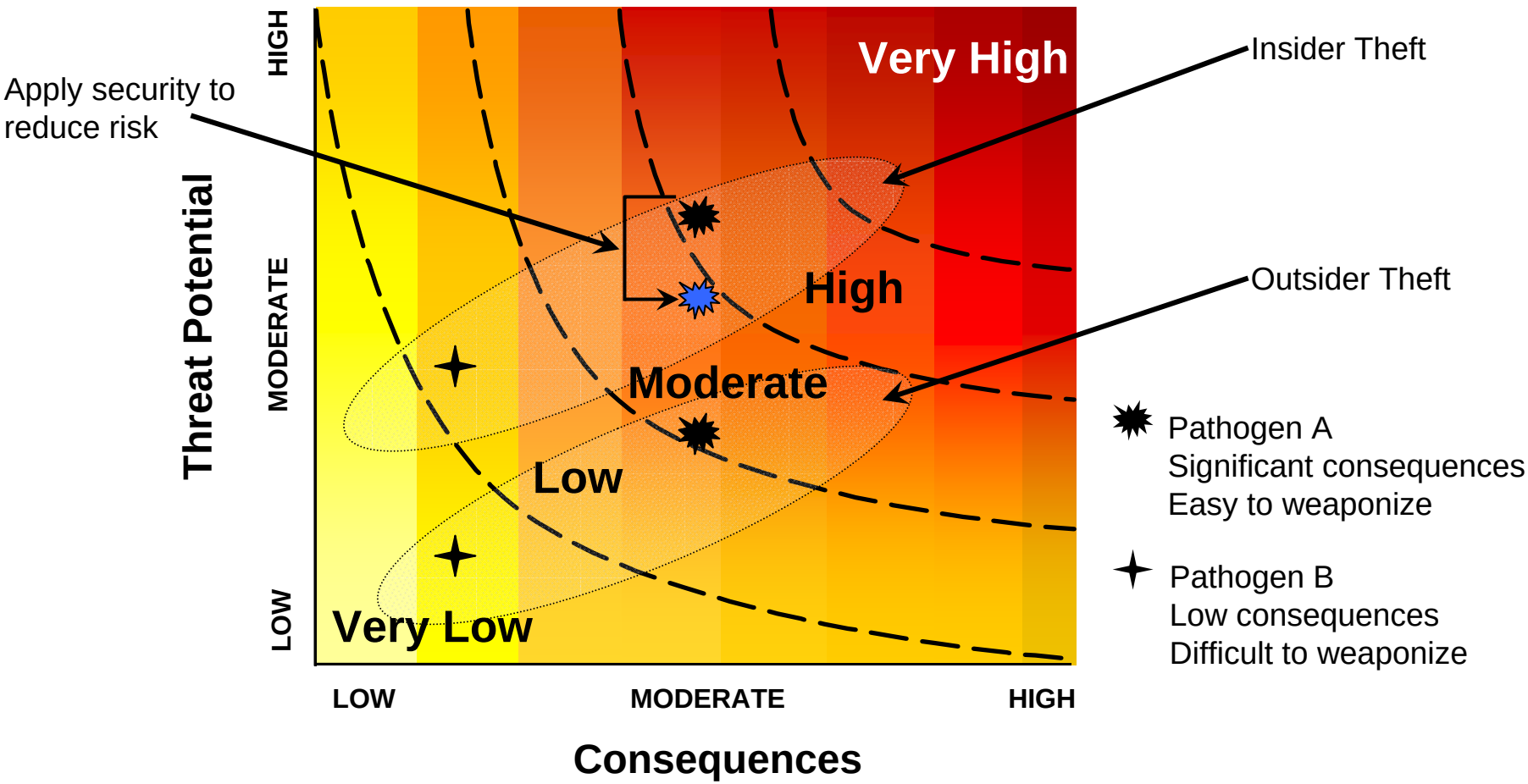
Biosecurity Risk Assessment: Threat Potential

Evaluate threat potential of possible adversaries:

- **Motive**
  - **Asset Attractiveness**
    - **How well does the acquisition or sabotage of the asset achieve the adversary's objective, or lead to achieving the adversary's objective?**
- **Means**
  - **Capability**
    - **Does the adversary have the skills, knowledge, and tools necessary to conduct the attack/meet the objective**
- **Opportunity**
  - **Environment**
    - **Is the adversary active in the area?**
    - **How recently have they acted in ways that may be threatening?**
    - **Has there been any indication of targeting?**

Biosecurity Risk: Insider vs. Outsider Threat



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Summary

- **Risk management is the goal**
  - **Requires understanding of problem through risk assessment**
- **Risk assessment**
  - **What might happen?**
  - **How likely is it to happen?**
- **Risk assessments need to be performed regularly**