Federal Select Agent Program (FSAP)

Overview
Biosafety Risk Assessment for Agriculture

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2018 FSAP RO/ARO Workshop
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USDA and OVERLAP SATs

USDA SELECT AGENTS AND TOXINS
African horse sickness virus
African swine fever virus
Avian influenza virus$^3$ Highly pathogenic
Classical swine fever virus
Foot-and-mouth disease virus$^*$
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum$^3$
Mycoplasma mycoides$^3$
Newcastle disease virus$^{2,3}$ virulent
Peste des petits ruminants virus
Rinderpest virus$^*$
Sheep pox virus
Swine vesicular disease virus

*Denotes Tier 1 Agent

https://www.selectagents.gov/SelectAgentsandToxinsList.html

USDA PLANT PROTECTION AND QUARantine (PPQ)
SELECT AGENTS AND TOXINS
Peronosclerospora philippinensis
(Peronosclerospora sacchari)
Phoma glycinciola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

OVERLAP SELECT AGENTS AND TOXINS
Bacillus anthracis$^*$
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei$^*$
Burkholderia pseudomallei$^*$
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus$^3$
**Risk Assessment**

Process to identify:

1. Hazardous characteristics of an infectious or potentially infectious agent or material
2. Activities that can result in a person’s exposure
3. Likelihood of a laboratory-acquired infection (LAI)
4. Probable consequences
Public Health
Risk Assessment

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Agriculture
Risk Assessment
Risk Assessment for Ag

• Susceptibility of multiple animal or crop species
• Geographic location
• Seasonal
• Endemic or Foreign Animal Disease
  ➢ Economic impact (domestic)
  ➢ Effects on international trade
  ➢ Disease status between countries and regions within countries
  ➢ Active control or eradication programs for the disease
Risk Assessment for Ag

- Activities
  - in-vitro vs. in-vivo, research vs. diagnostic vs. field work
- Decontamination and Waste Management
- Inactivation for further use
- Personnel Competencies (KSAs)
- Pest Control
- Incident Response (e.g., spill)

https://www.cdc.gov/mmwr/preview/mmwrhtml/su6002a1.htm
Risk Assessment for Ag

- Animal Handling & Occupational Health
  - Large vs. small
    - livestock, wildlife, aquatic species, arthropods, nematodes
  - Zoonotic Disease
  - Availability of data
  - Medical surveillance, effective post-exposure prophylaxis and treatment
  - Respiratory protection program, pre-exposure vaccines availability
- Relevant regulatory requirements
  - FSAP, CDC, USDA, NIH

Risk Assessment for Ag

IV. Pathogens of Veterinary Significance

- African horse sickness virus
- Lumpy skin disease virus
- African swine fever virus
- Lymphohematopoietic choriomeningitis virus
- Akananvirus
- African swine fever virus
- MAbs
- Avian influenza virus
- Menangle virus
- Bacteriophage
- Mycobacterium bovis
- Bacteriophage
- Mycoplasma mycoides subsp. mycoides

*Not all inclusive

Appendix D—Agriculture Pathogen Biosafety

The contents of this Appendix were provided by USDA. All questions regarding its contents should be forwarded to the USDA.

Contents:
1. Introduction
2. BL-3
3. BL-3, Ag
4. BL-3, Enhanced
5. Pathogens of Veterinary Significance
6. Summaries of Selected Agriculture Agents
7. Additional information

I. Introduction

Risk assessment and management guidelines for agriculture differ from human public health standards. Risk management for agriculture research is based on the potential economic impact of animal and plant morbidity, and mortality, and the trade implications of disease. Agricultural guidelines take this difference into account. Worker protection is important but great emphasis is placed on reducing the risk of agent escape into the environment. This Appendix describes the facility parameters and work practices of what has come to be known as BL-3, Ag. BL-3, Ag is unique to agriculture because of the necessity to protect the environment from an economic, high-risk

Animal Diseases associated with Potential Bioterrorist Agents

<table>
<thead>
<tr>
<th>Disease or Agent</th>
<th>Security of disease in potentially affected species</th>
<th>Prominent Clinical Signs</th>
<th>Incubation Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
<td>Mild, florid, and centrifugal, grizyme pig</td>
<td>Sudden death from sepsis with lack of rigor mortis; blood fails to clot; excitation followed by depression, or stoppage; blood fills mouth, nose, anus; edema, especially neck, thorax, and shoulders</td>
<td>3-7 days</td>
</tr>
<tr>
<td>Botulism</td>
<td>Fever, myasthenia</td>
<td>Muscle paralysis - progressive symmetrical flaccid; disturbed vision; unable to swallow or chew; death from respiratory or cardiac paralysis</td>
<td>24-72 hours</td>
</tr>
<tr>
<td>Plague</td>
<td>Rabbits, rodents, and ground squirrels, prairie dog</td>
<td>Variable</td>
<td>Several days</td>
</tr>
<tr>
<td>Tularemia</td>
<td>Rabbits, rodents, aquatic animals</td>
<td>Sudden high fever with lethargy and anorexia; stiffness; reduced mobility; tachypnea; tachycardia; prostration and death; military white necrotic lesions of liver, spleen or lymph nodes</td>
<td>1-5 days</td>
</tr>
<tr>
<td>Rift Valley Fever</td>
<td>Non-human primates</td>
<td>Fever, petechiae, bleeding from orifices and internal organs; skin rash; splenomegaly</td>
<td>2-16 days</td>
</tr>
<tr>
<td>Brucellosis</td>
<td>Wild ruminants</td>
<td>Variable</td>
<td>Several days</td>
</tr>
<tr>
<td>Brucellosis</td>
<td>Wild ruminants, buffaloes, black, etc.</td>
<td>Abscesses, stillborn or weak newborns; retained placenta; pneumonia; orchitis; epididymitis; arthritis; lameness; Goats: May also have mastitis</td>
<td>Variable</td>
</tr>
<tr>
<td>Cladres</td>
<td>Donkeys, mules, guinea pigs, hares</td>
<td>Ulcerated nodules on ears, upper respiratory tract, lungs; septicaemia high fever; thick mucopurulent nasal discharge; respiratory signs</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Melioidosis</td>
<td>Rodents, rabbits, kangaroos, other non-human animals, fish</td>
<td>Variable</td>
<td>Several days</td>
</tr>
</tbody>
</table>

http://www.cfsph.iastate.edu/Products/resources/WallChart.pdf
Animal Behavior & Handling
Animal Penning, Gating & Animal Welfare

- Tenderfoot flooring (rubber, no bedding)
- Rubber Mating (no bedding)
• Agriculture animals are **loosed-housed** or in **open caging** (cannot be housed in primary containment isolators or equivalent means of primary containment devices) *

* Enhancements may be required by USDA APHIS, other relevant regulatory entity, or local policies and procedures.
BSL-3Ag Animal Diseases

- African Swine Fever
- Classical Swine Fever (hog cholera)
- Rift Valley Fever
- Contagious caprine pleuropneumonia
- Contagious bovine pleuropneumonia
- Peste des Petites Ruminants
- Lumpy skin disease virus
- HPAI
- FMD
- Newcastle disease (velogenic)
- *Rinderpest virus
Risk Assessment - *Plant Health*

- Origin-imported or domestic
- Pure culture or field-collected
- Lab, growth chamber, greenhouse usage
- Vector studies
  - Arthropods, nematodes
- Trophic types
  - Obligate or facultative parasite
- Tropical vs. Temperate
- Fungal spore dispersal
- Special cases
  - Some bacteria produce endospores
  - Nematodes have resistant cysts
  - Some rust fungi have five different spores in their life cycle
    - The presence of rust alternate hosts
Risk Group Classification

Risk Group Database

Quicklinks: Bacteria Genus

Quicklinks: Viral Groups

Quicklinks: Fungi Genus

Quicklinks: Parasite Genus

Search Database

Enter any name of agent (genus, species, viral group, virus name): 

Human Pathogen:  □  Animal Pathogen:  □  Plant Pathogen:  □

Select Agent CDC:  □  Select Agent USDA:  □  Search

FREE App

Biocontainment – Plant Health


http://www.isb.vt.edu/documents/Plant%20Contain.text.PDFX-1a.pdf
<table>
<thead>
<tr>
<th>SELECT AGENT OR TOXIN</th>
<th>ENDEMICITY INFORMATION</th>
<th>INFECTIOUS DOSE</th>
<th>LABORATORY SAFETY &amp; CONTAINMENT RECOMMENDATIONS</th>
<th>TREATMENT (antidote or prophylaxis)</th>
<th>DISINFECTANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classical swine fever virus</td>
<td>Endemic in much of Asia, Central and South America, and parts of Europe and Africa</td>
<td>10 TCID&lt;sub&gt;50&lt;/sub&gt;</td>
<td>BSL-3 with enhancements. BSL-3-Ag &amp; ABSL-3, both with enhancements with no contact w/ susceptible hosts for 5 days.</td>
<td>No treatment</td>
<td>Inactivated by cresol, sodium hydroxide (2%), formalin (1%), sodium carbonate (4% anhydrous or 10% crystalline, with 0.1% detergent), ionic and non-ionic detergents, strong iodophors (1%) in phosphoric acid.</td>
</tr>
<tr>
<td>Rathayibacter toxicus</td>
<td>Australia and South Africa</td>
<td>3-6 mg/kg/ body weight</td>
<td>BSL-2</td>
<td>No treatment</td>
<td>Alcohol</td>
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</table>
### Appendix II: Example Procedural Risks

<table>
<thead>
<tr>
<th>Procedural Risks*</th>
<th>PPE</th>
<th>BEC Primary Containment</th>
<th>Engineering Controls/ Secondary Containment</th>
<th>Biosafety SOP(s) Training</th>
<th>OCC, Health Plan</th>
<th>Gasket on Lid</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Propagation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>Sterility testing and use of non-viable/exempt strains</td>
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<tr>
<td>Lack of appropriate immunizations</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Controlling</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Use safety cup (if available)</td>
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<tr>
<td>Sterilizing</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>Use hearing protection</td>
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<tr>
<td>Spiking</td>
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<td>X</td>
<td>X</td>
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<td>Bleeding</td>
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<td>Homogenizing</td>
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<tr>
<td>Skidding</td>
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<td>Lymphocytosis</td>
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<td>Flow Cytometry/ Culture Manipulation</td>
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<td>X</td>
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<tr>
<td>Automated plating/ Plates washing</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
<td>Use split kit</td>
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<tr>
<td>Spills/contamination</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Use of escalating</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>Avoid using glass columns when possible</td>
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<tr>
<td>Injection Procedures</td>
<td>X</td>
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<td>Lesions Incision</td>
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<td>Amniotic Fluid</td>
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<td>Amniotic Exposure</td>
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<td>Amniotic harvest</td>
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<td>X</td>
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<td>X</td>
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<td>Amniotic tissues</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Animal Bites</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Use of Sharps</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Inadequate Training</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
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<tr>
<td>Inadequate Safety Equipment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Inadequate Technique</td>
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<tr>
<td>Waste Handling and Inactivation Procedures</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Desensitization</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
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<tr>
<td>Selection and use of PPE</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Inadequate Syringe Labeling</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</tbody>
</table>

*List is non-comprehensive.
Incident Response & Reporting

• Releases (e.g., spills)
  ▪ Outside primary containment
    • Animal disease agent
      o Zoonotic, arthropod
        • Activation of a post-exposure medical surveillance/prophylaxis protocol
    • Plant disease agent
      o Arthropod-borne disease (vector)
  ▪ Incident reporting protocol
    • Evacuation, clean up
    • Proper disinfectant, contact time, final disposal
    • Reporting to FSAP
  ▪ Outside secondary containment
    • Impact to environment (e.g., livestock, natural resources, cash crops, plant nursery industry, other)
    • Reporting to FESAP, other Federal and State agencies

Waste Management

- Decontamination, Disinfection, and Sterilization

Risk Assessment

In addition to Biological:

- Chemical
- Radiological
- Sharps
  - Contaminated (needles, syringes, scalpels)
- Physical
  - Animal handling (bites, scratches, allergens)
Breakout Exercise:

Assessment of Risks Associated with Incident Response (e.g., spills)
Entity ABC, a large agriculture animal health research and diagnostic campus somewhere in the Southwest, consists of multiple BSL-2/ABSL-2, BSL-3/ABSL-3, and BSL-3Ag laboratories, vivarium and associated support facilities. Several of the laboratory/animal facilities store and/or handle SATs and are registered with the FSAP. Describe the incident response and reporting procedure(s) you would have in place in the following situations:

1. On a Friday afternoon, an employee noticed a small air leak on top of the fermentor head plate at the start of a fermentor kill cycle. The fermentor contained *B. abortus* Strain 19 live vaccine (attenuated strain). The leak was observed as a small bubble from a pressure fitting.

2. One Thursday night, there was an operational failure in the effluent waste stream (EDS system that services the BSL-3Ag facility) that led to a possible release of untreated effluent into the “clean contained” portion in the building’s basement. The EDS system is located in a free-standing building. Animals in the BSL-3Ag facility had been inoculated with *Brucella abortus* a few months prior the incident, and two had aborted 2 weeks prior the incident. Staff encountered the spill the following morning.

3. Employee was processing a diagnostic sample taken from a zoo animal that died 2 days before. The zoo is located near a region where cases of velogenic Newcastle disease virus (*vNDV*) have been recently reported. The sample is suspected to contain *vNDV* based on necropsy results. In the process of loading the sample from the shipping to container to the BSC, the employee inadvertently dropped it causing a spill on the floor.
Discussion

www.selectagents.gov

CDC: lrsat@cdc.gov or 404-718-2000

APHIS: AgSAS@aphis.usda.gov or 301-851-3300 option 3 (voice only)