Federal Select Agent Program (FSAP)

Overview
Biosafety Risk Assessment for Agriculture
USDA and OVERLAP SATs

**USDA SELECT AGENTS AND TOXINS**
- African horse sickness virus
- African swine fever virus
- Avian influenza virus
  - Highly pathogenic
- Classical swine fever virus
- Foot-and-mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- *Mycoplasma capricolum*
- *Mycoplasma mycoides*
- Newcastle disease virus
  - 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 glycincola* (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

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

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>African horse sickness virus ***</td>
<td>Loping B virus</td>
</tr>
<tr>
<td>African swine fever virus ***</td>
<td>Lumpy skin disease virus *</td>
</tr>
<tr>
<td>Akaara virus *</td>
<td>Malignant catarrhal fever virus (exotic strains or alcelaphine herpesvirus type 1)*</td>
</tr>
<tr>
<td>Avian influenza virus (highly pathogenic) **</td>
<td>Menangle virus *</td>
</tr>
<tr>
<td>Bacillus anthracis **</td>
<td>Mycobacterium bovis</td>
</tr>
<tr>
<td>Brucella abortus</td>
<td>Mycoplasma agalactiae</td>
</tr>
<tr>
<td>Brucella melitensis</td>
<td>Mycoplasma mycolides subsp. mycolides (small colony type) **</td>
</tr>
</tbody>
</table>

*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
I. Introduction
II. BSL-3.4-Ag
III. BSL-3, Enhanced
IV. Pathogens of Veterinary Significance
V. Summaries of Selected Agriculture Agents
VI. 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 BSL-3.4-Ag. BSL-3.4-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

#### Animal Disease From Potential Bioterrorist Agents

<table>
<thead>
<tr>
<th>Disease or Agent</th>
<th>IC/Organism</th>
<th>Severity of Disease</th>
<th>OSOM</th>
<th>Period</th>
<th>Prominent Clinical Signs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anthrax</strong></td>
<td>Bacillus anthracis</td>
<td>Mild: necrotic centers and contusions</td>
<td>Gray</td>
<td>2-3 days</td>
<td>Sudden death from septicaemia with lack of rigor mortis; blood fills clot; excitement followed by depression or stupor; blood from mouth, nose, anus; cutaneous, especially neck, thorax, and shoulders</td>
</tr>
<tr>
<td><strong>Botulism</strong></td>
<td>Clostridium botulinum</td>
<td>Severe</td>
<td>Yellow</td>
<td>24-72 hours</td>
<td>Muscular paralysis - progressive symmetrical flaccid paralysis, disturbed vision, unable to swallow or chew; death from respiratory or cardiac paralysis</td>
</tr>
<tr>
<td><strong>Plague</strong></td>
<td>Yersinia pestis</td>
<td>Moderate</td>
<td>Purple</td>
<td>Variable several days</td>
<td>High fever, extremely swollen lymph nodes (“buboes”); severe pneumatic septicaemia</td>
</tr>
<tr>
<td><strong>Tularemia</strong></td>
<td>Francisella tularensis</td>
<td>Mild</td>
<td>Yellow</td>
<td>1-10 days</td>
<td>Sudden high fever with lassitude and anorexia, stiffness, reduced motility; lachrymation; conjunctivitis; postural and death; mortality white necrotic base of tongue, spleen or lymph node</td>
</tr>
<tr>
<td><strong>Viral Hemorrhagic Fever</strong></td>
<td>Phn: Marburg; Losara Marburga</td>
<td>Mild: hemorrhagic</td>
<td>Red</td>
<td>2-16 days</td>
<td>Fever, petechiae; bleeding from orifices and internal organs; skin rash; splenomegaly</td>
</tr>
<tr>
<td><strong>Brucellosis</strong></td>
<td>Brucella melitensis</td>
<td>Mild: hemorrhagic</td>
<td>Red</td>
<td>Variable</td>
<td>Abscesses, stillbirth or weak newborns; reduced placental; placenta, ovaries, epididymis, arthritides; lameness; Goats: May also have mastitis</td>
</tr>
<tr>
<td><strong>Brucellosis</strong></td>
<td>Brucella abortus, B. melitensis, B. suis</td>
<td>Mild: hemorrhagic</td>
<td>Red</td>
<td>Variable</td>
<td>Abscesses, stillbirth or weak newborns; placenta, ovaries, epididymis, arthritides; lameness; Horns, suppurative basils (“lobules without”</td>
</tr>
<tr>
<td><strong>Crandis</strong></td>
<td>Brucella melitensis</td>
<td>Mild: hemorrhagic</td>
<td>Red</td>
<td>2 weeks</td>
<td>Ulcerated nodules on skin, upper respiratory tract, lungs, septicaemia; high temperature, high metabolic nasal discharge; respiratory signs</td>
</tr>
<tr>
<td><strong>Meloidosis</strong></td>
<td>Burkholderia pseudomallei</td>
<td>Mild: hemorrhagic</td>
<td>Red</td>
<td>Variable: Latency</td>
<td>Signs vary with site of lesion; supplicative or caseous lesions in lymph nodes; lungs, and viscera; pneumonia; possibly nasal discharge, arthritis or lameness; Horses: neurological coli; Goats: mastitis</td>
</tr>
</tbody>
</table>

Source: [http://www.cfsph.iastate.edu/Products/resources/WallChart.pdf](http://www.cfsph.iastate.edu/Products/resources/WallChart.pdf)
Animal Penning, Gating & Animal Welfare

Tenderfoot flooring (rubber, no bedding)

Rubber Mating (no bedding)
Ag Biosafety

- 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
- FMD
- Peste des Petites Ruminants

- Lumpy skin disease virus
- *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

Biocontainment – Plant Health


http://www.isb.vt.edu/documents/Plant%20Contain.text.PDFX-1a.pdf
## Hazardous Characteristics of Select Agents and Toxins* (both animal and plant diseases)

<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>
</tr>
</tbody>
</table>

NOTE: instructional use only and does not qualify as an entity specific assessment

https://www.selectagents.gov/bbp-appendixi.html
# Procedural Risks (Examples)

## Appendix II: Example Procedural Risks

<table>
<thead>
<tr>
<th>Procedural Risks*</th>
<th>PPE</th>
<th>BSC/Primary Containment</th>
<th>Engineering Controls/Secondary Containment</th>
<th>Biosafety SOP(s)</th>
<th>Occ. Health Plan</th>
<th>Gallet on Lid</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Laboratory/Animal Procurement</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Controlling</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Controlling</td>
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<td>X</td>
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<td>X</td>
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<tr>
<td>Instrumentation</td>
<td>X</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>Instrumentation</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Use hearing protection</td>
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<tr>
<td>Handling/Storage</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Stocking/Labeling</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Use of Labeled/Nonlabeled</td>
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<td>X</td>
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<tr>
<td>Automated glassware</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Use spill kit</td>
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<tr>
<td>Mouth-polyester and other ingestion</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Cell Line/Culture manipulation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Pressure column chromatography</td>
<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</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>X</td>
<td>X</td>
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<tr>
<td>Inoculated Human</td>
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<tr>
<td>Aerosol Exposure</td>
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<td>X</td>
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<tr>
<td>Reagent handling and disposal procedures</td>
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<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Necropsy/Processing</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Animal Bites</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Use of Sharps</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
<td></td>
</tr>
<tr>
<td>Inadequate Training</td>
<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Inadequate Safety Equipment</td>
<td>X</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 Facilities</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Unsafe Labeling and Inactivation Procedures</td>
<td>X</td>
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<td>X</td>
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<td>Decolonization</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
<td></td>
</tr>
<tr>
<td>Selection and Use of PPE</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Inadequate Equipment/Labeling</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</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](http://www.selectagents.gov)

**CDC:** [lrsat@cdc.gov](mailto:lrsat@cdc.gov) or 404-718-2000

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