

Plant Pathogen Select Agents: A Program Review



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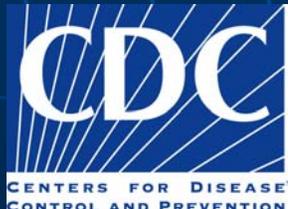
Plant Protection and Quarantine

Animal & Plant Health Inspection Service

U. S. Dept. of Agriculture

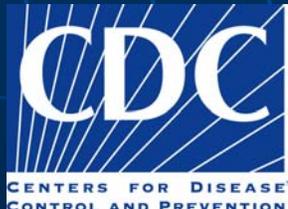
ABSA Annual Meeting

6 October 2007



Topics

- Plant Pathogen Select Agents
- Biocontainment and Specialty Rooms
 - Inspections
 - Growth Chambers
 - Greenhouses
- Plant Pest Permitting Requirements



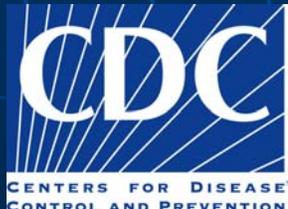
Agricultural Bioterrorism Protection Act of 2002

Title II, Subtitle B of

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

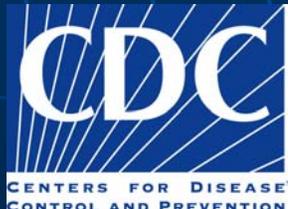
Regulations at:

- *7 Code of Federal Regulations Part 331*
(7 CFR 331): Plant select agents
- 9 CFR 121: Animal select agents



Current Plant Select Agents: Bacteria

| <u>Bacterial Agent</u> | Disease | Host |
|---|---------------------------------|--------|
| <i>Candidatus Liberobacter africanus</i> | Citrus Greening (Huanglongbing) | Citrus |
| <i>Candidatus Liberobacter asiaticus</i> | Citrus Greening (Huanglongbing) | Citrus |
| <i>Ralstonia solanacearum</i> Race 3 Biovar 2 | Bacterial Wilt, Brown Rot | Potato |
| <i>Xanthomonas oryzae</i> <i>pv. oryricola</i> | Bacterial Leaf streak | Rice |
| <i>Xylella fastidiosa</i> | Citrus variegated chlorosis | Citrus |



Proposed Plant Select Agents: Bacteria

Proposed Rule published in the Federal Register on August 28, 2007 with a 60 day comment period; comments due October 29, 2007

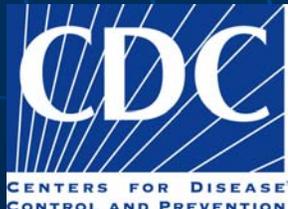
| <u>Bacterial</u> Agent | Disease | Host |
|--|---------------------------------|----------|
| <i>Candidatus Liberobacter africanus</i> | Citrus Greening (Huanglongbing) | Citrus |
| <i>Candidatus Liberobacter americanus</i> | Citrus Greening (Huanglongbing) | Citrus |
| <i>Ralstonia solanacearum</i> Race 3 Biovar 2 | Bacterial Wilt, Brown Rot | Potato |
| <i>Sclerophthora rayssiae</i> var. <i>zeae</i> | Brown Stripe downy mildew | Corn |
| <i>Xanthomonas oryzae</i> (all pathovars) | Bacterial Leaf streak | Rice |
| <i>Xylella fastidiosa</i> | Citrus variegated chlorosis | Citrus |
| <i>Rathayibacter toxicus</i> | Gumming Disease | Ryegrass |

Removal of *Candidatus Liberobacter asiaticus*



Current Plant Select Agents: Fungi

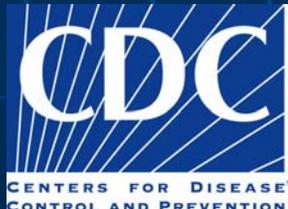
| <u>Fungal Agent</u> | Disease | Host |
|---|------------------------------|--------|
| <i>Peronosclerospora philippinensis</i> | Philippine downy mildew | Corn |
| <i>Sclerophthora rayssiae</i> var. <i>zeae</i> | Brown Stripe downy mildew | Corn |
| <i>Synchytrium endobioticum</i> | Potato Wart Potato Canker | Potato |



Proposed Plant Select Agents: Fungi

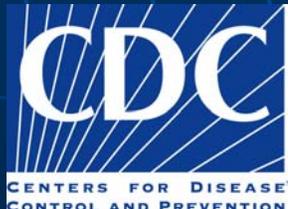
Proposed Rule published in the Federal Register on August 28, 2007 with a 60 day comment period; comments due October 29, 2007

| <u>Fungal Agent</u> | Disease | Host |
|--|----------------------------|--------------|
| <i>Peronosclerospora philippinensis</i> <i>syn P. sacchari</i> | Philippine downy mildew | Corn |
| <i>Sclerophthora rayssiae</i> var. <i>zeae</i> | Brown Stripe downy mildew | Corn |
| <i>Synchytrium endobioticum</i> | Potato Wart, Potato Canker | Potato |
| <i>Phoma glycinicola</i> | Red leaf blotch | Soybean |
| <i>Phytophthora kernoviae</i> | | Woody Plants |



Plant Pathogen Biocontainment

- Biocontainment -- prevention of accidental release of plant pathogens into the surrounding environment... as opposed to protection of the worker (*i.e.*, biosafety)
- Federal regulations require permitting and biocontainment of any plant pathogen that is imported or moved interstate (Plant Protection Act), and biocontainment of select agents regardless of source (Agricultural Bioterrorism Protection Act)



Plant Pathogen Biocontainment

- Mitigation measures (*i.e.*, permit conditions or registration containment requirements) are based on pathogen, host, distribution, dissemination methods, and intended use
- Since the plant pathogens listed by USDA as select agents are some of the potentially most destructive, containment requirements are rigorous



Plant Pathogen Biocontainment

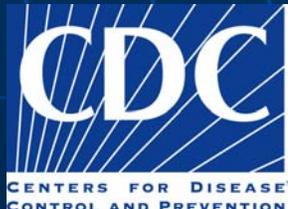
Plant Pathogen Research Specialty Rooms

■ Growth Chambers

- Internal, environmentally controlled rooms
- Small research plants
- Research requiring regulation of one or more environmental factors

■ Greenhouses

- Glasshouses for large scale production
- Large research plants and trees
- Research requiring regulation of environmental factors is not as critical



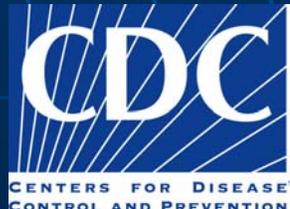
Plant Pathogen Biocontainment

Plant Pathogen Research Specialty Rooms

Growth Chambers



- Provide precise environmental controls:
 - Temperature, light, humidity
- Mitigations:
 - Collection and sterilization of plant water
 - Treatment and sterilization of plant material and soil
 - Access control



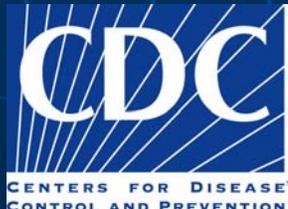
Plant Pathogen Biocontainment

Plant Pathogen Research Specialty Rooms

Greenhouses

External Features

- Location
 - Ground-level vs. Rooftop
 - Exterior vegetation
- Translucent Walls and Ceilings
 - Glass Break Detection- Sound, Motion, or Pressure
 - Sealed with caulk internally and externally



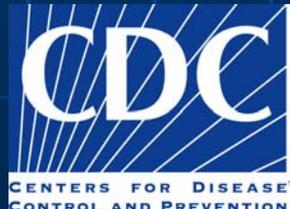
Plant Pathogen Biocontainment

Plant Pathogen Research Specialty Rooms

Greenhouses

Internal Features

- Floors
 - Monolithic, impervious material
 - Drains for water collection and sterilization prior to disposal
- Air Filtration
- Waste Disposal
 - Plant, soil material
 - Water
- Insect/Vector control



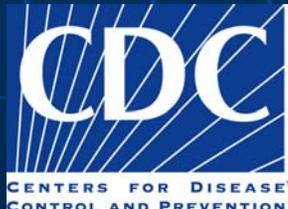
Plant Pathogen Inspections

- In general, inspections have not resulted in major findings.
 - Biocontainment of plant pathogens is adequately preventing accidental release of agents into the environment (all SA already required permitting and containment under Plant Protection Act)
- However, inspections of plant facilities have resulted in some general findings:



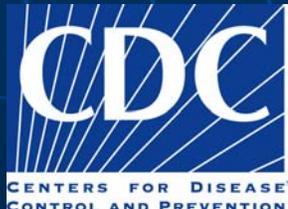
Plant Pathogen Inspections

- Findings
 - Entity Records
 - Security and Incidence Response Plans
 - Annual Review
 - Conduction and Documenting Drills and Exercises
 - Training
 - SRA approved individuals: annual, entity & agent specific
 - Escorted visitors into registered areas
 - Documentation of training and of methods to assure comprehension (*i.e.*, tests)



PPQ Plant Pathogen Inspections

- Findings (cont'd)
 - Site-specific physical security
 - Certification of Equipment
 - Autoclaves
 - Biosafety Cabinets



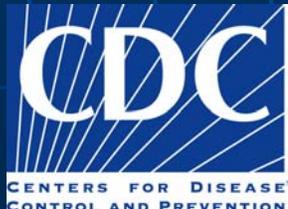
Plant Protection Act

- Provides a permit system for the importation and interstate movement of all plant pests (including plant pathogens)
- 7 CFR 330: Plant Pest Permitting Regulations
 - Regulates Plant Pests and infected plant material
 - Pathogens (bacteria, fungi, viruses, mycoplasmas)
 - Arthropods
 - Parasitic plants and Federal Noxious Weeds
 - Nematodes
 - Diagnostic samples (potentially infected plant material)



SAP/Permits Regulatory Requirements

| Activity | Permit PPA/330 ? | Register ABPA/331? |
|---|------------------------------------|--------------------|
| Collect samples potentially infected with a Select Agent, send for diagnosis within state | No | No |
| Collect samples potentially infected with a Select Agent, send interstate for diagnosis | Yes, receiver No, sender | No |
| Diagnostic lab maintains non-viable spores or extracted genetic material of a Select Agent to use as a positive control | Yes, interstate No, intrastate | No |
| Diagnostic lab maintains viable Select Agent spores or other material as positive control | Yes, interstate No, intrastate | Yes |
| Diagnostic lab saves (for whatever purpose) part of a sample later determined to be a Select Agent | Yes, interstate No, intrastate | Yes |
| Conduct research on a Select Agent (other than pure diagnostics) | Yes, interstate No, intrastate | Yes |
| Lab (Diagnostic or otherwise) receives <i>known</i> , viable Select Agent from other, permitted lab | Yes, interstate Yes, intrastate | Yes |



Questions ?

