



Risk Groups and Biosafety Levels Weren't Developed for Plant Pathogen Research

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Disclaimer

- I am an employee of APHIS-PPQ at the Center for Plant Health Science and Technology. I performed temporary duty permitting arthropod plant pests, evaluated containment facilities appropriateness for containing plant pathogens for the Permitting and Compliance Coordination (PCC) (formerly: the Permit Unit). I also conducted compliance activities. I am not an employee of the PCC currently. They are best equipped to answer policy questions.
- Select agent permits fall under a different regulation 7 CFR 331 and will not be discussed today.
- Bio-controls would take an entire presentation due to their permitting complexity.

NIH RDNA Guidelines (2016)

Institutional Biosafety Committee Composition

Section IV-B-4. Plant, Plant Pathogen, or Plant Pest Containment Expert

When the institution conducts recombinant or synthetic nucleic acid molecule research that requires Institutional Biosafety Committee approval in accordance with [Appendix P](#), *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*, the institution shall appoint at least one individual with expertise in plant, plant pathogen, or plant pest containment principles (who is a member of the Institutional Biosafety Committee).

APHIS Permitting Outline

- Parties involved with permitting decisions;
- What items require permits;
- Major factors determining if containment is needed;
- Describe containment risk determinants;
- Regulation 7 CFR 330 covering permit regulations is being considered for revision in the near future.

Permit Unit Reorganization now the: Permitting and Compliance Coordination (PCC)

- Permits and Compliance Coordination Unit
(Emily Pullins, Ph.D., Director)
- Containment, Soil, and Federal Noxious Weed
Permits (Natalia Weinsetel, Ph.D., Assistant
Director)
- Pest, Pathogen, and Biocontrol Permits
(Colin Stewart, Ph.D., Assistant Director)
- Imports, Regulations, and Manuals Unit
(Nicole Russo Ph.D., Director)

Who is involved in permitting decisions?

1. Permit Clerk checks for completeness of the application and to check previous permit history;
2. Assigned an Evaluation Scientist who:
 - determines if containment facility is required;
 - determines if an environmental assessment is needed;
 - performs an evaluator's analysis;
 - If the organism is able to be permitted at this level, the evaluator prepares the permit conditions;
 - may draft letters of no jurisdiction, denial, or letter of no permit required;
3. If needed, the Containment Scientist will discuss containment requirements with the applicant and evaluate if sufficient safeguards are present. The applicant may be asked to fill-out a questionnaire, provide photographs of spaces and equipment, and provide detailed SOP's;
4. The Evaluation Scientist drafts "Permit Conditions" for the applicant;

The screenshot shows a software interface with a table of permit applications. The table has four columns: Name, Applicant, Status, and Date/Time. The rows list various permit types such as 'Regulatory Assessment', 'Regulatory Assessment - Permit', 'Regulatory Assessment - Denial', etc. Some rows have checkboxes in the left margin, and some have small icons or status indicators. The interface is partially obscured by a blue box at the top left.

Who is involved in permitting decisions? (Continued)

5. Draft permit may go for review at request of a supervisor or the applicant and either another scientist or management will conduct the review
6. Both the State Plant Regulatory Official (SPRO-State employee, and the State Plant Health Director-Federal employee review the draft permit (15 days to respond);
7. Applicant review of draft permit conditions;
8. Submittal for a second Management review if necessary;
9. Applicant's response is evaluated, if no concerns the permit is issued.

Training Sheet

Application / Job

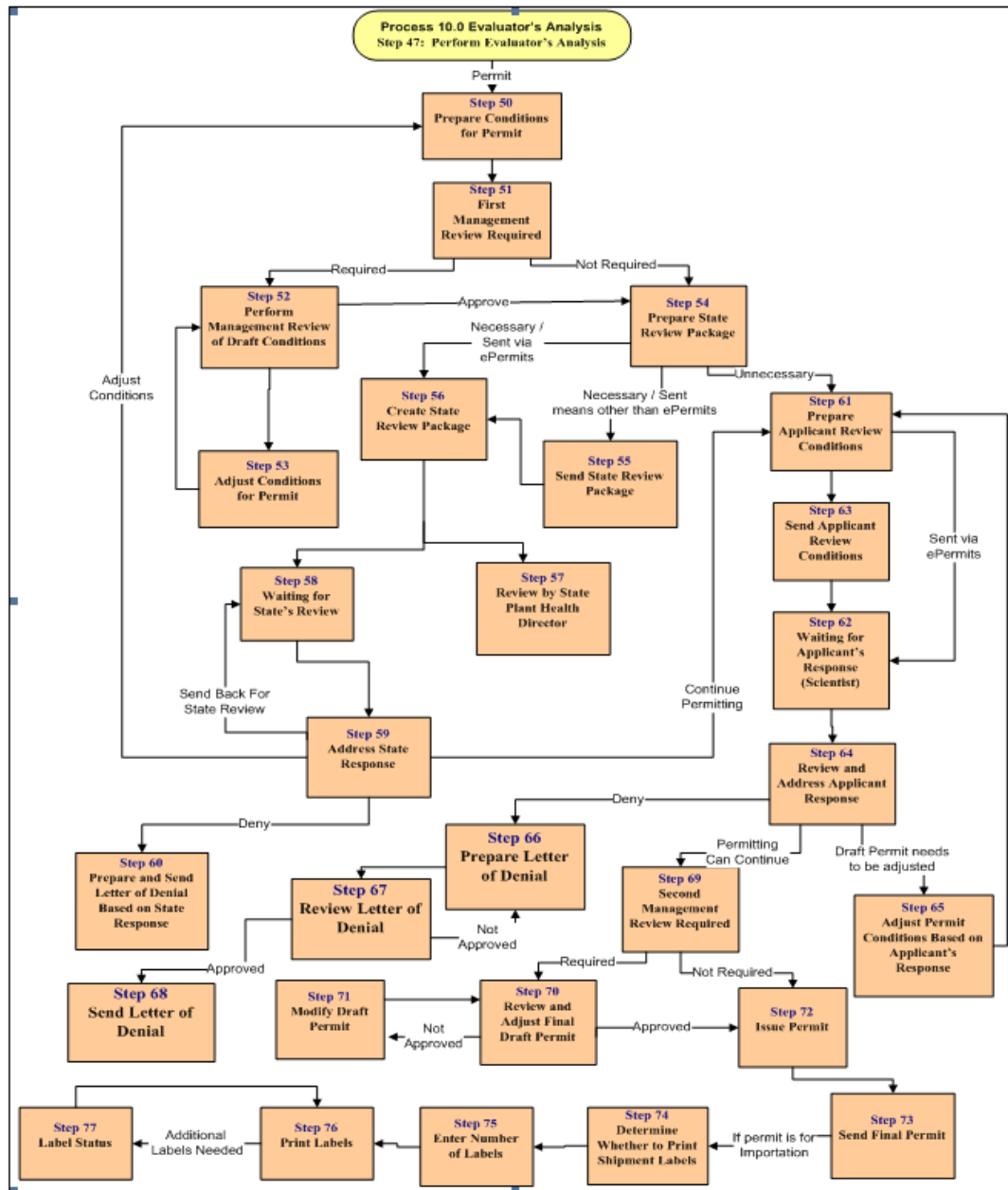
Application Summary

Application

Application Comment

Item	Applicant	Review	Responsibility
1. Progress note/Regulation Request			
2. Progress letter of intent/Regulation			
3. Review note/Regulation Request			
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100. Review note/Regulation Request			

Permit Issuance Flowchart



Risk Considerations

- APHIS does not use the CDC or other systems of Containment and risk levels, i.e. BSL-1, BSL-2, and BSL-3 although this is widely recognized. Instead APHIS uses biocontainment levels (BCL-I, BCL-II, and BCL-III) of low, medium, and high risk.
- If a given Containment Facility has a combination of high, medium, and/or low risk regulated organisms therein then the containment standard must be set at the highest risk level.
- Containment facilities with potential arthropod vectors of plant pathogens must not be in close proximity to plant pathogen containment facilities generally.

Basic information needed for a containment decision

- Point of origin (Foreign or domestic)
- Organism's distribution
- Biology and reproductive capacity
- Dissemination
- Vectoring capability
- Survival (resistant spore or pupal stage etc.)
- Host range

These factors inform the Evaluation Scientist's decision on whether containment is necessary.

APHIS PCC does not assign
“risk groups” or “biosafety levels”

They use “Biocontainment risk levels” of various
factors to evaluate the containment measures
needed.

- Low risk
- Medium or variable risk
- High risk

The Containment Scientist will determine the level of
containment required.

Many factors are considered to determine the “risk level” of an organism

- Origin-imported or domestic;
- Pure culture or field-collected;
- Lab, growth chamber, greenhouse usage;
- Vector studies;
- Trophic types-i.e. obligate parasite 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;

Origin of Pathogen

- Foreign: **High to Medium** Needs containment, BCLII*/III**, autoclave, biosafety cabinet II, lockable storage, other conditions, SOPs for permitting
- Domestic: Regulated - Domestic Quarantine **Medium to High** Needs containment, BCLII, autoclave, biosafety cabinet II, lockable storage, other conditions, SOPs for permitting
- Widely Prevalent: Low **May need containment*****

*Full inspection (every 3-Years)/ Risk level –Medium –e.g. *Fusarium oxysporum f.sp.*

** Full inspection (annually)/ Risk level – High – e.g. UG99

***cosmopolitan/ubiquitous, on widely prevalent list, to be moved domestically; and risk is extremely low

<http://www.bugwood.org/prevalent-spp.html>

Widely Prevalent Species

The Widely Prevalent projects are updated by regional coordinators around the country. In addition to providing information for plant pathologists and diagnosticians, the lists are used by APHIS-PPQ to develop a list of organisms that are common in each state to help expedite the permitting process for obtaining research isolates. The APHIS-PPQ list will be available on the [APHIS website](#).

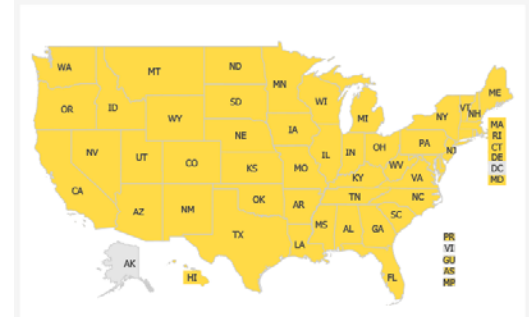
A "Widely Prevalent" organism is an organism that:

- Would raise no new regulatory concerns at the State or Federal level if it was identified
- Is widely distributed in any given five year period in the State where the host plant(s) is grown. It does not have to be widely prevalent every year at every location

Widely Prevalent Sites

Widely Prevalent Fungi
Widely Prevalent Bacteria
Widely Prevalent Viruses
Widely Prevalent Nematodes

Download combined state prevalent list by clicking on a state



Purity

- Field collected **High**
(See other factors –slide #12)
- Pure culture **Low to High**
(See other factors –slide #12)
- Ranking: Field collected > Pure culture
 - High Medium/Low

Intended Use

Greenhouse **High** (See other factors –slide #12)

Growth chamber **Medium** (See other factors –slide #12)

Lab **Low** (See other factors –slide #12)

Ranking: Greenhouse > Growth chamber > Lab

High

Medium

Low

Vector Studies

Arthropods (high mobility) **High**

Non Arthropods/ low mobility

Arthropods – e.g. adult scale insects **Variable**

Habitat

Air-borne **High**

Soil-borne **Variable**

Ranking: Air-borne > Soil-borne

High

Medium - Low

Dispersal

Air-borne	Low to High
Water-borne	Low to High
Vector-borne	Low to High

Tropical Host Plants versus Temperate Hosts

Tropical Pest to be researched in tropical zone **High**

Tropical Pest to be researched in temperate zone **Low**

Temperate Pest to be researched in temperate zone **High**

Temperate Pest to be researched in tropical zone **Low**

Types of Fungal Spore Dispersal

Dry spores adapted for aerial dispersal

High

Wet, sticky spores only moved by rain or splashing water

Variable

Airborne propagules

High to Medium

Non-airborne propagules

Variable

Example of a complicated life cycle (Rust Fungi –Uredinales)

Life cycles (Rust Fungi –Uredinales)

Insect dispersal stage **High**

Air-borne stage **High**

Dormant stage
(Not air disseminated) **Low**

Various spore types:

- 1 - Pycniospores (spermatia)insect dispersal
- 2 – Aeciosporesair-borne
- 3 - Urediosporesair-borne
- 4 - Teliosporesdormant stage (Not disseminated)
- 5 – Basidiosporesair-borne or rain dispersed.

Alternate Hosts (Rust)

Both in containment or near containment **High**

One host in containment **Low**



An example: *Gymnosporangium juniperi-virginianae*

Special Cases

Bacteria Endospore-formers	High
Non-endospore-formers	Variable
Nematode: Cyst Nematodes	High
Non-cyst Nematodes	Variable

Arthropods-Additional factors

- Usage: Research vs. zoos or butterfly houses/ insect displays;
- Mobility of all life stages (except eggs/ova);
- Origin: tropical vs. temperate;
- Host Range: wide vs. narrow;
- Arthropod size: large arthropods easier to see and capture;
- Feeding location: internal feeding vs. external;
- Reproductive rate: life cycles per year.

Noxious weeds

Regulated under 7CFR 360

Major factors

- Aquatic vs Terrestrial;
- Dissemination: airborne seeds, survival characteristics, or seeds/fruit attractive to birds and animals;
- Seed size (Minute/Medium/Large);
- If plant is propagated: means and location;
- Plant's native environment compared to research location;

Federal Noxious Weed List

https://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist.pdf

Parasitic-seed plants

Regulated under 7CFR 330

Parasitic Greenhouse	High	Needs greenhouse, containment, PPC- 3, autoclave, lockable storage, other conditions, SOPs for permitting
Research Lab (Growth chamber)	Medium	Needs growth chamber, containment, PPC- 2-3, autoclave, lockable storage, other conditions, SOPs for permitting
Research Lab	Low	Needs containment, PPC- 2-3, autoclave, lockable storage, other conditions, SOPs for permitting
Dissemination air-borne	High	Use applicable outcomes above based on intended use
Dissemination not air-borne	Low	Use applicable outcomes above based on intended use
Seeds	High	Use applicable outcomes above based on intended use
Other plant parts (cuttings)	Low	Use applicable outcomes above based on intended use
Tropical plant to be researched in tropical zone	High	Use applicable outcomes above based on intended use
Tropical plant to be researched in temperate zone	Low	Use applicable outcomes above based on intended use
Temperate Plant to be researched in temperate zone	High	Use applicable outcomes above based on intended use
Temperate plant to be researched in tropical zone	Low	Use applicable outcomes above based on intended use

Plant Pest Containment Level

Level 1: Facility includes permanent structures such as laboratories, greenhouses and screen-houses. Windows that can be opened must be fitted with appropriate screens. An autoclave or incinerator must be available to treat/destroy waste.

Level 2: Facility includes permanent structures such as laboratories and greenhouses but not screen-houses. Containment is achieved through facility design, operational procedures and the use of specialized equipment. All PPC-1 physical and operation requirements also apply to PPC-2.

Level-3: The highest level of containment. All PPC-1 and PPC-2 physical and operation requirements also apply to PPC-3. Containment is achieved through the use of highly specialized facility with stringent procedures.

Proposed 7 CFR 330 rule changes

- Codify APHIS policy;
- Soils;
- Bio-controls;
- Possibly offer exempt organisms lists.

Helpful resources available from the Permit Coordination Compliance (PCC) branches

- Containment Facility Guidelines for Noxious Weeds and Parasitic Plants
- Containment Guidelines for Non-Indigenous, Phytophagous Arthropods and Their Parasitoids and Predators
- Containment Guidelines for Plant Pathogenic Nematodes
- Containment Guidelines for Non-Indigenous Snails
- Containment Guidelines for Plant Pathogenic Bacteria
- Containment Facility Guidelines for Viral Plant Pathogens and Their Vectors
- Containment Facility Guidelines for Fungal Plant Pathogens

https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_containment/ct_containment_facility_inspections

ABSA Risk Group Database published by NIH: Sweden has developed Risk Groups for a few plant pathogens. *Plant pathogens finally made a list.*

The screenshot shows a web browser window displaying the ABSA Risk Group Database. The browser address bar shows the URL: <https://my.absa.org/tiki-index.php?page=Riskgroups>. The website header includes the ABSA logo and the text "my.ABSA.org For the Biosafety Professional". The navigation menu includes "HOME", "CALENDAR", "FAQS", "RISKGROUPS", and "HELP".

The main content area is titled "Risk Group Database". On the left, there is a "Search Database" section with a search input field and several checkboxes for "Human Pathogen", "Animal Pathogen", and "Plant Pathogen". Below this, there are two search results for "Bacteria" and "Fungus".

Bacteria Search Results:

Genus	Species
Acidovorax	spp.

NIH:
BMBL:
Australia/New Zealand: 2
Belgium:
Germany:
EU:
Singapore:
Singapore Schedule:
Switzerland:
UK:
Human Pathogen: n Animal Pathogen: n Plant Pathogen: y
Select Agent CDC: n Select Agent USDA: n
Canada PSDS:

Fungus Search Results:

Genus	Species
Acremonium	strictum

NIH:
BMBL:
Australia/New Zealand:
Belgium: 2 notes: Syn: Cephalosporium acremonium
Germany: 1 notes: Syn: Cephalosporium acremonium
EU:
Singapore:
Singapore Schedule:
Switzerland: 2 notes: h; synonym of Cephalosporium acremonium
UK:
Human Pathogen: n Animal Pathogen: n Plant Pathogen: y
Select Agent CDC: n Select Agent USDA: n
Canada PSDS:

Fungus Search Results:

Genus	Species
Aibugo	candida (var. candida)

NIH:

On the right side of the page, there is a "Search Tips" section and a "Risk Classification Criteria" section. The "Search Tips" section includes a note about the "Risk Group Database app" and a list of factors for consideration: Pathogenicity of the organism, Mode of transmission and host range, Availability of effective preventive measures (e.g., vaccines), Availability of effective treatment (e.g., antibiotics), and Other factors. The "Risk Classification Criteria" section includes a link to "CDC/NIH Guidelines (2009)".

The Windows taskbar at the bottom shows the system clock as 10:25 AM on 9/16/2016.

Thank you for your interest!



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