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;

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

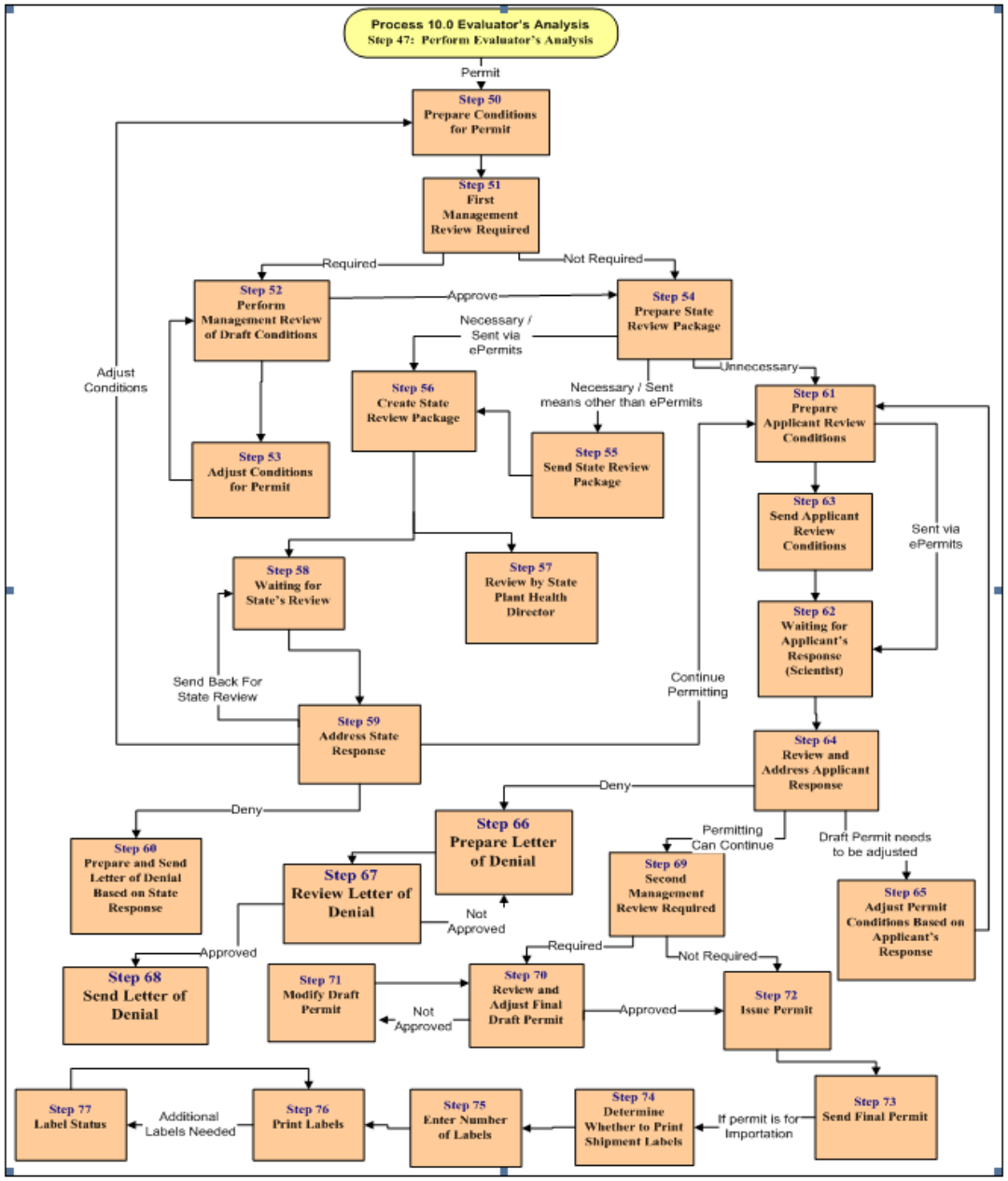
6. Both the State Plant Regulatory Official (SPRO-State employee, and the State Plant Health Director-Federal employee review the draft permit (15 days to respond);

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.

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

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 – Aeciospores ……air-borne
3 - Urediospores ……..air-borne
4 - Teliospores ……..dormant stage (Not disseminated)
5 – Basidiospores ……air-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

https://www.aphis.usda.gov/plant_health/permits/organism/downloads/parasitic_plant_genera.pdf

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.

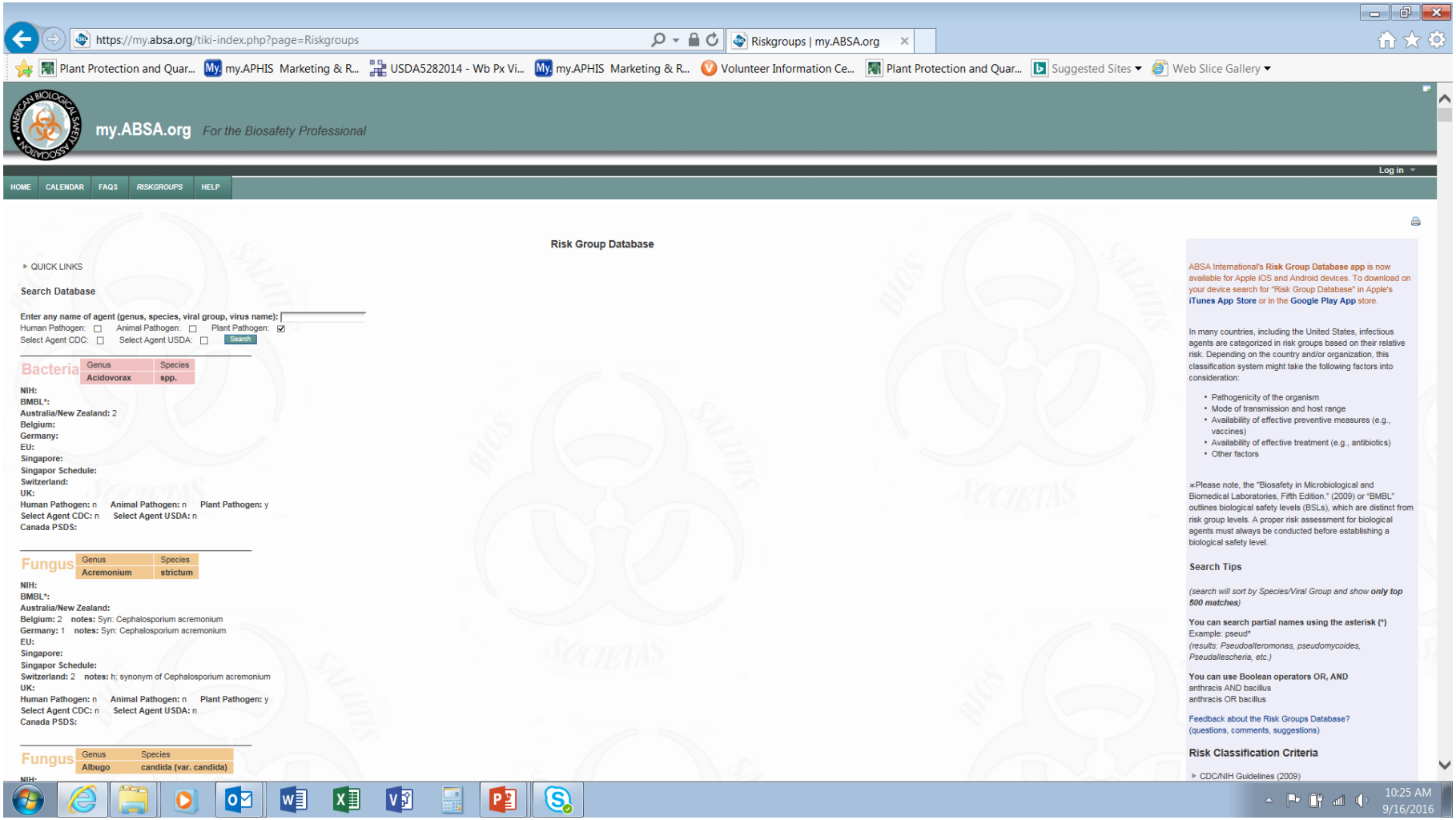
Helpful resources available from the Permit Coordination Compliance (PCC) branches

- 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*.



Thank you for your interest!

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