



USDA Permitting of Plant Pests and Biocontrol Organisms

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Outline



- Confidential Business Information (CBI)
- Evaluation of Field Release Applications for Soil Microbials (Bacteria and Fungi)

Confidential Business Information (CBI)



All documents submitted to PPQ are subject to the Freedom of Information Act (FOIA) which requires that records submitted to federal agencies be made available to the public.

- Section (b) (4) allows exemptions from disclosure based on trade secrets and commercial and financial information
- Exemption based on the idea that disclosure could cause financial harm

Confidential Business Information (CBI)



- To claim it:
 - Submit a detailed letter justifying CBI claims
 - Both a CBI-containing and CBI-deleted version of the document

Confidential Business Information (CBI)



- Allowable:
 - Novel species names of soil microbials, biocontrol agents, pests, and diseases
 - Points of origin and destination (excluding county and state names)
 - Quantities
 - Novel methods, procedures, design protocols

Confidential Business Information (CBI)



- Things that are not typically allowable:
 - Species names of common species
 - County and state names
 - Applicant name and contact information
 - Information such as intended use (lab, greenhouse, field studies) that becomes meaningless without the species names

Confidential Business Information (CBI)



- PPQ's CBI handling responsibilities
 - Office of General Counsel said that we cannot share CBI even with states with strict confidentiality laws
 - If we do, we forfeit permit holders' claims of confidentiality in the event of a Freedom of Information Act request
- State needs to contact companies directly
- Encouraged companies to take a proactive approach with states

Confidential Business Information (CBI)- why bother?



Field Studies: Soil Microbials



- “Bio-prospecting” plants thriving in hostile environments
 - Endophytes, associated bacteria
 - Confer drought or salt tolerance
- Farmers in other parts of the world using bacteria
 - Pesticides, fertilizers expensive
 - Companies consider this “green technology”
- Going directly to field: lab/ greenhouse work often does not translate into field results

Permitting Process for Soil Microbials- Demystifying the “Black Box”



Authority and Role



- APHIS gets authority to regulate plant pests and biological control agents from Plant Protection Act of 2000
 - Plant Pest Regulations, 7 CFR 330
- National Environmental Policy Act Implementing Procedures, 7 CFR 372



Authority and Role



- Memo of Understanding with Environmental Protection Agency (EPA)
 - APHIS PPQ: regulate non-genetically modified species within our jurisdiction: 10 acres land or less nationwide/ year
 - APHIS PPQ: 1 acre or less surface area of water
 - EPA regulates tests on greater areas



Field Studies: Soil Microbials



- Mode of action
 - Is it a pest?
 - Is it a direct biological control agent?
 - Does it parasitize, prey on, or help plant by harming pests through antibiosis?
 - Does it act indirectly (induced resistance?)
 - Is it strictly a plant growth enhancer?
 - *Rhizobium*, *Azotobacter*: enhance plant growth by improving nutrient uptake

Field Studies: Soil Microbials



- Prevalence data for domestic isolates:
 - Widely prevalent lists
 - Scientific literature
 - Cooperative Extension bulletins
 - Unpublished proprietary company surveys (Confidential Business Information issues)

Field Studies: Soil Microbials



- National Environmental Policy Act- domestic
 - Required to do an environmental assessment for organisms unless they can be categorically excluded
 - **Releases into a state where the organism is either native or an established introduction**
 - Frequently ask companies for additional data

Field Studies: Soil Microbials



- National Environmental Policy Act- domestic (cont'd)
 - “Doughnut hole effect”



Field Studies: Soil Microbials



- National Environmental Policy Act- domestic (cont'd)
 - If not categorically excluded, Economic Impact Statement needed- long process, usually dropped from permit.

Field Studies: Soil Microbials



- Foreign isolates- biological equivalency of widely prevalent species
 - Species under EPA authority- maybe different strains
 - Need to confirm, match up species with state lists
 - Genomic data (16S RNA) subunit comparison or whole genome
 - 16 S subunit similarity 95% or better with type strain

Field Studies: Soil Microbials



- National Environmental Policy Act
 - Required to do an environmental assessment for genetically modified and non-indigenous species unless they can be categorically excluded
 - Organism must be same species or essentially be the biological equivalent of existing species
 - APHIS must have jurisdiction over organism



United States Department of Agriculture



Field Studies: Soil Microbials



- National Environmental Policy Act
 - Bioaccumulation- most of the organisms don't accumulate over time- outcompeted
 - Need to consider if organism will harm threatened and endangered species

Questions?

