Agricultural and Plant Biosafety Program Management at Rutgers University

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ABSA Annual Meeting 2017
- Diversity of Rutgers’ Agricultural and Plant Research
- Improvements to Plant Biosafety Program Management
- Challenges and Achievements
Diversity of Research and Locations

**Studying mechanisms of action of ricin and shiga toxin**

**Identifying genes for improving biofuel traits**

**Prevent adhesion of *E. coli* (tested for human materials)**

**Field study-Transgenic Regulated by USDA-APHIS**
Regulations

- Safe to eat
- Safe to grow
- rDNA concerns
- Select Agents/Pathogens
- Environmental safety
- IBC Registration (as needed)
- Permits (as needed)
- Control Measures
  - Engineering Controls
  - Access
  - Training
  - Record Keeping
  - Labeling
Identifying the Gaps in the Program

- Outreach to Plant PIs (IBC requirements)
- Plant Biosafety Training Module
- Autoclave validation program Implementation
- In-house Inspection
Online Laboratory Safety, Biosafety and Bloodborne Pathogen Refresher Training

Plants Biosafety Levels, Risk Assessment

The NIH guidelines and other federal and institutional policies discussed in the previous module are intended to prevent the dissemination of transgenic materials and plant pests beyond the experimental facility into the surrounding ecosystem. Thus, recombinant plant and plant pathogen (both indigenous and exotic) research should be subjected to a risk assessment to assess the appropriate biosafety level, containment and work practice. However, before assessing risk it is important to understand the different plant biosafety levels that exist. Plant biosafety levels are divided depending on the pathogenicity of the material/organism and lay a strong foundation for the risk assessment section.

### Plant biosafety levels

Plant biosafety level is a combination of physical and biological containment practices with the purpose of:

- avoiding unintentional release of regulated article outside the restricted area
- protecting our agriculture and natural ecosystems

There is only limited guidance on containment available from regulatory agency like USDA-APHIS (which primarily regulates plant materials and related research), hence, the biosafety levels defined below are primarily based on transgenic information from Appendix P of NIH guidelines.

There are four biosafety levels for plant biosafety BL1-P to BL4-P. Each biosafety level (BSL) builds upon each other. At Rutgers, we primarily conduct research which falls under BSL1-P and BSL2-P practices. However, all four plant biosafety levels are briefly discussed here.

**BSL1-P**

Organisms that are generally recognized as compatible with the environment (GRACE) may be handled at BSL1-P. GRACE organisms have virtually no potential for adverse effects on human health or natural ecosystems and have virtually no potential for the transfer of genetic material to other organisms for rapid reproduction.
• Autoclave Validation
  - Bacterial spore testing

• Periodic testing
  - at least once a month
  - once per week for transgenic research facilities

• Record and log maintenance checks
Greenhouse In-house Inspection

BSL-1 Waste Collection

Transgenic Label

Non-Transgenic Label
Agricultural Field In-house Inspection

- Access Control
- Bagging
- Labeling

- Volunteer Monitoring
- Waste disposal (plants and soil)
- Field equipment cleaning
- Pest Program
Challenges

- Limited Plant-Related Research Regulations
- Regulation Ambiguity
- Communication Challenges
- Training and Administrative Management
Achievements

- IBC Registration
- Plant Research Inventory and Risk Assessment
- Plant Research Specific Training
- Successful USDA-APHIS Inspections
- Autoclave Validation Program
- Greenhouse/ Field Inspections
- Rutgers EHS (Biosafety) Team
- Rutgers’ IBC Members
- Greenhouse Facility Managers and Staff
- Plant Departments/ NJAES Leadership
RESOURCES

A Practical Guide to Containment: Greenhouse Research with Transgenic Plant and Microbes (click here for pdf version)

USDA-APHIS permits and inspection
https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

USDA-APHIS Biotechnology Regulatory Services-Permit User’s Guide
click here (for pdf version)

How the federal government regulates biotech plants

NIH Guidelines (Updated April 2016)