

# Audit Process for Trials with USDA- APHIS Regulated Material

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# Qualifications

- Compliance inspections of more than 700 trials at over 300 field sites since 1999
- Management of Biotech Field Inspection Program for 4 years
- Training Government inspectors in Africa for the Bill Gates Foundation
  - Type of sites includes Sponsor Facilities, University, Extension, Private Cooperators, Seed Company, Government (USDA), Glasshouses, Licensees, Start-up Companies

# What is APHIS and What do they do?

- Animal and Plant Health Inspection Service (APHIS)
- Responsible for protecting American agriculture against pests and diseases
- Grant approvals to field test or move biotech plant material

# What is APHIS and What do they do?

- Regulate field testing of genetically engineered plants
- Assure safe testing, under controlled circumstances, of biotechnology-derived (biotech), new plant varieties

# What is APHIS and What do they do?

- Inspect field tests to assure compliance
- Review field test reports and data submitted by Sponsors
- Deregulate biotech crops

# What are the USDA Requirements?

7 CFR part 340

# Primary Objectives

- Prevent the unintentional release and persistence of regulated material in the environment
- Prevent harvested commodities derived from regulated material from entering commerce as food or feed products

# USDA Performance Standards

1. Proper shipping and maintenance at destination
2. No inadvertent mixing of materials in environmental releases
3. Maintaining identity and adequate devitalization
4. Elimination of viable vector agents
5. No persistence in the environment
6. No volunteer plants/volunteers managed



# USDA Performance Standards

- Shipped in such a way that viable plant material is unlikely to be disseminated while in transit
- Maintained at destination facility in such a way that there is no inadvertent release into environment
- Maintained in such a way that the identity of all material is known while it is in use

# USDA Performance Standards

- Planted in such a way that there is no inadvertent mixing with non-regulated plant materials of any species which are not part of the environmental release
- Contained/devitalized when no longer in use
- Field trial must be conducted such that
  - Regulated article will not persist in environment
  - No offspring can be produced that could persist in the environment

# USDA Performance Standards

- Upon termination of field test:
  - No viable material shall remain which is likely to volunteer in subsequent seasons, or
  - Volunteers shall be managed to prevent persistence in the environment
- Sponsors write “Design Protocols” which indicate steps they will take to meet USDA Performance Standards

# Compliance Assessment

What Should You Look For?

# Documentation Review

- Notification or Permit
  - Effective date, event, ship to/release site, allowed acreage
- Seed receipt/chain of custody
  - Date, event, address
- Compliance paperwork
  - Acreage planted, proper monitoring, GPS
- Previous year's volunteer data
  - Adequate monitoring, volunteer removal

# Seed Storage Tour

- Seed Containment and Identification
  - Adequate shipping containers- at least double (unless triple is required)
  - Labeling of shipping box – contents, USDA#
  - Adequate storage facility – limited access, some permits require signage
  - Method of seed transport to/from planting site – labeled with contents and USDA# (including planter boxes), properly contained

# Plot Tour, Pollen Containment

- Isolation distance adequate
  - Gardens, weeds
  - Check distance with GPS, if close to minimum
- Plot borders (pollen sink)
  - Non-regulated, same maturity/growth stage
  - Unbroken (no alleys or farm roads)
  - Required width
- Pollination procedures
  - Clothing changes, sticky mats (greenhouse)

# Prevention of Inadvertent Mixing/Accidental Release

- Personnel training-include farmers, interns
- Location/labeling of plot-adequate distance from commercial, permanent labeling
- Equipment cleaning-where/how cleaned
- Adequate alleyways for equipment moving
- Harvest procedures-turn rows, cleaning
- Final disposition-extra seed, plots
- Sample Processing-visit area



# Common Compliance Issues

- Planting before effective date
- Movement/release of unapproved events
- Releasing in unapproved county
- Inadequate isolation distance or borders
  - Borders don't germinate, overplanting into isolation area, gardens
- Planting more than allowed
- Shipping after expiration date

# QUESTIONS?

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