

Biotech Field Inspection Checklist (USDA-APHIS Regulated Material)

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Qualifications

- Compliance inspections of more than 900 trials at over 500 field sites since 1999
- Management of Biotech Field Inspection Programs for 7 years
- Have trained Government inspectors in Africa for the Gates Foundation and conducted inspections in the Philippines
- Type of sites includes Sponsor Facilities, University, Extension, Private Cooperators, Seed Company, Government (USDA), Glasshouses, Licensees, Start-up Companies

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

340.3 (apply to notifications)

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

Compliance Assessment

What should be on a Checklist?



Documentation Review

- Notification or Permit
 - Copy on site of acknowledgement letter or issued permit
 - Effective date, lines/events, ship to/storage/release site, allowed acreage
- Seed receipt/chain of custody
 - Date, event, address
- Compliance paperwork
 - Acreage planted, proper monitoring, GPS accurate
- Previous year volunteer monitoring records
 - 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 – typically contents, USDA#
 - Adequate storage facility – limited access, windows locked, drains screened, some permits require signage
 - Method of seed transport to/from planting site – properly contained, labeled with contents and USDA# (including planter boxes)

Plot Tour, Pollen Containment

- Isolation distance adequate
 - Gardens, weeds
 - Check distance with GPS, if close to minimum
- Plot borders (pollen sink) are required width
 - Non-regulated, same maturity/growth stage
 - Unbroken (no alleys or farm roads)
- Flower bagging, tassel removal timing
- Temporal isolation well documented
- 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 tour- clean, rodent-free

Common Potential Issues

- Planting before effective date
- Movement/release of unapproved events
- Releasing in unapproved county
- Inadequate isolation distance or borders
 - Overplanting into isolation area, gardens, prohibited plants, border issues (germination, roads, different maturity, width)
- Planting more than allowed
- Shipping after expiration date or to unapproved location

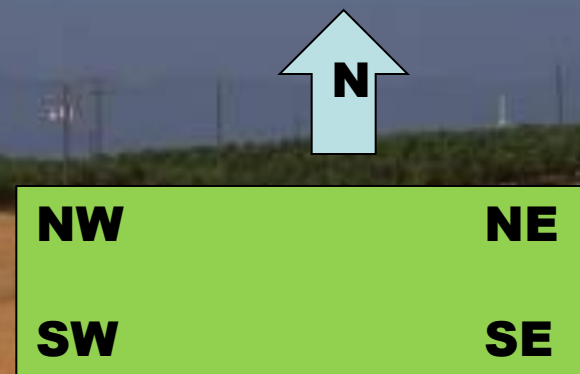
Other Common Observations

- GPS measured using one type of unit but recorded in another (e.g., measured in deg-min-sec but recorded in decimal degrees)
- GPS recorded in data is incorrect based on inspector measurements (e.g., Google earth used by researcher instead of device in the field so coordinates are not at corner of field)

Easy Way to Spot GPS Issues

- If plot is close to a rectangle shape and oriented straight then the latitude for North corners should match each other and same for south corners. Longitude for both east corners should match and same for both west corners

- NW 27.3030, -92.4020
- NE 27.3030, -92.4011
- SW 27.3022, -92.4020
- SE 27.3022, -92.4011



Other Common Observations

- Data not recorded for monitoring visits or records not available
- Comparisons not done/recorded correctly (e.g., regulated vs. non-regulated, misunderstanding of “weediness”)
- Difficult to find due to lack of plot map
- No documentation indicating that specific requirements (e.g., permits) were met

Other Common Observations

- Lack of adequate monitoring especially for distant locations
- “Someone else does that” syndrome
 - Other employee
 - Farmer, land owner
- Lack of control/destruction of volunteers
- Lack of documentation for monitoring and/or destruction

Reporting Issues

- Major issues typically get reported
- Other issues may be a judgment call
 - Wildlife issues
 - Weather related
 - Flooding
 - Non-continuous border
- Everything should be reported to sponsor contact (i.e., no judgment calls at field site)



QUESTIONS?

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