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Compliance Permit Inspection Overview

Last Modified:

APHIS performs physical inspections (in person) of authorized field trial sites to ensure compliance with the regulations and permit conditions. APHIS also performs inspections virtually: virtual inspections are referred to as Monitoring and Evaluation Interviews or MEIs.

Trained inspectors (from BRS, APHIS' Plant Protection and Quarantine (PPQ) program and with a participating state inspection program), conduct inspections. Methods used to assess compliance during inspections include: records review, interview, observation, and measurement and mapping. BRS ensures all inspectors are specifically trained to conduct BRS inspections.

BRS has designed the inspection process to be objective by having inspectors use a series of questions that they can answer with "yes", "no", or "not applicable." An inspector will not pose these specific questions during the inspection, but they will derive answers to them through a multi-faceted inspection. To ensure thoroughness, inspectors also include a written description of observations to provide clarification and additional details that are not covered by "yes", "no", or "not applicable" responses. The inspector will often need to ask the on-site responsible person a number of initial questions, review records, and make field observations to answer the questions. Inspectors can report other observations as part of a summary of

findings in the inspection report.

To assist the inspector in preparing for an inspection, BRS provides information about the specific authorization, such as a copy of the permit and the regulatory conditions associated with the trial, as well as a copy of the design protocols and/or standard operating procedures submitted with the application for permit.

BRS initially reviews completed inspection reports for quality to ensure inspectors submit all the appropriate information. Following the quality review, BRS evaluates the inspection report for compliance with the regulations. If BRS identifies noncompliance, BRS will specify the necessary corrective action, and take additional follow up steps, as appropriate. BRS provides the inspection outcomes to the responsible person to whom the permit is issued.

Example Permit Inspection Questions

- Does the responsible person have a copy of the design procedures or protocols for the field trial?
- Do the shipping and packing containers used for this field trial meet the specifications in the Release Permit?
- Were packing and shipping materials used for this field trial cleaned out and disposed of to meet the Release Permit?
- Were transport and storage containers employed so as to fully contain the regulated article at the field trial location?
- Are seed bags, packages, pots, or other containers used for the regulated article clearly and durably marked so that each article under this permit can be distinguished and identified by the responsible person throughout the field trial process?
- Did the permit holder provide you with an up-to-date map of sufficient detail showing the field site(s) for regulated articles under this permit?
- Is the total area of the field site(s) at or below the total amount of acreage approved in the Release Permit?
- Are the type(s) of regulated article(s) in the field trials at this location (organism/trait) exactly and only those stated in the Release Permit?
- If border rows are present in the field trial site, are they grown to meet Permit Conditions?

- Is the design and management of the outermost boundary of the field site(s) sufficient to assure segregation and confinement during all field operations and growth stages?
- Is the field trial planted to achieve the isolation distance that is specified in the Release Permit?
- Are measures being taken to minimize or prevent expected human or animal incursions onto the field trial?
- Do records show that equipment used in this field trial meets the specifications for the frequency and type of cleaning required in the Permit Conditions and design procedures/protocols?
- If flower removal was used to control reproduction, was the technique employed successfully and recorded?
- If flower bagging was used to control reproduction, was the technique employed successfully and recorded?
- If border rows were used to control reproduction, was the technique employed successfully and recorded?
- If temporal isolation (flowering time) was used to control reproduction, was the technique employed successfully and recorded?
- Does the responsible person have monitoring and removal records for sexually compatible plants within the isolation area of the field trial?
- Were field operations to manage growth of the regulated article fully employed?
- Do descriptions or records demonstrate that the responsible person is monitoring for deleterious/negative effects expressed by the regulated crop on itself, other plants, non-target species, or the environment?
- Does the responsible person have a schedule and plan to monitor for volunteers?
- Were operations to dispose and devitalize the regulated article (including field trial borders) fully employed?
- Did your inspection find that this field trial is free of any potential non-compliance incidents?
- Overview of noncompliance history.
- Notices of inspection findings are subsumed in the table.
- ROP has guidance documents here for submitting reports via email or mail; no changes anticipated at this time

More Information

- View Noncompliance History
- View Table of Pharma Inspection Findings

Related Links

How to Report an Unauthorized or Accidental Release

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