

Breadcrumb

1. [Home](#)
2. Print
3. Pdf
4. Node
5. Entity Print

Compliance and the Inspection Process

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APHIS verifies compliance with the conditions contained in permits and notifications by inspecting fields, records and associated facilities.

Inspections may be done in person or virtually; virtual inspections are referred to as Monitoring and Evaluation Interviews (MEIs). Trained inspectors (from BRS, APHIS' Plant Protection and Quarantine (PPQ) program, or a participating state inspection

program), conduct inspections on behalf of BRS. Methods of verification used for inspection include: records review, interview, observation, and measurement and mapping.

BRS determines the frequency and number of field test site inspections by assessing the relative risk of each type of trial and by other criteria described below. BRS conducts least one inspection for every permit resulting in a planted field trial.

Compliance Incidents

Most persons authorized to engage in regulated activities have a successful history of compliance with APHIS regulations. From time-to-time, a noncompliance incident may occur. Noncompliance incidents can include failing to notify APHIS in the event of an unauthorized release, failing to follow permit conditions (such as isolation distances or volunteer monitoring requirements), and planting at a field test site before an authorization becomes effective or after it expires. When noncompliance occurs, BRS assesses the nature and seriousness of the noncompliance and determines appropriate steps to follow up, ranging from issuing regulatory correspondence to requesting an investigation and seeking sanctions for alleged noncompliance.

Inspections for Permits

Permits require responsible persons to follow procedures described in their applications, the design protocols (e.g., standard operating procedures) they have submitted, and the standard permit conditions and supplemental permit conditions assigned by BRS. BRS ensures compliance with its permit requirements by performing thorough inspections. All permits receive at least one inspection within each authorized state where a field test site is planted each year. Plants engineered to produce pharmaceutical or industrial proteins are inspected up to seven times before, during, and after the planting occurs to verify compliance with permit conditions. These inspections are performed at critical times during field testing, including pre-release, release, reproductive control, harvest, post-harvest and two volunteer monitoring inspections. BRS tracks inspection-related information to assure that all required inspections are accomplished.

Inspection Results

After every inspection, inspectors prepare a detailed inspection report. BRS then issues feedback correspondence to the responsible person based on findings documented in the inspection report. The correspondence typically falls into one of the following categories:

- Notice of Compliance – the inspection revealed no deviations from the regulations or permit conditions, including conditions described on the permit application.
 - Note: If the analysis revealed activities or circumstances that could lead to a noncompliance incident in the future, the Notice of Compliance will provide notice of BRS' concerns and possible solutions to prevent noncompliance incidents.
- Notice of Noncompliance - the inspection revealed deviations from the regulations or permit conditions. BRS may require corrective action and indicate documentation that must be provided to BRS once corrective action is taken, as appropriate, usually within a given time frame.
- Warning Letter - the inspection revealed one or more serious deviations from the regulations or permit conditions. BRS requires a prompt written response, immediate corrective action, and evidence of action taken within a given time frame.

BRS also uses these and other letters to communicate findings not specifically related to inspections, such as noncompliance for late submittal of required reports.

Reports and Notices

APHIS requires responsible persons to submit certain reports and notices under the regulations and as part of the requirements of the authorization. Reports and notices provide compliance-related information about regulated materials. Each report and/or notice is associated with a specific permit or notification, and has requirements for due dates and information. BRS uses reports and notices for initiating inspection processes and verifying the status of the authorization and any actions taken under it, such as planting and volunteer monitoring. A report has information on activities that already happened, and a notice contains information on planned activities that will occur in the future.

- [Access to Reports and Notices User's Guide](#)
- [Access to ePermits \(XML\) Instructions for Reports and Notices](#)

Inspection Selection and Frequency Table

Authorization Type	Selection	Frequency	Additional Inspections
Pharma-Industrial Permit (perennial)	Non-random	2 in-season inspections of each site the year of planting, at least one each subsequent year	1 inspections the following growing season, 1 the next growing season**
Pharma-Industrial Permit (annual)	Non-random	5 in-season inspections of each site in each state where planted	2 inspections the following growing season
Permit (perennial)	Non-random	At least one site inspected in each state where growing each year	Post-harvest inspections as needed
Permit (annual)	Non-random	At least one site inspected in each state where planted	Higher frequency for large-scale trials
Notification	Randomly selected by computer model	If selected, at least one site inspected in one state*	As needed*

Related Links

[How to Report an Unauthorized or Accidental Release](#)

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