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Compliance and Inspection Overview

Last Modified:

BRS has a comprehensive compliance evaluation and inspection system that uses science and risk criteria to identify any potential noncompliance with APHIS' biotechnology regulations.

As part of the inspection process, BRS evaluates release sites, facilities, equipment, records, and reports to evaluate compliance. Authorizations require permit and

notification holders to report potential noncompliance to BRS within designated time frames.

When we identify a noncompliance, our focus is on quickly restoring compliance with regulatory requirements to protect U.S. agriculture and prevent inadvertent commingling with commodity crops. Instances of noncompliance with low potential to impact agriculture or the environment may require correcting records, submitting required reports, or improving monitoring procedures. Instances of noncompliance with a greater potential to impact agriculture (such as unauthorized or accidental releases) can require destruction of field test sites, quarantine of harvested crops, or entering into compliance agreements. When self-reports occur, authorization holders have typically already started to implement corrective actions.

Expand All

Reports and Notices

Persons authorized to engage in regulated activities must submit certain reports to BRS to communicate compliance-related information. Each report and/or notice has specific information requirements and due dates. In general, a report provides BRS with information on activities that already occurred, and a notice provides BRS with information on planned activities that will occur in the future.

In addition to information BRS receives through reports and notices, BRS gathers its own information during inspections to document findings and ensure compliance with the regulations and permit conditions.

- **Guide to Submitting Data for Reports and Notices in APHIS eFile**
  - **Response to Comments for Guide to Submitting Reports and Notices** (233.45 KB)

Noncompliance History

Most persons authorized to engage in regulated activities have a successful history of compliance with APHIS regulations. From time-to-time, noncompliance occurs. In these instances, BRS assesses the nature and seriousness of the noncompliance and determines appropriate actions, ranging from issuing regulatory correspondence to requesting an investigation and enforcement action, as appropriate.

View Noncompliance History

Compliance and the Site Inspection Process

BRS has a comprehensive inspection system that uses science and risk criteria to identify potential instances of noncompliance. Inspection planning involves many factors, including geographic location, time of year, species, the risk of crop persistence, compliance history, and the type of authorization (permit or notification).

Learn More About the Compliance and Site Inspection Process

Report an Unauthorized/Accidental Release of a Regulated Article or Noncompliance Incident

As specified in regulations, persons engaging in regulated activities must notify APHIS of any possible or actual unauthorized movements or releases of the regulated material. This includes accidental releases or those caused by flooding or other weather events. Time frames for reporting depend upon the type of incident or observation. It is important to carefully read the applicable regulations and conditions associated with an authorization to ensure compliance at all times.

Report an Unauthorized Release

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