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Compliance and Inspection Overview

Last Modified:



BRS has a comprehensive 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 facilities, equipment, records, and reports of potential noncompliance incidents. Authorizations under the permitting procedures require that noncompliance incidents be self-reported within designated

time frames.

If an incident occurs, our focus is to quickly restore compliance with regulatory requirements to protect U.S. agriculture and prevent inadvertent commingling within the food supply. Incidents with low potential impacts may require simple remedial actions, such as correcting clerical errors, installing fencing, or improving monitoring procedures. Serious incidents (such as unauthorized or accidental releases) can require destruction of field test sites, quarantine of harvested crops, formal corrective action plans, or other long-term measures. When self-reports occur, authorization holders have typically already started to implement corrective actions. BRS strives for long-term compliance by working to reassess and modify existing procedures to prevent recurrence of incidents.

BRS may refer a serious incident, or a history of incidents, to APHIS' Investigative and Enforcement Services (IES) for further investigation. BRS also works closely with State/Territorial Departments of Agriculture and other government agencies, including the Food and Drug Administration, the Environmental Protection Agency and the Department of Justice, to ensure compliance with APHIS regulations. The [Plant Protection Act](#) authorizes broad sanctions for noncompliance, including civil penalties up to \$1.1 million.

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 is associated with a permit or notification, and has specific requirements for due dates and information. A **report** provides information on activities that **already happened**, and a **notice** contains information on planned activities that will occur **in the future**.

Reports that persons submit to BRS in connection with regulated activities are separate and apart from BRS-prepared inspection reports, which record observations made independently by inspectors to document inspection findings and ensure compliance with the regulations and permit conditions.

- [Guide to Submitting Data for Reports and Notices in APHIS eFile](#) (748.02 KB)
 - [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, compliance incidents or patterns of noncompliance occur. When this 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.

[View Noncompliance History](#)

Compliance and the Site Inspection Process

BRS has a comprehensive inspection system that uses science and risk criteria to identify any potential 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 and permit conditions, 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 differ depending upon the type of incident or observation and the conditions associated with the authorization. It is important to carefully read the applicable regulations and conditions associated with an authorization to ensure full compliance at all times.

[Report an Unauthorized Release](#)

Compliance Assistance

BRS provides compliance assistance to those involved in biotechnology research and development, including small businesses and academic researchers, to facilitate compliance with APHIS regulations (7 CFR part 340). Compliance assistance is provided through a variety of mechanisms including learning opportunities, template procedures, and the Biotechnology Quality Management Support (BQMS) Program.

[Learn More About the Compliance Assistance Program](#)

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