BRS Factsheet
Biotechnology Regulatory Services

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

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APHIS Biotechnology: Compliance and Inspections

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), through its Biotechnology Regulatory Services (BRS) program, is responsible for regulating the introduction (importation, interstate movement, and field release) of genetically engineered (GE) organisms such as plants, insects, micro-organisms, and any other organisms that are known to, or could be, a plant pest.

BRS understands that public confidence in the regulatory system is critical. To that end, our policies are science based, measurable, and communicated to the public.

Through a strong regulatory framework, BRS works to ensure the safe and confined introduction of GE organisms. This is accomplished in large part through BRS' Compliance and Inspection Branch (CIB), which was established as part of BRS' commitment to strengthen and improve compliance and inspection actions. BRS' CIB is dedicated to ensuring that developers of GE organisms maintain and adhere to all permit conditions and Federal regulations by providing consistent quality inspections, comprehensive document tracking and reporting, and prompt and uniform enforcement actions. Compliance is accomplished through a variety of measures, including inspections, strong educational and outreach efforts, and comprehensive investigations and audits. BRS understands that public confidence in the regulatory system is critical. To that end, our policies are science based, measurable, and communicated to the public.

BRS CIB's primary office is located at APHIS Headquarters in Riverdale, MD. Additional CIB staff, including Regional Biotechnologists (RBTs), are stationed in two regional offices, one in Fort Collins, CO, and another in Raleigh, NC.

The RBTs coordinate inspections in their respective regions, provide technical assistance and training to inspectors, and conduct higher risk investigations. Designated compliance officers at headquarters are assigned to developers of GE organisms to facilitate clear communications about field-test conditions and requirements to ensure continuity. This work is supported by onsite inspections conducted by experts from APHIS' Plant Protection and Quarantine (PPQ) program.

BRS works closely with PPQ, the State departments of agriculture, and with other Federal agencies, including the Food and Drug Administration and the Environmental Protection Agency, to monitor compliance with regulations.

GE Field-Test Inspections

A developer wishing to introduce a GE organism must obtain the necessary authorization from BRS before proceeding. Depending on the nature of the GE organism, an applicant files either a notification or a permit application for APHIS review. Most plants are field-tested under notification, a streamlined approval process that is often used for plants that are altered with common agronomic traits. The permitting process involves a more comprehensive review and is used for GE organisms that could pose an elevated risk, such as plants that produce pharmaceutical or industrial compounds.

BRS inspects field trials using the relative risk of each type of trial to determine the frequency and number of inspections performed. Notifications are considered somewhat safer trials than permit authorizations. While each permitted field test is inspected at least once, the BRS compliance staff uses a system with definitive selection criteria to identify the notifications that may represent the greatest risk.

Several parameters are used to select notifications for inspections, such as a regulat-

ed article's traits and characteristics, applicant tenure, and acreage planted. Each notification receives a total score based on all factors. A computer program generates the scores, and those notifications with the highest scores are assigned to APHIS' field force for inspection.

APHIS inspectors perform targeted, risk-based inspections of field tests grown under notification. Inspection manuals contain notification inspection checklists that inspectors use to record their observations during inspections. Items on the checklist correspond with BRS' performance standards. Performance standards are comprised of guidelines that BRS expects all developers to comply with, including isolation distances, confinement measures, and harvesting procedures. The checklist also contains extensive guidance indicating what an inspector must look for to determine if the inspected party is complying with the performance standards. This guidance contributes to the uniformity of inspection results among all inspectors.

BRS ensures compliance with its permit conditions by performing frequent and thorough inspections and audits. Permitted field tests are inspected at least once, and plants engineered to produce pharmaceutical and industrial proteins are inspected up to seven times before, during, and after the field trial to verify that developers are carefully following the conditions set forth by BRS. These inspections are performed at critical times during field testing, including preplanting, flowering, harvesting, and postharvest. BRS maintains a comprehensive database that captures and tracks inspection-related information to assure that all required inspections are accomplished.

After every inspection, inspectors prepare detailed reports. The BRS compliance staff also issues feedback correspondence to the developer based on findings documented in the inspection report. The correspondence falls into one of the following three categories:

- No deviations—The inspection revealed no deviations from the regulations or permit conditions.
- Guidance—The inspection revealed minor deviations from the regulations or permit conditions. BRS requests voluntary corrective action.
- Warning—The inspection revealed serious deviations from the regulations or permit conditions. BRS requires a prompt written response and immediate corrective action.

Noncompliance Incidents

Most developers comply with BRS regulations. However, when a developer does not adhere to APHIS' regulations and permit conditions, BRS refers to these events as "noncompliance incidents." Noncompliance incidents can include a number of issues. For example, some incidents involve administrative issues, such as the wrong name on a permit. Others include failing to notify APHIS in the event of vandalism or destruction of a field test; failing to obtain a permit; and failing to follow performance standards, such as isolation distances.

Planting at a field-test site before a permit becomes effective and planting after it expires also qualify as noncompliance incidents.

In such cases, BRS seeks immediate corrective actions from developers so they can become compliant with regulations. An example of this would be requiring the developer to implement a mandatory compliance training program for their staff. Depending on the seriousness of the incident, BRS may refer the case to APHIS' Investigative and Enforcement Services (IES) for further investigation. In addition to identifying noncompliance incidents during inspections, developers conducting field tests must identify and self-report potential noncompliance incidents to BRS. The regulations require that self-reports be made immediately following the incident and be followed up by a written report within 24 hours. Many developers have compliance reporting programs as part of their operating procedures to comply with BRS regulations and ensure safe field testing. For the fiscal year ending September 30, 2005, developers self-reported 76 percent of all noncompliance incidents.

Investigative and Enforcement Services

BRS' compliance staff works closely with IES to initiate formal investigations of developers who may not be adhering to regulations, permit or notification conditions, or requirements.

Events that lead to a formal IES investigation include

- Failure to respond to a warning letter,
- Repeated violations,
- Failure to carry out promised corrective actions,
- Violations of regulations or permit conditions,
- Suspected fraud,
- Risks to the food and/or feed supply,
- Risks to the environment, and
- Inability to conduct safe field trials.

The findings may lead to an offer to enter into a stipulation settlement agreement that could include the payment of monetary civil penalties. Cases that are not resolved by a settlement agreement or involve repeat violators are referred to USDA's Office of General Counsel (OGC). OGC may file a complaint seeking civil penalties against the violator or, where appropriate, may refer the case to the U.S. Department of Justice for the initiation of civil or criminal proceedings.

All cases referred to IES are posted on the APHIS BRS Web site, <http://www.aphis.usda.gov/brs>, when the investigations are complete.

Inspector Training

BRS assures that its inspection personnel are trained and highly skilled. BRS provides technical assistance and thorough training to its inspectors, the majority of which are APHIS' own seasoned professionals from its PPQ program. BRS also works closely with the State departments of agriculture on compliance initiatives. A pilot training and certification program is being evaluated to determine if State inspectors can supplement PPQ inspectors for inspection of field tests grown under notification.

Through its core curriculum for PPQ and State inspectors, BRS ensures that its inspection personnel are equipped with the necessary training to get the job done, get it done right, and get it done safely and economically.

BRS inspectors courses cover

- Introduction to genetic engineering and transgenic organisms,
- Regulatory authority,
- Handling confidential business information,
- Conducting inspections,
- Gathering information and making preparations,
- Reporting findings, and
- Inspecting farm equipment.

BRS developed a comprehensive database to track completion of inspection assignments issued to PPQ; this database allows efficient inspection tracking and followup. BRS recently produced a revised inspection manual, including detailed inspection checklists, checklist guidance, and procedures for completing an inspection report. Additional guidance is provided in monthly, quarterly, and annual meetings between BRS and PPQ.

As science progresses, BRS will continue to evaluate the implications of new technologies, enhance compliance procedures, and develop appropriate regulations to meet the science's challenges while continuing to safeguard American agriculture, the Nation's food supply, and the environment.

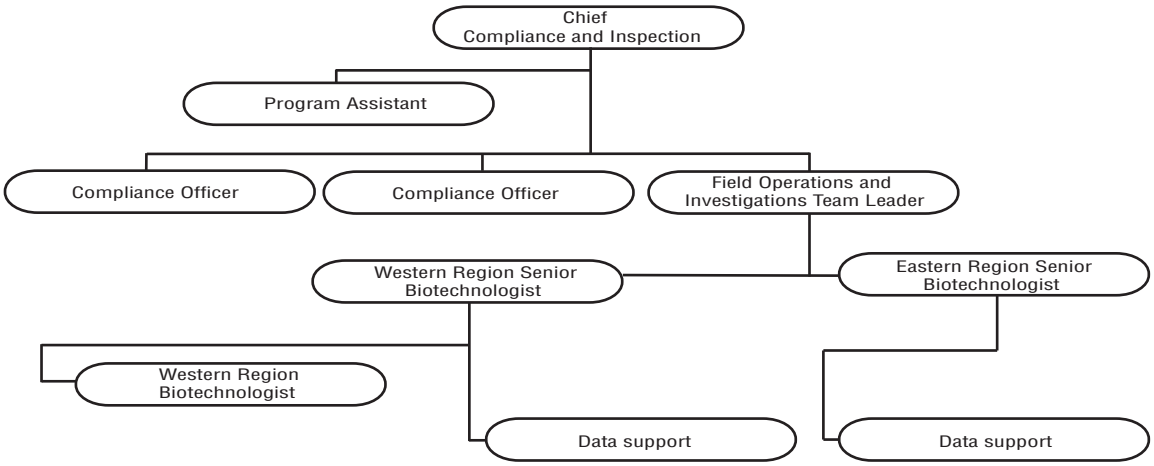
Additional Information

For more information about compliance with APHIS' biotechnology regulation and inspection of GE field tests, or to report compliance incidents, please call (301) 734–5690 or contact

USDA–APHIS–BRS
Regulatory Operations Program
Compliance and Inspections Branch
4700 River Road, Unit 147
Riverdale, MD
20737–1236
Telephone (301) 734–5690
or visit the BRS Web site at

<http://www.aphis.usda.gov/brs>.

COMPLIANCE AND INSPECTION BRANCH



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