BRS Factsheet

Biotechnology Regulatory Services

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

June 2008

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.

APHIS Biotechnology: Compliance with Regulations

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 certain genetically engineered (GE) organisms such as plants, insects, microorganisms, and any other organisms that are known to be, or could be, a plant pest.

Through its regulatory framework, BRS works to ensure the safe and confined introduction of regulated GE organisms. This is achieved in large part through BRS' Compliance and Inspection Branch (CIB). CIB is dedicated to ensuring that developers of regulated GE organisms maintain and adhere to Federal regulations and all permit conditions.

Compliance is accomplished by CIB officials through a variety of measures, including: high-quality inspections; educational and outreach efforts; comprehensive investigations and audits; prompt and uniform enforcement efforts; and voluntary quality management systems.

CIB's primary office is located at APHIS Headquarters in Riverdale, MD. Additional CIB staff are stationed in regional offices in Fort Collins, CO, and in Raleigh, NC.

CIB regional staff coordinate inspections in their respective regions, provide technical assistance and training to inspectors, and participate in field investigations. Compliance officers at headquarters facilitate clear communications with developers of regulated GE organisms about field-test conditions and requirements to ensure regulatory conformity. This work is supported by onsite inspections conducted by APHIS' Plant Protection and Quarantine (PPQ) program.

GE Field-Test Inspections

A developer wishing to introduce a regulated 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. In contrast, 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.

Based on the relative risk of each type of field trial, BRS officials determine the frequency and number of inspections to be performed. For example, BRS inspects at least one field-test release for each State listed on a permit. For field tests authorized by notifications, the BRS compliance staff uses selection criteria to identify which notifications represent the greatest risk and to choose which they should inspect.

When selecting notification field tests for inspection, BRS officials consider several factors, and assign each notification a score based on those factors. Biological and management factors used for scoring include: the type of regulated article, the acreage of plot(s), the number of sites, and the developer's recent compliance history. Notifications with the highest scores are more likely to be selected for inspection.

APHIS officials perform inspections tailored to the specific requirements for notifications and the varying types of permits. Guidelines for accomplishing each type of inspection are found in the BRS Inspection Manual. The manual provides detailed guidance on what inspectors must look for at critical points throughout the release or

movement of regulated materials. The inspection manual—along with the associated training for APHIS inspectors—contributes to the uniformity of the agency's inspections.

For permits authorizing the field trial release of organisms containing pharmaceutical and industrial compounds, BRS ensures compliance with permit conditions by performing more frequent inspections. APHIS officials inspect these field tests five times during establishment and growth, and twice in subsequent years to monitor for volunteers and to verify that developers are carefully following the conditions established by BRS.

Officials perform inspections at critical times throughout the field testing, including during pre-planting, flowering, harvesting, and postharvest. BRS maintains a comprehensive database that tracks inspection-related information to ensure that all required inspections are accomplished.

After every inspection, APHIS officials prepare detailed written reports. The BRS compliance staff then provides feedback correspondence to the permittee based on the findings documented in the inspection report. If an inspection reveals no regulatory concerns, BRS sends the permittee a Notice of Compliance.

Noncompliance Incidents

When developers do not adhere to APHIS regulations, BRS refers to these events as "noncompliance incidents." These incidents take many forms. Some involve administrative problems, such as a developer listing the wrong location 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, or planting a field-test site before a permit becomes effective.

In such cases, BRS seeks immediate corrective actions from developers to achieve compliance. For example, BRS may require a developer to destroy a planting, remove flowers, or add new identification markers to a field trial site boundary.

Typically, potential noncompliance incidents are revealed during BRS inspections or by industry self-reports to BRS. APHIS regulations require developers to report certain incidents to BRS. Additionally, other parties may report suspected noncompliance incidents to APHIS for review.

CIB enforcement staff analyze and respond to incidents. Regional biotechnologists and regulatory specialists identify potential noncompliance incidents and may initiate responses to mitigate critical situations. Situations that pose immediate threats to food, feed, or the environment require quick attention. BRS may require written corrective action plans for severe or complex incidents. Incidents reported to BRS or identified by inspection are also analyzed by headquarters staff.

This often results with officials issuing a written response to a developer. Responses fall into one of the three following categories:

- Notice of Compliance—the analysis revealed no deviations from BRS regulations or permit conditions. Notices may include observations of conditions that could lead to a future noncompliance incident and suggestions to prevent it.
- Notice of Noncompliance—the analysis revealed deviations from BRS regulations or permit conditions. BRS requests corrective action, and often requests documentation of the action taken.
- Warning Letter—the inspection revealed one or more serious deviations from BRS regulations or permit conditions.

BRS requires a written response, corrective action, and evidence of action taken within a given timeframe.

Compliance Assistance

The APHIS Biotechnology Quality Management System (BQMS) is a voluntary compliance assistance service currently under development. This program is being designed to help universities, small businesses, and large companies develop sound management practices to enhance compliance with regulatory requirements for field trials and movements of regulated GE agricultural organisms.

The BQMS program is based on an internationally recognized standard of quality management and can be implemented flexibly by the diverse members of the regulated community. The BQMS program will consist of third-party audits to verify that a participating organization has successfully established a system for managing movements and field releases of regulated GE agriculture. The program emphasizes proactive and preventive procedures.

Therefore, participants will be encouraged to correct deficiencies discovered in a system audit before compliance problems develop.

APHIS intends to oversee the BQMS program in partnership with USDA's Agricultural Marketing Service (AMS), which will manage the audit component of the program and accredit third-party auditors. USDA will not require permit applicants to participate in BQMS. The BQMS compliance assistance service—through effective outreach and verification activities integrated within the BQMS program—will help the regulated community proactively and voluntarily maintain compliance. It is designed to build participating organizations' commitment to sound controls, communication, and effective adherence to Federal requirements.

Investigations and Penalties

BRS' compliance staff works closely with APHIS' Investigative and Enforcement Services (IES) to initiate and conduct formal investigations. Together, IES and BRS officials conduct formal investigations to examine developers who may not be adhering to regulations, permit conditions, or other requirements.

Investigators also gather information regarding incidents or allegations when it is not clear whether violations have occurred. Investigative results assist with the analyses, correction, and written responses to incidents. Events that lead to formal IES investigations include:

- A serious alleged violation of regulations or permit conditions,
- A pattern of repeated alleged violations,
- A history of violations and penalties,
- A failure to carry out required corrective actions, and
- A failure to respond to a warning letter.

Formal investigation may result in BRS and IES concluding that an infraction occurred. If so, BRS officials then determine whether to begin the penalty process, which may include developing a settlement agreement.

BRS refers those cases that are criminal in nature, that are not offered for settlement, or that are not resolved by a settlement agreement to USDA's Office of General Council (OGC). OGC may file a complaint with a USDA administrative law judge seeking civil penalties against the developer, or, where appropriate, refer the case to the U.S. Department of Justice for potential criminal proceedings.

BRS posts cases resolved through completed IES investigations on the compliance history Web page. The address is http://www.aphis.usda.gov/biotechnology/compliance_history.shtml.

Additional Information

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

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