

Executive Summary

Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits (Audit Report 50601-8-Te)

Results in Brief

The number of approved applications to field test genetically engineered (GE) crops in the United States has increased significantly since 1986, when the Department began regulating experimental GE plants. Since that time, the U.S. Department of Agriculture (USDA) has approved over 10,600 applications for more than 49,300 field sites. Biotechnology companies are investing millions of dollars to develop new GE plants, some with the goal of commercializing them for use as food, feed, industrial compounds, and medicines. The rapid growth of agricultural biotechnology, and its prominent position in the public eye, increases USDA's responsibility to ensure that regulated GE plants, including their pollen and seeds, do not persist in the environment. However, as the number of approved applications to field test new GE plants continues to rise, we are concerned that the Department's efforts to regulate those crops have not kept pace.

To evaluate the Animal and Plant Health Inspection Service's (APHIS) controls over releases and movements of regulated GE plants, we visited 91 field test sites in 22 States that were either planted or harvested. We inspected the sites for compliance with APHIS' requirements for the growing or postharvest season. We found that APHIS, the USDA agency that oversees biotechnology regulatory functions for the Department, needs to strengthen its accountability for field tests of GE crops. In fact, at various stages of the field test process—from approval of applications to inspection of fields—weaknesses in APHIS regulations and internal management controls increase the risk that regulated genetically engineered organisms (GEO) will inadvertently persist in the environment before they are deemed safe to grow without regulation.

Accountability for GE Crops Needs Improvement

Depending on the nature of the GE crop, APHIS authorizes field tests through two methods: permits and notifications. For field tests of high-risk GE crops, such as those designed to produce pharmaceutical and industrial compounds, APHIS issues permits. For GE crops that APHIS considers low-risk based on its scientific experience with the plants, applicants can use the more streamlined notification process. We found, however, that APHIS lacks basic information about the field test sites it approves and is responsible for monitoring, including where and how the crops are being grown, and what becomes of them at the end of the field test.

- Of primary concern, the precise locations of all GE field test sites planted in the United States are not always known. After authorizing field tests,

APHIS does not follow up with all permit and notification holders to find out exactly where the fields have been planted or if they have been planted at all. In some cases, APHIS may only be aware of the State and county where an applicant plans to conduct a field test. Without knowing the locations of all planted field test sites, including their global positioning system (GPS) coordinates, APHIS cannot effectively monitor permit and notification holders' compliance with field test requirements. In January 2005, APHIS issued a memorandum that requested notification holders to voluntarily submit GPS coordinates or other information to identify the field test after planting.

- Before approving field tests, APHIS does not review notification applicants' containment protocols, which describe how the applicant plans to contain the GE crop within the field test site and prevent it from persisting in the environment. Instead, APHIS allows notification holders to provide the protocols verbally if their field test sites are selected for inspection. Since notifications comprise the vast majority of field test authorizations, this policy undermines both the field test approval and inspection processes.
- At the conclusion of the field test, APHIS does not require permit holders to report on the final disposition of GE pharmaceutical and industrial harvests, which are modified for nonfood purposes and may pose a threat to the food supply if unintentionally released. As a result, we found that two large harvests of GE pharmaceutical crops remained in storage at the field test sites for over a year without APHIS' knowledge or approval of the storage facility.

In addition, APHIS does not thoroughly document its reviews of applications in the official files. Specifically, APHIS biotechnologists do not sufficiently document their review process and scientific basis for approving initial field test applications. APHIS also does not effectively track information required during the field tests, including approved applicants' progress reports, which should contain the results of field tests, including any harmful effects on the environment. Although we noted that many permit and notification holders submit these required progress reports late or not at all, APHIS does not always follow up to obtain the information.

Weaknesses in Inspections and Enforcement

APHIS' field test inspection process can be improved in a number of areas. Inspection requirements are vague and there is a lack of coordination between the two APHIS units responsible for the inspection program, Biotechnology Regulatory Services (BRS) and Plant Protection and Quarantine (PPQ). BRS is responsible for overall management of the program, while PPQ officers perform most of the actual inspections of GE field test sites. We found that BRS does not have a formal, risk-based process for selecting individual sites

for inspection, and that PPQ does not complete all of the inspections BRS requests, including inspections of pharmaceutical and industrial crops.

For example, we found that PPQ did not inspect all pharmaceutical and industrial field test sites five times during the 2003 growing season, as APHIS has announced to the public. APHIS has also stated publicly that pharmaceutical and industrial field test sites would be inspected twice during the postharvest period, or the year following the end of the field test, during which the field must be monitored for regrowth of the GE crop. In one case, a violation at a pharmaceutical field test site in our sample went undetected because PPQ did not perform the required inspections at that site during the 2003 postharvest monitoring period.

Further contributing to the inspection problem, neither BRS nor PPQ kept track of the total number of inspections that are actually completed. Although APHIS agreed to improve its tracking of inspection reports following an Office of Inspector General (OIG) audit more than 10 years ago, the agency continued to lack an effective, comprehensive management information system to account for all inspections and their outcomes. In fact, we found 11 violations that were not recorded in BRS' compliance infractions database at the time of our audit, even though they were reported to BRS or could have been identified from information BRS already had. APHIS took administrative action on only 1 of those 11 violations.

APHIS subsequently advised us that in September 2004, it had implemented some changes in the inspection process that included an agreement between BRS and PPQ that clarified responsibility for conducting inspections. BRS also developed a methodology for selecting notifications for inspection based upon risk. However, our review of the agreement between BRS and PPQ found that it did not include inspections of nonpharmaceutical and nonindustrial permits. BRS continues to select entire permits and notifications for PPQ to inspect which may cover numerous field test sites. Consequently, BRS has no assurance that the highest risk field sites are inspected. Also, BRS initiated an interim inspection tracking system in February 2005, during our audit, but the effectiveness of this system has not been reviewed or tested by the OIG.

Even if APHIS improves its inspection process, we found that APHIS has not updated its regulations to reflect the Plant Protection Act of 2000, under which APHIS carries out its biotechnology oversight duties. Also, an Office of the General Counsel official advised us that APHIS currently does not have legislative authority to hold applicants financially responsible for costs incurred by USDA due to an unauthorized release of regulated GEOs. Because APHIS cannot require applicants to provide proof of financial responsibility before it authorizes field tests, USDA may have to bear the expense of removing GE material from the environment in the event of an unintentional release.

Inadequate Guidance for Containing GE Crops and Seeds

Finally, we found that APHIS guidance should be strengthened to prevent the persistence of GE crops outside the field test. For example, APHIS does not specify when GE crops must be destroyed, or “devitalized,” following the field test. Approved applicants sometimes allow harvested crops to lie in the field test site for months at a time, their seeds exposed to animals and the elements. Also, because APHIS has not specifically addressed the need to physically restrict edible GE crops from public access, we found a regulated edible GE crop, which had not gone through the Food and Drug Administration’s regulatory process for approval for human consumption, growing where they could easily be taken and eaten by passersby.

GE crops have come to play an important role in American agriculture, and many crops currently being field tested will eventually be approved as safe to grow and eat without regulation. However, while they remain under USDA’s jurisdiction, GE crops and harvests—especially those developed for pharmaceutical and industrial purposes—must be carefully regulated. Although we noted relatively few violations of existing requirements at the time of our field visits, we concluded that APHIS’ current regulations, policies, and procedures do not go far enough to ensure the safe introduction of agricultural biotechnology. To meet its strategic goals and inspire public confidence in USDA’s biotechnology regulatory program, APHIS must continue to refine and strengthen the GEO field release process.

Recommendations In Brief

To maintain accountability for regulated GE crops, APHIS needs to require more information both prior to and during the field test. Specifically, APHIS needs to:

- obtain GPS coordinates of all planted field test sites, enabling APHIS to identify where regulated GE crops are planted at any given time;
- obtain all applicants’ scientific protocols for conducting field tests;
- obtain reports on the final disposition of high-risk pharmaceutical and industrial harvests; and
- seek legislative authority to require permit applicants, based on the level of risk, to provide proof of financial responsibility, in the event of an unauthorized GEO release.

To strengthen monitoring of GE field test sites, APHIS needs to formalize its inspection process and assign and coordinate the responsibilities of BRS and PPQ. APHIS also needs to update its regulations and develop a comprehensive management information system for tracking the receipt and review of all information associated with GEO release permits and notifications.

Finally, to make sure that approved applicants take appropriate steps to prevent GE crops from proliferating outside the field test site, APHIS needs to develop guidance that specifically addresses devitalization deadlines and edible crops.

Agency Response

In its response dated November 2, 2005, APHIS officials generally agreed with OIG's recommendations and have completed or began implementing 23 of the 28 recommendations in the report.

APHIS is in the process of requiring GPS coordinates of each field site on the 28-day planting reports, requiring the reporting of the disposal of GE pharmaceutical and industrial harvest in the field report submitted 21 days prior to harvest, and obtaining a determination from the Office of the Secretary to seek legislative authority to require applicants to provide proof of financial responsibility in the event of an unauthorized GEO release.

APHIS has established a Memorandum of Understanding (MOU) between BRS and PPQ to formalize inspection responsibilities, better coordinate inspections in regions, and ensure inspections are completed in a timely manner. APHIS is in the process of updating, consolidating and clarifying its regulations in regards to GE regulated field releases and incorporating provisions of the Plant Protection Act of 2000. APHIS has also designed a single management information system for tracking permit and notification inspections and field test reports.

APHIS disagreed with recommendations associated with obtaining notification applicants' scientific protocols for conducting field tests, reviewing these protocols by biotechnologists, and distributing these protocols to PPQ officers to use in conducting inspections of field sites under notification. APHIS also contends that the current system of performance-based regulatory standards for notifications is effective at protecting the American agriculture. Lastly, APHIS did not agree with developing policy guidelines for restricting public access to edible regulated crops when conducting field tests and with developing policies and procedures for selecting specific field test sites for inspection based on risk.

OIG Position

We generally concur with APHIS' response for 23 of the 28 recommendations in the report and have reached management decision on one recommendation. Actions necessary to reach management decision on the remaining recommendations are discussed in the Findings and Recommendations sections.

APHIS stated that its current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. We believe that these performance-based regulatory standards do not preclude submission of protocols to APHIS prior to approval of the field test. By not obtaining copies of the protocols, APHIS is relinquishing its

regulatory responsibility in favor of self-certification by the notification applicants—namely, the applicants merely certify in their notification applications that they will meet the performance standards. Further, approved protocols are important control documents that PPQ officers should receive from BRS before they perform an inspection.

Although APHIS disagreed with developing policy guidelines for restricting public access to field tests of edible regulated GE crops, APHIS' strategic plan states that its mission includes protecting human health and safety. The edible GE crops under APHIS' jurisdiction are regulated and, therefore, we believe that access should be controlled. Edible regulated GE crops cannot be grown without restrictions and should not be available even for unauthorized human consumption, while still regulated.

Although two APHIS units, BRS and PPQ, share responsibility for inspections of field test sites, BRS is responsible for the overall inspection process. However, under the current site selection process, once BRS has selected a notification or permit for inspection PPQ is then allowed to choose the specific inspection site. The National Academy of Sciences states that risks must be assessed according to the organism, trait, and environment. Thus, the environment is an important risk factor which BRS should use in the selection of field sites for inspection to ensure that the highest risk sites are always selected.