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Southwest Region

Audit Report

Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits

Audit 50601-8-Te
December 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

DEC 8 2005

REPLY TO
ATTN OF: 50601-8-Te

TO: W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

ATTN : William J. Hudnall
Deputy Administrator for Marketing and
Regulatory Programs – Business Services

FROM: Robert W. Young /s/
Assistant Inspector General for Audit

SUBJECT: Controls Over Issuance of Genetically Engineered Organism Release Permits

This report presents the results of the subject audit. Your written response to the draft report, dated November 2, 2005, is included in its entirety as exhibit A with excerpts and the Office of Inspector General's (OIG) position incorporated into the relevant Findings and Recommendations sections of the report.

Based on your response, we accepted management decision on Recommendation 25. Please follow Departmental and your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer, Director, Planning and Accountability Division (OCFO/PAD).

Although we agree with most of the other planned corrective actions, we could not accept management decision on all other recommendations. Documentation and actions needed to reach management decisions for these recommendations are described in the OIG Position section of the report.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementing those recommendations for which management decision has not been reached. Please note that the regulation requires a management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management

decision to prevent being listed in the Department's annual Performance and Accountability Report.

We appreciate your timely response and the courtesies and cooperation extended to us by members of your staff during the audit.

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.

Abbreviations Used in This Report

APHIS	Animal and Plant Health Inspection Service
BBEP	Biotechnology, Biologics and Environmental Protection
BIDS	Biotechnology Integrated Database System
BRS	Biotechnology Regulatory Services
CFR	Code of Federal Regulations
EIS	Environmental Impact Statement
GE	Genetically engineered
GEO	Genetically engineered organism
GPS	Global positioning system
MOU	Memorandum of Understanding
OIG	Office of Inspector General
PPQ	Plant Protection and Quarantine
USDA	United States Department of Agriculture

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Background and Objectives

Background

Through modern biotechnology, also called genetic engineering, scientists can transform the genetic makeup and function of one organism by inserting genetic material from another organism. Agricultural biotechnology sometimes involves modifying the genetic material of one species with genes from another species—plant or nonplant—producing transgenic crops with traits not found in nature or traditional crossbreeding. For example, corn altered with a bacterial gene to produce its own insecticide has become one of the most common genetically engineered (GE) crops, along with GE soybeans and cotton. In addition to food and feed, GE crops are being developed to produce a variety of pharmaceutical and industrial substances.

In recent years, the number of acres of regulated GE plants for which the U.S. Department of Agriculture (USDA) has oversight responsibilities has increased markedly, from over 8,700 acres proposed for 1994 to over 67,000 acres proposed for 2004.

Federal Oversight of GE Crops

USDA shares responsibility for regulating biotechnology in the United States with two other Federal agencies. The Environmental Protection Agency oversees GE plants that produce their own pesticides, while the Food and Drug Administration regulates food and feed products produced from GE crops. USDA's Animal and Plant Health Inspection Service (APHIS) oversees the environmental release of new GE plants and determines whether they are safe to grow. Within APHIS, the Biotechnology Regulatory Services (BRS) unit carries out the agency's biotechnology oversight responsibilities under the Plant Protection Act of 2000,[1] which replaced the Federal Plant Pest Act and the Plant Quarantine Act.

APHIS regulations[2] in Title 7, Code of Federal Regulations (CFR), part 340 dated January 1, 2003, focus on whether a genetically engineered organism (GEO) is a plant pest. Based on APHIS' broad definition of "plant pest,"[3] almost all GEOs are considered "regulated articles"[4] that must meet APHIS requirements for introduction into the environment. APHIS approves and monitors introductions of regulated GE crops—specifically, movements into and through the United States and field tests. After conducting a field test of a

[1] 7 United States Code 7701-7772, dated June 20, 2000

[2] Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests"

[3] APHIS defines a plant pest as "Any living stage of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."

[4] Organisms and products altered or produced through genetic engineering that are plant pests, unclassified organisms, or organisms whose classifications are unknown.

GEO, developers may petition APHIS, requesting that the article no longer be regulated under 7 CFR 340, dated January 1, 2003. More than 60 GEOs, such as Roundup Ready® cotton, corn, and soybeans, have received deregulated status.

Notifications and Permits: The Approval Process

Before conducting a field trial of a new GE crop, developers must apply for APHIS approval through one of two processes: notification or permit.

Notifications, the most common application method, are used to introduce certain familiar GE plants that do not present novel plant pest risks.[5] APHIS biotechnologists determine whether the GE plants meet the six eligibility criteria for the notification approach. Specifically, to qualify for introduction under a notification, the plant must not:

- be listed as a noxious weed;
- be transformed with genetic material that has not been stably integrated into the plant genome;
- contain genes of unknown function;
- cause the production of an infectious entity, be toxic, or be intended for pharmaceutical use;
- pose a significant risk of creating any new plant virus; and
- contain genetic material from animal or human pathogens.

Under this streamlined approach, which APHIS began offering in 1993, applicants must notify APHIS at least 30 days in advance of planting. In 2004, almost 97 percent[6] of all field trials of regulated GE crops were conducted under notifications.

In comparison to notifications, the permit process—for GE plants that do not meet the six notification eligibility criteria—requires more detailed information from the applicant. Applications for permits must be submitted at least 120 days in advance of the proposed release. Currently, permits are required for the introduction of transgenic plants that APHIS considers to pose greater safety risks—for example, those that produce pharmaceutical or industrial compounds, or those modified with human genes.

To obtain a notification, an applicant must meet certain eligibility and performance standards. The eligibility standards describe the kinds of GE plants that can be introduced in a field test. The performance standards outline general guidelines for planting, growing, harvesting, and shipping

[5] Transgenic plants that meet the eligibility criteria specified in 7 CFR 240.3(b)1-6, dated January 1, 2003
[6] Of 959 total approved applications, 930 were notifications.

GE crops to ensure the plant and its progeny will not persist in the environment outside the field trial.

To obtain a permit, an applicant must submit its proposed field test to be reviewed and approved by APHIS on a case-by-case basis. There are no eligibility requirements and no performance standards in the regulations for GE plants grown under permits.

Applicants for notifications and permits must develop protocols specifying how they will conduct the field trial to meet the performance standards. Protocols contain information specific to the applicant's field test, such as:

- how the applicant plans to isolate the GE crop from neighboring non-GE crops (for example, through border rows of non-GE crops);
- how the applicant plans to devitalize (destroy) or otherwise dispose of the crop at the conclusion of the field test; and
- how the applicant plans to monitor the field for volunteers (regrowth of the GE crop on the field test site following the field test).

APHIS biotechnologists review permit and notification applications and forward a summary of their review and recommendations to the biotechnology regulatory officials in the State where the field trial is to be conducted. Once those officials have approved the applications, APHIS issues the permits and notifications authorizing the field tests. According to the APHIS website, APHIS approved 45 permits and 1,929 notifications from October 2001 through September 2003. Current APHIS policy allows applicants to file one application for multiple field release sites in many different States.

Reporting, Inspections, Movements, and Infractions

For both permits and notifications, approved applicants must submit field test results to APHIS within 6 months of the completion of the field test. Depending on the nature of the permit or notification, APHIS may also require approved applicants to submit other progress reports during the field test. Reporting requirements vary depending on the acreage and location of the GE material and the company requesting the permit or notification. The following table shows some of the progress reports APHIS may require.

Report Type	Information Included	Required For
Planting notice	Advance notice of when and where the crop goes in the ground (7-10 days prior to planting)	Most pharmaceutical and industrial permits, some other permits
4-week/28-day report	Number of plants actually planted, GPS coordinates of the field, distance to nearest sexually compatible crop	Most pharmaceutical and industrial permits, some other permits
Harvest/termination notice	Anticipated harvest of the crop	Most pharmaceutical and industrial permits, some other permits
Monitoring report	Dates of visits to field, number and disposition of volunteers observed (if any)	Some permits
Field test data/ 6-month report	Methods of observation, resulting data, analysis of deleterious effects on other plants, organisms, and the environment	Required by regulation for all permits and notifications
Notice of decision not to plant	Cancellation of a planned field test site	Notifications (requested)

To ensure that approved applicants are complying with permit and notification conditions, APHIS may conduct inspections of field test sites and storage locations. APHIS' BRS works with Plant Protection and Quarantine (PPQ), a separate APHIS unit, to monitor field test sites. Although BRS biotechnologists inspect some pharmaceutical field test sites and other sites authorized under permits, PPQ officers conduct most of the inspections.

Like field tests, movements of regulated articles, such as GE seeds, are authorized under permits and notifications. Approved applicants must take measures to minimize dissemination of GEOs into the environment during movement and while in the receiving facility. BRS may arrange an inspection of the receiving facility to verify that it is adequate to prevent release of the regulated article into the environment.

Failure of applicants to submit complete and accurate information for all permit activities or to comply with performance standards may result in a fine of up to $250,000, imprisonment for up to 5 years, or both. Failure to comply with performance standards under permit or notification conditions can also result in compliance infractions, and the applicant can be ordered to take remedial action to prevent the spread of plant pests and/or be fined.

Evolution of APHIS Biotechnology Oversight

APHIS' biotechnology regulatory operation has undergone several reorganizations since its inception in 1987. Prior to 1997, APHIS assigned biotechnology functions to its Biotechnology, Biologics and Environmental Protection (BBEP) unit. In 1997, APHIS reassigned those functions to its PPQ unit. In June of 2002, APHIS consolidated all plant biotechnology activities into the current biotechnology unit, BRS.

In 1994, USDA's Office of Inspector General (OIG) issued an audit report[7] to BBEP. The report identified problems with APHIS' oversight of GEOs—specifically, a lack of procedures to track inspection reports and follow up on violations or potential violations. BBEP generally agreed with the recommendations to improve management and handling procedures and to create a new management information system for tracking permit and notification information.

Objectives

The objectives of our audit were to determine whether APHIS' controls provide reasonable assurance that movements and releases of GEOs in the environment are in accordance with laws, regulations, and departmental procedures, and that they are effective in minimizing the inadvertent release of GEOs in the environment. As part of our overall assessment, we evaluated APHIS' controls over the application process, management and oversight of field tests, and enforcement.

[7] Audit Report 33099-9-Hy, dated August 1994

Findings and Recommendations

Section 1. Overall Assessment

Finding 1 — APHIS Needs a More Cohesive Formal Process to Manage GEO Field Releases

As USDA's regulatory gatekeeper for GEO field tests and shipments, APHIS is tasked with establishing effective controls to prevent the inadvertent release of regulated GE material. APHIS has relied heavily on a case-by-case assessment of the risks related to each GE field release, and it has assured the public that its controls over the field test process are rigorous and effective. However, we found that APHIS' current approach is not sufficient to manage field releases of regulated GE crops. At some critical stages of the process, from the initial review and approval of applications to inspections of field test sites and enforcement activities, APHIS lacks clear, comprehensive requirements and effective internal controls to minimize the risk of inadvertent release of GEOs into the environment.

Since 1986, APHIS has authorized more than 49,300 proposed field tests of experimental GE crops. According to APHIS officials, even the agency's critics have acknowledged that no demonstrable negative environmental impacts have arisen from the field tests that have been planted. Our field test site visits indicated that developers of regulated GE crops have, on the whole, complied with APHIS' broad requirements for field tests. At the 91 sites[8] we visited, we found 13 instances of noncompliance at 11 sites. We also learned of two additional violations at sites we did not visit. The only widespread violation we identified pertained to 193 movements of GE seeds, which APHIS allowed to be shipped in nonmetal containers, in violation of its own requirements.

Our audit revealed that the agency needs to work toward a more cohesive formal process for managing GEO field releases.

Gaps in Field Test Requirements

We found that APHIS guidance for conducting field tests is neither consolidated nor comprehensive. APHIS regulations[9] governing field releases do not include specific requirements to guide applicants during all phases of the process. To supplement the regulations, APHIS has issued guidance in various other forms, including Federal Register notices, memoranda, the APHIS website, and a manual for companies conducting

[8] Selected from a universe of 1,020 field test sites, which we developed (see Scope and Methodology)
[9] 7 CFR 340, dated January 1, 2002 and 2003

field tests. Yet, for some critical aspects of the field test process, APHIS has not established any specific requirements, either formal or informal.

For example, APHIS has not addressed the need for approved applicants conducting field tests to restrict public access to edible GE crops. Regulated GE crops are not distinguishable from traditional crops and have not been approved as safe to grow without regulation. In the absence of specific guidance, we found that one applicant planted regulated edible GE crops in an open field, where they were accessible to the public from a road and an adjacent nonregulated field.

Similarly, APHIS has not addressed the need for approved applicants conducting field tests to:

- provide the exact location of each planted field test site (see Finding 2);
- set a timeframe for disposing of harvests of high-risk GE crops at the end of the field test (see Finding 7); and
- promptly destroy GE crops at the conclusion of the field test so that their seeds do not spread outside the field test site (see Finding 8).

By closing these gaps in its existing guidance, APHIS can reduce the probability that GE crops will be inadvertently released into the environment, where some may persist unchecked.

Need for Greater Consistency in Communication and Implementation of Policy

We found that APHIS' public policy on the frequency of field test inspections differs from its actual practice. In the March 10, 2003, Federal Register, APHIS announced that it would "increase the number of inspections" during the 2003 growing season so that field test sites planted under pharmaceutical and industrial permits may be inspected seven times—up to five times during the growing season and twice during the postharvest period. In a press conference, an APHIS official demonstrated the agency's commitment to this goal by reiterating this policy for pharmaceutical crops: "Every test site will be inspected at least five times during the growing season and two times in the following season." However, for the 2003 growing season, APHIS did not conduct five inspections at each pharmaceutical and industrial field test site in our sample (see Finding 5).

APHIS has also understated to the public the percentage of inspected sites with compliance infractions. At the time of our audit work, APHIS reported on its website a 1.6 percent noncompliance rate for 7,402 authorizations of field tests. However, we found that "authorizations" represented the total number of approved permits and notifications, not all of which were planted, rather than the number of planted fields inspected by PPQ or reported to

APHIS by approved applicants. Since APHIS presents this noncompliance rate as evidence of its monitoring program's effectiveness, it is critical that APHIS report only the noncompliance rate on planted fields actually inspected by PPQ or reported by approved applicants.

In another inconsistency, we found that APHIS disregards its own regulations for shipments of GE seeds. Federal regulations require double metal containers for shipments of regulated GE material, regardless of whether the shipments are made under permits or notifications. According to the regulations, shippers can request a variance from the metal container requirement if they justify their request. On its website and in the user's manual for introductions, however, APHIS allows shippers to forgo using metal containers for regulated articles shipped under notifications. APHIS also allows permit holders to forgo using metal containers without obtaining formal variances. As a result, we found widespread use of nonmetal containers, such as bags and boxes, for shipping GE seeds. Metal containers were not used for any of the 199 interstate shipments in our sample (81 shipments under permits and 118 shipments under notifications). Only 6 of those shipments (2 shipments under a permit and 4 shipments under notifications) received variances from APHIS, leaving 193 shipments in violation of the regulations. To avoid inconsistent interpretation of its regulations, APHIS needs to clarify its regulations for shipments of GE seeds.

Enforcement Ability Limited by Incomplete Regulations

To make its requirements transparent to the public and enable it to take enforcement action when necessary, APHIS needs to assemble its various pieces of guidance in a comprehensive set of regulations. Especially in the sensitive area of GE crops, APHIS needs to ensure that its field release requirements are complete, consistent, subject to public scrutiny, and enforceable by regulation.

We noted that APHIS has not finished updating its regulations to comply with the Plant Protection Act of 2000, which was enacted on June 20, 2000. On July 16, 2001, APHIS partially updated its regulations to include the new authority of the Secretary of Agriculture to subpoena documentary evidence and witnesses to prosecute violators. APHIS still needs to update its regulations to reflect other provisions of the Act, which grant new regulatory authority to the Secretary of Agriculture for controlling noxious weeds. On January 23, 2004, APHIS began the process of updating its regulations by announcing in the Federal Register that it would prepare an environmental impact statement (EIS), in connection with potential changes to the regulations, regarding the movement and release of certain GEOs.

Internal Management Needs Improvement

Besides clarifying its regulations governing GE crops, APHIS needs to strengthen its internal processes for managing the field release program. Of greatest concern, APHIS' BRS has divided responsibility for monitoring field test sites between itself and PPQ; although BRS has overall control of the inspection program, it shares the authority to conduct inspections with PPQ. APHIS, however, has not clearly delineated the mutual responsibilities of BRS and PPQ in regard to inspections of GE field test sites. In the absence of an integrated, coordinated process between the two APHIS units, we found that PPQ was not performing the majority of inspections requested by BRS (see Finding 5). Although BRS and PPQ signed a MOU in September 2004, the MOU did not cover inspections of nonpharmaceutical and nonindustrial release permits, as well as movement permits. It also did not commit BRS to provide PPQ with planted notification sites to be inspected, nor did it require PPQ to perform all inspections requested by BRS.

Additionally, BRS and PPQ sometimes failed to follow their own internal procedures for reporting and enforcing noncompliance with regulations. We found that PPQ officers did not always prepare inspection reports or report violations found during our joint reviews. In addition, BRS received six reports of violations from PPQ officers, companies, and OIG. BRS also had other information in its files that it could have used to identify five additional violations. Thus, for 11 of the 15 violations identified during our audit, BRS had enough information to take administrative action, such as issuing a letter of warning. However, our review of BRS' compliance infraction database found that, as of December 17, 2003, none of the 11 violations was recorded. Although we found that BRS sent a guidance letter on 1 of the violations, it took no action on the other 10 violations (see Finding 5).

BRS advised us that, in 2004 and 2005, a new compliance branch subsequently began following up on compliance reports by auditing, reviewing, analyzing, and closing over 30 alleged violations.

APHIS also needs to further refine its procedures for selecting field test sites for inspection. At the time of our audit, the selection procedures were undocumented. APHIS advised us that, in April 2004, it began assigning risk scores to notifications, using a documented methodology, in order to direct PPQ inspections to higher risk GEOs. However, as before, the lists of notifications did not identify the exact locations of planted sites. Instead, the lists identified only the number of sites in each State. An APHIS official told us that APHIS plans to modify the risk scoring system as the agency gains experience with it.

Finally, we found that APHIS needs to document its procedures for approving applications—a function currently left to the judgment of

individual APHIS biotechnologists. To manage and track the volume of field test information it receives and reviews, APHIS also needs an effective, comprehensive management information system. At the time of our audit, APHIS lacked such a method of tracking field test data, including inspection reports and field test progress reports (see Findings 5 and 6). In 2005, APHIS implemented an interim inspection tracking system pending implementation of a comprehensive management information system.

We concluded that, to establish a cohesive oversight process for GE field releases, APHIS must continue to strengthen both its regulations and its internal management practices.

Recommendation 1

Revise and consolidate policies, procedures, and regulatory requirements for GE field releases.

Agency Response.

APHIS stated that this recommendation is consistent with the priorities set by BRS, including the revision of its regulations. APHIS stated that it will publish a draft programwide EIS in early 2006 and a proposed rule will follow. Rules are developed through public notice and comment, and therefore can take several years for completion. In addition, BRS has begun the consolidation and revision of guidance materials into a single *User's Guide* and expects to have a draft version completed in the spring of 2006.

OIG Position.

We agree with APHIS' planned corrective actions. To reach management decision, APHIS needs to provide estimated timeframes for implementation of the new regulations and the revised *User's Guide*.

Recommendation 2

Revise and clarify policies and regulations regarding the use of metal shipping containers.

Agency Response.

APHIS stated that it will clarify the shipping container requirements for permits and notifications in the revised regulations and *User's Guide*. BRS has begun the consolidation and revision of guidance materials into a single *User's Guide* and expects to have a draft version completed in the spring of 2006.

OIG Position.

We agree with APHIS' planned corrective actions. To reach management decision, APHIS needs to provide estimated timeframes for the implementation of the revised regulations and *User's Guide*.

Recommendation 3

Update regulations to incorporate the provisions of the Plant Protection Act of 2000.

Agency Response.

APHIS stated that it will publish a draft programwide Environmental Impact Statement (EIS) in early 2006. The EIS lays the foundation for a proposed rule to follow. The rule will include the provisions of the Plant Protection Act of 2000.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide an estimated timeframe for implementation of the new regulations.

Recommendation 4

Prioritize completion of the management information systems to track all information on permits and notifications.

Agency Response.

APHIS stated that BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, the Biotechnology Integrated Database System (BIDS), is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide the estimated timeframe for implementation of the ePermits tracking system and BIDS. Specifically, for the ePermits tracking system, APHIS needs to provide the estimated

completion dates for each phase of the ePermits tracking system: notification submissions, permit submissions, PPQ remote access to design protocols, and PPQ access to BRS imposed field test requirements.

Recommendation 5

Develop policy guidelines that address restricting public access to edible regulated GE crops, based on the risk of the type of crop, when conducting field tests.

Agency Response.

APHIS disagrees with this recommendation. APHIS understands that the intent of this recommendation is to assure food safety. However, APHIS stated that the system of science-based risk assessment that is currently in place already addresses this issue. BRS can, for example, use permit conditions to require restricted access for any special cases where it might be deemed appropriate based on risk. The need for restricted access is most effectively addressed on a case-by-case basis where the biotechnologist can consider the type of trial, potential risks of the organism, and other information specific to the permit such as the exact site and locale.

FDA has supported the APHIS requirements and practices for edible regulated GE crops that have not undergone or completed FDA food safety review. FDA has authority over the safety of plant foods, including food from deregulated GE plants.

OIG Position.

We can not accept APHIS' management decision for this recommendation. To reach management decision, APHIS needs to provide its science-based risk assessment of regulated GE crops. APHIS also needs to provide FDA's food safety review and approval of APHIS requirements and practices for edible regulated GE crops.

Although APHIS is responsible for overseeing regulated GE crops and seeds, we found that, during the application process, the agency does not obtain certain critical information that it needs to carry out its oversight responsibility. Instead, APHIS relies on permit and notification holders to supply the necessary information at the time of field test inspections. Furthermore, we found that APHIS biotechnologists do not thoroughly document their scientific reviews of the information that applicants are required to submit.

Companies and organizations that wish to field test a regulated GEO must obtain APHIS approval by applying for either a permit or notification.

- The notification procedure is a simple, streamlined method of obtaining APHIS permission to introduce GEOs that APHIS considers relatively low-risk. To qualify, GEOs must meet specific eligibility criteria established by APHIS, and the applicant must agree to comply with performance standards designed to ensure biological confinement of the GE crop.[10]

- GE crops that do not qualify for the notification process require permits, which are used for experimental plants that APHIS considers higher risk, such as plants that produce pharmaceutical and industrial compounds. Permit applications require more detailed information about the field test, and APHIS evaluates them more closely than applications for notifications.

We found that APHIS is not aware of the locations of all planted GE field test sites, weakening its oversight of the field release program. APHIS does not always require permit and notification applicants to identify the precise location of field sites where they plan to plant experimental GE crops, nor does it follow up with approved applicants to obtain this information once the crops are in the ground. In fact, APHIS may know only the business address or State and county where the field is planted. We also found that, even though the vast majority of field tests are conducted under notifications, notification applicants are not required to submit their written protocols, which describe how the applicant plans to contain the GE crop within the field test site. Instead, APHIS allowed applicants to verbally discuss their written protocols at the time APHIS conducted its field test inspections. On May 2, 2005, APHIS revised its approval letter for notifications to require written protocols at the time of inspection.

[10] Performance standards are detailed in 7 CFR 340.3©, dated January 1, 2003.

Given the increasing numbers of field test applications each year—from 9 requested applications in 1987 to over 950 in 2004—APHIS must take action to strengthen its controls over the application process.

Finding 2 Locations of Planted GE Field Test Sites Are Not Always Known

APHIS cannot fulfill its responsibility to oversee GE field tests without knowing the exact locations of planted field test sites. We found that APHIS does not consistently collect precise location information during the field test process, either at the time of application or while the field test is underway. For our sample of 91 field tests,[11] the applications did not disclose the exact locations. In fact, we found that four companies that held either a permit or notification did not have location information readily available for some of their planted field test sites. APHIS' lack of a master list identifying where GE crops are planted impairs its ability to monitor compliance with field test requirements.

Precise Locations Not Included in Application

APHIS regulations in effect during 2002 and 2003 state that applicants requesting approval to field test a regulated article under the notification process must provide the field site location for the release.[12] Applicants requesting a permit are required to provide a detailed description of the field trial location of the regulated article.[13] Despite the regulations, APHIS officials told us that applicants cannot determine the exact site locations with any accuracy prior to planting. Because the regulations do not specify the kind of location information applicants must submit, APHIS receives a variety of location descriptions, many of which are not sufficient to locate the field test site. Of the 23 permit applications[14] we reviewed, 85 percent indicated the company's business address as the planting location. Of the 28 notification applications[15] we reviewed, none specifically identified field site locations.

On January 14, 2004, APHIS issued a letter to pharmaceutical and industrial permit applicants that provided new and updated instructions for submitting a permit application. Specifically, the letter required submission of GPS coordinates for all field test sites, after planting, to establish the boundaries of the site. However, the new requirement for GPS coordinates does not extend

[11] Selected from an universe of 1,020 field test sites, which we developed (see Scope and Methodology).
[12] 7 CFR 340.3(d)(2)(iii), dated January 1, 2002 and 2003
[13] 7 CFR 340.4(b)(11), dated January 1, 2002 and 2003
[14] Selected from a universe of 32 permits, which we developed (see Scope and Methodology)
[15] Selected from a universe of 228 notifications, which we developed (see Scope and Methodology)

to notifications or permits other than pharmaceutical and industrial.[16] On January 24, 2005, APHIS issued a memorandum that requested, but did not require, notification holders to submit GPS coordinates or other information to identify the site after planting, effective April 5, 2005. A BRS official advised us that the notification holders currently provide this information voluntarily, because the regulations do not require them to submit it.

Supplementary Reports Inconsistent on Location

Because any location information included in the application is submitted before planting takes place, APHIS needs additional information to locate the field test sites that have actually been planted. Based on the biotechnologist's review of the permit application and experience with the applicant, APHIS can require permit applicants to provide supplementary reports. However, we found that, like the field test applications, these supplementary reports do not always require specific location information that would allow APHIS to easily locate the field test sites. Furthermore, APHIS does not uniformly require these reports for all permits, and they are not required at all for notifications.

Two of the supplementary reports that APHIS requires from some approved permit applicants are planting notices and 4-week/28-day reports. The planting notice indicates when a crop is about to be planted, and the 4-week/28-day report provides more detailed information on the field location once the field test is underway. Our review of 53 permit field sites included 20 field sites planted under 13 pharmaceutical and industrial permits**.** All 13 permit holders were required to submit planting notices and 12 were required to submit 4-week/28-day reports. However, only 8 of those 12 permit holders were required to provide GPS coordinates on their 4-week/28-day reports; three failed to provide this information. Although not required to do so by APHIS, one permit holder indicated the specific field site location on the planting notice.

In addition to planting notices and 4-week/28-day reports, APHIS may also require permit holders to submit harvest/termination notices, which inform APHIS of the anticipated harvest date for the GE crop. APHIS also requests, but does not require, that approved notification applicants provide 5 days' notice if they decide not to proceed with field testing at an approved location; approved permit applicants are not required to notify APHIS if they decide not to plant at a proposed field test location. Because it does not always require harvest/termination notices and decisions not to plant from all permit and notification holders, APHIS was not aware that 30 of the approved field test sites in our sample had not been planted or that 8 sites had been harvested. Without knowing which proposed field test locations have not

[16] The letter also applies to bioremediation permits, which were not covered in this audit. Bioremediation is the use of biological agents, such as bacteria or plants, to remove or neutralize contaminants, as in polluted soil or water.

been planted or have been removed from the ground, APHIS cannot effectively monitor compliance with field test requirements through onsite inspections.

Inspections Hindered by Missing Information

Lacking a master list of planted field test sites, APHIS must rely on approved applicants or their representatives (cooperators, farmers, planters, or researchers) to provide the exact location of GE crops before a site inspection can be performed. This is not an effective control, especially given that some of the permit and notification holders do not have exact location information readily available. Of the 12 companies we contacted for this information, 4 were not able to provide locations for some of their planted GE test sites, even 1 to 2 weeks after our request. One company representative said the company's information could contain errors or omissions due to the short timeframe, and three others said their lists of planted sites were incomplete. In fact, although 1 representative was able to provide locations for about 350 of the company's field tests, the representative wrote that the company did not have planting and location information on about 1,000 additional field tests. Another representative said that it would take from 1 to 3 months to gather the location information.

Additionally, because APHIS does not require all approved applicants to notify the agency when they terminate a field test or decide not to plant, it cannot supply PPQ with a valid list of planted sites to inspect. For example, according to a PPQ regional program manager, an average of 20 percent of the inspection requests his office received from BRS in 2003 and 2004 were for field test sites that had not been planted. Thus, APHIS dedicated valuable resources to compiling inaccurate inspection lists and contacting applicants who had not planted regulated GE crops.

Database Inadequate to Track Vital Information

To track field test information, APHIS uses a computerized database that was implemented in 1992. Our review of the database found that it does not have data fields to record proposed and planted field test site locations and to track significant events at field test sites. Significant events include planting, harvesting, cancellation, or termination of the field test. The database also does not alert APHIS when requested information is late or has not been received from approved applicants (see Finding 6). According to an APHIS official, the agency is currently working to design a new system that will track all necessary field test information with potential implementation in September 2005.

We concluded that, in order to maintain accountability for regulated GE crops, APHIS needs to know precisely where those crops are planted. An APHIS official told us that identifying the precise location of a field test site

at the time of application is an unrealistic requirement, because applicants cannot determine the exact site locations with any accuracy prior to planting. However, on January 24, 2005, APHIS issued a memorandum that requested notification holders to submit GPS coordinates or other information to identify the site after planting, effective April 5, 2005. Specifically, the memorandum requested, but did not require, the State, county, internal identification number (if available), central GPS coordinate, or address. The memorandum also requested that notification holders advise APHIS of sites listed in the notification that they do not intend to plant.

Although APHIS officials told us that voluntary compliance by major notification holders has been high, APHIS needs to strengthen its reporting requirements for field tests so that inspections can be made at critical stages of the process for permits and at least once for a sample of notifications.

Recommendation 6

Revise regulations to require all permit and notification holders to submit planting notices, 4-week/28-day reports, and harvest/termination reports for all field test sites.

Agency Response.

APHIS agrees in part with this recommendation but disagrees with the requirement for planting notices for the notifications because these notices are necessary only in cases where a preplant inspection is warranted. With the completion of the new regulations, BRS will require the 4-week/28-day reports for all field tests. Thus, BRS will know what has been planted within 28 days for all field tests. BRS has already strengthened reporting guidelines for notifications in the 2005 growing season and is currently evaluating the various field report requirements for permits and notifications with the conclusions to be reflected in the new regulations. BRS already requires reports six months after harvest/termination.

OIG Position.

We can not accept APHIS' management decision for this recommendation for three reasons.

- BRS is currently evaluating the various field report requirements for permits and notifications. As a result, the corrective action plan is contingent on the results of the evaluation.
- BRS did not propose interim measures that require notification and permit holders to submit 4-week/28 day reports pending release of the new regulations.

- The 6-month field test report is not adequate for a timely harvest/termination notice, because the 6-month field test report is due half a year after the harvest or termination of the field test.

To reach management decision, APHIS needs to provide a corrective action plan based on its evaluation of field reporting requirements. APHIS also needs to implement interim measures until its regulations are revised.

Recommendation 7

Revise regulations to require all permit and notification holders to submit the GPS coordinates of field test sites on all reports submitted after planting.

Agency Response.

APHIS stated that this recommendation is consistent with the direction set by BRS and, in fact, BRS has already requested that GPS coordinates of each field site be submitted in 28-day planting reports. Additionally, BRS is incorporating field test location information requirements into its regulatory revisions.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide an estimated timeframe for implementing the new regulations.

Recommendation 8

Revise regulations to require all permit and notification holders to submit notices of decision not to plant if they decide to cancel an approved field test location.

Agency Response.

APHIS has made revision of its regulations a priority, and this issue will be addressed as part of that process. Currently, this information is already requested of all growers through our guidelines.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide an estimated implementation date for the revised regulations.

Recommendation 9

Complete work on the management information system and ensure that it is capable of recording necessary information related to field test sites, including the specific location of each field site and the dates of significant events.

Agency Response.

APHIS referenced its response to Recommendation 4. It stated that a new database system is already designed to capture all of the OIG-recommended information and more. BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, BIDS, is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for implementation of the referenced information systems.

Finding 3 Written Field Test Protocols Are Not Always Obtained From Applicants

Most field tests of regulated GE crops are conducted under notifications. APHIS, however, does not require notification applications to include written protocols, which describe the procedures applicants will use to meet the field test performance standards prescribed by regulation.[17] Consequently, protocols do not undergo scientific review by an APHIS biotechnologist prior to approval of the notification application. Instead, because the procedures for crops planted under notification are well known, APHIS allows approved applicants to provide verbal protocols at the time of inspection. This practice impacts the integrity of both the approval and inspection processes.

Field test protocols detail how applicants will meet the critical performance standards for introductions of GE crops, including devitalization, monitoring for volunteer plants, and preventing inadvertent mixing of regulated GE articles with nonregulated articles. APHIS regulations do not require notification applicants to submit a written copy of their protocols with the application. Rather, the regulations state only that APHIS may issue guidelines regarding scientific procedures, practices, or protocols that it has found acceptable. A person who wishes to field test a GE crop may follow APHIS' protocol guidelines or adopt different protocols. When an applicant chooses to follow different protocols, the applicant may, but is not required to, discuss the matter in advance with APHIS to ensure that the protocols will be acceptable to APHIS.[18]

No Scientific Review of Notification Protocols

Because notification applicants are not required to submit their protocols with the application, APHIS biotechnologists do not review notification protocols for adequacy prior to granting the notification. An APHIS study issued in 2001 shows that such a preliminary review is necessary. The study, which covered mid-1997 to 2000, concluded that some notification protocols might not be adequate to meet the field test performance standards and identified several major areas in need of improvement. In a letter to its customers dated March 19, 2001, APHIS addressed those issues by providing guidance on some plant species' persistence in the environment, methods to minimize pollen movement, and elimination of volunteers. However, APHIS did not implement management controls requiring notification applicants to submit written protocols with their applications for scientific review, a requirement

[17] 7 CFR 340.3©, dated January 1, 2003
[18] 7 CFR 340.3, dated January 1, 2003, footnote 5

that would have enabled APHIS to determine whether performance standards would be met.

In contrast to the notification application process, APHIS requires permit applicants to submit a detailed description of the proposed procedures, processes, and safeguards that will be used to prevent the dissemination of regulated GEOs at each planned field test site.[19] These higher risk permit protocols undergo a biotechnologist review for adequacy before the permit is approved. Until APHIS extends this review to notifications, some notification protocols may not be adequate, increasing the risk of inadvertent release of GEOs into the environment.

Contradictory APHIS Guidance

Once it approves the notification application, APHIS does not require notification holders to provide written protocols during the field test. Our review of 90[20] notification approval letters found that APHIS allowed all notification holders to provide verbal protocols to the PPQ inspector; APHIS regulations[21] do not specify that the protocols must be in writing. However, APHIS' inspection manual[22] contradicts the approval letters and the regulations by directing PPQ inspectors to determine if notification holders have written protocols and if they are following the protocols.[23] The manual also states that if the notification holder or cooperator does not have a copy of the site-specific protocols at the time of inspection, it is a violation of the notification. This lack of uniform APHIS guidance undermines the inspection process.

As part of our review, we conducted joint inspections with PPQ officers at 87[24] of the 91 field sites in our sample. When we asked one company for copies of the protocols for nine of its notification sites, a company representative advised us that APHIS regulations[25] did not require written protocols. Instead, the company's field personnel provided a verbal description of the protocols. Without a copy of the company's written protocols that had been approved by APHIS, the inspectors could not be certain which protocols the notification holder was following and whether those protocols met the performance standards. After we completed our field visits, the company provided the written protocols to us; however, it was too late for us to determine whether the protocols were followed in the field.

On May 2, 2005, APHIS revised its approval letter for notifications to require written protocols at the time of inspection. However, in contradiction, the

[19] 7 CFR 340.4(12), dated January 1, 2003
[20] This included 28 approval letters from our original sample and 64 added during fieldwork.
[21] 7 CFR 340.3, dated January 1, 2003, footnote 5
[22] Biotechnology Inspection Manual for Notification Field Release, page 3.21, March 2002
[23] Biotechnology Inspection Manual for Notification Field Release, page 3.19, March 2002
[24] PPQ officers were not available to accompany us on the inspections of four field sites.
[25] 7 CFR 340.3, dated January 1, 2003, footnote 5

revised inspection manual distributed to PPQ officers in February 2005 states that notification protocols do not have to be in writing. To ensure that field test procedures are effective, we concluded that APHIS should require notification applicants to submit protocols in writing at the time of application, review them for adequacy, and ensure that PPQ officers have access to the protocols before they inspect the field site.

Recommendation 10

Amend regulations to require applicants for notifications to submit written protocols prior to approval of the field test.

Agency Response.

APHIS disagrees with this recommendation. While APHIS does evaluate written protocols for permits, it believes that the current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. Based on APHIS' familiarity with the crops eligible for notification, it does not feel it is warranted to require or review written protocols prior to approval of field tests. Performance-based regulatory standards are commonly used in APHIS and other regulatory agencies, and APHIS' use of this approach for notifications has been acknowledged as appropriate by the National Academy of Sciences. The intent of the notification procedure is to provide an administratively streamlined process for trials of crop-trait combinations with which APHIS already has a great deal of experience and familiarity.

OIG Position.

We can not accept APHIS' management decision for this recommendation. Performance-based regulatory standards do not preclude submission of protocols to APHIS prior to approval of the field test. Performance-based regulatory standards set objectives and desired outcomes without specifying how they are to be achieved, thus giving approved applicants the flexibility to determine how these objectives/outcomes can be met. 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. Yet, in 2001, APHIS' own survey of notification protocols found that some protocols may not be adequate to meet the field test performance standards. Without documented approved protocols, APHIS has no basis to determine if the applicant's procedures meet the performance standards. To reach management decision, APHIS needs to provide its science-based support for its policy that written protocols will not be required or reviewed prior to approval of field tests.

Recommendation 11

Require and document biotechnologist reviews of notification protocols to ensure they are sufficient to meet performance standards.

Agency Response.

APHIS disagrees with this recommendation, referring to its response to Recommendation 10. While APHIS does evaluate written protocols for permits, it believes that the current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. Based on APHIS' familiarity with the crops eligible for notification, it does not feel it is warranted to require or review written protocols prior to approval of field tests. Performance-based regulatory standards are commonly used in APHIS and other regulatory agencies, and APHIS' use of this approach for notifications has been acknowledged as appropriate by the National Academy of Sciences. The intent of the notification procedure is to provide an administratively streamlined process for trials of crop-trait combinations with which APHIS already has a great deal of experience and familiarity.

OIG Position.

We can not accept APHIS' management decision for this recommendation. Performance-based regulatory standards do not preclude biotechnologist reviews of notification protocols to ensure they are sufficient to meet performance standards. To reach a management decision, APHIS needs to propose an appropriate management control to ensure that protocols meet performance standards.

Recommendation 12

Distribute written protocols to PPQ officers to use in conducting inspections of field test sites planted under notifications.

Agency Response.

APHIS stated that PPQ officers currently have access to written protocols at the field test site. In addition, field test design protocols for notifications will be included in APHIS' database system (see response to Recommendation 4), which can be accessed by PPQ inspectors prior to their inspections.

OIG Position.

We can not accept APHIS' management decision for this recommendation. Like the approved notifications, the protocols are important control documents that the PPQ officers should receive from APHIS before the inspection. The field design protocols, mentioned in APHIS' response, are

only examples of possible protocols for certain crops. Since notification holders are not required to follow these examples, deviations from the examples are not violations. To reach management decision, APHIS must obtain and distribute written protocols to PPQ officers as a part of the applications it already distributes to PPQ.

Finding 4 Scientific Reviews of Field Test Applications Are Not Sufficiently Documented

In our review of the official files for 10 pharmaceutical permits, we found little documentary evidence of the scientific reviews performed by APHIS biotechnologists. We attributed this to the fact that APHIS biotechnologists do not follow a standardized process to document scientific reviews of permit applications. APHIS also has not issued policies and procedures requiring supervisory reviews of the biotechnologists' work. Although the biotechnologists' current application reviews may be adequate, documented, standardized processes and supervisory review help ensure that the scientific reviews are consistent and sufficient for approving the introduction of regulated GE crops, including pharmaceuticals and industrials.

OIG is not equipped to evaluate the scientific adequacy of individual biotechnologist's reviews, and we did not attempt to do so. However, we examined the official files to determine what documentation was maintained to support the scientific review. The Government Accountability Office's Standards for Internal Control in the Federal Government[26] states that internal controls need to be clearly documented and the documentation should be readily available for examination. Review is one kind of internal control.

APHIS has not described the biotechnologist review process in detail in the APHIS BRS Permit Functions Quality Manual,[27] which documents procedures for processing applications. For permits, APHIS staff explained that documentation of scientific review is to include the biotechnologist's initials on a tracking sheet; a completed form identifying the plant's genes and other characteristics; their initials or signature on a letter reporting the results of the review to the State regulatory personnel where planting was proposed; and their initials on the APHIS approval letter. Additionally, in 2003, APHIS issued two draft checklists for limited reviews of pharmaceutical and industrial permit applications. The checklists are specific to reviewing and approving applicants' protocols for cleaning equipment and storage facilities, and for reviewing and approving the applicants' employee training programs.

[26] GAO/AIMD-00-21.3.1, dated November 1999
[27] January 31, 2003

During our fieldwork, we obtained copies of the official files for 10 pharmaceutical permits,[28] which APHIS considers high-risk. Our review found that the files did not contain sufficient information to disclose the extent of the biotechnologist's reviews or the criteria they used to arrive at their decisions. Although the files contained letters to State regulatory personnel, we found that other required documentation was not always in the files. For all 10 of the permits, the tracking sheet was not in the file or not initialed. For 7 of 10 permits, the form to identify the plant's genes and other characteristics was also not in the file or not completed. Furthermore, nine of the approved permits had not undergone supervisory review, an essential control over the application approval process.

Even if the required documentation had been present in the files, we concluded that it would not be sufficient to describe the biotechnologists' complete review process. Specifically, the documentation was not sufficient because it did not describe the scope of the biotechnologists' review of risks associated with introducing a particular GE plant and how the applicant planned to mediate those risks. Scientific criteria for approving a field test application might address the likelihood of the unintentional spread of GEOs or the establishment of wild GEO populations, and the effects of regulated GE crops on other species.

Recommendation 13

Develop and implement policies and procedures for documenting the scientific process and criteria for approving applications, and require supervisory reviews of biotechnologists' work.

Agency Response.

APHIS stated that BRS has developed and implemented six new standard operating procedures related to the scientific review process. BRS is currently formulating plans for increased documentation and supervisory review of the process. Many of these plans will be implemented before the end of fiscal year 2006. However, BRS believes major actions to address this recommendation will continue to be ongoing to ensure that a continual process of updating and improvement is in place. Further, the consolidated *User's Guide* under development will articulate our review process and approval criteria.

[28] Judgmental sample of 10 pharmaceutical permits planted in 2002

OIG Position.

We agree with planned corrective actions. To reach management decision, APHIS needs to provide timeframes for implementation of the corrective action described.

Permit and notification holders must ensure that planted GE crops do not persist in the environment outside the field test site. Once the field test ends, GE crops must be properly destroyed or disposed of, and the field test site must be monitored for volunteer plants or regrowth of the crop in the following season. At these critical stages of the field test process, effective management and oversight are essential to reduce the risk of inadvertent persistence of regulated GE crops in the environment. We found several weaknesses in APHIS' controls over field tests—specifically, inspections, reporting from permit and notification holders, and postharvest guidance.

Management of Inspections Needs Improvement

Two APHIS units, BRS and PPQ, share responsibility for inspections of GE field test sites. BRS manages the overall inspection process, but it relies on PPQ to perform the majority of the inspections; BRS performs few inspections itself. However, at the time of our audit, the two units had not clearly delineated how they would coordinate their inspection-related activities. We found that PPQ did not conduct all inspections of high-risk pharmaceutical crops that were requested by BRS. Also, BRS did not establish objectives for inspecting a specific number of notification field test sites. Therefore, many inspections requested by BRS were not conducted by PPQ. We found that this was because PPQ did not know what APHIS' inspection expectations were for either pharmaceutical/industrial permits or other permits/notifications.

In September 2004, BRS and PPQ entered into a MOU to clarify the relationship between BRS and PPQ regarding the inspection program for field test sites. However, we found that the MOU did not cover inspections of nonpharmaceutical and nonindustrial release permits, and movement permits. It also did not commit BRS to provide PPQ with planted notification sites to be inspected, nor did it require PPQ to perform all the inspections requested by BRS.

During most of our audit, BRS also did not have an effective means of tracking inspection requests and results. As a result, it was not aware of which sites had been inspected or the total number of inspections performed. At the end of our audit, in 2005, BRS advised that it had implemented an interim system for tracking inspections, while a new system is being developed.

Reporting Problems Not Addressed

APHIS requires various reports from permit and notification holders at different points in the life cycle of the GE crop, from advance notice of planting to the final field test results required from all approved applicants. We found that permit and notification holders often submitted the required reports late or not at all. Because it does not have an effective system for tracking receipt of field test progress reports, APHIS does not always follow up on late and missing reports or assess penalties for noncompliance.

Postharvest Guidance Incomplete

At the conclusion of the field test, APHIS requests that permit and notification holders properly dispose of all GE plant material and monitor their field test sites to ensure that volunteer plants do not persist in the environment during the following growing season. However, we found that APHIS has not established timeframes for promptly devitalizing crops at the conclusion of the field test. APHIS also does not require permit holders to notify it of the final disposition date of high-risk GE harvests.

Although APHIS has taken positive steps toward remedying inspection problems during our audit, it needs to continue strengthening its field test inspections, reporting process, and postharvest guidance in order to carry out one of the goals of its strategic mission: ensuring the safe release of agricultural biotechnology.

Finding 5 APHIS Needs to Establish an Effective Inspection Program to Monitor Regulated GE Crops

APHIS was not using its inspection authority effectively to monitor field tests of GE crops. We found that, until 2004, APHIS lacked a formal risk-based process for selecting field test sites for inspection and that the majority of assigned inspections were not completed. Specifically, APHIS announced to the public that pharmaceutical and industrial field sites would be inspected 5 times during the 2003 growing season, but, in fact, we found that only 1 of 12 sampled pharmaceutical field test sites met this requirement. Additionally, 46 percent of the notifications[29] APHIS selected for inspection were not inspected. We also noted that inspectors did not always report violations at field test sites, and APHIS did not follow up on all violations that were reported. These problems stemmed from APHIS' lack of clear, complete inspection requirements, as well as a lack of coordination between BRS and PPQ, the APHIS units that share responsibility for monitoring GE field test

[29] Field test sites with releases ending during or after June 2002, the month in which BRS' responsibilities for biotechnology began.

sites. As a result, APHIS had little assurance that field tests are being conducted safely, in a way that minimizes the potential for GE plants to persist in the environment.

APHIS regulations, dated January 1, 2003,[30] do not specify the number of inspections required at GE field test sites or how field test sites should be selected for inspection. Instead, BRS and PPQ followed an informal process to carry out inspections of GE field test sites. Although BRS had no documented process for selecting field test sites before 2004, a BRS official told us that BRS forwarded all permits and a sample of 10 to 12 percent of approved notifications to 2 PPQ regional managers for inspection. The PPQ regional managers then distributed the requests for inspections to the appropriate APHIS State plant health director for assignment to PPQ officers.

Although APHIS had not issued inspection requirements directly to BRS and PPQ, APHIS announced in the Federal Register on March 10, 2003, that all field test sites planted under pharmaceutical and industrial permits may be inspected seven times—up to five times during the growing season and twice during the postharvest period. In a March 6, 2003, press conference, making a public commitment to this goal, an APHIS official assured the public that all pharmaceutical and industrial sites would be inspected five times during the growing season and two times during the postharvest period. For all other permits and selected notifications, an APHIS official told us that PPQ attempted to inspect at least one field test site planted under each permit or notification. However, at the time of our audit, we found that PPQ did not know what APHIS' inspection expectations were for either pharmaceutical/industrial permits or other permits/notifications.

Requested and Required Inspections Not Performed

PPQ did not inspect all pharmaceutical and industrial field test sites planted in 2003 five times during the growing season, contrary to the inspection guidelines APHIS announced to the public and published in the March 2003 Federal Register. In fact, only 1 of our sample of 12 pharmaceutical and industrial sites planted in 2003 had all 5 required inspections. Only 18 of the 55 (11 x 5) potential inspections were performed for the remaining 11 sites in 2003. According to the Federal Register notice and APHIS management, PPQ also should have inspected pharmaceutical and industrial fields planted in 2002 twice during their postharvest period in 2003. We found that only 7 of the 14 (7 sites x 2) potential inspections were performed for our sample of 7 pharmaceutical sites planted in 2002. Because PPQ did not conduct all postharvest inspections, the following potential violation at a high-risk pharmaceutical field test site went undetected:

[30] 7 CFR 340, dated January 1, 2003

- In September 2003, we visited a field test site where a permit holder had planted a pharmaceutical crop in 2002. PPQ had not inspected the site during the postharvest monitoring period in 2003. When we visited the site, we learned that the permit holder's cooperator had planted soybeans on the field, violating APHIS requirements that restrict the production of food and feed crops at pharmaceutical and industrial GE field test sites in the following season.[31] Those GE field test sites are to be left fallow in the following growing season so that volunteer GE plants are not inadvertently harvested with an unregulated food crop. Although the cooperator's 2003 monitoring record stated that the 2002 GE field was fallow, the cooperator told us that he had planted unregulated soybeans in the former GE field and cut them down the day before our visit. He left the soybeans standing in the larger field surrounding the former GE field.

We also found a similar incident at a field test site that PPQ inspected only once during the 2003 postharvest monitoring period. The cooperator planted unregulated soybeans in 2003 on the same acreage where a pharmaceutical crop was planted during the 2002 growing season. However, the PPQ officer did not report this as a violation to BRS (see "Inspection Results Not Reported or Tracked"[32] below).

According to BRS records, a total of 906 notifications were referred to PPQ for inspection. Our review found that PPQ conducted only 485 inspections, or approximately 54 percent of those requested. Thus, for 46 percent of the notifications that should have been inspected, APHIS had no assurance that field tests were conducted in accordance with regulations.

Neither BRS nor PPQ was aware of the number of inspections completed. Despite previous OIG audit recommendations to develop an inspection tracking system,[33] BRS lacked an adequate method of accounting for all inspections and their outcomes, including inspections of high-risk pharmaceutical fields. Although PPQ's Western region used a database to track some inspections, PPQ's Eastern region did not have a similar tracking system. The Eastern region's PPQ manager stated that, if BRS requested a field test inspection for a specific permit and BRS did not receive the inspection report, it was BRS' responsibility to follow up and ensure the inspection was completed. BRS, however, did not have a followup process to determine if requested inspections were completed.

At the end of our audit, in 2005, BRS advised that it had implemented an interim system and procedures for initiating, numbering, tracking, and receiving written followup on every inspection. It is using the interim system

[31] Federal Register, section II.1.B, March 10, 2003
[32] Field test sites with releases ending during or after June 2002, the month in which BRS' responsibilities for biotechnology began.
[33] In Audit Report 33099-9-Hy, dated August 1994, OIG recommended that APHIS' Biotechnology, Biologics and Environmental Protection, a predecessor of BRS, work with PPQ to develop procedures to account for and verify all PPQ inspection reports, noting violations or potential violations.

while a new system is being developed. The effectiveness of the interim system has not been reviewed or tested by OIG.

Selection Process Not Documented or Site-Specific

Prior to April 2004, APHIS' process of selecting notifications from the BRS database and forwarding them to PPQ for inspections was undefined and ambiguous. We found that BRS had not documented how it selected its sample of 10 to 12 percent of notifications for inspection. According to an APHIS official, the notification sample was selected based on risk factors—such as crops with new gene variations, applicants who had not conducted field tests before, and applicants with previous violations. However, we found no documentation of the risk factors used to select notifications for inspection.

APHIS advised us that, in April 2004, it began using a documented methodology to assign risk scores to notifications and direct PPQ inspections to higher risk GEOs. An APHIS official also told us that APHIS plans to modify the risk scoring system as the agency gains experience with it. However, as before, rather than selecting specific field test sites for inspection, BRS forwards entire permits and notifications to PPQ, even though each permit or notification may cover numerous field test sites. PPQ then decides which field test site to inspect under a given permit or notification, sometimes based on how convenient the site is for the inspector to visit. APHIS should select specific field test sites for inspection according to their risk level. As discussed in Finding 2, however, APHIS could not select specific sites for inspection because APHIS did not always know if, and where, approved field test sites were planted. Consequently, APHIS had no assurance that the highest risk field test sites were being selected for inspection.

Inspection Results Not Reported or Tracked

BRS and PPQ sometimes failed to follow their own internal procedures for reporting noncompliance with regulations. PPQ officers did not always prepare inspection reports and did not always report violations of regulations[34] found during our joint review. During our joint inspections with PPQ officers, we found a pharmaceutical site that was not left fallow and two cases where monitoring records for pharmaceutical crops were not maintained by the cooperators. We also identified one applicant who had exceeded the approved acreage to plant under notification. The PPQ officers did not report these violations to BRS.

We also found that BRS failed to take action on 11 violations—6 violations reported to BRS by PPQ officers, approved applicants, and OIG and 5 other

[34] 7 CFR 340.3 and 340.4, dated January 2003

violations that BRS could have identified from information it already had. The six reported violations included a lack of dedicated storage facilities for farm equipment, failure to retain border rows, shipment of a regulated article after the notification expired, two instances of planting with no permit, and one instance of planting in an unapproved location. Regarding the five identifiable violations, BRS failed to compare the permit requirements with the field test progress report, which would have identified two violations of shipping requirements and two violations for planting regulated articles in unapproved locations. BRS also failed to identify another pharmaceutical site that was not left fallow, even though the PPQ officer's report, while not reporting a violation, mentioned the current crop growing at the site.

Our review of BRS' compliance infraction database found that, as of December 17, 2003, none of the 11 reported or identifiable violations was recorded, and BRS took action on only 1 of the 11 violations. The BRS official maintaining the database could not explain why the compliance infractions were not recorded in the database. The failure to report inspection results and follow up on violations increases the risk of an unauthorized release of regulated GEOs into the environment.

In 2004 and 2005, a new compliance branch began following up on all compliance reports by auditing, reviewing, analyzing, and closing over 30 alleged violations, but took no action on the remaining 10 violations.

By finalizing its inspection tracking system, further defining the relationship between BRS and PPQ, and refining its inspection requirements and selection procedures, APHIS can significantly strengthen the inspection process and its oversight of regulated GE plants.

Recommendation 14

Establish requirements for the number of field-site inspections to be performed for permits and notifications.

Agency Response.

APHIS stated that BRS has always had requirements for field-site inspections. The Compliance and Enforcement Branch has implemented documentation procedures for field-site inspections and strengthened and clarified the requirements for the selection of field sites. APHIS is continuing to strengthen its inspection requirements by developing new procedures for selection of field-site inspections based upon key risk-related factors, and is always updating and improving its procedures based upon experience and new knowledge about risk-related factors. APHIS is also considering additional inspection requirements as it develops its new regulations.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide additional information on how APHIS will establish requirements for the selection of specific field sites and the number of sites to be inspected and the timeframes for implementation of the corrective actions described.

Recommendation 15

Develop and implement written policies and procedures for selecting specific field test sites for inspection based on risk.

Agency Response.

APHIS disagrees with this recommendation, stating that individual field-trial sites within a given notification or permit are of comparable risk. Once a notification or permit has been selected for inspection by BRS' risk assessment, allowing PPQ inspectors the flexibility to choose the specific inspection site within the permit or notification encourages more efficient use of Government resources without compromising safety.

OIG Position.

We can not accept APHIS' management decision for this recommendation. The National Academy of Sciences states that "risks must be assessed according to the organism, trait, and environment."[35] Thus, the environment—i.e., the field site location—is an important risk factor that should be considered in selecting field test sites for inspection. To reach management decision, BRS needs to issue criteria for assessing environmental risks as guidance for selecting fields for inspection.

Recommendation 16

Clarify the specific roles and responsibilities of BRS and PPQ in the MOU regarding the selection and inspection of nonpharmaceutical and nonindustrial release permits, and movement permits.

Agency Response.

APHIS stated that BRS and PPQ have already established an MOU that addressed BRS' inspection requirements for each type of permit, including nonpharmaceutical and nonindustrial permits, as well as the notifications. The MOU was originally written in a manner so that responsibilities were clear to both BRS and PPQ and was implemented without any problems.

[35] National Academy of Sciences, Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation, page 63, finding 2-4

However, OIG interpreted the language in the MOU differently and suggested that problems could arise. BRS and PPQ have made revisions to the MOU to address this concern.

OIG Position.

To reach management decision, APHIS needs to provide the details of changes made to the MOU and the date the process was implemented.

Recommendation 17

Finalize the inspection tracking system and ensure that it is effective in recording the receipt of inspection reports, inspection results, and the number of inspections completed.

Agency Response.

APHIS stated that this recommendation is consistent with the priorities already set by BRS. BRS currently has a system in place to track all of the recommended data and an improved database system for tracking inspection and field data reports has now been fully developed and will be operational after a final review by the Office of the Chief Information Officer (see response to Recommendation 4).

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for implementation of the corrective actions described.

Recommendation 18

Finalize and implement management controls to require reporting of all inspections to BRS for review and followup on violations of regulations.

Agency Response.

APHIS stated that the problems cited by OIG are currently addressed by an interim system already in place. Now that these management controls are operational, they will be consolidated into BIDS to increase the automation of the process (see response to Recommendation 4). APHIS' management controls are designed to assure that inspectors complete reports for all inspection assignments and that compliance officers review these reports and follow up with appropriate correspondence or enforcement actions when noncompliance incidents are reported.

OIG Position. We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for implementation of BIDS.

Finding 6 Field Test Progress Reports Are Not Adequately Monitored

In addition to inspections, APHIS monitored compliance with field test regulations during 2002 and 2003 by requiring various reports from permit and notification holders during the field test. These reports contain important information on the status of the field test site and the results of the field test, including any detrimental environmental impacts. We found, however, that APHIS had not established an adequate system to monitor the receipt of required progress reports by permit and notification holders. Without such a system, APHIS cannot effectively follow up on, or assess penalties for, missing and late reports. Unless APHIS receives, tracks, and reviews all required reports from permit and notification holders, progress reporting does not serve its purpose as a control to monitor compliance with field test requirements.

APHIS regulations require all permit and notification holders to submit a field test data report within 6 months of termination of the field test.[36] The field test data report, also called the 6-month report, documents the methods of observation, resulting data, and analysis of any deleterious effects on plants, other organisms, or the environment. Based on the biotechnologist's review of the application and experience with the applicant and the specific crop, some approved permit applicants are also required to submit planting notices, 4-week/28-day reports, or harvest/termination notices. The planting notice indicates when a crop is about to be planted; the 4-week/28-day report provides more detailed information about the field once it is planted; and the harvest/termination notice notifies APHIS when the field is to be harvested or the field test terminated, indicating the start of the monitoring period.

[36] 7CFR 340.3(d)(4) and 7 CFR 340.4(f)(9), dated January 1, 2003, state that field test reports must be submitted to APHIS within 6 month "after termination of the field test." Since APHIS guidance was unclear, and the regulation states "termination of the field test," we determined the due date using field destruction dates (when that data was available) and harvest dates (when no field destruction date was available).

Reports Not Submitted or Submitted Late

Our analysis of required reporting for high-risk pharmaceutical and industrial permits, other permits, and notifications in our sample found that applicants did not always submit progress reports in a timely manner, if at all. To determine reporting requirements, we reviewed regulations, permit conditions, and/or supplemental permit conditions for our sample sites.[37]

Pharmaceutical/Industrial Permits

For all pharmaceutical and industrial permits, approved applicants are required to submit field test data reports; all pharmaceutical and industrial permits also require planting notices and/or harvest notices, and most require 4-week/28-day reports. We reviewed required reports for 1 industrial and 12 pharmaceutical permits for 22 field test sites[38] and found that APHIS could not produce 11 of the 20 field test data reports (55 percent) due from pharmaceutical and industrial permit holders. Our review also showed that APHIS could not produce 36 percent of the planting notices, 10 percent of the 4-week/28-day reports, and 45 percent of the harvest notices that were due from the permit holders.

- Other Permits

  All of the other permits in our sample required field test data reports, but only some required planting notices, 4-week/28-day reports, and/or harvest notices. We reviewed a total of 52 field test sites authorized under 18 other approved permits and found that APHIS could not produce 24 of the 43 field test data reports that were due (56 percent). Of the 52 field test sites, APHIS required planting notices for 48 sites, 4-week/28-day reports for 2 sites, and harvest notices for 47 sites. APHIS did not receive 10 of 47 (21 percent) of the planting notices and 16 of 41 (39 percent) of the harvest notices due. However, APHIS did receive all required 4-week/28-day reports.

- Notifications

  Finally, we reviewed documentation for a total of 113 field test sites for 88 approved notifications. Regulation requires approved applicants for notifications to submit a field test data report to APHIS. Our analysis showed that 11 of 73 (15 percent) of the field test data reports due were not submitted to APHIS. Of the 62 reports (73 – 11 = 62) that were

[37] At each sample site, we reviewed the site's planting records and GEO field releases (plantings) for FYs 2002 and 2003. We then reviewed records for these additional field releases to determine reporting requirements. Thus, the results of our review include our complete sample plus our review of the documentation of additional plantings identified during our field visits. Finally, we reviewed information collected at APHIS, information collected at the field sites during our visits, and information provided by APHIS to determine which required reports had been received by APHIS.

[38] Because APHIS does not keep track of how many field test sites are planted under permits and notifications, we determined individual field test sites associated with permits and notifications based on our sample universe and information obtained during field site visits.

submitted, 28 of 62 (45 percent) were submitted late. Six-month field test data reports were not due on 33 notification sites during the time of our fieldwork. There was not enough information for us to make a determination on seven notification sites. Our analysis is summarized below:

Analysis of Required Reports for 113 Field Test Sites under Notifications	
11	Not submitted
28	Submitted late
34	Submitted on time (62 – 28 = 34)
33	Not due
7	Unable to determine
113	Total field test sites with required reports

Current Database Inadequate to Track All Required Reports

Our analysis of applicant reporting disclosed that APHIS does not have an effective method, manual or computerized, to determine when or if required progress reports are submitted. APHIS' manual filing system does not lend itself to tracking receipt of reports. According to APHIS officials, progress reports for notifications are also logged into the computer system APHIS uses to store field test information. The database has a field to track the date of receipt of the 6-month field test report for notifications, but only one date and, thus, only one field test data report can be tracked, even though many notifications cover numerous field test sites. For permits, APHIS does not track the date of receipt of the 6-month field test report and other required reports in the database. APHIS officials informed us that an updated database capable of tracking field test progress reports for both permits and notifications is being developed, and it is expected to be implemented in the fall 2005.

Unclear Due Date for Field Test Data Report

Our analysis of missing and late reports was further complicated by the unclear due date for the field test data report. According to regulations, the field test data report (commonly referred to as the 6-month report) is due within 6 months after termination of the field test.[39] This could be interpreted as 6 months after harvest, 6 months after destruction of the field test site, 6 months after the termination of the last field test (if more than one test is being performed under a permit or notification), or 6 months after the permit or notification expires. APHIS defines termination as either harvest of the crop or destruction of the fields planted under each permit or notification

[39] 7 CFR 340.3(d)(4) and 7 CFR 340.4(f)(9), dated January 1, 2003

number. On occasion, APHIS has also allowed the report to be submitted within 6 months after the expiration of the permit or notification, enabling applicants with multiple field sites under a single permit or notification or number to combine the information from all plantings into one report. However, in order to be able to track submission of the field test data report, APHIS needs to clearly define "termination of the field test" and establish a firm due date for the report.

Further Coordination Between BRS and PPQ Needed

The weaknesses in coordination between BRS and PPQ, discussed in the previous finding, were further exemplified by problems tracking required reports. As a condition of the permit, some permit holders were instructed to provide planting and harvest/termination notices to the PPQ regional offices instead of directly to BRS. One PPQ regional manager recorded some information from the planting and harvest notices into his own computer system. However, this information was not submitted to BRS, and BRS never requested the information. To track receipt of required planting and harvest notices, APHIS needs a management information system that captures all critical information related to the field test process and is available to authorized personnel to monitor compliance with performance standards. In 2005, BRS began working to implement changes that will result in all reports coming to BRS directly.

Available Sanctions Not Imposed

Regulations[40] and permit conditions allow APHIS to withdraw a permit or deny future permits if conditions of any permit have not been met. We found that APHIS has not been applying this sanction to applicants who are in violation of regulations or permit conditions by not submitting required reports on or before the dates they are due. APHIS also does not always follow up on reports of violations by applicants.

For example, APHIS' ineffective management information system allowed the issuance of 4 permits and 947 notifications to Applicant A from April 2002 through July 2004, even though it was in violation of permit conditions by not submitting required planting notices for 1 permit. Similarly, APHIS issued 68 notifications and 2 new permits to Applicant B despite its failure to file required planting and harvest notices for 3 previous permits; Applicant B also did not ensure that APHIS received the field test data reports in a timely manner. In another example, APHIS did not follow up on a violation reported three times by Applicant C. Applicant C violated the regulations by planting regulated articles without a permit.[41]

[40] 7 CFR 340(g), dated January 1, 2003
[41] 7 CFR 340.0(a)(1), dated January 1, 2003

As long as APHIS does not assess penalties for some violations of field test regulations and permit conditions, some approved applicants may become complacent at times about following regulations.

Recommendation 19

Finalize the database for recording all information related to field test progress reports for permits and notifications, including planting notices, harvest notices, and cancellation notices, to identify violations.

Agency Response.

APHIS stated that, in its response to Recommendation 4, BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, BIDS, is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide specific timeframes for implementation of the corrective actions described.

Recommendation 20

Clarify guidance to define the term "termination of the field test" and establish a firm due date for field test data reports.

Agency Response.

APHIS stated that beginning in 2006, BRS will communicate to notification and permit holders clarified guidelines regarding the due dates for field reports and our use of the phrase "termination of the field test."

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for completion of the corrective actions described.

Recommendation 21

Establish and implement controls that require all reports (inspection and progress) be submitted to BRS for tracking and review.

Agency Response.

APHIS stated that BRS addressed this issue in Recommendations 4 and 18. The problems cited by OIG are currently addressed by an interim system already in place. A system tracking permit and notification inspection and field data reports, BIDS, is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide the implementation date of BIDS.

Recommendation 22

Prescribe procedures for following up on missing and late progress reports.

Agency Response.

APHIS concurs with this recommendation. The problems cited by OIG are currently addressed by an interim system already in place. The database that tracks completion of field reports and inspections (BIDS) has been developed to identify missing/late reports to compliance staff (see responses to Recommendations 4 and 6).

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide the implementation date of BIDS.

Recommendation 23

Impose sanctions for missing and late progress reports.

Agency Response.

APHIS stated that BRS already considers a range of responses to missing or late reports that are progressive and are proportional to the nature and magnitude of the violation, up to and including revocation of existing permits or denial of future permits.

OIG Position.

We can not accept APHIS' management decision for this recommendation. To reach management decision, BRS needs to provide us with written policies and procedures delineating when it will impose sanctions and what actions it will take, if reports are missing or late.

Finding 7 APHIS Lacks Controls Over Final Disposition of GE Pharmaceutical Harvests

APHIS did not ensure that permit holders actually dispose of GE pharmaceutical and industrial harvests as indicated on the permit application—either through devitalization, shipment to another location, or replanting. Because APHIS controls were not effective to detect whether disposition of pharmaceutical harvests was timely, we found two sites where a pharmaceutical permit holder[42] stored large quantities of pharmaceutical crops for over a year without APHIS' knowledge. Until APHIS requires applicants to disclose the date and details of final disposition, harvests of pharmaceutical and industrial crops could be shipped or disposed of improperly, possibly entering the food supply or the environment.

APHIS regulations[43] require permit applications to include a detailed description of the proposed method of final disposition of the GE crop. However, the regulations do not require applicants to disclose when the disposition will occur. They also do not require permit holders to submit periodic post-harvest reports to update APHIS on the quantity and location of GE material in storage and whether or not the disposition has actually occurred.

We found that two large harvests of GE pharmaceutical crop were stored for over a year by Applicant F cooperators (farmers conducting field tests for Applicant F), even though the permits did not contain information about the storage period so that it could be assessed by APHIS. During our field site reviews, we found that an Applicant F cooperator stored more than half a ton of a GE pharmaceutical crop for 15 months. In another State, 1.4 tons remained in storage at the cooperator's farm for 17 months. The cooperators said that they were waiting for instructions from Applicant F, who eventually instructed them to ship the harvests back to their headquarters. Although the permit applications for the field tests in these two States disclosed that the harvests would be shipped back to Applicant F's headquarters, they did not indicate when the shipments would occur. Thus, the lengthy storage of the pharmaceutical harvests was not approved by APHIS and the safety protocols

[42] Sample field sites that planted pharmaceutical crops in 2002
[43] 7 CFR 340.4(b)(14), dated January 1, 2003

of the storage facilities could not be assessed. Also, PPQ did not perform inspections during the extended storage to ensure that the GE crops were safely contained in the facilities.

Furthermore, we noted that APHIS' official records contained no reports from Applicant F indicating that the harvests were in storage. APHIS needs information to determine whether approved applicants are fulfilling permit conditions for high-risk GE crops. Specifically, APHIS must require reports of significant events, including harvest amounts, storage locations, and final disposition, whether by devitalization, shipment, or replanting. Proper periodic reporting would identify violations of performance standards and increase assurance that regulated GEOs will not be inadvertently released.

Recommendation 24

Require applicants to disclose in the permit application when they plan to dispose of GE pharmaceutical and industrial harvests.

Agency Response.

APHIS stated that BRS will request this data to be provided in the field report submitted 21 days prior to harvest, as opposed to inclusion in the permit application, because projected dates are more accurate closer to the end of the growing season.

OIG Position.

We can not accept APHIS' management decision for this recommendation. To reach management decision, APHIS needs to establish written policies that require, as a supplemental permit condition, the date of disposition in the field report submitted 21 days prior to harvest and require APHIS' biotechnologists to document their review and approval of the disposition date.

Recommendation 25

Require PPQ officers to determine, when conducting post-harvest inspections, if any regulated GEOs are stored and are adequately contained.

Agency Response.

APHIS stated that inspecting for onsite storage of regulated GE plants is currently a part of our post-harvest inspections. In addition, the worksheet for post-harvest inspections that has been in use for several years includes questions about seed storage and security. Therefore, this recommendation has already been implemented.

OIG Position.

We accept management decision for Recommendation 25. To achieve final action, APHIS needs to send the Office of the Chief Financial Office, Planning and Accountability Division, its current post-harvest inspection worksheet.

Recommendation 26

Require permit holders to timely report the amount, location, and actual disposition of pharmaceutical and industrial GE harvests, including devitalization, shipment to another location, or replanting.

Agency Response.

APHIS agrees, in part, with this recommendation. APHIS will require additional information about the disposition of materials derived from plants engineered to produce pharmaceutical and industrial compounds, including expected timeframes for devitalization. However, requirements for reports on final dispositions are not necessary to ensure confinement measures are met, because this information is already captured in permit conditions and preharvest reports.

OIG Position.

We can not accept APHIS' management decision for this recommendation. APHIS is responsible for regulating biotechnology and, therefore, should know where regulated GE pharmaceutical harvests are being stored and when final disposition occurs. Permit conditions and preharvest reports can provide only estimated dates of final disposition, not actual dates. To reach management decision, APHIS needs to establish procedures that require permit holders to report the amount and location of pharmaceutical harvests and the date of final disposition.

Finding 8 GE Crops Were Not Promptly Destroyed

Due to a lack of APHIS guidance, applicants did not devitalize GE crops promptly at the conclusion of three field tests in our sample. Neither APHIS regulations[44] nor the APHIS "User's Guide for Introducing Genetically Engineered Plants and Microorganisms" specify the timeframe for devitalizing GE crops after they are no longer needed for research. If GE crops are not devitalized in a timely manner, there is a risk they could be dispersed in the environment by wind or other elements, field personnel or visitors, farm equipment, or foraging birds and other animals.

APHIS regulations[45] state that, at the conclusion of the field test, no viable material should remain that is likely to volunteer in subsequent seasons, and that volunteers must be managed to prevent persistence in the environment. Devitalization ensures that the crops do not persist in the environment and produce offspring. Methods of devitalization include:

- incorporating into the soil for decomposition;
- treating with a herbicide;
- mulching or chipping;
- exposing to high temperatures by autoclaving, baking, or incineration;
- exposing to the winter elements (e.g., potato tubers); or
- composting at a monitored location.

Although nothing came to our attention to suggest that specific instances of delayed devitalization had negative impacts on the environment, the following three examples found during our field test site visits demonstrate the need to establish timeframes for devitalization based on a case-by-case analysis of risk. All three fields were planted under notifications.

Destruction of GE Crop Delayed

Twenty days after harvest, we found a GE edible crop still in the field. Although company personnel had harvested the crop on August 20, 2003, some of the crop was left, cut in half with seeds exposed or lying still whole in the field on September 9, 2003. The following day, September 10, the company disced the remaining crop once to devitalize it. Discing left the crop in pieces, exposing more seeds than on September 9.

[44] 7 CFR 340.3 and 7 CFR 340.4, dated January 1, 2003
[45] 7 CFR 340.3(c)(6)(i) and (ii), dated January 1, 2003

On October 27, 2003, a company representative advised that they had disced the crop further, so that the field was clean by October 21, 2003. The representative also stated that the field would be monitored for volunteers for a year after harvest. According to the representative, discing is a normal practice and has been accepted for many years by APHIS. From 1997 to 2003, APHIS approved one permit and several notifications for the company's GE research. However, we concluded that delayed discing increases the likelihood that birds or other animals would carry off some of the exposed seeds from the field. In that case, monitoring the field would not prevent the persistence of the GE crop elsewhere in the environment.

GE Crop Left in Field

On September 10, 2003, we found a GE crop, which had reportedly been cut down sometime between August 13 and August 31, 2003, lying exposed in a field. The crop had formed two border rows that acted as a "pollen sink," trapping pollen from an adjacent GE field trial. As a pollen sink, the border rows were considered GE crops and should have been devitalized promptly. Instead, the cut rows were left lying on top of the field, as shown in the following photograph. According to an APHIS official, allowing GE crops to lie in the field increases the likelihood that wind and other agents will disperse seeds from the plants.

Destroyed east border row, September 10, 2003

GE Crop Left in Compost Pile for up to 6 Months

For up to 6 months at a time, GE plants and their produce remained piled in a composting area at Applicant G. They were left to dry out so they could be burned.

In June 2000, the scientist responsible for the field test sent a copy of the protocols to APHIS, at APHIS' request. According to the protocols, "stalks of individual plants will be severed at the soil line, allowed to dry and removed to a collection pile for subsequent burning. [Produce] will be collected periodically and buried or burned." The protocols did not disclose the length of the delay between collecting and devitalizing the produce. In August 2003, the scientist revised the devitalization protocols, but, like the 2000 protocols, the new protocols did not disclose the length of the delay between piling the GE plants and produce in the composting area and devitalizing them.

According to an applicant representative, rats eat the produce, leaving small holes, but do not bite deeply enough to reach the seeds.

Recommendation 27

Establish and implement timeframes for devitalizing GE crops.

Agency Response.

APHIS agrees with this recommendation. APHIS is committed to developing written standards that specify expected timeframes for devitalization. APHIS has already started the process of developing the science-based standards and will continue to work on this issue to ensure full implementation by early 2006.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide specific timeframes for implementation of the corrective actions described.

A key component of APHIS' regulatory program is its ability to take enforcement action in response to violations of field test regulations. If APHIS detects violations of field test requirements through inspections, or if permit and notification holders fail to submit field test reports, APHIS may take enforcement action. However, we found that APHIS needs to update its regulations to ensure that, if a violation occurs, it will be handled swiftly and effectively.

Impacting its enforcement authority, APHIS' current regulations do not require permit and notification applicants to provide proof of financial responsibility. Thus, in the event of an unauthorized GEO release or other compliance infraction, USDA may have to assume financial responsibility for removing regulated GE crops from the environment or the food supply.

Finding 9 Applicants Are Not Required to Provide Proof of Financial Responsibility

APHIS approves applicants to conduct field tests without ensuring they will be able to pay the costs associated with an unauthorized GEO release or other compliance infraction. As a result, USDA may have to assume financial responsibility for removing regulated GE crops from the environment or the food supply.

Under current laws and regulations, applicants for permits or notifications are not required to provide proof of financial responsibility as part of the approval process. However, the following two high-profile incidents highlight the need for APHIS to obtain proof of financial responsibility from applicants prior to approving introductions of regulated GE crops.

In 2002, for example, Applicant D failed to properly monitor field test sites in two States where a pharmaceutical crop had been planted the previous year. PPQ inspectors found volunteer stalks of the GE crop in both fields, which had been replanted with soybeans. In one State, BRS decided to harvest and destroy the conventional crop planted within a 1,320-foot radius of the soybean field, a total of 155 acres, in case the pharmaceutical crop volunteers had been flowering at the same time as the surrounding conventional crop.

In another State, the soybean field was harvested before the pharmaceutical crop's volunteers were removed from the field. APHIS ordered Applicant D to hold the harvested soybeans while USDA supervised the destruction of the GE volunteers still in the field. Instead, the harvested soybeans were

delivered to an elevator, where they were commingled with other harvests. As a result, USDA purchased approximately 500,000 bushels of soybeans that may have commingled with the GE volunteers. Costs to acquire the soybeans were estimated at $2.75 million to $3.75 million. Subsequently, Applicant D agreed to provide proof of financial responsibility consisting of either a deposit of money, liability insurance, or a surety bond before APHIS approval of any future field testing; to pay a civil penalty of $250,000; and to reimburse USDA for costs incurred at the field test site in one of the States.

Also in 2002, Applicant E filed for bankruptcy and, according to a former employee, went out of business, during the postharvest monitoring period of a field test of a GE pharmaceutical crop. Applicant E never paid the cooperator who was conducting the field test on the company's behalf, and APHIS agreed that the cooperator was not legally responsible for monitoring the field for volunteers. Although the cooperator agreed to monitor the field, APHIS may not be able to obtain such assistance in all cases.

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 unauthorized releases of regulated GEOs. In light of the incidents described above, APHIS should seek legislative authority to require permit applicants to provide proof of financial responsibility to indemnify USDA for costs incurred due to an unauthorized release of a GEO. The required proof of financial responsibility should be based on the level of risk of the GEO and other risk factors, such as the applicant's experience with the type of GEO and APHIS' past experiences with the applicant.

Recommendation 28

Seek legislative change to obtain the 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.

Agency Response.

APHIS stated that it does not have the authority to accept this recommendation. It will, however, refer the matter to the Office of the Secretary, for a policy decision, and further action as appropriate, within 30 days.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide us with the policy determination made by the Office of the Secretary.

Scope and Methodology

Our audit was conducted at APHIS/BRS headquarters located in Riverdale, Maryland; the PPQ Western Regional Office in Ft. Collins, Colorado; and 91 field test sites in 22 States. Our audit was conducted between May 2003 and April 2005.

We initiated this audit as a result of an audit survey conducted in 2001 of the Department's controls over the release of GEOs into the environment. Based on our fieldwork, we identified a number of systemic weaknesses in the regulation of field releases of GE crops. Our survey revealed weaknesses in the approval process for field releases, field site inspections, and interstate movements of regulated GEOs.

We selected 107 field test sites (comprised of 69 permit sites and 38 notification sites) from a universe of 1,020 field test sites (comprised of 32 permits and 228 notifications) located in the continental United States and Hawaii. We were unable to inspect 30 sites because they were not planted and another 8 because they had been harvested. We then substituted 22 additional sites from our universe for a total of 91 sites (53 sites under 23 permits and 38 sites under 28 notifications).

Our initial universe of 1,020 field test sites planted or to be planted with regulated GE crops consisted of 982 fields with expected harvest dates during or after September 2003, and 38 fields planted with pharmaceutical GE crops in 2002, which were to be reinspected for volunteers in 2003. Since APHIS did not maintain a list of planted GE fields, we developed our universe by:

- obtaining a list developed by APHIS of fields planted with pharmaceutical crops in 2002 that were to be reinspected for volunteers in 2003;
- identifying companies with pharmaceutical permits approved in 2001 and 2002 from lists provided by APHIS;
- identifying companies with permits renewed or amended in 2001, 2002, and 2003 from a list provided by APHIS;
- contacting the companies for information about the regulated GE fields that they planted or planned to plant from January 1, 2003, through September 30, 2003;
- reviewing reports from USDA/Agricultural Research Service's database to identify research that might include field trials of regulated GE crops;
- asking the USDA/Agricultural Research Service to contact our tentative selection of applicants to obtain information about whether they had

planted regulated GE crops from January 1, 2003, through September 30, 2003;
- reviewing reports in the Current Research Information System[46] to identify research that might include field trials of GE crops;
- asking APHIS to review our tentative selection of the Current Research Information System projects to determine whether the research was regulated by APHIS; and
- asking APHIS to contact the approved applicants (of the regulated Current Research Information System projects) to obtain information about whether they had planted regulated GE crops from January 1, 2003, through September 30, 2003.

During the audit, we also drew six separate judgmental samples.

- 199 movements made to or from the sampled field test sites in 2002 and 2003 to determine whether applicants complied with regulations for movement of GE regulated articles. The documentation was obtained from the personnel at the sampled field sites.
- 10 official files for pharmaceutical GEOs planted in 2002 to review the evidence of BRS scientific reviews. We judgmentally selected the files from a list that BRS provided showing 2002 pharmaceutical sites that were to be reinspected in 2003.
- 90 notifications to determine whether applicants were required to have written protocols at the field sites.
- 22 field test sites for pharmaceutical and industrial permits to determine if permit holders were complying with APHIS reporting requirements.
- 52 field test sites for other permits to determine if permit holders were complying with APHIS reporting requirements.
- 113 field test sites for notifications to determine if field test data reports were submitted to APHIS.

Our audit was performed in accordance with Generally Accepted Government Auditing Standards. To accomplish the audit objectives, we performed the following steps:

- applicable laws, regulations, and guidance concerning regulated GE crops;
- reviewed APHIS policies, procedures, and controls concerning GE crops;
- interviewed BRS Headquarters and PPQ regional officials;
- visited field test sites where regulated GE crops were planted;
- interviewed PPQ officers and persons conducting field tests; and
- interviewed cooperators regarding field release operations under permits and notifications.

[46] A public database administered by USDA's Cooperative State Research, Education, and Extension Service

Exhibit A- Agency Response

USDA

APHIS Response to 50601-8-TE

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

1400 Independence Avenue SW
Room 317 EW
Washington, DC 20250

TO: Robert W. Young
Assistant Inspector General for Audit

FROM: W. Ron DeHaven
Administrator

NOV 2 2005

SUBJECT: APHIS Response to OIG Report, "Controls Over Issuance of Genetically Engineered Organism Release Permits (50601-8-TE)"

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on this report. We have provided overall comments about the role and responsibilities of APHIS' Biotechnology Regulatory Services (BRS), and specific comments about the report's findings and recommendations.

APHIS is committed to protecting U.S. agriculture and ensuring the safety of the nation's food supply. As a part of this responsibility, APHIS established BRS in 2002, to elevate the Agency's focus and priority on biotechnology regulatory activities. It is the role of BRS to rigorously and appropriately regulate genetically engineered (GE) organisms to ensure that they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture. Further, since its establishment, BRS has set a clear direction to strengthen the regulatory process, to ensure safety by using the best science available to evaluate risks, and to support the process with a strong compliance and enforcement program.

The findings and recommendations in the Office of Inspector General's (OIG) report affirm the direction BRS set for itself and the many actions BRS has taken to accomplish its goals. Although OIG began its review in April of 2003, less than a year after BRS was created, the early direction set by BRS has enabled them to complete or begin implementing twenty-three of the twenty-eight recommendations in the OIG report. BRS has:

- Gained interagency agreement on the focus of a historic revision of APHIS biotechnology regulations and published a Notice of Intent to prepare a program-wide Environmental Impact Statement (EIS) with a proposed rule to follow that will reflect experiences gained and position BRS to meet the challenges ahead;

APHIS Response to 50601-8-TE

- Conducted more than two dozen stakeholder group meetings to solicit input for the EIS and revised regulations, held a workshop regarding the reduction of regulatory burdens for specialty crops and to further engage the states, hosted a workshop with the National Association of State Departments of Agriculture (NASDA) and established a cooperative agreement with the National Plant Board (NPB) to provide mechanisms for early state input on Federal biotechnology regulatory issues;

- Established a compliance and enforcement branch, with a dedicated team of headquarters and regional compliance officers, to ensure that all those involved in the field testing of GE crops understand and adhere to the regulations set forth by the program;

- Established a Memorandum of Understanding (MOU) with APHIS' Plant Protection and Quarantine (PPQ) to formalize inspection responsibilities, better coordinate inspections in respective regions, enhance technical assistance and training to inspectors, and ensure inspections are completed in a timely manner;

- Revised procedures to document a formal, risk-based criteria process to determine which field tests are inspected, as well as performance standard checklists and to revise program inspection manuals;

- Enhanced tracking procedures to improve efficiency and better document inspection activities, planting requirements, and other key information, as well as designed a single database to consolidate information related to field tests and provide a central warehouse of information for BRS;

- Designed a consolidated and updated *Biotechnology Regulatory Services User's Guide* (User's Guide) for the regulated community and interested public, which will incorporate all existing guidance materials into a single, accessible, easy-to-understand resource and clarify BRS policy and procedures.

Since 1987, APHIS has safely regulated GE organisms and provided oversight and enforcement for over 10,000 field tests with no demonstrable negative environmental impacts having arisen from these tests. To assure field tests are safely carried out, APHIS uses long accepted science-based principles, confirmed by the National Academy of Sciences, for the safe introduction of GE organisms.

APHIS recognizes that even successful programs can be improved and that change is necessary to keep current with changing technological trends. To that end, APHIS appreciates the work of the OIG in developing this report and the recommendations contained within. Below are our responses to the findings and recommendations.

Recommendation 1: Revise and consolidate policies, procedures, and regulatory requirements for GE field releases.

APHIS Response: This recommendation is consistent with the priorities set by BRS, including the revision of its regulation to incorporate the experience gained through nearly 20 years of regulation and the provisions of the Plant Protection Act of 2000. In 2003, BRS participated in a formal interagency discussion and coordination process with various Federal agencies including the Coordinated Framework Agencies (i.e., FDA, EPA). At the conclusion of this process, BRS gained inter-agency agreement on key aspects of APHIS' regulation revisions. BRS initiated the process of revising its regulations in January 2004 by publishing a Notice of Intent to prepare a program-wide Environmental Impact Statement (EIS). BRS will publish a draft Programmatic EIS in early 2006 and a proposed rule will follow. Rules are developed through public notice and comment, and therefore can take several years for completion. However, APHIS is committed to revising the rule. In addition, BRS has begun the consolidation and revision of guidance materials into a single *User's Guide*, and expects to have a draft version completed in the spring of 2006.

Recommendation 2: Revise and clarify policies and regulations regarding the use of metal shipping containers.

APHIS Response: As part of the new direction set by BRS, clarification of shipping container requirements for permits and notifications will be covered in the revised regulations. In addition, this issue is being addressed by the development of a consolidated and revised *User's Guide*. Again, BRS has begun the consolidation and revision of guidance materials into a single *User's Guide*, and expects to have a draft version completed in the spring of 2006.

Recommendation 3: Update regulations to incorporate the provisions of the Plant Protection Act of 2000.

APHIS Response: An early priority established by BRS was the revision of its regulation to incorporate the provisions of the Plant Protection Act of 2000 and to reflect the experience and knowledge gained through years of regulating biotechnology. In 2003, BRS participated in a formal interagency discussion and coordination process with various Federal agencies including the Coordinated Framework Agencies (i.e., FDA, EPA). At the conclusion of this process, BRS gained inter-agency agreement on key aspects of APHIS' regulation revisions. In January 2004, BRS published a Notice of Intent to prepare a program-wide Environmental Impact Statement (EIS) which lays the foundation for a proposed rule that will include provisions of the Plant Protection Act of 2000. BRS has conducted more than two dozen stakeholder group meetings to solicit input for the EIS and regulatory revisions, hosted a workshop with the National Association of State Departments of

Agriculture (NASDA) and established a cooperative agreement with the National Plant Board (NPB) to provide mechanisms for early and systematic state input into BRS' regulatory revision process. BRS will publish its draft Programmatic EIS in early 2006, with a proposed rule to follow. BRS is committed to the completion of the process of revising the rule.

Recommendation 4: Prioritize completion of the management information systems to track all information on permits and notifications.

APHIS Response: Since the creation of BRS, the completion of comprehensive state-of-the-art management information systems has been a high priority for APHIS. BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, the Biotechnology Integrated Database System (BIDS), is fully developed and only awaits final review by the Office of the Chief Information Officer.

Recommendation 5: Develop policy guidelines that address restricting public access to edible regulated crops when conducting field tests.

APHIS Response: APHIS disagrees with this recommendation. APHIS understands that the intent of this recommendation is to assure food safety. However, we feel that the system of science-based risk assessment that we currently have in place already addresses this issue. BRS can, for example, use permit conditions to require restricted access for any special cases where it might be deemed appropriate based on risk. The need for restricted access is most effectively addressed on a case-by-case basis where the biotechnologist can consider the type of trial, potential risks of the organism, and other information specific to the permit such as the exact site and locale.

Within the United States government, FDA has authority over the safety of plant foods, including foods from GE plants. EPA has authority over the safety of pesticide components in GE plants that are engineered to express proteins intended to protect the plants from insects or diseases. Food and agriculture biotechnology policy is coordinated through the Office of Science and Technology Policy (OSTP) under what is known as the Coordinated Framework for Biotechnology. The agencies regularly discuss various aspects of food and agriculture biotechnology oversight, either through OSTP-led meetings or communication at the technical level. Through those processes, FDA and EPA are kept apprised of APHIS' requirements for field testing of bioengineered food crops, including crops that have not undergone or completed

all applicable food safety review, and have supported the APHIS requirements and practices for such crops.

Recommendation 6: Revise regulations to require all permit and notification holders to submit planting notices, 4-week/28-day reports, and harvest/termination reports for all field test sites.

APHIS Response: BRS has already strengthened reporting guidelines for notifications in the 2005 growing season and is currently evaluating the various field report requirements for permits and notifications with the conclusions to be reflected in the new regulations. APHIS agrees in part with this recommendation but disagrees with the requirement for planting notices for the notifications because these notices are necessary only in cases where a pre-plant inspection is warranted. With the completion of the new regulations, BRS will require the 4 week/28 day reports for all field tests. Thus, BRS will know what has been planted within 28 days for all field tests and BRS already requires reports six months after harvest/termination.

Recommendation 7: Revise regulations to require all permit and notification holders to submit the GPS coordinates of field test sites on all reports submitted after planting.

APHIS Response: This recommendation is consistent with the direction set by BRS and in fact, BRS has already requested that GPS coordinates of each field site be submitted in 28-day planting reports. Additionally, BRS is incorporating field test location information requirements into its regulatory revisions.

Recommendation 8: Revise regulations to require all permit and notification holders to submit notices of decision not to plant if they decide to cancel an approved field test location.

APHIS Response: BRS has made revision of its regulations a priority and this issue will be addressed as part of that process. Currently, this information is already requested of all growers through our guidelines.

Recommendation 9: Complete work on the management information system and ensure that it is capable of recording necessary information related to the field test sites including the specific location of each field site and the dates of significant events.

APHIS Response: See response to Recommendation 4. A comprehensive and state-of-the-art management information system was identified as an early priority for BRS

and BRS has made much progress on this initiative. In fact, our new database system is already designed to capture all of the OIG recommended information and more.

Recommendation 10: Amend regulations to require applicants for notifications to submit written protocols prior to approval of the field test.

APHIS Response: APHIS disagrees with this recommendation. While we do evaluate written protocols for permits, we believe that the current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. Based upon our familiarity with the crops eligible for notification, we do not feel it is warranted to require or review written protocols prior to approval of field tests. Performance-based regulatory standards are commonly used in APHIS and other regulatory agencies, and our use of this approach for notifications has been acknowledged as appropriate by the National Academy of Science. The intent of the notification procedure is to provide an administratively-streamlined process for trials of crop-trait combinations with which APHIS already has a great deal of experience and familiarity.

Recommendation 11: Require and document biotechnologist reviews of notification protocols to ensure they are sufficient to meet performance standards.

APHIS Response: APHIS disagrees with this recommendation. See response to Recommendation 10.

Recommendation 12: Distribute written protocols to PPQ officers to use in conducting inspections of field test sites planted under notification.

APHIS Response: PPQ officers currently have access to written protocols at the field test site. In addition, field test design protocols for notifications will be included in our database system (see response to Recommendation 4), which can be accessed by PPQ inspectors prior to their inspections.

Recommendation 13: Develop and implement policies and procedures for documenting the scientific process and criteria for approving applications and require supervisory review of biotechnologists' work.

APHIS Response: Another early priority for BRS was strengthening science-based risk assessment policies and procedures. BRS has developed and implemented six new standard operating procedures (SOPs) related to the scientific review process. BRS is currently formulating plans for increased documentation and supervisory

review of the process. Many of these plans will be implemented before the end of fiscal year 2006. However, BRS believes major actions to address this recommendation will continue to be ongoing to ensure that a continual process of updating and improvement is in place. Further, the consolidated *User's Guide* under development will articulate our review process and approval criteria.

Recommendation 14: Establish requirements for the number of field site inspections to be performed for permits and notifications.

APHIS Response: BRS has always had requirements for field site inspections. The Compliance and Enforcement Branch has implemented documentation procedures for field site inspections and strengthened and clarified the requirements for the selection of field sites. We are continuing to strengthen our inspection requirements by developing new procedures for selection of field-site inspections based upon key risk-related factors, and are always updating and improving our procedures based upon our experience and new knowledge about risk-related factors. We are also considering additional inspection requirements as we develop our new regulations.

Recommendation 15: Develop and implement written policies and procedures for selecting specific field test sites for inspection based on risk.

APHIS Response: APHIS disagrees with this recommendation. Individual field trial sites within a given notification or permit are of comparable risk. Once a notification or permit has been selected for inspection by BRS risk assessment, allowing PPQ inspectors the flexibility to choose the specific inspection site within the permit or notification encourages more efficient use of government resources without compromising safety.

Recommendation 16: Clarify the specific roles and responsibilities of BRS and PPQ in the MOU regarding the selection and inspection of non-pharmaceutical and non-industrial release and movement permits.

APHIS Response: BRS and PPQ had already established an MOU that addressed BRS' inspection requirements for each type of permit, including non-pharmaceutical and non-industrial permits as well as the notifications. The MOU was originally written in a manner so that responsibilities were clear to both BRS and PPQ, and was implemented without any problems. However, OIG interpreted the language in the MOU differently, and suggested that problems could arise. BRS and PPQ have made revisions to the MOU to address your concerns.

Recommendation 17: Finalize the inspection tracking system and ensure that it is effective in recording the receipt of inspection reports, inspection results, and the number of inspections completed.

APHIS Response: This recommendation is consistent with the priorities already set by BRS. BRS currently has a system in place to track all of the recommended data and an improved database system for tracking inspection and field data reports has now been fully developed and will be operational after a final review by the Office of the Chief Information Officer (see response to Recommendation 4).

Recommendation 18: Finalize and implement management controls to require reporting of all inspections to BRS for review and follow-up on violations.

APHIS Response: Since the creation of BRS, the completion of our management information systems has been a high priority for APHIS, therefore we agree with the recommendation. The problems cited by OIG are currently addressed by an interim system already in place. Now that these management controls are operational, they will be consolidated into the BIDS system to increase the automation of the process (see response to Recommendation 4). Our management controls are designed to assure that inspectors complete reports for all inspection assignments and that compliance officers review these reports and follow up with appropriate correspondence or enforcement actions when noncompliance incidents are reported.

Recommendation 19: Finalize the database for recording all information related to field test progress reports for permits and notifications, including planting notices, harvest notices, and cancellation notices, to identify violations.

APHIS Response: As stated in response to Recommendation 4, since the creation of BRS, the completion of comprehensive state-of-the-art management information systems has been a high priority for APHIS. BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, the Biotechnology Integrated Database System (BIDS), is fully developed and only awaits final review by the Office of the Chief Information Officer.

Recommendation 20: Clarify guidance to define the term "termination of the field test" and establish a firm due date for field test data reports.

APHIS Response: When BRS was established, it set a goal to be more transparent and began actions to clarify policies and guidance. As part of those efforts, beginning in 2006, BRS will communicate to notification and permit holders clarified guidelines regarding the due dates for field reports and our use of the phrase "termination of the field test."

Recommendation 21: Establish and implement controls that require all reports (inspection and progress) to be submitted to BRS for tracking and review.

APHIS Response: BRS has addressed this issue as it has been raised in Recommendations 4 and 18. See responses to Recommendations 4 and 18.

Recommendation 22: Prescribe procedures for following up on missing/late progress reports.

APHIS Response: The database that tracks completion of field reports and inspections has been developed to identify missing/late reports to compliance staff (see responses to Recommendations 4 and 6).

Recommendation 23: Impose sanctions for missing and late progress reports.

APHIS Response: BRS already considers a range of responses to missing or late reports that are progressive and are proportional to the nature and magnitude of the violation, up to and including revocation of existing permits or denial of future permits.

Recommendation 24: Require applicants to disclose when they plan to dispose of GE pharmaceutical and industrial harvest in the permit application.

APHIS Response: BRS will request this data to be provided in the field report submitted 21 days prior to harvest, as opposed to inclusion in the permit application, because projected dates are more accurate closer to the end of the growing season, therefore APHIS agrees with this recommendation, in part.

Recommendation 25: Require PPQ officers to determine, when conducting post-harvest inspections, if any regulated GEOs are stored and adequately contained.

APHIS Response: Inspecting for on-site storage of regulated GE plants is currently a part of our post-harvest inspections. In addition, the worksheet for post-harvest

inspections that has been in use for several years includes questions about seed storage and security. Therefore, this recommendation has already been implemented.

Recommendation 26: Require permit holders to timely report the amount, location, and actual disposition of pharmaceutical and industrial GE harvests, including devitalization, shipment to another location, or replanting.

APHIS Response: APHIS agrees, in part, with this recommendation. APHIS will require additional information about the disposition of materials derived from plants engineered to produce pharmaceutical and industrial compounds, including expected timeframes for devitalization. However, requirements for reports on final dispositions are not necessary to ensure confinement measures are met, because this information is already captured in permit conditions and pre-harvest reports.

Recommendation 27: Establish and implement timeframes for devitalizing GE crops.

APHIS Response: APHIS agrees with this recommendation. APHIS is committed to developing written standards that specify expected timeframes for devitalization. APHIS has already started the process of developing the science-based standards, and will continue to work on this issue to ensure full implementation by early 2006.

Recommendation 28: Seek legislative change to obtain the authority to require permit applicants, based on level of risk, to provide proof of financial responsibility in the event of an unauthorized GEO release.

APHIS Response: APHIS does not have the authority to accept this recommendation. We will, however, refer it to the Office of the Secretary for a policy decision, and further action as appropriate, within 30 days.

Glossary of Terms

Applicant	Person who applies for a permit or notification to introduce a GEO.
Border row	A perimeter of non-GE plants surrounding GE plants at a field test site.
DNA	Deoxyribonucleic acid (DNA). The basis for genetics and heredity, DNA is found within the nucleus of most plant and animal cells.
Devitalization	Methods of rendering transgenic material nonviable (dead) and, therefore, no longer a potential plant pest subject to regulation. Methods could include dry heat, steam heat, crushing, deep burial, and/or chemical treatment.
Disposition	What becomes of the crop after the field test, including harvest for shipment or replanting, or destruction.
Field test	Planting of GE crops in the environment to test their agronomic properties.
Gene	A segment of DNA that typically codes for a protein. A gene is also a unit of heredity.
Genetic engineering	Process by which DNA from one or more organisms is inserted into the genetic material of a second organism so that the second organism (host) expresses new traits. Also called biotechnology.
Industrial plants	Plants engineered to produce industrial compounds include those plants that meet the following three criteria: (1) the plants are engineered to produce compounds that are new to the plant, (2) the new compound has not been commonly used in food or feed, and (3) the new compound is being expressed for nonfood, nonfeed industrial uses. Industrial uses include, but are not limited to, detergent manufacturing, paper production, and mineral recovery.
Introduction	Importation, interstate movement, or confined release into the environment.
Monitoring	Applicants' protocol of adequate duration to ensure all plant volunteers have been eliminated.
Movement	To ship, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States.

Notification	A streamlined procedure under APHIS regulations by which regulated articles may be introduced into the environment, such as for a field test. The notification application is submitted at least 30 days in advance of the proposed release into the environment.
Performance standards	A set of six conditions that notification holders must meet in order to ensure containment of the introduced regulated article.
Permit	A written authorization from APHIS to allow release of a regulated article into the environment. The permit application is submitted at least 120 days in advance of the proposed release into the environment.
Permit conditions	APHIS requirements that must be met to prevent the dissemination and establishment of plant pest.
Pharmaceutical plants	Any plant manipulated by recombinant DNA technology to express a gene encoding a biological or drug product.
Pollen sink	A perimeter of nontransgenic plants that surround transgenic plants and acts as a pollen sink for insect pollinators.
Protocols	Description of the methods to be used during the field test to meet the performance standards or permit/notification conditions.
Regulated article	Any organism that has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 7 CFR 340.2, dated January 1, 2003, and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown.
Release	The use of a regulated article outside the physical constraints of a laboratory, greenhouse, fermenter, or other contained structure.
Transgene	A gene transferred into another organism by means of biotechnology.
Transgenic crop	An agricultural crop that expresses one or more transgenes.
Volunteer plants	Plants originating from seeds of a GE crop planted the previous season.

Informational Copies of this report have been distributed to:

Administrator, APHIS	
Attn: Agency Liaison Office	(9)
General Accountability Office	(1)
Office of the Chief Financial Officer	
Director, Planning and Accountability Division	(1)
Office of Management and Budget	(1)