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OFFICE OF INSPECTOR GENERAL

Controls Over APHIS' Introduction of Genetically Engineered Organisms

Audit Report 50601-0001-32

September 2015

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What Were OIG's Objectives

Our objective was to determine whether APHIS adequately controls the introduction of GE organisms into the environment.

What OIG Reviewed

Our audit reviewed permits, notifications, and the petition review process at APHIS' Biotechnology Regulatory Service's (BRS) Headquarters in Riverdale, MD; the APHIS-BRS' Eastern Compliance Assurance Branch office in Raleigh, NC; and 27 field test sites in 6 States.

What OIG Recommends

APHIS should implement the corrective actions it agreed to for three prior recommendations; develop adequate controls for field trial locations; codify a written process for the risk-based selection of permits for inspection; update its compliance database; make compliance history a factor in the distribution of permits and notifications; and track and record all steps in the petition review process.

OIG reviewed APHIS' controls over the release of genetically engineered organisms into the environment

What OIG Found

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) oversees the environmental release of genetically engineered (GE) organisms that may pose a risk to plant health. In our 2005 assessment, we found weaknesses in APHIS' regulations and internal management controls that increased the risk that regulated GE organisms inadvertently would persist in the environment before those GE organisms were deemed safe to grow without regulation.

Our current review found that APHIS has not implemented the agreed upon corrective actions for 3 of the 28 recommendations from a 2005 report, nor has the agency developed a timeline for resolving these recommendations, which included consolidating regulations for minimizing inadvertent release of GE material, regulating the movement of GE seeds, and incorporating additional authority to control noxious weeds. Furthermore, weaknesses still exist in relation to three recommendations for which corrective actions were implemented regarding progress reporting, inspection site selections, and sanctions for noncompliance. Specifically, we found that APHIS does not (1) have adequate controls in place to monitor field trial locations; (2) have a written process for selecting permits for inspection based on risk; (3) maintain a compliance database that is complete, accurate, and consistent; (4) use compliance history in approving applications for permits or notifications; and (5) maintain sufficient records of a petition's progress through the review process.

Overall, we concluded that APHIS needs to take steps to tighten its control and oversight over the release of GE organisms into the environment.

The agency agreed with our recommendations and we were able to reach management decision on the majority of the recommendations.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: September 22, 2015

AUDIT NUMBER: 50601-0001-32

TO: Kevin Shea
Administrator
Animal and Plant Health Inspection Service

ATTN: Marilyn Holland
Deputy Administrator
Marketing and Regulatory Programs Business Services

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Controls Over APHIS' Introduction of Genetically Engineered Organisms

This report presents the results of the subject audit. Your written response to the official draft report, dated August 27, 2015, is included in its entirety at the end of this report, with excerpts and the Office of Inspector General's position incorporated into the relevant sections of the report. Based on your written response, we accept your management decision on Recommendations 1, 3, 4, 5, 6, 7, 9,10, and 12. Management decision has not been reached for Recommendations 2, 8, 11, and 13. The actions needed to reach management decision for these recommendations are described under the relevant OIG Position sections.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decisions have not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions.

This report contains publically available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

Table of Contents

Background and Objective

Background

Agricultural biotechnology includes a range of techniques—including both genetic engineering and traditional breeding techniques—that alter living organisms or parts of organisms to make or modify products, improve plants or animals, or develop micro-organisms for specific agricultural uses. In its regulations for genetically engineered (GE) organisms, the U.S. Department of Agriculture (USDA) defines genetic engineering as the genetic modification of organisms by recombinant deoxyribonucleic acid techniques. GE crops have a wide variety of traits that can benefit farmers, consumers, and the environment. For example, GE crops can tolerate drought conditions and herbicides, resist insects and viruses, and provide enhanced quality and nutrition for consumers.

Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology[1] describes the Federal system for evaluating products developed using modern biotechnology. The three Federal agencies primarily responsible for regulating the safe use of GE organisms are the Environmental Protection Agency (EPA), the U.S. Department of Health and Human Services' Food and Drug Administration (FDA), and USDA's Animal and Plant Health Inspection Service (APHIS). EPA regulates pesticides, including plants with plant-incorporated protectants,[2] to ensure public safety. FDA has primary responsibility for ensuring the safety of human food and animal feed, as well as proper labeling and safety of all plant-derived foods and feed. Through its Biotechnology Regulatory Services (BRS) program, APHIS oversees the introduction (importation, interstate movement, or release[3]) of GE organisms that may pose a risk to plant health.[4]

BRS authorizes the introduction of certain GE organisms into the United States by issuing permits and acknowledging notifications. For the introduction of GE organisms that pose a plant pest[5] risk, BRS issues permits. Permit applications provide details about the nature of the GE organism to be introduced and the conditions that will be used to prevent the spread and establishment of the organism in the environment. Different types of permits (industrial, pharmaceutical product, phytoremediation, and traditional) require that different types of information be submitted and reviewed. The individual who is issued a permit must comply with permit conditions set forth in Title 7 Code of Federal Regulations (CFR) §340.4 and

[1] 51 Federal Register 23302, *Coordinated Framework for Regulation of Biotechnology*, June 26, 1986.
[2] Plant-incorporated protectants are pesticides intended to be produced and used in a living plant.
[3] "Release into the environment" is the use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.
[4] Plant Protection Act, Public Law 106-224, June 20, 2000.
[5] A plant pest is "any living stage (including active and dormant forms) 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." Title 7 Code of Federal Regulations (CFR) Part 340, *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,* 340.1, May 2, 1997.

supplemental conditions imposed by BRS. Permits are valid for up to 3 years from the effective date.

A notification is an administratively-streamlined alternative to a permit. The GE plant must meet specified eligibility criteria, and the introduction must meet certain pre-defined performance standards. By submitting a notification, the applicant certifies that the regulated article and introduction will meet the specified eligibility criteria and performance standards. Eligibility criteria are characteristics of the regulated article (i.e., the plant) and the introduced genetic material. Specifically, the eligibility criteria are:

- recipient organism is not listed as a noxious weed or considered to be a weed in the area of release;
- the introduced genetic material is stably integrated in the plant genome;
- the function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease;
- the introduced genetic material does not create an infectious entity, create a substance toxic to non-target organisms, or create products intended for pharmaceutical or industrial use;
- the regulated article does not pose significant risk of creating new plant viruses; and
- the regulated article does not contain sequences from human or animal pathogens.

Upon BRS' approval, an acknowledged notification is valid for one year from the date of acknowledgement. The introduction cannot proceed until on or after the date of acknowledgement.

Both permits and notifications are subject to inspection by trained Federal and/or State inspectors. Inspectors evaluate field tests, facilities, equipment, developer's records, and potential incidents. Methods of verification used for inspection include records review, interview, observation, and measure and mapping. All permits receive at least one inspection within the State(s) where release occurs each year. Plants engineered to produce pharmaceutical or industrial proteins are inspected up to seven times (before, during, and after release). Notifications are selected on a statistically valid random sampling basis for inspection. After APHIS or State inspectors complete an inspection, the inspectors prepare an inspection report which is submitted to BRS' compliance branches.[6]

If an inspection reveals no regulatory concerns, BRS sends the responsible person[7] a Standard Notice of Compliance. When responsible persons do not adhere to APHIS regulations, BRS refers to these events as "noncompliance incidents." These incidents take many forms. Some involve administrative problems, such as a developer listing the wrong location on a permit. Others include failing to notify APHIS in the event of vandalism or destruction of a field test, failing to obtain a permit, or planting a field-test site before a permit becomes effective. Incidents may result in a responsible person receiving a Notice of Compliance with Comments

[6] BRS' compliance branches are the Compliance Assurance Branch as well as the Compliance Evaluation and Enforcement Branch.

[7] A responsible person is the person who has control and will maintain control over the introduction of the regulated article and assure compliance with all permit conditions and regulatory requirements.

(NOC),[8] Notice of Noncompliance (NONC),[9] or Warning Letter (WL).[10] In such cases, BRS may seek corrective actions to achieve compliance. For example, BRS may require the responsible person to implement a mandatory compliance training program for their staff. Depending on the seriousness of the incident, BRS may refer the case to APHIS' Investigative and Enforcement Services for further investigation.

In addition to being subject to inspection, planting reports are required from permit holders and are frequently requested, but not required by regulations, from notification holders. At a minimum, planting or release reports and field test reports must be submitted to APHIS for each location of activities authorized by permit. According to guidance to all responsible persons, planting reports must be submitted to APHIS or postmarked by the 15th of the month following the month in which the planting occurred. A field test report[11] must be submitted to APHIS within six months of the termination[12] of an environmental release under both permits and notifications. Additional reports may be required for permits, depending upon the type (traditional or pharmaceutical/industrial) of field trial being conducted.

Our 2005 audit of the controls over GE organism release permits disclosed weaknesses in APHIS' regulations and internal management controls; these weaknesses increased the risk that regulated GE organisms would inadvertently persist in the environment before they were deemed safe to grow without regulation.[13] In 2005, we concluded that APHIS needed to strengthen its accountability for field tests of GE crops. Specifically, APHIS did not:

- have a cohesive formal process to manage GE organism field releases,
- always know the precise locations of the GE field test sites planted,
- always obtain the written field test protocols from applicants,
- sufficiently document the scientific reviews of field test applications,
- establish an effective inspection program to monitor regulated GE crops,
- adequately monitor the field test progress reports,
- have controls in place over the final disposition of GE pharmaceutical harvests, and
- ensure GE crops were promptly destroyed.

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[8] This letter is issued when an incident is determined not to be a violation of the regulation, but the analysis revealed activities or circumstances that could lead to a non-compliance incident in the future and/or there are specific compliance concerns that need to be communicated back to the responsible party. The responsible party is the entity who has control and maintains control over the introduction of the regulated article and assures compliance with all standards, conditions, and regulatory requirements.

[9] This letter is issued when an incident is a violation of the regulation.

[10] This letter is issued when an incident is a violation of the regulation and is deemed severely serious, involves a severely culpable responsible party, or possesses other specific aggravating criteria.

[11] A field test report describes the condition of planted material—if there is any remaining in the field, if it was disposed of and how, or if it was harvested. Information is submitted for each planted location listed in the permit or notification. Final field test reports require that each release site be accounted for. Thus, each site must have either a No-Planting record or one or more Planting records.

[12] Termination is typically defined as harvesting or destroying the regulated article(s). Because APHIS does not always know the actual termination date in advance, APHIS considers the field test report to be due no later than six months after the expiration of the permit or notification.

[13] Audit Report 50601-0008-Te, *Controls Over Issuance of Genetically Engineered Organism Release Permits*, December 2005.

After conducting a field test of a GE organism, developers may petition APHIS to no longer consider (1) the article regulated or (2) no longer list it as being a plant pest or containing plant pests. Beginning in late 1999, the petition process started experiencing a slowdown and increased variation of all major steps, which APHIS attributed to such factors as increased petition volume, petition complexity, and petition length. According to APHIS, the process steps were unclear and lacked deadlines; petition progress was challenging to track; and there was competition for resources. The Petition Process Improvement Project was launched in December 2010, with the goal of identifying and implementing solutions to significantly and measurably improve the speed and predictability of the petition process without affecting the quality of decision making. The Petition Process Improvement Project provided a streamlined, standardized process with defined deadlines; resource management and tracking tools; clearer separation of plant pest risk assessment and National Environmental Policy Act functions; and earlier opportunity for public involvement.

Objective

Our objective was to determine whether APHIS has established adequate controls over the introduction of GE organisms into the environment. Specifically, we assessed controls to minimize the inadvertent release of GE organisms and provide reasonable assurance that movements and releases of GE organisms in the environment are in accordance with laws and regulations. As part of this audit, we also ascertained the status of corrective actions in response to recommendations made in a prior report.

Section 1: Management Oversight and Accountability

Finding 1: APHIS Needs to Implement its Corrective Actions

In 2005, we published a report detailing broad-ranging problems with APHIS' regulation of GE crop field testing. The report included 28 recommendations to help the agency strengthen that process. Since then, APHIS has implemented corrective actions for 25 of the 28 recommendations, but 3 remain unaddressed. Specifically, the agency has not developed a timeline for consolidating regulations for minimizing inadvertent release of GE material, regulating the movement of GE seeds, and incorporating additional authority to control noxious weeds. In addition, while corrective actions were implemented for 25 recommendations, weaknesses still exist in relation to 3 of these recommendations (see Exhibit B). We found several weaknesses in APHIS' controls over field tests–specifically progress reporting, inspection site selections, and sanctions for noncompliance. This has occurred because, when APHIS published proposed changes in regulations for public comment, it received over 5,500 responses containing more than 88,000 signatures.[14] The range and variety of these comments slowed the agency, and we acknowledge that responding to them was a significant undertaking. Additionally, corrective actions APHIS implemented for three other recommendations did not fully address the previously identified weaknesses. We maintain that APHIS must develop a reasonable timeline for implementing corrective actions to address these remaining recommendations and implement corrective actions for previously identified weaknesses that still exist. Until APHIS closes the gaps in its existing guidance, the agency's additional authority to control noxious weeds is not transparent; it cannot take enforcement action; and it risks inconsistent interpretation of its regulations. Additionally, effective management and oversight are essential to reduce the risk of inadvertent release of regulated GE crops in the environment.

Within APHIS, the BRS unit carries out the agency's biotechnology oversight responsibilities authorized by the Plant Protection Act of 2000.[15] According to the Act, no person shall import, enter, export, or move in interstate commerce any plant pest unless it is authorized and in accordance with regulations issued by the Secretary of Agriculture to prevent introduction or dissemination within the United States. Departmental Regulation requires agencies to implement agreed-upon corrective actions associated with audit recommendations in a timely manner.[16] *Office of Management and Budget (OMB) Circular A-123*[17] requires appropriate internal control to be integrated into each system established by agency management to direct and guide its operations. Deficiencies identified, either through an internal review or an external audit, should be evaluated and corrected. A systematic process should be in place for addressing deficiencies. *OMB Circular A-123* also provides that management should identify risks that may prevent the organization from meeting its objectives. When identifying risks, management should consider previous findings.

[14] APHIS received 5,580 comment forms which contained approximately 88,300 signatures.
[15] Plant Protection Act, Public Law 106-224, June 20, 2000.
[16] Departmental Regulation 1720-001, *Audit Follow-up and Management Decision*, November 2, 2011.
[17] OMB Circular A-123, *Management's Responsibility for Internal Control,* December 21, 2004.

The Government Accountability Office (GAO)[18] adopted five components of internal control, one of which provides the discipline and structure that affects the overall quality of internal control, influences how control activities are structured, and requires the oversight body and management to establish and maintain an environment that sets a positive attitude toward internal control. The components also include assessing risks, establishing control activities (i.e., policies, procedures, techniques, and mechanisms), using effective information and communication, and monitoring performance over time and promptly resolving identified issues.

Corrective Actions Not Implemented – Three Recommendations

The prior audit found that APHIS' approach was 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 lacked clear comprehensive requirements and effective internal controls to minimize the risk of inadvertent release of GE organisms into the environment. The prior audit concluded that, to make its requirements transparent to the public and enable it to take enforcement action when necessary, APHIS needed to assemble its various pieces of guidance in a comprehensive set of regulations. On June 20, 2006, APHIS agreed to revise the regulations and projected completion of a final rule in late calendar year 2007. However, this final rule has not yet been completed.

In **Recommendation 1**, we recommended that APHIS revise its regulations to consolidate all requirements for conducting field tests of regulated material. The prior audit revealed that APHIS needed to work toward a more cohesive formal process for managing GE organism field releases. At that time, APHIS' guidance for conducting field tests was neither consolidated nor comprehensive. The regulations did not include specific requirements to guide applicants during all phases of the process.

During our current audit, APHIS stated that the policies and procedures have been consolidated internally, but acknowledges that this does not meet the spirit of the recommendation from the 2005 audit report. We noted that APHIS has developed several user's guides and standard operating procedures (SOP); however, the requirements have not yet been consolidated into a comprehensive regulation. Due to the lack of regulatory guidance, incidents of potential noncompliance that are reported for notifications and permits are not treated consistently. For example, when planting reports are not received for a notification, the responsible person receives a NOC.[19] However, when planting reports are not submitted for a permit, the responsible person receives a NONC.[20] For instance, of 86 notification incidents referred to APHIS' compliance branch between October 1, 2012, and April 14, 2014, 9 were referred because of late or missing planting reports and received a NOC. However, two permits received a NONC for not submitting planting reports during this same time frame. APHIS stated this was because the regulation did not require planting reports for notifications; therefore, the responsible

[18] GAO-14-704G, *Standards for Internal Control in the Federal Government,* September 2014.
[19] This letter is issued when an incident is determined not to be a violation of the regulation, but the analysis revealed activities or circumstances that could lead to a non-compliance incident in the future and/or there are specific compliance concerns that need to be communicated back to the responsible party.
[20] This letter is issued when an incident is a violation of the regulation.

person cannot receive a NONC, even though the acknowledgement letters[21] and notification user's guide requires planting reports to be submitted.

In **Recommendation 2**, we recommended that APHIS clarify its regulations regarding the use of metal shipping containers. The prior audit identified a widespread violation pertaining to 193 movements of GE seeds, which APHIS allowed to be shipped in nonmetal containers, in violation of its own requirements. Federal regulations require double metal containers for shipments of regulated GE material.[22] According to the regulations, shippers can request a variance from the metal container requirement if they justify their request.[23] However, APHIS' website and its user's manual allowed shippers to forgo using metal containers for regulated articles shipped under notifications. Also, the agency allowed permit holders to forgo using metal containers without obtaining formal variances. The prior audit concluded that APHIS needed to clarify its regulations for shipments of GE seeds to prevent inconsistent interpretation.

APHIS officials explained that they have tried to address shipping container problems without making a rule change. However, in its response to the prior recommendation, APHIS agreed to issue a revised final rule to clarify the use of metal shipping containers. While APHIS' regulation requires triple containment[24] for GE organism shipment, it does allow responsible persons to obtain a variance from the metal shipping containers required for permits. In addition, notification holders do not have to request a variance when choosing not to use metal shipping containers, in accordance with performance standards outlined in the regulation. During our review, we noted that the responsible persons were adhering to these requirements, in accordance with the regulation. To guard against further noncompliance with these shipping containment provisions, APHIS still needs to revise its regulation to more clearly differentiate between the provisions for permits and notifications.

Lastly, in **Recommendation 3** of the prior audit report, we recommended that APHIS update its regulations to incorporate the provisions of the Plant Protection Act of 2000, under which the agency carries out its biotechnology oversight duties. The prior audit noted that APHIS had not finished updating its regulations to comply with the Act, which was enacted on June 20, 2000. On July 16, 2001, APHIS had partially updated its regulations to include the new authority to subpoena documentary evidence and witnesses to prosecute violators. However, APHIS still needed to update its regulations to reflect other provisions of the Act, which granted new regulatory authority to the Secretary of Agriculture for controlling noxious weeds. The agency stated that the new regulation would incorporate these provisions of the Act.

However, to date, these three recommendations remain unaddressed, almost a decade after the prior report and 15 years after the passage of the Plant Protection Act. APHIS does not currently have a timeline for implementing the agreed-upon corrective actions.

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[21] Acknowledgement letters are sent to notification applicants authorizing them to perform the movement and/or release of the regulated article.

[22] Title 7 CFR Part 340, *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,* 340.8(b)(2), May 2, 1997.

[23] Title 7 CFR Part 340, *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,* section 340.8(c), May 2, 1997.

[24] All seeds shall be transported in a sealed plastic bag, inside a sealed metal container, which shall be placed inside a second sealed metal container.

When we spoke to APHIS officials about these recommendations, they explained their attempt to revise the regulation. The officials stated that they issued a proposed rule in October 2008 to amend the regulations, including significant changes to the scope of the regulations and the mechanics of APHIS' regulatory oversight. The agency received over 5,500 responses, containing more than 88,000 signatures,[25] in response to the proposal from a variety of stakeholders, including advocacy groups; State, Tribal, and foreign governments; university researchers; trade associations; regulated entities; and private citizens. The comments varied considerably between those seeking stronger regulations and those seeking less strict regulations.

APHIS officials stated that since 2008, the revision has been a work in process in order to address the voluminous amount of comments. In addition, they stated that rule changes are subject to several layers of review before they can be approved and this rule change was highly controversial. The revision process is ongoing.

At the beginning of our current audit, APHIS officials stated that the agency's goal was to have the regulation to OMB by the end of fiscal year (FY) 2014; however, the agency has missed this deadline. The proposed rule was withdrawn in March 2015. APHIS officials are still working to revise the regulation, but were unable to provide us with an estimated completion date.

We acknowledge the challenge APHIS faces in developing new regulations that respond to the interests of the many differing stakeholders in this case; however, APHIS must develop a reasonable timeline for implementing agreed upon corrective actions for these remaining recommendations.

Corrective Actions Were Insufficient or Rescinded – Three Recommendations

The prior audit found that APHIS did not effectively track information required during the field tests through progress reports. Many permit and notification holders submitted the required progress reports late, or not at all, and APHIS did not always follow up to obtain the information or assess penalties for noncompliance. Furthermore, APHIS did not have a formal, risk-based process for selecting individual sites for inspection. The prior audit 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. However, we noted that these weaknesses still exist, even after the agreed-upon corrective actions were implemented or, in one case, rescinded by the agency.

In **Recommendation 19**, we recommended that APHIS finalize its database for recording all information related to field test progress reports for permits and notifications. In 2005, we reported that applicants did not always submit progress reports for field trial locations in a timely manner, if at all. Also, we reported that APHIS did not have an effective method, manual or computerized, to determine when or if required progress reports were submitted. In response to our recommendation, APHIS developed the Biotechnology Integrated Database System. However, this system has been retired; e-Permits is currently the comprehensive electronic

[25] See additional explanation in footnote 14.

permit data collection and management system used to track all activities associated with APHIS processes. During our current audit, we found that progress reports are still submitted late, or not at all, and e-Permits does not have a method to identify late or missing reports (see Finding 2).

In **Recommendation 15**, we recommended that APHIS develop and implement written policies and procedures for selecting specific field test sites for inspection based on risk. At that time, the selection process was undefined and ambiguous, there was no documentation of the risk factors used, and APHIS had not documented how it selected its sample for inspection. In response to our recommendation, APHIS began assigning risk scores and planned to modify the risk scoring system as it gained experience with it. However, during our current audit, we found that APHIS no longer uses the risk scoring system and is, once again, operating with an undocumented methodology (see Finding 3).

In **Recommendation 23**, we recommended that APHIS impose sanctions for missing and late progress reports. We reported that the regulations and permit conditions allowed APHIS to withdraw a permit or deny future permits if the conditions of any permit were not met; however, the agency had not been applying this sanction.[26] In response to our recommendation, APHIS developed procedures which describe the types of sanctions and when these sanctions are to be imposed. However, during our current audit, we found that APHIS still does not utilize the sanction of withdrawing permits or denying future applications based on a history of noncompliance (see Finding 5).

Specific recommendations to address these weaknesses are stated at the end of each related finding.

We concluded that APHIS' internal control system lacked adequate oversight to ensure implementation of control activities, monitor performance, and promptly resolve identified issues. Thus, there is reduced assurance that APHIS can prevent an inadvertent release of regulated GE crops into the environment. Therefore, APHIS needs to emphasize and strengthen controls over its approval and monitoring of GE crops.

Recommendation 1

Develop an action plan, with a timeline, for implementing the actions agreed to in Recommendations 1, 2, and 3 of Audit Report 50601-0008-Te. Also, implement a process to ensure that the actions are completed within the established timeframes.

Agency Response

In its August 27, 2015, response, APHIS agreed with the recommendation and stated that it was consistent with the priorities identified by APHIS in the December 2005 OIG Audit Report,[27] and continues to be a high priority goal for the agency. APHIS further stated that it withdrew its

[26] Based on the examples presented in the prior report, "permit," in this case, includes both permits and notifications.
[27] Audit Report 50601-0008-Te, *Controls Over Issuance of Genetically Engineered Organism Release Permits*, December 2005.

2008 proposed rule on February 27, 2015, that would have amended the regulations regarding the introduction (importation, interstate movement, and field release) of certain GE organisms which would have, among other changes, addressed the open recommendations in the previous report. APHIS received over 88,300 comments on the proposed rule and decided to start anew with stakeholder engagements aimed at exploring alternative policy approaches. Specifically, APHIS stated that in May 2015, it began an open and robust dialogue with stakeholders to drive the development of future regulatory or policy approaches by holding a series of webinars and opening a docket in the *Federal Register* to obtain written public comments.

APHIS stated that it will submit a regulatory work plan to propose a change to current regulations that addresses the recommendations in the 2005 and current audit, where applicable. This work plan will be submitted to the Office of Budget and Program Analysis (OBPA) for Departmental clearance by October 1, 2015, and will have a draft proposed rule for Departmental review by September 30, 2016. It further stated that since it does not control the process going forward, it cannot predict the timing or the final outcome of rulemaking. APHIS also stated that on July 2, 2015, the White House's Office of Science and Technology Policy launched a year-long effort to review the Coordinated Framework for the Regulation of Biotechnology which may affect the nature and timing of the regulatory changes.

OIG Position

We accept APHIS' management decision on this recommendation.

Section 2: Monitoring and Tracking of Field Testing

Finding 2: APHIS Needs to Improve its Field Trial Monitoring

We determined that APHIS still does not have adequate controls in place to account for and sufficiently monitor all field trial locations. In our review of 599 permits and notifications, we found: 14 plantings went unreported; 39 plantings were not reported on time; and 46 incidents of potential noncompliance went unreported. We also found that APHIS does not review the final field test reports to ensure that all possible planting locations are accounted for and all plantings have been reported. These inadequate monitoring conditions occurred because APHIS' information system is not capable of tracking and identifying late or missing reports or referring (to APHIS' compliance branch) incidents of late or missing reports. Additionally, the agency does not have a policy or process in place to review reports. As a result, at any given time, APHIS is not aware of the status of all planted field trial locations, and not all planted locations are included in the universe of sites to be selected for inspection. Consequently, inadvertent releases of GE organisms are at risk of occurring.

Regulations[28] require that permit holders follow the permit and supplemental conditions[29] of their permits. Further, APHIS' supplemental conditions require multiple progress reports to be submitted. Not submitting these reports is a regulatory violation for permit holders. Specifically, the supplemental conditions require the submission of planting reports[30] no later than the 15th day of the month following the date of release. For notifications, APHIS issues acknowledgment letters,[31] which provide key details on notifications and require that planting reports be submitted. However, the regulation does not stipulate that the requirements outlined in the acknowledgement letters be followed or require planting reports. Both notifications and permits have a regulatory requirement to submit an end of field test report[32] within six months after termination. However, because APHIS does not always know the actual termination date in advance, APHIS considers the field test report to be due no later than six months after the expiration of the permit or notification.

OMB requires[33] agency management to develop and maintain effective internal controls. They should design management structures that help ensure accountability for results. According to

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[28] Title 7 CFR Part 340, *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*, Section 340.4(f), August 6, 2007.
[29] Permit conditions, which shall be listed on the permit, are deemed by the Administrator as necessary, and must be complied with, to prevent the dissemination and establishment of plant pests. Supplemental conditions, imposed by APHIS, are tailored to the permit's action along with the regulated conditions. The supplemental conditions include the reporting requirements for each permit.
[30] A planting report contains either planting or no-planting data for each release site on the original permit or notification. Planting reports are used to identify the size, location, and duration of all plant environmental releases.
[31] Acknowledgement letters are sent to notification applicants authorizing them to perform the movement and/or release of the regulated article in accordance with 7 CFR 340.3.
[32] A field test report describes the condition of planted material—if there is any remaining in the field, if it was disposed of and how, or if it was harvested. Information is submitted for each planted location listed in the permit or notification. Final field test reports require that each release site be accounted for. Thus each site must have either a No-Planting record or one or more Planting records.
[33] OMB Circular A-123, *Management's Responsibility for Internal Control,* December 21, 2004.

GAO,[34] automated control activities tend to be more reliable because they are less susceptible to human error and typically more efficient.

Reports are used to communicate important information about regulated materials covered by permits and notifications. Each report is associated with a permit or notification that contains one or more release sites, and each release site can be planted or monitored several times over the permit's or notification's lifespan. The reports serve various purposes, such as initiating an inspection process, verifying the progress of an introduction, or monitoring compliance. Therefore, all the holders of active permits and notifications that contain release sites need to submit reports to APHIS in order for APHIS to know the status of each release. These reports may be submitted electronically, through e-Permits, or outside of e-Permits, via mail or email.[35] However, we identified several examples of deficiencies in APHIS' monitoring of regulated GE crops.

APHIS Cannot Account for All Approved and Planted GE Crop Locations

By comparing 599 approved permits and notifications identified in APHIS' data file[36] to various listings of permits and notifications for plantings which had been reported to APHIS, we identified 103 permits and notifications that had not been reported, according to the agency's records.[37] After speaking to the agency about why a report had not been received for these permits and notifications, we concluded that permit and notification holders do not always submit the required reports in a timely manner, or sometimes do not submit them at all.

Specifically, we found that during FY 2013, responsible persons did not submit planting reports for 14 permits and notifications, although plantings had occurred. In addition, permit and notification holders submitted late planting reports in another 39 instances, with 29 of these being submitted after our request for a list of FY 2013 plantings. We found that 6 of these 29 planting reports were submitted more than a year after their plantings. As a result, APHIS explained that these six could not be inspected because it received the planting reports after the crops were harvested.

When we asked why these planting reports were submitted so late, APHIS was unable to provide an explanation. We did note that APHIS' current information system (e-Permits) does not include a field for report due dates, which would assist with identifying when to expect reports and act as a warning for missing reports, which would initiate follow-up actions by the agency. Currently, APHIS compares the planting reports to the data file in order to identify permits and notifications that have not been reported, which is a

[34] GAO-14-704G, *Standards for Internal Control in the Federal Government,* September 2014.
[35] Reports that are submitted via mail or email must be scanned into e-Permits and attached to the corresponding permit or notification; therefore, the information contained in these reports is not searchable.
[36] This file was a download of all notification and permit data, provided by APHIS from its website. The information on the website is from e-Permits. We identified 599 permits and notifications that were approved for FY 2013 as of December 3, 2013.
[37] The 103 permits and notifications include: 38 for which reports are not required; 45 that submitted late (39 late planting reports and 6 late "reports of no planting"); and 20 that did not report anything to APHIS (14 planted but did not submit a planting report and 6 expired but did not submit "report of no planting").

cumbersome process. Additionally, we determined that the data file does not identify actual release sites, but only the States in which each responsible person proposes a release. Therefore, the manual process currently in place would only tell the agency if a planting has occurred in one of the proposed States, but would not provide the specific location of all approved release sites. As a result, we believe that APHIS' monitoring controls were not sufficient to track submitted reports and identify missing reports for all plantings of GE regulated crops.

The agency stated that it is aware of the negative impacts of not receiving reports in a timely manner. APHIS officials agree and recognize this as a problem and have recently implemented a Business Process Improvement initiative which will focus on obtaining these reports and reviewing their contents. However, this issue was presented to APHIS in our 2005 audit report and is still a weakness. Therefore, APHIS must ensure that it implements the corrective actions to fully address the issue. Doing so will further mitigate the risk of unauthorized releases occurring without the agency's knowledge and allow APHIS to improve its monitoring of releases through inspections.

APHIS Lacks a Process for Referring Late or Missing Reports to its Compliance Branch

Even if APHIS' information system provided the ability to better track submitted reports and identify late and missing reports, the agency's system does not include a method to refer reporting-related incidents to its Compliance Evaluation and Enforcement Branch (compliance branch) for review and determination of consequences. Through our review of permits and notifications with unreported plantings, we determined that APHIS does not have a documented process for referring incidents of late or missing progress reports to its compliance branch. Our analysis revealed permits and notifications where the responsible person either did not submit a report to APHIS or submitted a late report. We followed up with the agency to determine if these incidents of late or missing reports had been referred to the compliance branch.

In April 2014, the agency provided us documentation confirming 46 (of the 55)[38] incidents in which the planting reports were either late or never submitted for FY 2013. However, the agency had not identified these incidents and did not refer them to the compliance branch until March and May 2014, after our inquiry. When we inquired about a missing report, APHIS followed up with the responsible person and sent an email to its compliance branch, notifying them of the missing report. According to APHIS, the e-Permits system does not automatically issue an incident referral when a planting report is missing; rather, APHIS telephonically notifies the compliance branch and follows up

[38] These 55 permits and notifications consist of those that should have been referred to compliance staff for a late or unsubmitted report. However, we did not have a compliance incident number to indicate that it had been referred. (The compliance incident number, assigned by APHIS, is used to record self-reported and third party incidents in the compliance database and is automatically assigned, by e-Permits, to incidents referred from inspection reports.) There were 13 (of 14 mentioned in footnote 22) instances of an unsubmitted planting report and 42 (of 45 mentioned in footnote 22 because 3 had already been referred to the compliance branch, indicated by an incident number in the compliance database) instances of late planting report submission, or a late "report of no planting."

with an e-mail. Late reports are not normally referred. Although we credited those responsible persons that submitted planting reports during our review, the compliance branch's draft SOP specifies that reports more than 31 days late are considered missing; therefore, the 39 reports we noted should have been characterized as such.[39]

APHIS Lacks a Process for Reviewing Progress Reports Received

We reviewed nine permits and notifications where the final field test reports were submitted outside of e-Permits.[40] These reports were manually submitted to APHIS via mail or email and there was no control in place to verify that all reported plantings were included on the final field test report.[41] We compared the planting reports and final field test reports and determined that APHIS does not analyze the final field test reports to account for all locations approved in the permits or notifications. We found that one notification's final field test report did not identify 12 of 21 plantings that were reported to the agency. This same final field test report did not account for 34 of 46 approved sites at which the responsible person could conduct field tests.

APHIS was unaware of both discrepancies because the final field test reports are not reviewed and compared to the original permit or notification to verify that all agency-approved release sites are identified in the report. Nor does the agency compare the final field test report to the planting reports to ensure that the responsible party reported all releases/plantings. As APHIS officials explained, they review final field test reports to identify terminated sites. Without reviewing and verifying that final field test reports account for all agency-approved release sites and reported plantings, the agency may not know the status of an introduction, under permit or notification, at all approved release sites. This could lead to the unnoticed, unintended releases of regulated articles into the environment. Therefore, we believe that APHIS does not have adequate monitoring controls; specifically, there is no summary review of reports to verify that all plantings have been reported and accounted for at all approved release sites.

Although it is APHIS' policy to inspect every permit within each State where a release occurs, the agency is unable to do so if it is not aware of the plantings. Receiving notice of a field trial after it has ended does not allow APHIS officials to properly monitor the release for compliance with all requirements. Furthermore, if the agency does not thoroughly review the reports received, then it will not know the status of approved release sites. Lastly, APHIS officials must utilize the sanctions available to them for those responsible persons that do not submit their progress reports in a timely manner, in order to correct the problem. Without these controls in place, the agency is unable to properly account for and monitor compliance of all approved

[39] Permit and notification holders submitted late planting reports in 39 instances, as discussed in the previous subsection of this finding.
[40] These permits and notifications are out of the 29 additional samples selected to verify that required reports (such as the final field test, annual, and volunteer monitoring reports) were received (see Scope and Methodology).
[41] If the final field test report was submitted through APHIS' e-Permits system, a planting report would have already been submitted containing either planting records or a "no planting" explanation for each release site (field trial location). In other words, the planting status of all release sites must be accounted for before the final field test report can be submitted.

release sites, which leaves room for inadvertent releases into the environment without the agency's knowledge and without consequence.

Recommendation 2

Develop and implement policies which require APHIS officials to analyze reports to (1) ensure that all release sites are included, (2) identify discrepancies, and (3) require immediate resolution.

Agency Response

In its August 27, 2015, response, APHIS agreed with this recommendation. APHIS stated that it launched a Signature Business Process Improvement (SBPI), in November 2014, through a multi-phased approach to enhance compliance oversight of authorized and regulated GE field trials. The strategic objective of SBPI is to create an effective process that tracks, reviews, and analyzes planting and volunteer monitoring reports. APHIS' BRS will implement the project in phases to address missing planting reports for a permit or notification and volunteer monitoring reports. After these phases are complete, BRS will extend business improvements to other reports, such as field test reports, and implement approaches to cross reference information in these reports with planting reports to ensure all planting locations are accounted for. These processes will be incorporated into the new information system (APHIS e-File) that is under development, and the system is expected to be operational by August 31, 2016.

APHIS further stated that in July 2015, BRS implemented procedures to identify and address late planting reports utilizing the current e-Permit system, and is currently working on a process to identify and address missing planting reports utilizing the current e-Permit system. As stated in APHIS' response to Recommendation 4, procedures to identify missing planting reports will be completed by January 31, 2016.

In addition, in July 2015, BRS launched a new initiative to improve consistency of policy development and review. BRS will ensure documented processes, such as SOPs, align with BRS' respective policies and that the documented processes are also catalogued, tracked, and re-reviewed.

OIG Position

While we agree with APHIS' planned corrective actions, we are unable to reach management decision for this recommendation. To reach management decision, APHIS needs to provide the specific timeframes for developing the policies for the processes outlined in response to this recommendation and it needs to provide the date that the processes will be incorporated into the SOPs.

Recommendation 3

Develop and implement a process, within the new information system, to document report due dates, as well as track, search, and monitor the status of progress reports. In addition, include a

process to refer report discrepancies, as well as missing and late reports, to APHIS' compliance branch.

Agency Response

In its August 27, 2015, response, APHIS stated that it agrees with this recommendation. It further stated that the new information management system, e-File, will better meet the needs of the Agency and the regulated community, and is a high priority for APHIS. APHIS' BRS will develop and implement features within e-File to document report due dates and to track, search, and monitor the status of progress reports. BRS will also develop features within e-File to refer report discrepancies, and missing and late reports, to BRS' compliance branch. These features will be incorporated into the new information system which is expected to be fully operational by August 31, 2016.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 4

Until a new information system is fully operational,[42] enter into e-Permits the data for all progress reports received via mail, email, etc.; this method will allow APHIS officials to track and search all received reports.

Agency Response

In its August 27, 2015, response, APHIS stated that it agrees, in part, with this recommendation. It stated that under APHIS' current information system, e-Permits, APHIS is unable to enter data for all progress reports received outside of e-Permits, such as through postal mail and e-mail. Also, e-Permits does not have built-in functions to allow APHIS officials to track and search reports. APHIS further stated that it would be impractical to make changes to the current e-Permits system, as it would require significant changes to the program code, increase the cost of the current contract, and take many months to write the program code changes, test them, and deploy them.

APHIS stated that it has implemented an interim solution until the e-File system is fully operational. It has developed a stand-alone Microsoft Access database to track and monitor progress reports received via e-Permits and through other avenues. Because APHIS is implementing a new information system, e-File, the agency is directing its resources towards its completion and avoiding the use of its resources to make enhancement to e-Permits, a system destined to be decommissioned.

[42] APHIS' goal is to have the new system fully operational in calendar year 2016.

OIG Position

We accept APHIS' management decision on this recommendation.

Section 3: Compliance

Finding 3: APHIS Needs to Document How Sites Are Selected for Inspection

APHIS' current policy does not specify the steps to perform a monthly selection of permits for inspection, based on risk. The current policy does not detail the risk factors or how these factors will be evaluated, how often the selection process will be performed, who is responsible for performing and reviewing the selection(s), or how the selection will be documented. This occurred because APHIS officials replaced inspection site selection procedures developed in response to our prior audit recommendation, but they did not carry forward the detail of the earlier procedures. Because APHIS' current practice does not document the steps to perform a monthly selection of permits for inspection, the agency's methodology cannot be verified to ensure compliance with its stated selection process. Without detailed policies and supporting documentation, we were unable to sufficiently review APHIS' process for selecting inspection sites in order to identify potential weaknesses. If there are weaknesses in this process, APHIS officials will not be able to make improvements to provide assurance that movements and releases are in accordance with laws and regulations.

OMB requires[43] agency management to develop and maintain effective internal controls. Those controls include well-defined documentation processes that contain an audit trail and verifiable results so that someone not connected with the procedures can understand the assessment process. According to GAO,[44] effective documentation assists in management's design of internal control by establishing and communicating the who, what, when, where, and why of internal control execution to personnel. Documentation also provides a means to communicate that knowledge, as needed, to external parties, such as external auditors.

In May 2009, in response to a recommendation in our prior audit,[45] APHIS developed and implemented procedures which detailed a risk-based selection process for permits for inspection. Although these procedures were prepared to assist staff in meeting regulatory requirements for the oversight of regulated field tests for permits of GE organisms, they have been superseded. When we spoke to APHIS officials they explained that the older process needed improvements. First, the new process is based on the planting reports and not just the authorizations (approved permit applications); basing it on just the authorizations led to many cancelled inspection requests because the regulated material had either been harvested or had not yet been planted. Second, the agency changed to a monthly instead of quarterly selection process because quarterly selection resulted in missed planting cycles.[46] Current policies state that APHIS determines the frequency and number of field trial inspections by assessing the relative risk of each type of trial

[43] OMB Circular A-123, *Management's Responsibility for Internal Control,* December 21, 2004.
[44] GAO-14-704G, *Standards for Internal Control in the Federal Government,* September 2014.
[45] Recommendation number 15, Audit Report 50601-0008-Te, *Controls Over Issuance of Genetically Engineered Organism Release Permits*, December 2005.
[46] A planting cycle is the time it takes for the approved permit or notification's environmental release to achieve the desired traits. Therefore, a missed planting cycle would mean the environmental release has been destroyed prior to the inspection.

and other criteria;[47] however, it does not identify the risk factors or the evaluation methodology. The policy also states that, for every release permit, the release will be inspected at least once annually in every State in which a field release is performed, but it does not discuss the steps to be taken in order to meet this objective.

We reviewed the monthly listings of plantings and compared them to the monthly listings of inspections to determine how the selections were made. For example, in June 2014 APHIS officials provided a spreadsheet listing of 825 rows of planting data for permits for which they had received planting reports from April 29, 2014, through May 23, 2014. The agency also provided a list of 102 permitted sites selected for inspection. We compared these listings, but were unable to identify why or how each site was selected and the agency was not able to provide us with documentation which indicated the basis for their monthly selections for inspection.

We asked why the current policy does not mention a risk-based selection process, to which APHIS officials replied that several factors are considered when selecting permit sites (such as whether the agency has made prior visits to the cooperator, the amount of acreage, and when the planting occurred).[48] APHIS acknowledged that these risk factors are not in the current policy because the process has been evolving over the years. Furthermore, they explained that biotechnology[49] is constantly changing, so they have been learning about what is needed while still allowing some flexibility in their process. However, they are planning to document the current process in a SOP. When we asked APHIS officials if they document why a particular site is selected for inspection, agency officials explained that they do not because this would make an already time-consuming process even more cumbersome.

Although APHIS officials maintain that their current selection process is still risk-based, they have not developed a written procedure that details: (1) the steps for a risk-based selection of field test sites for inspection, (2) how to evaluate the risk factors, and (3) how staff is to document each selection. Moreover, we were unable to obtain and review any documentation to verify that the stated process has been fully implemented. Therefore, we believe that the current procedure does not provide enough details concerning how selections should be made. We maintain that, until the risk-based process is fully documented, APHIS cannot offer assurances that it is appropriately prioritizing and selecting permits for inspections, based on risk.

[47] APHIS officials stated that additional criteria such as planting acreage, planting date, and location information are used for selecting field trial inspections.
[48] The cooperator is the person responsible for conducting the release at a specific location.
[49] Agricultural biotechnology is a range of tools that alter living organisms or parts of organisms to make or modify products, improve plants or animals, or develop micro-organisms for specific agricultural uses.

Recommendation 5

Develop and implement a detailed selection policy for permits for inspection that discusses what risk factors will be evaluated and how risk factors will be evaluated. The policy should also require staff to document the monthly process for permit selections.

Agency Response

In its August 27, 2015, response, APHIS stated that it agrees with this recommendation. APHIS stated that BRS will develop a policy that details what risk factors will be evaluated and how risk factors will be evaluated. The policy will also address roles and responsibilities of staff, how (and how often) the inspection selection process is performed, and how the selection is documented. APHIS also stated that BRS will ensure such documented processes align with their respective policies and that the policies and processes are catalogued, tracked, and reviewed. This policy will be completed July 31, 2016.

OIG Position

We accept APHIS' management decision on this recommendation.

Finding 4: APHIS Needs to Document How Sites Are Selected for Inspection

Based on our review of APHIS' compliance database—which is used to track incidents noted by inspectors and biotechnologists or that are self-reported—we determined that the database was incomplete, inaccurate, and inconsistent. This occurred because APHIS does not have adequate, up-to-date procedures in place to sufficiently guide staff through the incident management process. APHIS' Incident Management SOPs are still in draft form. Furthermore, to document incidents, APHIS manually enters the information into a Microsoft Access database, which was not designed to assign multiple incident categories, when necessary. This prevents staff from accurately describing violations. According to the agency, the ability to accurately track these violations is critical to identifying and analyzing trends and ensuring accountability. However, without complete, accurate, and consistent data, APHIS cannot identify patterns and weaknesses, which would assist it in strengthening program controls.

According to GAO,[50] management designs control activities in response to the entity's objectives and risks to achieve an effective internal control system. Control activities are the policies, procedures, techniques, and mechanisms that enforce management's directives to achieve the entity's objectives and address related risks.

In order to effectively regulate GE fields, potential issues of noncompliance must be reported to APHIS' compliance branch. To track the incidents, the regulatory specialist is required to record the incident in the Microsoft Access incident tracking database. APHIS' current SOP[51] explains the role of a regulatory specialist when an incident is reported; however, this SOP is focused on late, missing, or incorrect reports that need to be filed with APHIS. It does not describe how database fields can be used accurately to capture incident details.

The compliance branch has a draft SOP,[52] which details incident reporting and recording. According to the draft SOP, there are three types of referrals: (1) results of an inspection (referrals/inspections); (2) directly reported by the responsible party (self-report); or (3) reported by a third-party (third-party). The draft SOP also states that a regulatory specialist shall categorize incidents into one or more of the available categories.[53]

Based on our review of APHIS' incident tracking database—a manual system kept outside of e-Permits—we determined that the database was incomplete, inaccurate, and inconsistent. Although the database includes multiple fields (e.g., compliance tracking number, permit or

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[50] GAO 14-704G, *Standards for Internal Control in the Federal Government,* September 2014.
[51] Management and Analysis of Compliance Incidents Referred from Inadequate Permittee Reports, CI SOP 3.0.13 Inadequate Permittee Reports, version 2, May 10, 2010.
[52] Incident Management, Compliance Evaluation and Enforcement Branch SOP 21.0, Version 1.0, revised February 13, 2014. The compliance branch is currently operating under this revised, draft SOP.
[53] Available categories are as follows: none – not a compliance incident; act of nature; animal or human incursion; border row or isolation distance insufficiency; failure to comply with Standard Permit Conditions; failure to comply with Supplemental Permit Conditions; failure to maintain identity, or devitalize after use; failure to meet performance standards; mixture of regulated and non-regulated materials; movement to areas not authorized; failure to obtain or maintain authorization; persistence in the environment; release in areas or quantities not authorized; shipping insufficiency; failure to submit reports as required; failure to clean or sufficiently clean equipment; or other.

notification number, organization, applicant's name, crop type, incident category, incident origin, inspection number, etc.), the compliance branch stated that the database cannot record multiple categories within a field. Regulatory specialists are therefore instructed to select the "best suited" or "primary" category based upon the description of the incident. The compliance branch further explained that allowing for multiple category selection would render the field unsearchable and that the agency needs to be able to run queries on the database. Being able to include multiple categories for one incident would allow the compliance branch to identify all the responsible persons that are having problems in more than one area. For example, if a notification holder was not submitting reports, allowing volunteers to grow, and planting in the wrong location, the regulatory specialist would try and determine which primary category to assign, rather than selecting all that applied.[54] Unless APHIS includes multiple categories for each incident, the agency cannot run trend analyses that will adequately reflect the scope of these incidents.

In addition, we tried to use the category field to complete a trend analysis, but found errors within this field. Specifically, we had questions on 21 incident categories that did not seem to accurately describe the incident. When we spoke to APHIS officials about how these categories were applied, they agreed that 7 were used incorrectly, but indicated the other 14 were correctly categorized. For one of the seven, the category was "other;" however, the category should have been "failure to comply with supplemental permit conditions," which is a violation of the regulation and should have received a NONC.[55] The incident received a NOC.[56] APHIS officials generally explained that the data field, "Category," was not originally part of the database, but was added later. At that time, two regulatory specialists went back and added categories for all incidents and, in some cases, selected the wrong category.

We maintain that, since APHIS uses the number of release site inspections found to be in compliance versus those noncompliant with the regulation as a tool to determine compliance rate, it is vital that APHIS consistently give noncompliances for similar violations. If it does not, then the compliance rate may not be accurate. In addition, consistent categories would also enable the compliance branch to conduct meaningful trend analyses to determine weaknesses in the GE program.

Additionally, we found that APHIS is not using its incident tracking database to consistently ensure that corrective actions were taken to address the incidents identified. We reviewed three different data fields containing due dates to determine if the compliance branch requested any follow-up action from the responsible person on each incident recorded. Of the 315 incidents referred to the compliance branch for FY 2012 through April 14, 2014, 92 received NONCs and 176 received NOCs.[57] Of the 92 incidents that received NONCs, only 28 were required to submit follow-up documentation to APHIS, explaining actions taken to prevent the incident from

[54] A volunteer is when viable material remains and flowers in subsequent seasons.
[55] Notice of Noncompliance letter is issued when an incident is a violation of the regulation.
[56] Notice of Compliance with Comment letter is issued when an incident is determined not to be a violation of the regulation, but the analysis revealed activities or circumstances that could lead to a non-compliance incident in the future and/or there are specific compliance concerns that need to be communicated back to the responsible party.
[57] The remaining 47 incidents were either waiting compliance determination by the compliance branch as of April 14, 2014, referred to Investigative and Enforcement Services, or received a WL or letter of standard compliance.

recurring. Of the 176 that received NOCs, only 21 were required to submit follow-up documentation. According to APHIS, the regulatory specialists determine if actions to prevent recurrences are needed on a case-by-case basis. If corrective actions are not deemed necessary, then follow-up documentation is not requested. While reviewing the database, we were not able to determine why some incidents required follow-up documentation, while in other incidents, no documentation was requested. By not including this information in the database, the agency cannot perform a review of the incident management process using the database to identify if incidents were being handled in an effective manner.

We believe that APHIS needs to improve how it records and tracks these results. Although APHIS stated that it cannot assign multiple categories because the Microsoft Access database will not allow them to do so, we maintain that the Microsoft Access databases do allow multi-valued fields and queries of these fields. In addition, APHIS needs to issue a final SOP that guides the regulatory specialists through evaluations of incidents and directs them to enter the information into the database.

Recommendation 6

Update the compliance database to allow for more than one category to be selected to identify the compliance incident.

Agency Response

In its August 27, 2015, response, APHIS agreed with this recommendation and stated that the compliance database was updated in November 2014, and now allows multiple categories to be selected for compliance incidents, allowing for more robust analysis. This database will be used in conjunction with the Incident Management SOP discussed in response to Recommendation 7. APHIS will implement the new SOP and database by February 29, 2016.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 7

Finalize and implement the Incident Management SOP, which should require officials to document the reasons that incidents do not require additional follow-up.

Agency Response

In its August 27, 2015, response, APHIS agreed with this recommendation. APHIS stated that it is currently working to finalize and implement the Incident Management SOP. This SOP will address how to document decision making regarding whether incidents do or do not require additional follow-up. To help ensure consistency, the Incident Management SOP will also provide guidelines for when follow-up may not be necessary. APHIS also stated that it will ensure that the SOP is in alignment with BRS policy, and that the SOP and policy are

catalogued, tracked, and reviewed. The Incident Management SOP will be finalized by February 29, 2016.

OIG Position

We accept APHIS' management decision on this recommendation.

Section 4: Application Processing

Finding 5: APHIS Should Improve Its Permit Application Process by Requiring the Review of Past Noncompliances

Although APHIS tracks organizations' compliance history and has policies and authorities in place, the agency still does not use the compliance incident history in determining whether to approve applications for permits or notifications. We found that 8 organizations continued to receive permits and notifications, even after they collectively had 260 incidents reported over the past 2 years. This occurred because APHIS' current approval process does not require biotechnologists to review compliance history. Even if the biotechnologists did wish to review noncompliances, the e-Permits system does not include a compliance module to track all incidents and make them available during the approval process. As a result, APHIS approved organizations for additional notifications and permits, even though the organizations had a history of unauthorized environmental releases or other noncompliances.

Though the APHIS Administrator may deny the issuance of a permit or notification based on the responsible party not maintaining safeguards or observing conditions required in previous permits, those APHIS employees who reviewed applications are not required to review compliance history.

We performed an analysis of the compliance database[58] to determine the number of times any one organization may have had a reported compliance issue. We found that, from October 1, 2011, to April 14, 2014, there were 391 permits and notifications with compliance issues reported—137 received a NONC; 206 received a NOC; 3 received civil penalties; and 6 received Warning Letters (WL).[59] Of the 391[60] permits and notifications with compliance incidents referred to the compliance branch, 260 issues related to 8 organizations, all having 10 or more incidents in less than 2 years. One organization was cited for 122 incidents, of which 14 were for "movement to or from areas not authorized," 11 were for "failure to maintain identity or devitalize after use," 10 were for "failure to obtain or maintain authorization," and 10 were for "persistence in the environment."

Biotechnologists were not, however, using this compliance history when they reviewed and approved new applications for permits or notifications. According to the e-Permits tracking sheet,[61] a review of the compliance history is not required prior to approval of the application, nor is it required by the permit or notification SOP on workflows. When we spoke to the biotechnologists, we found that they did not consult this separate database when they reviewed new applications. The agency was able to provide evidence of only one instance in which an

[58] The compliance database is a Microsoft Access database, maintained separately from e-Permits, that is used to document all compliance incidents referred as a result of inspections, self-reports, or third party reports.
[59] For the remainder, 14 received Standard Notices of Compliance (NOCS), 3 were closed with memos, and 22 had not been determined as of April 14, 2014. An NOCS is issued when an inspection report reveals no violations of the regulation and does not contain any issues that need to be communicated to the responsible party.
[60] The database contained 315 incident numbers; however, some of these numbers were associated with multiple permit and/or notification numbers.
[61] The tracking sheet is the workflow for an application which shows the status and assignment of each task.

organization received denial letters (in 2002) for two notifications due to past noncompliance related to inappropriate sites at which it chose to conduct field trials.

We discussed this issue with APHIS officials and they stated that they do not formally review past compliance history, explaining instead that, if they are aware of past compliance issues, they may make supplemental conditions more stringent or encourage the organization not to submit or simply withdraw an application. Also, they explained that the organizations are self-policing; if the company has one cooperator that receives multiple violations, it will not use that cooperator in the future.

If the compliance data was maintained within e-Permits, the data would be more readily available to the biotechnologists during their review of the applications. According to the agency, a new information system is being developed that will replace e-Permits. We believe that APHIS can strengthen its controls over its permit and notification process by requiring biotechnologists to review organizations' compliance history during the approval process. To assist biotechnologists through the approval process in the future, APHIS should include a compliance module as it develops a new information system.

Recommendation 8

Incorporate compliance reporting and tracking of all incidents in the information system being developed.

Agency Response

In its August 27, 2015, response, APHIS agreed with this recommendation and stated that a new information management system (e-File) that meets the needs of the agency and its regulated community is a high priority. APHIS stated that it will incorporate compliance reporting and tracking of incidents in the information system. APHIS also stated that because BRS has specialized, unique needs for compliance reporting and tracking, some features may need to be customized and developed after the initial release of e-File. APHIS' BRS will continue to maintain and use its Microsoft Access compliance database until compliance reporting and tracking of all incidents is fully incorporated into e-File. APHIS expects that processes that can be implemented without customization will be incorporated into the new information system by August 31, 2016.

OIG Position

While we agree with APHIS' planned actions, we cannot accept management decision on this recommendation. In order to reach management decision on this recommendation, APHIS needs to provide the date that compliance reporting and tracking of all incidents including those that require a customized feature, will be incorporated in the new information system.

Recommendation 9

In the interim, share the compliance database with the biotechnologists responsible for the review and approval of applications, so that compliance history can be reviewed during the approval process.

Agency Response

In its August 27, 2015, response, APHIS stated that BRS' Regulatory Operations Programs (ROP) personnel who currently maintain the compliance database have begun meeting with BRS' Biotechnology Risk Analysis Programs (BRAP) personnel who are responsible for the review and approval of authorizations to provide compliance information and to assess other needs beyond what is currently in the database. ROP will then make any necessary changes to the Microsoft Access compliance database, discussed in the response to Recommendation 4, such that relevant compliance history can be taken into account during this year's application review process for field trials.

APHIS also stated that ROP and BRAP are currently developing a policy for coordination between the two programs. The sharing of compliance information will be incorporated into this policy, which will be finalized by December 31, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 10

Develop and implement procedures for the approval process for notifications and permits which include reviewing the compliance issues against the organization and the responsible party.

Agency Response

In its August 27, 2015, response APHIS agreed with this recommendation. In reviewing authorizations for introductions of GE organisms, it will consider information from the compliance database regarding the compliance history of applicants. APHIS stated that this step will be added to the current permit and notification SOPs to ensure that checking compliance history is a part of reviewing an authorization prior to disposition and the administrative record will reflect completion of this step. APHIS also stated that if compliance issues are identified that may impact the approval of an authorization, BRAP will coordinate with ROP to determine the best course of action. The possible actions include, but are not limited to, flagging the authorization for inspection, adding permit conditions, or denying the authorization. The use of compliance information in the approval of authorizations will be a topic for discussion at bi-weekly coordination meetings between BRAP and ROP. APHIS further stated that using compliance information prior to issuing an authorization will be implemented during this year's application season. BRS will make changes to the SOPs, reflecting the change by June 30, 2016.

OIG Position

We accept APHIS' management decision on this recommendation.

Section 5: Reviews of Petitions for Non-Regulated Status

Finding 6: APHIS Needs to Better Document its Petition Review Process

In our analysis of two of the six petitions that APHIS has approved in its current petition review process, we found that APHIS does not maintain sufficient records to support a petition's progress through the review process. This occurred because APHIS does not have an effective system for maintaining petition process documents. Thus, APHIS cannot ensure that petitions complete each step of the review process; instead, APHIS only monitors "major steps."[62]

Federal agencies must make and preserve records containing proper documentation of the functions, policies, decisions, procedures, and essential transactions of the agency.[63] Such records must allow proper scrutiny by duly authorized agencies of the Government.[64] In addition, agencies must implement a records management program that allows complete records to be identified, preserved, and readily located.[65]

After conducting a field test of a GE organism, a responsible person may petition APHIS to obtain non-regulated status for the organism. The petition review process consists of 22 or 32 steps, depending on the complexity of the petition. The process provides defined deadlines, as well as assigns staff processing responsibilities. The processes involve various meetings, reviews, approvals, and public comment. APHIS, however, only maintains documents for what it considers the "major steps," which are the deficiency letter, the completeness letter, the Plant Pest Risk Assessment, and the draft/final Environmental Assessment.

For example, in one petition we audited, we could not verify that a petition completed 8 of the 22 steps. The eight steps involved meetings, as well as document review and approval. During the process, the agency is to hold a meeting to brief management about the petition and any problems that may arise. APHIS does not document who attended the meeting, when the meeting occurred, or what was discussed and decided. However, agency officials acknowledged that it would be beneficial to better document these meetings.

In addition, APHIS lacks adequate policies and procedures regarding the specific decision documents that should be maintained for all petitions reviewed. The current policy does not provide adequate guidance for the retention of petition documents generated or meetings held during the review process. The agency's policy instructs staff to maintain decision documents for a period of five years. The guidance, however, does not define "decision documents," how the documents should be maintained, or where they should be stored. Without clear, well-established policies and procedures, staff is unaware of how to maintain and store relevant documents.

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[62] Major steps are considered to be the high-level milestones of the process which are made available to the public (such as the deficiency letter, completeness letter, Plant Pest Risk Assessment, and draft/final Environmental Assessment); minor steps are the remainder of the steps in the process, such as review of required documents.
[63] Title 36 CFR Part 1220, *Federal Records*, section 1220.30(a), July 1, 2012.
[64] Title 36 CFR Part 1222, *Creation and Maintenance of Federal Records*, section 1222.22(c), July 1, 2012.
[65] Title 36 CFR Part 1222, *Creation and Maintenance of Federal Records*, section 1222.34, July 1, 2012.

APHIS officials stated that they are in the process of developing a documentation system that will track all documents and steps of the petition process, both major and minor. Known as the Petition Tracking System, the system is supposed to automate the workflow process, display the petition status and history, and assist in managing and tracking the petition process. The system is currently in the testing phase, with expectations of becoming operational in FY 2015.

We also noted that, although APHIS' regulation[66] states that a petition decision will be made within 180 days, both petitions we reviewed were in process for more than 500 days. For the six petitions that completed the process from July 2013 through March 2014, the average processing time was 722 days. The time frames ranged between 548 and 806 days. APHIS acknowledges that the petition review process does not comply with the 180-day timeframe established by the regulations. Agency officials explained that, if the regulations were re-written, the 180-day timeframe should be adjusted or eliminated to account for the changes in the review process.

In order for APHIS to improve the overall management of the petition process, it needs to strengthen its internal controls over document retention and maintenance. It also needs to complete development and implementation of the tracking system that will monitor each of the steps in the process. In addition, APHIS needs to revise the regulations concerning the 180-day timeframe to reflect the agency's current practices. Until it strengthens these internal controls and implements the tracking system, APHIS cannot effectively monitor the petition review process.

Recommendation 11

Develop and implement specific policies and procedures for the retention and maintenance of all petition documents for each step of the petition process.

Agency Response

In its August 27, 2015, response, APHIS agreed with this recommendation and stated that documents generated during the review of a petition will be stored in a SharePoint Petition Tracking System. Each document will be tagged with a specific document type, (e.g., Petition; Finding Of No Significant Impact (FONSI); Environmental Analysis (EA); Petitioner Letter(s), etc). The SharePoint Tracking System will track when and by whom each document is created, revised, and approved. APHIS will implement the SharePoint Petition Tracking System by May 31, 2016.

In addition, APHIS stated that in 2014 BRS initiated an effort—as part of it operational goals to improve internal administrative processes for the storing and retention of all official records—to pursue tools that enable e-collaboration and records management to include the official documents related to and created by the Petition Tracking System to ensure the appropriate level of storing and retention of all official records. This effort is an ongoing, continuous improvement project.

[66] Title 7 CFR Part 340, *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*, Section 340.6(d)(3), May 2, 1997.

OIG Position

We cannot accept APHIS' management decision on this recommendation. In order to reach management decision, APHIS needs to include retention and maintenance procedures for all petition documents in the SOP currently being developed for the petition process (described in APHIS' response to Recommendation 12 below) and provide a date for the inclusion of these procedures.

Recommendation 12

Develop and implement a Petition Tracking System that identifies each step in the petition process to allow effective monitoring of the process.

Agency Response

In its August 27, 2015, response, APHIS agreed with this recommendation and stated that it will first finalize a thorough set of written SOPs to ensure the timely review and management oversight of the steps in the petition process. This SOP will outline each step in the process to include responsibilities for creating and approving petition documents. The steps in the SOP will then be implemented within an electronic Petition Tracking System in SharePoint. The Petition Tracking System will record and retain all the relevant steps outlined in the SOP and track each step as it progresses or is completed with user identifications (step owner), dates, time stamps and document identifiers. In addition, APHIS stated that the Tracking System will retain and store all documents created, including e-mails. The tracking system security features will permit only authorized users to access the system in order to perform actions related to document creation, routing, and approval. Finally, APHIS stated that the system will allow program management to track the progress of each petition on either the landing page for a specific petition, a dashboard that allows a snapshot of all petitions, or in reports. APHIS will implement the tracking system by May 31, 2016.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 13

Comply with the regulatory timeframe or revise the regulation to remove the 180-day petition decision timeframe in order to reflect the current timeframes required for the new review process.

Agency Response

In its August 27, 2015, response APHIS agreed with this recommendation and stated that on November 14, 2011, it announced plans to streamline and improve the agency's process for making determinations on petitions for nonregulated status for GE organisms. APHIS also stated that since the petition process was first added to APHIS biotechnology regulations in 1992, the time it took the agency to reach a final decision grew from an average of six months to 3 to 5 years or more. As a result of announced improvements, APHIS has reduced the length of the petition review by more than half, while maintaining the highest scientific rigor of its reviews. Starting in 2015, APHIS stated that it will meet these new timelines for all new petition requests for non-regulated status. It further stated that it believes that these new timelines represent the optimal balance between delivering high performance service and rigorous scientific review expected by the public and the Administration. APHIS will address this recommendation in its proposed change to the regulation.[67] By October 1, 2015, APHIS will submit a regulatory work plan to OBPA for Departmental clearance and will have a draft proposed rule for Departmental review by September 30, 2016.

OIG Position

While we agree with APHIS' planned action, we cannot accept management decision on this recommendation. In order to reach management decision on this recommendation, APHIS needs to provide the specific timelines it will meet when completing reviews of petition requests under the new review process.

[67]Title 7 CFR Part 340, *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,* 340, May 2, 1997.

Scope and Methodology

We conducted a nationwide audit of APHIS controls over the introduction of GE organisms into the environment at APHIS-BRS' Headquarters located in Riverdale, Maryland; the APHIS-BRS' Eastern Compliance Assurance Branch office in Raleigh, North Carolina; and 27 field test sites in 6 States (see Exhibit A). Our audit was conducted between November 2013 and February 2015.

Our audit covered a total of 1,104 approved permits and notifications for FY 2013 and FY 2014, through August 27, 2014.[68] From this universe, we selected 27 field trial sites to visit based on the type of authorizations (5 pharmaceutical permits, 15 traditional permits, and 7 notifications); the type of inspector (Plant Protection and Quarantine or State);[69] the number of inspections scheduled for a given month; and the type of inspections being conducted (pre-planting, planting, flowering, harvest, post-harvest, and volunteer monitoring). We also selected a sample of 46 permits and notifications applied for in FY 2013 to review the required reports and determine if they were submitted timely and contained all required information.[70] To verify that required reports (such as final field test, volunteer monitoring, and annual reports) were received, a second sample was selected of 29 permits and notifications that were applied for, dating back to FY 2009.[71] We also reviewed the compliance database for FY 2012 through April 14, 2014, which contained a total of 315 reported incidents. Additionally, we obtained a list of 13 petitions undergoing the improved petition review process, 6 of which were complete. We reviewed the final documentation for four of the six that had completed the review process and all available documentation in support of the entire review process for the remaining two.[72] All sample selections were made non-statistically.

To accomplish our objectives, we:

- Reviewed the pertinent laws and regulations governing GE organisms and the current policies and procedures APHIS has established as guidance for inspections and enforcement of its regulations.

[68] There were 599 approved in FY 2013 and 505 approved in FY 2014. APHIS directed OIG to its website in order to obtain this public data. OIG confirmed that this data is updated on a daily basis.
[69] The 27 field trial sites relate to permits and notifications that were approved in FY 2012 through FY 2014 and inspected in FY 2014. A Plant Protection and Quarantine (PPQ) inspector is an employee of APHIS while a State Biotechnology Inspector is a State official. Both are trained by APHIS-BRS to conduct inspections.
[70] We sampled 7 percent of the 2013 traditional permits and notifications (595 x 7 percent = 42) and relied upon Excel's Data Analysis Sampling to generate a random sample of 42 traditional permits and notifications, plus the 4 pharmaceutical permits, to select a total of 46 permits and notifications.
[71] The sample of 29 permits and notifications was selected based on expiration date and the first one listed in each month that was not already included in the initial FY 2013 sample of 46 permits and notifications. The selection dated back to FY 2009 to ensure that multi-year permits had expired more than 6 months prior to the selection. Multi-year permits are the only permits required to submit annual reports. Final field test reports are not due until 6 months after the permit expires and volunteer monitoring reports are due at the end of the monitoring period.
[72] These two were selected because one was one of the first to complete the transitional process (started in the old process and transitioned to the improved process) and the other was the only one to complete the new process entirely.

- Reviewed APHIS' actions in response to the 28 recommendations in the previous OIG audit[73] to identify the controls currently in place.
- Interviewed APHIS personnel at Headquarters, and the Eastern Compliance Assurance Branch, to gain an understanding of the processes in place.
- Reviewed the monthly field test site inspection selections to evaluate the stated process.
- Accompanied PPQ and State inspectors on 27 field trial site (see Exhibit A) visits to determine if inspections were being conducted in accordance with current guides.
- Interviewed PPQ and State inspectors to gain an understanding of their level of experience and training received.
- Reviewed the compliance database to ensure that all incidents of noncompliance were identified and infractions were treated equitably.
- Reviewed the permit and notification approval process to determine if past compliance history is evaluated.
- Selected multiple samples of permits and notifications from the universe for reviews of required progress reports to determine if information was submitted timely and accurately.
- Reviewed the petitions that have been processed since the inception of the Petition Process Improvement Project in 2010 to determine if the required steps were completed and documented.

We did not perform any tests of the e-Permits information system used by the agency to determine the overall reliability of the data. Therefore, we make no representation as to the adequacy of the information system.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions, based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions, based on our objectives.

[73] Report No. 50601-0008-Te, *Controls Over Issuance of Genetically Engineered Organism Release Permits*, December 2005.

Abbreviations

APHIS .....Animal and Plant Health Inspection Service
BRS .....Biotechnology Regulatory Services
CFR .....Code of Federal Regulations
e-Permits .....APHIS Comprehensive Electronic Permitting System
EPA .....Environmental Protection Agency
FY .....Fiscal Year
FDA.....Food and Drug Administration
GAO .....Government Accountability Office
GE .....Genetically Engineered
NOC .....Notice of Compliance with comments
NONC .....Notice of Noncompliance
OIG .....Office of Inspector General
OMB .....Office of Management and Budget
PPQ .....Plant Protection and Quarantine
SOP .....Standard Operating Procedure
USDA.....Department of Agriculture
WL .....Warning Letter

Exhibit A: Locations of Field Visits

OIG Sample Number	BRS Inspection Number	Type of Authorization	State	Crop	Type of Inspector
14-01	14-231	Traditional Permit	TX	Cotton	PPQ
14-02	14-246	Notification	TX	Corn	PPQ
14-03	14-257	Notification	IL	Corn	PPQ
14-04	14-295	Traditional Permit	IL	Soybean	PPQ
14-05	14-298	Traditional Permit	IN	Corn	PPQ
14-06	14-301	Traditional Permit	IN	Corn	PPQ
14-07	14-341	Traditional Permit	IA	Soybean	PPQ
14-08	14-338	Traditional Permit	IA	Alfalfa	PPQ
14-09	14-386	Notification	IL	Corn	PPQ
14-10	14-388	Notification	IA	Corn	PPQ
14-11	14-390	Notification	IN	Corn	PPQ
14-12	14-576	Pharmaceutical Permit	KS	Rice	State
14-13	14-577	Pharmaceutical Permit	KS	Rice	State
14-14	14-578	Pharmaceutical Permit	KS	Rice	State
14-15	14-579	Pharmaceutical Permit	KS	Rice	State
14-16	14-585	Notification	CA	Corn	PPQ
14-17	14-608	Notification	CA	Corn	PPQ
14-18	14-699	Traditional Permit	CA	Grape	PPQ
14-19	14-700	Traditional Permit	CA	Walnut	PPQ
14-20	14-738	Pharmaceutical Permit	CA	Tobacco	PPQ
14-21	14-293	Traditional Permit	IL	Corn	PPQ
14-22	14-292	Traditional Permit	IL	Corn	PPQ
14-23	14-291	Traditional Permit	IL	Corn	PPQ
14-24	14-302	Traditional Permit	IN	Corn	PPQ
14-25	14-303	Traditional Permit	IN	Corn	PPQ
14-26	14-299	Traditional Permit	IN	Corn	PPQ
14-27	14-300	Traditional Permit	IN	Corn	PPQ

Exhibit B: Prior Audit Recommendation in Which Weaknesses Still Exist

Recommendation Number	Recommendation	Final Corrective Actions Taken	Current Audit Finding	Weaknesses Identified in Current Audit
1	Revise and consolidate policies, procedures, and regulatory requirements for GE field releases.	Issued a proposed rule in October 2008 which received more than 5,500 responses containing over 88,000 signatures. The revision process is ongoing.	1	APHIS has not developed a timeline for resolving this recommendation. The regulations do not include specific requirements to guide applicants during all phases of the process.
2	Revise and clarify policies and regulations regarding the use of metal shipping containers.	Issued a proposed rule in October 2008 which received more than 5,500 responses containing over 88,000 signatures. The revision process is ongoing.	1	APHIS has not developed a timeline for resolving this recommendation. The agency risks inconsistent interpretation of its regulations.
3	Update regulations to incorporate the provisions of the Plant Protection Act of 2000.	Issued a proposed rule in October 2008 which received more than 5,500 responses containing over 88,000 signatures. The revision process is ongoing.	1	APHIS has not developed a timeline for resolving this recommendation. The agency's additional authority is not transparent.

15	Develop and implement written policies and procedures for selecting specific field test sites for inspection based on risk.	Developed procedures which detailed a risk-based selection process for permits for inspection. However, this procedure is no longer in place.	3	The current policy does not detail the steps to perform a selection of permits for inspection, the risk factors to be evaluated, how the factors will be evaluated, how often the selection will be performed, or how the selection will be documented.
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.	Developed an information system that records some information related to field test progress reports.	2	APHIS' system is not capable of recording progress report due dates or identifying late or missing progress reports. APHIS does not have a process for referring incidents of late or missing progress reports to compliance. Also, APHIS does not have a process for reviewing received progress reports.
23	Impose sanctions for missing and late progress reports.	Developed procedures which describe the types of sanctions and when these sanctions are to be imposed on a case-by-case basis, through various letters.	5	APHIS does not use the compliance incident history in determining whether to approve applications for permits or notifications. The regulations and permit conditions allow APHIS to withdraw a permit or deny future permits if conditions of any permit were not met; however, the agency has not been applying this sanction.

USDA'S
ANIMAL AND PLANT HEALTH
INSPECTION SERVICE'S
RESPONSE TO AUDIT REPORT

United States Department of Agriculture

Animal and Plant Health Inspection Service

Office of the Administrator

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MEMORANDUM

TO: Gil Harden August 27, 2015
Assistant Inspector General
for Audit

FROM: Kevin Shea /S/
Administrator

SUBJECT: APHIS Response and Request for Management Decision on OIG Report "Controls Over APHIS' Introduction of Genetically Engineered Organisms" (50601-01-32)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on your July 31, 2015, Official Draft Report. We have restated each Recommendation below along with our planned corrective actions and the timeframes for implementation of these actions.

Recommendation 1: Develop an action plan, with a timeline, for implementing the actions agreed to in Recommendations 1, 2, and 3 of Audit Report 50601-0008-TE. Also, implement a process to ensure that the actions are completed within the established timeframes.

APHIS Response: APHIS agrees with this Recommendation. This Recommendation is consistent with the priorities identified by APHIS in the December 2005 OIG Audit Report, "Controls Over Issuance of Genetically Engineered Organism Release Permits" (50601-08-TE), and continues to be a high priority goal for APHIS. On February 27, 2015, APHIS withdrew its 2008 proposed rule that would have amended the regulations regarding the introduction (importation, interstate movement, and field release) of certain genetically engineered organisms which would have, among other changes, addressed the open Recommendations in the 2005 Audit Report. APHIS received over 88,300 comments on the proposed rule. Based on the scope of comments received, and in light of the experience we have gained over the past 28 years -- especially in the 7 years since the 2008 proposed rule was published -- as well as continuing advances in biotechnology, APHIS decided to withdraw the proposed rule and begin anew, with fresh stakeholder engagements aimed at exploring alternative policy approaches. Specifically, in May 2015, APHIS began an open and robust dialogue with stakeholders to drive the development of future regulatory or policy approaches by holding a series of webinars. In addition, APHIS opened a docket in the *Federal Register* to obtain written public comments in response to four questions. Between the webinars and the docket comments, APHIS received more than 220,000 comments.

APHIS will submit a regulatory work plan to propose a regulatory change to 7 CFR part 340 that addresses the Recommendations in the 2005 and current audit, where applicable. By October 1, 2015, APHIS will submit a regulatory work plan to the Office of Budget and Program Analysis (OBPA) for Departmental clearance; the first step in the process, and will have a draft proposed rule for Departmental review by September 30, 2016. However, since APHIS does not control the process going forward, we cannot predict the timing or the final outcome of rulemaking. We note that on July 2, 2015 the White House's Office of Science and Technology Policy launched a year-long effort to review the Coordinated Framework for the Regulation of Biotechnology which may affect the nature and timing of regulatory changes APHIS may propose. Furthermore, the U.S. House of Representatives recently passed a GE labeling bill that amends the Plant Protection Act, and if enacted, would result in a need to change our regulations.

Recommendation 2: Develop and implement policies which require APHIS officials to analyze reports to (1) ensure that all release sites are included, (2) identify discrepancies, and (3) require immediate resolution.

APHIS Response: APHIS agrees with this Recommendation. In November 2014, APHIS launched a Signature Business Process Improvement (SBPI) to enhance compliance oversight of authorized regulated genetically engineered (GE) field trials. The strategic objective of the SBPI is to create an effective process that tracks, reviews, and analyzes planting and volunteer monitoring reports. APHIS is achieving this initiative through a multi-phased approach. In addition, in July 2015, APHIS' Biotechnology Regulatory Services (BRS) implemented procedures to identify and address late planting reports, which includes an automated report for planting reports received through the current electronic permitting system, *e*-Permits. BRS is now working on a process to identify and address missing planting reports.

By January 2016, BRS will implement this first phase of its project for missing planting reports for a permit or notification (authorizations). This phase will include the development of a reports database and reminder emails to authorization holders who have not yet submitted a planting report. The second phase of this project, to be implemented by April 2016, will focus on ensuring all planting locations for an authorization are accounted for. BRS has also developed a project work plan for volunteer monitoring reports (phase 3), which focuses on developing procedures, by June 2016, for tracking, reviewing, and analyzing volunteer monitoring reports. After completing these phases, BRS will extend business improvements to other reports, such as field test reports, and implement approaches to cross reference information in these reports with planting reports to ensure all planting locations are accounted for. These processes will be incorporated into the new information system (APHIS *e*-File) that is under development, and we expect the system to be operational by August 31, 2016.

In addition, in July 2015, BRS launched a new initiative to improve consistency of policy development and review to ensure that: (1) BRS policies are catalogued, tracked, and shared with staff and other affected individuals; (2) such policies are reviewed and approved at an appropriate management level; (3) procedures for re-review of policies are implemented on an established cycle; and (4) BRS policies remain effective and efficient. BRS will also ensure documented processes, such as Standard Operating Procedures (SOPs), align with BRS' respective policies and that the documented processes are also catalogued, tracked, and re-reviewed. BRS employees will be notified of these processes and policies at the September 2015 "BRS All-Hands Meeting." All future process and policy updates will be done via official email and at regularly occurring staff meetings.

Recommendation 3: Develop and implement a process, within the new information system, to document report due dates, as well as track, search, and monitor the status of progress reports. In addition, include a process to refer report discrepancies, as well as missing and late reports, to APHIS' compliance branch.

APHIS Response: APHIS agrees with this Recommendation. The new information management system, *e*-File, which will better meet the needs of the Agency and the regulated community, is a high priority for APHIS. BRS will develop and implement features within *e*-File to document report due dates and to track, search, and monitor the status of progress reports. BRS will also develop features within *e*-File to refer report discrepancies, missing, and late reports, to BRS' compliance branch. These features will be incorporated into the new information system which we expect to be fully operational by August 31, 2016.

Recommendation 4: Until a new information system is fully operational, enter into ePermits the data for all progress reports received via mail, email, etc.; this method will allow APHIS officials to track and search all received reports.

APHIS Response: APHIS agrees, in part, with this Recommendation. Under APHIS' current information system, *e*-Permits, APHIS is unable to enter data for all progress reports received outside of *e*-Permits, such as through postal mail and e-mail. Also, *e*-Permits does not have built-in functions to allow APHIS officials to track and search reports. Furthermore, it would be impractical to make changes to the current *e*-Permits system, as it would require significant changes to the program code, increase the cost of the current contract, and take many months to write the program code changes, test them, and deploy them.

APHIS has implemented an interim solution that addresses this Recommendation until the *e*-File system is fully operational. APHIS has developed a stand-alone Microsoft Access database to track and monitor progress reports received via *e*-Permits and through other avenues. Because APHIS is implementing a new information system, *e*-File, the agency is directing its resources towards its completion, avoiding the use of its resources to make enhancement to *e*-Permits,

a system destined to be decommissioned. In July 2015, APHIS implemented changes to improve its process for identifying late planting reports and is currently working on procedures to identify missing planting reports (see response to Recommendation 2). These procedures will be complete by January 31, 2016.

Recommendation 5: Develop and implement a detailed selection policy for permits for inspection that discusses what risk factors will be evaluated and how risk factors will be evaluated. The policy should also require staff to document the monthly process for permit selections.

APHIS Response: APHIS agrees with this Recommendation. Consistent with the efforts mentioned in our response for Recommendation 2, BRS will develop a policy that details what risk factors will be evaluated and how risk factors will be evaluated. The policy will also address roles and responsibilities of staff, how (and how often) the inspection selection process is performed, and how the selection is documented. BRS will ensure such documented processes align with their respective policies and that the policies and processes are catalogued, tracked, and reviewed. The policy will be completed July 31, 2016.

Recommendation 6: Update the compliance database to allow for more than one category to be selected to identify the compliance incident.

APHIS Response: APHIS agrees with this Recommendation. The compliance database was updated in November 2014 and now allows multiple categories to be selected for compliance incidents, allowing for more robust analysis. This database will be used in conjunction with the Incident Management SOP (see response for Recommendation 7). APHIS will implement the new SOP and database by February 29, 2016.

Recommendation 7: Finalize and implement the Incident Management SOP, which should require officials to document the reasons that incidents do not require additional follow-up.

APHIS Response: APHIS agrees with this Recommendation. APHIS recognizes that it is important to document decisions regarding whether incidents do or do not require follow-up to ensure consistency and equitable treatment of regulated entities. APHIS is currently working to finalize and implement the Incident Management SOP. This SOP will address how to document decision making regarding whether incidents do or do not require additional follow-up. To help ensure consistency, the Incident Management SOP will also provide guidelines for when follow-up may not be necessary. We will ensure that the SOP is in alignment with BRS policy, and that the SOP and policy are catalogued, tracked, and reviewed. The Incident Management SOP will be finalized by February 29, 2016.

Recommendation 8: Incorporate compliance reporting and tracking of all incidents in the information system being developed.

APHIS Response: APHIS agrees with this Recommendation. A new information management system (*e*-File) that meets the needs of the Agency and its regulated community is a high priority. APHIS will incorporate compliance reporting and tracking of incidents in the information system. Because BRS has specialized, unique needs for compliance reporting and tracking, some features may need to be customized and developed after the initial release of *e*-File. BRS will continue to maintain and use its Microsoft Access compliance database until compliance reporting and tracking of all incidents is fully incorporated into *e*-File. We expect that processes that can be implemented without customization will be incorporated into the new information system by August 31, 2016.

Recommendation 9: In the interim, share the compliance database with the biotechnologists responsible for the review and approval of applications, so that compliance history can be reviewed during the approval process.

APHIS Response: APHIS agrees with this Recommendation. APHIS understands that the intent of this Recommendation is to ensure that compliance history is used as a review factor during the approval process for authorizations. BRS' Regulatory Operations Programs (ROP) personnel who currently maintain the compliance database have begun meeting with BRS' Biotechnology Risk Analysis Programs (BRAP) personnel who are responsible for the review and approval of authorizations to provide compliance information and to assess other needs beyond what is currently in the database. ROP will then make any necessary changes to the Microsoft Access compliance database (see response to Recommendation 4) such that relevant compliance history can be taken into account during this year's application review process for field trials.

ROP and BRAP are currently developing a policy for coordination between the two programs. The sharing of compliance information will be incorporated into this policy, which will be finalized by December 31, 2015.

Recommendation 10: Develop and implement procedures for the approval process for notifications and permits which include reviewing the compliance issues against the organization and the responsible party.

APHIS Response: APHIS agrees with this Recommendation. In reviewing authorizations for introductions of GE organisms, we will consider information from the compliance database regarding the compliance history of applicants. This step will be added to the current permit and notification SOPs to ensure that checking compliance history is a part of reviewing an authorization prior to disposition; the administrative record will reflect completion of this step. If compliance issues are identified that may impact the approval of an authorization, BRAP will coordinate with ROP to determine the best course of action. Possible actions include, but are not limited to, flagging the authorization for inspection,

adding permit conditions, or denying the authorization. The use of compliance information in the approval of authorizations will be a topic for discussion at bi-weekly coordination meetings between BRAP and ROP. Using compliance information prior to issuing an authorization will be implemented during this year's application season. BRS will make changes to the SOPs reflecting the change by June 30, 2016.

Recommendation 11: Develop and implement specific policies and procedures for the retention and maintenance of all petition documents for each step of the petition process.

APHIS Response: APHIS agrees with this Recommendation. Documents generated during the review of a petition will be stored in a SharePoint Petition Tracking System. Each document will be tagged with a specific document type, (e.g., Petition; Finding Of No Significant Impact (FONSI); Environmental Analysis (EA); Petitioner Letter(s), etc). The SharePoint Tracking System will track when and by whom each document is created, revised, and approved. APHIS will implement the SharePoint Petition Tracking System by May 31, 2016.

In addition, in 2014, APHIS BRS initiated an effort -- as part of it operational goals to improve internal administrative processes for the storing and retention of all official records -- to pursue tools that enable e-collaboration and records management to include the official documents related to and created by the Petition Tracking System to ensure the appropriate level of storing and retention of all official records. This effort is an ongoing continuous improvement project.

Recommendation 12: Develop and implement a Petition Tracking System that identifies each step in the petition process to allow effective monitoring of the process.

APHIS Response: APHIS agrees with this Recommendation. APHIS will first finalize a thorough set of written SOPs to ensure the timely review and management oversight of the steps in the petition process. This SOP will outline each step in the process to include responsibilities for creating and approving petitions documents. The steps in the SOP will then be implemented within an electronic Petition Tracking System in SharePoint. The Petition Tracking System will record and retain all the relevant steps outlined in the SOP and track each step as it progresses or is completed with user identifications (step owner), dates, time stamps and document identifiers. In addition, the Tracking System will retain and store all documents created, including e-mails. The tracking system security features will permit only authorized users to access the system in order to perform actions related to document creation, routing, and approval. Finally, the system will allow program management to track the progress of each petition on either the landing page for a specific petition, a dashboard that allows a snapshot of all petitions, or in reports. APHIS will implement the tracking system by May 31, 2016.

Recommendation 13: Comply with the regulatory timeframe or revise the regulation to remove the 180-day petition decision timeframe in order to reflect the current timeframes required for the new review process.

APHIS Response: APHIS agrees with this Recommendation. On November 14, 2011, APHIS announced plans to streamline and improve the Agency's process for making determinations on petitions for nonregulated status for GE organisms. Since the petition process was first added to APHIS biotechnology regulations in 1992, the time it took the Agency to reach a final decision grew from six months on average to three to five years or more. As a result of announced improvements, APHIS has reduced the length of the petition review by more than half, while maintaining the highest scientific rigor of its reviews. Starting in 2015, APHIS will meet these new timelines for all new petition requests for non-regulated status.

By taking these steps to improve the petition process, APHIS believes it can deliver to its regulated community and the public a more predictable process, without compromising the quality of the analysis supporting our decision making. The improvements to APHIS' petition process were part of USDA Secretary Thomas Vilsack's effort to transform USDA into a high-performing organization that focuses on the public it serves. These process improvements are part of that effort aimed at improving the public's experience, modernizing and streamlining processes, reducing costs, accelerating delivery, and using innovative technology to advance public service. APHIS believes that these new timelines represent the optimal balance between delivering high performance service and rigorous scientific review expected by the public and the Administration.

Updating the regulations at 7 CFR part 340 to align with provisions of the Plant Protection Act of 2000 for regulating products of biotechnology that pose a risk to plant health is a high priority goal for APHIS, and we are moving forward as quickly as possible. APHIS will address this recommendation in its proposed regulatory change to 7 CFR part 340. By October 1, 2015, APHIS will submit a regulatory work plan to OBPA for Departmental clearance and will have a draft proposed rule for Departmental review by September 30, 2016. However, since APHIS does not control the process going forward, we cannot predict the timing or the final outcome of rulemaking. We note that on July 2, 2015 the White House's Office of Science and Technology Policy launched a year-long effort to review the Coordinated Framework for the Regulation of Biotechnology which may affect the nature and timing of regulatory changes APHIS may propose. Furthermore, the U.S. House of Representatives recently passed a GE labeling bill that amends the Plant Protection Act, and if enacted, would result in a need to change our regulations.

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