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Southeast Region

Audit Report

Animal and Plant Health Inspection Service
Evaluation of the Implementation
of the Select Agent or Toxin Regulations
Phase I

Report No. 33601-2-AT
June 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

June 23, 2005

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

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

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

SUBJECT: Animal and Plant Health Inspection Service
Evaluation of the Implementation of the Select
Agent or Toxin Regulations Phase I (33601-2-At)

This report presents the results of the subject audit. Your response to the report, dated May 24, 2005, is included as exhibit A, with excerpts and the Office of Inspector General's (OIG) position incorporated into the Findings and Recommendations section of the report.

Based on the response, we have reached management decision on Recommendation 9. To achieve management decision on Recommendations 1 through 8 and 10, we need additional corrective actions as outlined in the OIG Position section of the report, following each recommendation.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned and the timeframes for implementation of those recommendations for which management decisions have not yet been reached. Please note that the regulation requires that management decisions be reached on all recommendations within a maximum of 6 months from report issuance.

Executive Summary

Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations Phase I, Audit Report No. 33601-2-At

Results in Brief

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188, signed June 12, 2002), included provisions for enhancing controls over dangerous biological agents and toxins. The Act addressed the lack of authority for the Secretary of Agriculture to regulate possession of biological agents that, through acts of Bioterrorism, could have a devastating impact on the domestic agricultural economy.[1] With the passage of the Act, the Secretary of Agriculture was required to promulgate regulations to establish and maintain a list of each biological agent and each toxin that is determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act further requires that the Secretary, through regulations, provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of listed agents and toxins including safeguard and security measures and controls to limit access to individuals that have a legitimate need to handle or use such agents or toxins. The Animal and Plant Health Inspection Service (APHIS) was delegated authority to administer the regulations for the U.S. Department of Agriculture (USDA).

The primary objective of this audit is to evaluate APHIS' implementation of regulations governing the possession, use, and transfer of biological agents and toxins. The audit is being conducted in two phases. In Phase I, our objective was to evaluate the agency's overall implementation of the regulations governing the possession, use, and transfer of biological agents and toxins. Specifically, we performed tests to determine if APHIS had implemented adequate controls and procedures to ensure that (1) registration records were adequate and complete, (2) oversight activities were appropriately coordinated with the Center for Disease Control and Prevention (CDC), (3) approvals of laboratory security plans were consistent and supportable, and (4) safeguards were in place for transferring listed agents and toxins to protect animal and plant health. In Phase II (Audit No. 33601-3-At), we are performing field visits to locations where listed agents and toxins are used or stored to determine whether established controls are functioning as designed by examining registered entities' compliance with the regulations. This report presents the results regarding Phase I of our review.

APHIS published regulations establishing the initial list of agents and toxins on August 12, 2002, and regulations establishing the access controls, and safeguard and security measures on December 13, 2002. However, we found that APHIS had not fully implemented controls for enforcing safeguard and

[1] House of Representatives Conference Report No. 107-481, dated May 21, 2002.

security measures to prevent access to dangerous biological agents and toxins. APHIS incorporated the select agent program (SAP) separately into two existing services, the Plant Protection and Quarantine (PPQ) and Veterinary Services (VS), without ensuring coordination and timely legislative compliance between the two units. This occurred, in part, because APHIS has not established an official within the agency hierarchy who is responsible for coordinating the two components of its SAP; officials did not believe that any one person knew enough about both animal and plant pathogens.

We found that APHIS has not taken adequate steps to ensure that all entities possessing, using, or transferring listed agents and toxins had registered as required by the Act. The agency had not reconciled entities' initial notifications of possession received in October 2002 with entity registrations it subsequently received in March 2003. The Act requires entities to register so that APHIS can ensure that they have a lawful purpose for possessing, using, or transferring listed agents and toxins, and to ensure the entities comply with safeguard and security regulations. APHIS had not performed the reconciliation because it (1) did not have access to the notification of possession database maintained by the CDC and (2) did not develop a national registration database as required by the Act. Reconciliations performed as a result of our inquiries and a Management Alert we issued on June 8, 2004, found that three entities unlawfully possessed select agents after the March 12, 2003, registration deadline. Two of the entities identified possessed select agents that posed a severe risk to plant health, and the other entity possessed a select agent that posed a severe risk to both animal and human health. Among the agents was Eastern equine encephalitis, one of the most pathogenic mosquito-borne diseases in the United States, fatal to 35 percent of the people it infects. APHIS witnessed the destruction of the select agents at all three entities.

APHIS had not developed a national database of registered entities, as required by the Act. APHIS and CDC initially undertook the development of their own respective databases, but later decided to integrate the two systems resulting in a delay in development of the required database. The Act requires that the Secretary of Agriculture maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons possess, use, or transfer, and information regarding the characterization of such agents and toxins. The purpose of the database is to facilitate the identification of the agents and their location as well as their source. The absence of the database hinders APHIS ability to readily identify the locations where dangerous biological agents and toxins are stored and used, and in turn diminishes the agency's ability to effectively monitor compliance with safety and security requirements.

APHIS granted provisional registrations to entities without determining whether their security plans provided adequate safeguard and security measures. Regulations allowed for provisional registration if an entity could show by November 12, 2003, that it was providing proper security. However, APHIS officials stated that the regulation's intention to "minimize disruption of research" took precedence over the need to fully comply with security requirements by the deadline. Consequently, APHIS reviewed registration applications only to ensure a security plan had been submitted, not that it met the requirements of the regulations. As a result, the agency had not taken sufficient action to ensure that registered entities have implemented adequate safeguard and security measures to comply with the legislation and regulations.

APHIS had not established policies and procedures to ensure that inspections of the registering entities were consistent and thorough. APHIS officials attributed the lack of policy and procedures to the control structure within the agency. No single office or individual prescribed a consistent format for the inspections or for the presentation of inspection results. Inspections performed by VS and PPQ did not provide clear documentation concerning the nature or extent of deficiencies, and did not always conclude as to whether security measures implemented by the registered entities were adequate. As a result, APHIS inspection reports were not sufficiently documented to show whether registered entities had implemented adequate safeguard and security measures to prevent access to select agents and toxins to protect them from use in domestic or international terrorism.

Although some inspections revealed deficiencies at laboratories applying to use and store select agents, APHIS did not always notify the establishments of the results of the inspections and address, in writing, the nature of the deficiencies. APHIS had not established an appropriate mechanism for following up on deficiencies found during the inspections. We were unable to determine whether APHIS had advised inspected laboratories of inspection results and, if so, whether the entities had corrected cited deficiencies. As a result, APHIS could not ensure that appropriate corrective action was taken by the registered entities to comply with the regulations regarding safety and security.

APHIS did not strengthen controls within its existing permit systems to adequately ensure that listed agents or toxins were only transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin. This occurred because APHIS personnel believed its permit systems, as currently structured, met the new legislative requirements and incorporated the permit requirements into the regulations for the listed agents and toxins. APHIS also required that individuals wishing to transfer listed

agents and toxins intrastate obtain permits.[2] However, we found that existing permits (1) were too broad in scope to distinguish between select and non-listed agents or toxins and (2) did not provide sufficient information to readily determine whether individuals who had obtained permits that could be used for transferring listed agents or toxins were approved through registered entities. As a result, APHIS could not ensure that existing permits were issued only to individuals who demonstrated that they were complying with the requirements of the Act.

Recommendations In Brief

We are recommending that APHIS designate an official who will be responsible for the SAP, who can issue policies and procedures, and otherwise coordinate program activities, including the immediate task of developing a national registration database.

We are recommending that APHIS strengthen its registration oversight and determine whether entities fully comply with all regulations, including those governing security. After making such a determination, APHIS should either grant or deny full registration. APHIS should also establish formal procedures for performing security inspections at the registered entities in order to ensure that the inspections are consistent and thorough, and that documented and supportable conclusions are made concerning the adequacy of security measures. The procedures should provide that APHIS inform the entities of the results of the inspections and perform followup inspections when deficiencies are found. In addition, the agency should develop and provide formalized training for staff performing the inspections to address security measures.

Finally, we are recommending that APHIS strengthen controls for transfers of listed agents or toxins by establishing a separate and secure permit system for the SAP to help ensure that only registered entities and authorized individuals have or obtain permits that can be used for such agents or toxins. We are also recommending that APHIS update the permit form to distinguish permits for listed agent or toxin transfers from those for non-listed agent or toxin transfers. In addition, we are recommending that APHIS update the regulations to include these requirements in order to promote greater control and accountability over the listed agent or toxin program.

Agency Response

APHIS provided a written response to the official draft report on May 24, 2005. We have incorporated applicable portions of the response into the Findings and Recommendations section of this report. The agency response is included as exhibit A.

[2] The existing systems only required permits for importation and interstate transfers, not for intrastate transfers.

OIG Position

Based on the agency's response, we have reached management decision on Recommendation 9. Management decisions on Recommendations 1 through 8 and 10 can be reached once the agency has provided us with the additional information outlined in the Findings and Recommendations section of the report.

Abbreviations Used in This Report

APHIS
Animal and Plant Health Inspection Service 1
BSE
Bovine Spongiform Encephalopathy 23
CDC
Centers for Disease Control and Prevention 1
CFR
Code of Federal Regulations 1
CJIS
Criminal Justice Information Services 2
EEE
Eastern equine encephalitis 11
HHS
Department of Health and Human Services 1
IES
Investigative and Enforcement Services 10
NCIE
National Center for Import and Export 5
OIG
Office of Inspector General 12
PPQ
Plant Protection and Quarantine 4
RO
Responsible Official 2
SAP
select agent program 4
SOP
Standard Operating Procedures 7
the Act
Public Health Security and Bioterrorism Preparedness and Response Act of 2002 1
USDA
U.S. Department of Agriculture 1
VS
Veterinary Services 4

Table of Contents

Background and Objectives

Background

Plant and animal biological agents and toxins are considered "select" agents if they appear on a list prepared by the U.S. Department of Agriculture (USDA), and published in Federal Regulations in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) (the Act). The Agricultural Bioterrorism Protection Act of 2002[3] provides for the regulation of those agents and toxins that have the potential to pose a severe threat to animal and plant health or to animal and plant products. In the Federal Regulations, USDA listed 53 organisms requiring regulation, including Bacillus anthracis, Foot and mouth disease virus, and Plum pox potyvirus.

The Act also provides for the regulation of biological agents and toxins listed as dangerous by the Department of Health and Human Services (HHS). Where both HHS and USDA list the same agents, known as overlap agents, the Act provides for interagency coordination between the two departments. The Centers for Disease Control and Prevention (CDC) has responsibility for enforcing the Act on behalf of HHS; the Animal and Plant Health Inspection Service (APHIS) has responsibility for enforcing the Act on behalf of USDA.

The Act requires all persons in possession of any select biological agent or toxin, including those select agents listed by CDC, to notify CDC or the Secretary of Agriculture of such possession. APHIS published the first list of select agents and toxins as an interim rule to Federal Regulations in August 2002. The notification forms were due to APHIS no later than October 11, 2002.

The Act also required USDA's Secretary to establish:

- safety requirements for select agents, ensuring that appropriate skills exist to handle the agents and that proper laboratory facilities are available to contain and dispose of them;

- security requirements to prevent access to select agents for use in domestic or international terrorism or for any other criminal purpose; and

- requirements to protect animal and plant health and animal and plant products, in the event of a transfer of a select agent.

APHIS published the final list of select agents and toxins on December 13, 2002. The list of plant agents appeared in 7 Code of Federal Regulations (CFR) 331 and the list of overlap and animal agents appeared in 9 CFR 121.

[3] Title II, subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 is cited as the "Agricultural Bioterrorism Protection Act of 2002."

Both regulations established the safety, security, and transfer requirements for the select agents.

One other requirement set forth by the Act (and repeated in the Federal Regulations) was that all entities possessing, using, or transferring select agents must register with the appropriate regulatory agency, APHIS or CDC. Entities with overlap agents could register with either agency. As part of the registration process, the entities' responsible official (RO), the alternate RO, the entity, and—where applicable—the individual who owns or controls the entity must undergo a security risk assessment by the Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation. Moreover, those individuals identified by an entity as having a legitimate need to handle or use select biological agents or toxins must undergo a security risk assessment by the CJIS Division.

To minimize the disruption of research and educational projects that were underway as of the effective date of the regulations (February 11, 2003), APHIS and CDC established a phase-in period that gave individuals and entities until November 12, 2003, to reach full compliance with the regulations. The phase-in dates were as follows:

- By March 12, 2003, the RO was to submit the registration application package to the regulatory agency. The official was also to transmit to the Attorney General the names of the RO, the entity, and the individual who owned the entity.

- By April 11, 2003, the RO was to submit to the Attorney General the names of all the individuals with the entity that had a legitimate need to use the select agents.

- By June 12, 2003, the RO was to submit to APHIS the security section of the entity's security plan.

- By September 12, 2003, the RO was to implement the security section of the entity's biocontainment/biosafety and security plan.

- By November 12, 2003, the registration application process was to be complete and the entity in full compliance.

On November 3, 2003, APHIS and CDC amended the regulations to allow for the issuance of provisional registrations for all entities and individuals meeting all of the requirements of the regulations.[4]

[4] In order to meet requirements, the Attorney General, prior to November 12, 2003, must have received all of the information required by the Attorney General to conduct a security risk assessment, which may include fingerprint cards, etc.

APHIS and CDC may issue a provisional registration certificate to current possessors of select biological agents or toxins if the individual who owns the entity and the entity itself otherwise meet all of the other requirements.

Objectives

The primary objective of this audit was to evaluate APHIS' implementation of regulations governing the possession, use, and transfer of biological agents and toxins. Specifically our objectives were to determine if APHIS had implemented adequate controls and procedures to ensure that (1) registration records are complete, (2) oversight activities were appropriately coordinated with CDC, (3) approvals of laboratory security plans were consistent and supportable, and (4) safeguards were in place during the transfers of select agents to protect animal and plant health. This is the first phase of our review of APHIS' implementation of select agent regulations.

In Phase II (Audit No. 33601-3-At), we are performing field visits to locations where listed agents and toxins are used or stored to determine whether established controls are functioning as designed by examining registered entities' compliance with the regulations.

Findings and Recommendations

Section 1: APHIS Controls Over the Select Agent Program (SAP)

Finding 1 APHIS Had Not Designated a RO to Oversee the SAP

APHIS incorporated the SAP separately into two existing services, the Plant Protection and Quarantine (PPQ) and Veterinary Services (VS), without ensuring coordination and timely legislative compliance between the two units. This occurred, in part, because APHIS has not established an official within the agency hierarchy who is responsible for coordinating the two components of its SAP; officials did not believe that any one person knew enough about both animal and plant pathogens. Consequently, APHIS had not fully implemented controls for enforcing safeguard and security measures to prevent access to dangerous biological agents and toxins, as required by legislation.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, was enacted to enhance controls over dangerous biological agents and toxins. In part the title II, subtitle B of the Act,[5] addressed the lack of authority for the Secretary of Agriculture, under legislation effective at that time, to regulate possession of biological agents and toxins that pose a severe threat to plant or animal health. The Act requires the Secretary to both establish and enforce safeguard and security measures to prevent access to dangerous biological agents and toxins that affect either animals and plants so that they may not be used in domestic or international terrorism, or for any other criminal purpose. It also requires the establishment of procedures to protect animal and plant health, and animal and plant products in the event of a transfer of biological agents.

Because the SAP was absorbed into two existing programs created to administer previous legislation and regulations, no single official was delegated the responsibility to ensure that all provisions for enhancing controls over biological agents and toxins were timely and effectively implemented. Neither VS nor PPQ issued instructions or procedures for implementing the Act. As a result, APHIS did not perform timely or sufficient reviews to determine whether entities had registered as required or had established appropriate safeguard and security measures to comply with the implementing regulations.

Even though the legislation was effective on December 13, 2002, VS did not appoint a director for its SAP until February 9, 2004, almost 14 months after

[5] Also known as "The Agricultural Bioterrorism Protection Act of 2002."

the program was to be implemented. Prior to that date, the SAP was one of several assigned to the Director of Technical Trade Services for the National Center for Import and Export (NCIE). Program staff was largely drawn from NCIE, and key program personnel were still being added during the course of our audit. For example, we found that the security manager that approves applicants' security plans was not in place until April 2004, resulting in a significant delay before substantive reviews of security plans were started. A veterinary medical officer that evaluates permits for select agents was not added until June 2004.

When PPQ implemented its SAP, it did not update its organization chart to reflect the select agent function. We were told that the Assistant Director for Biological and Technical Services in the Plant Health Program headed the SAP for PPQ. PPQ used staff members from Permit Services, Pest Permit Evaluations, and Pest Containment Facility Evaluation branches to carry out select agent activities. The PPQ staff divided their time between their other duties and their assigned tasks related to the SAP.

A good internal control environment requires that the agency's organizational structure clearly define key areas of authority and responsibility and establish appropriate lines of reporting. Internal control comprises plans, methods, procedures, and actions to meet objectives such as ensuring compliance with applicable laws and regulations.[6] By incorporating the SAP into two existing programs, no single official within APHIS had been given overall responsibility to see that provisions of the Act had been timely and fully implemented. The following are examples of implementation issues affected by the lack of a single official with overall responsibility.

- We found that APHIS did not ensure that all entities possessing, using, or transferring select agents or toxins were properly registered. It was not until 15 months after the deadline for registering to possess, use, or transfer select agents that APHIS completed procedures to identify entities that had not registered and unlawfully possessed select agents. PPQ was able to perform a manual reconciliation between initial notifications of possession and subsequent registrations, but did not follow up on discrepancies until after our inquiries. VS was not able to timely perform the review because CDC had delayed providing the needed notification of possession database to APHIS so that an automated reconciliation could be performed. Although a delay in obtaining a notification of possession database significantly hindered the agency's ability to perform a reconciliation to determine if all persons had registered their listed agents or toxins, the issue was not elevated to a higher level within APHIS. (See Finding No. 2)

[6] "Standards for Internal Control in the Federal Government, published by the General Accountability Office in November 1999.

- APHIS had not established written procedures for ensuring that laboratory inspections were consistent and thorough to determine whether entities implemented security measures commensurate with the risks of the pathogens involved. APHIS had no defined methodology for determining whether laboratory security was adequate, and no formal reporting or tracking systems to summarize and track the results of the inspections or corrective actions. This occurred because no single office or individual directed a consistent format for the inspections. We found that APHIS inspections were not sufficiently documented to show whether registered entities had implemented adequate safeguard and security measures as required by the regulations. (See Finding No. 5)

We concluded that the lack of a single responsible official for the SAP and the fact that the agency had not timely allocated resources to effectively manage program operations, contributed to the issues identified in this report. During the audit, we found that APHIS:

- did not ensure that all entities possessing, using, or transferring select agents or toxins were properly registered (Finding No. 2);

- did not establish a national database of select agents as required by the Act (Finding No. 3);

- did not ensure that registrants had adequate security plans before granting provisional registration status (Finding No. 4);

- did not establish policies and procedures to ensure consistent and thorough inspections (Finding No. 5);

- did not establish followup procedures for deficiencies identified during inspections (Finding No. 6); and

- did not strengthen controls within its existing permit systems to adequately ensure that listed agents or toxins were only transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin (Finding No. 7).

In addition, sensitive data was compromised because both VS and PPQ staff members who have no need to access the data can nevertheless do so. The Act forbids Federal agencies from disclosing any registration or transferring information that would identify the select agents involved or the identity or location of the person possessing the agents. We identified at least 45 staff that had access to the sensitive data, while only 8 were assigned to work with select agents.

Recommendation 1

Designate an official who will be responsible for the SAP, who can issue policies and procedures, and otherwise coordinate program activities.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *The APHIS Administrator is the official responsible for the APHIS * * * SAP. The APHIS Administrator has delegated responsibility for the SAP to managers in the APHIS' * * * VS and * * * PPQ programs. Currently, program activities are coordinated and policies and procedures are agreed to and issued jointly by managers of the VS and PPQ programs. An example of this would be the recent interactions between the VS and PPQ SAP managers in regards to the creation of the shared select agent system. APHIS will develop [Standard Operating Procedures](SOP) describing the working relationship between the VS and PPQ SAPs. The SOPs are scheduled for completion by May 30, 2005.*

OIG Position. The intent of our recommendation is to ensure that someone is designated the responsibility to oversee the SAP, and ensure that APHIS has policies and procedures in place for ensuring that registered entities have safeguard and security measures to prevent access to dangerous biological agents and toxins. We agree that the administrator has the overall responsibility for the program, as he does for all APHIS programs. However, since the SAP is a critical part of protecting the safety and health of the nation's plants and animals, the agency should establish clear lines of authority for seeing that all provisions of the legislation are carried out. In order to reach management decision on this recommendation, please describe the responsibilities that will be assumed by each of the VS and PPQ managers, and how APHIS will ensure that policies and procedures are implemented for the program as a whole.

Recommendation 2

Restrict access to sensitive data only those individuals whose job requires access.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *SAP files are kept secure in a limited-access file room shared by VS and PPQ. Only program staff with a "need-to-know" have access to the file room. Access/entry into the file room is controlled by key card. Program staff also must have security clearances before getting access to the file room.*

OIG Position. We agree with the actions taken for the file room access. In order to reach management decision, please describe how electronic data for the SAP will be safeguarded.

With the passage of the Act, the Secretary of Agriculture was required to promulgate regulations to establish and maintain a list of each biological agent and each toxin that is determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires entities to register so that APHIS can ensure that they have a lawful purpose for possessing, using, or transferring listed agents and toxins, and to ensure the entities comply with safeguard and security regulations. We found that APHIS not only lacked adequate procedures to ensure that all laboratories possessing, using, or transferring the select agents were registered as required, but also had not developed a national database of registered entities, as required by the Act.

The Act requires that the Secretary of Agriculture shall maintain a national database of agents and toxins posing a severe threat to animals and plants, including the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins. APHIS and CDC initially undertook the development of their own respective databases, but later decided to integrate the two systems resulting in a delay in development of the required database. The absence of the database hinders APHIS ability to readily identify the locations where dangerous biological agents and toxins are stored and used, and in turn diminishes the agency's ability to effectively monitor compliance with safety and security requirements.

Finding 2 APHIS Did Not Ensure That Everyone Registered as Required

APHIS had not taken adequate steps to ensure that all entities possessing, using, or transferring listed agents and toxins had registered as required by the Act. This occurred because the agency had not reconciled entities' initial notifications of possession it received in October 2002 with entity registrations it subsequently received in March 2003. The Act requires entities to register so that APHIS can ensure that they have a lawful purpose for possessing, using, or transferring listed agents and toxins, and to ensure the entities comply with safeguard and security regulations. APHIS did not perform the reconciliation because it (1) did not have access to the notification of possession database maintained by CDC and (2) did not develop a national registration database as required by the Act (see Finding No. 3). As a result, APHIS had not identified entities that violated the law by failing to register. In response to our inquiries and a Management Alert, APHIS performed a reconciliation and identified entities unlawfully possessing select agents after the March 12, 2003, registration deadline.

The Act requires that 60 days after the promulgation of the interim final rule (issued on August 12, 2002), all persons in possession of select biological agents or toxins shall notify the Secretary of such possession. The Act and implementing regulations also require persons wishing to possess, use, or transfer select agents and toxins to register with APHIS or CDC. Under the law and regulations, notifications of possession were due on October 8, 2002, and registrations were due on March 12, 2003.

APHIS had not performed a reconciliation between the notifications of possession and the registration applications to ensure that all possessors of listed agents and toxins applied for the required registration. Although PPQ initially informed us that they had reconciled notifications of plant pathogens to the registrations, they could not provide documentation to explain why only 17 registration applications were received compared to 31 notifications of possession. Based on our inquiries, PPQ followed up on the discrepancies, and forwarded information for two entities to APHIS' Investigative and Enforcement Services (IES). IES determined that the two entities were in violation of the Act, because they possessed select agents, Xanthomonas oryzae pv. Oryzicola,[7] and Ralstonia solanacearum race 3, biovar 2,[8] and they had not registered with APHIS. IES witnessed the destruction of the select agents while onsite. APHIS determined that none of the remaining notifications required registration.

While the volume of PPQ notifications was small enough for a manual reconciliation, VS determined that it needed CDC's notification database to do an automated reconciliation with VS registrations. Consequently, according to the director of the VS SAP, VS had not reconciled over 2000 notifications of possession with its 73 registrations.

The director of VS' SAP said she had pursued getting the database, but had difficulty obtaining the database containing the notification of possession information from CDC. She stated that she had made previous requests to obtain the database, and had a contractor ready to perform the reconciliation. Although this issue significantly hindered the agency's ability to perform a reconciliation to determine if all persons had registered their listed agents or toxins, it was not elevated to a higher level within APHIS. Based on our inquiries, the director sent e-mail to CDC on February 23, 2004, again requesting the database. However, CDC did not provide the notification of possession database until April 2004.

CDC officials told us that a Security Officer for HHS initially determined that the notification of possession database should be designated as "classified/secret." This meant that all staff having access to the database had

[7] Xanthomonas oryzae pv. Oryzicola causes bacterial diseases in rice.
[8] Ralstonia solanacearum race 3, biovar 2 is a bacterial pathogen that causes wilt disease in several agricultural crops, such as potatoes, tomatoes, peppers, and eggplant.

to have a secret level clearance. According to CDC officials, APHIS was not prepared to handle secret-level information, causing a delay in providing the agency access to the database. During our audit, however, the Deputy Secretary for HHS determined that the database should be classified as "sensitive, but unclassified." APHIS received the database on April 1, 2004.

Although VS had the CDC database in April of 2004, it did not perform the reconciliation we had recommended. We issued a Management Alert to the APHIS Administrator on June 8, 2004, describing the results of PPQ's reconciliation and recommending that APHIS continue to reconcile all its notifications and registrations. As a result of the Management Alert, VS performed the reconciliations and determined that two entities were in possible violation of the Act because they possessed biological agents that may be or were select agents, and had not registered.

One entity possessed Newcastle Disease but did not know which strain of the virus it had. Exotic Newcastle, particularly destructive to birds, is a select agent, whereas domestic Newcastle is not. An outbreak of exotic Newcastle could severely impact the U.S. poultry industry, as was shown by a recent contained outbreak in California. The entity possessing the virus surrendered it to the VS laboratory for testing. On August 30, 2004, we were informed that initial testing did not detect the exotic strain, however, more testing is required. The second entity acknowledged that it possessed Eastern equine encephalitis (EEE) virus, a select agent that can infect both horses and people. Thirty-five percent of the people who contract EEE die from it, and another 35 percent who survive the disease have neurological deficits. The entity possessing the EEE had not used it for years and agreed to destroy it as soon as oversight of the destruction could be coordinated with APHIS. This was accomplished on August 13, 2004.

Because of the actions APHIS took to address our June 8, 2004, Management Alert, we are not making further recommendations regarding this finding.

Finding 3 — APHIS Had Not Established a National Database of Select Agents

APHIS had not developed a national database of registered entities, as required by the Act. APHIS and CDC initially undertook the development of their own respective databases, but later decided to integrate the two systems resulting in a delay in development of the required database. The Act requires that the Secretary of Agriculture shall maintain a national database of agents and toxins posing a severe threat to animals and plants, including the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins. The purpose of the database is to facilitate the identification of the agents and their location as well as their

source. The absence of the database hinders APHIS' ability to readily identify the locations where dangerous biological agents and toxins are stored and used, and in turn diminishes the agency's ability to effectively monitor compliance with safety and security requirements.

The Act requires that no later than 60 days after promulgation of the interim final rule, all persons possessing the biological agents or toxins included on the list must notify the Department of the possession. The Act does not specify a timeframe in which USDA must develop the national database. However, we believe that the development of the database should be a priority because it provides a means of determining, in an emergency situation, where select agents and toxins are located and of ensuring that their possession, use, and transfer can be tracked. The provisions of the Act were designed to provide protection against the effects of misuse of select agents and toxins, whether inadvertently or as the result of terrorist or criminal acts.

APHIS managers are presently setting up a secure area and a "stand-alone" computer system so that they can develop the required registration database. Until the registration database is in place, the agency does not have an efficient or effective means to readily identify the names and locations of all registered persons having select agents and toxins to ensure that all entities are complying with the regulations.

APHIS' response to the Management Alert, received on July 27, 2004 states:

> *VS concurs with [the Office of Inspector General's](*OIG*) first recommendation to prioritize the development of a national database. Indeed, this activity is already occurring. It is important to note that both APHIS and the *** (CDC) initially undertook development of their own respective database systems. All of the data that will be in the national database is currently available to CDC and APHIS program managers; it just is not yet in a single database.*
>
> *Nevertheless, since January 2004, the Technology Sub-Committee of the CDC/USDA Working Group has been working on this issue. The sub-committee has recently overseen the completion of a "gap analysis" of CDC and USDA's systems. The purpose of this analysis was to evaluate the differences between the two systems' requirements and designs and to provide options for a timely, cost efficient integration of the two systems that would result in a "national registration database". This integrated system will not only apply to select agent or toxin registration, but will also apply to transfer reports; theft, loss, or release reports; identification reports; and exemption requests.*

As of October 8, 2004, however, APHIS still could not provide us a summary of critical information regarding where select agents and toxins are located. Even though the program managers may have access to all the data, it would be difficult and time consuming to identify the critical information needed to effectively monitor compliance with safety and security requirements. We concluded that APHIS should proceed to compile, into a single database, critical information, including the names and locations of registered entities, the listed agents and toxins such entities are possessing, using, or transferring (including the characteristics of such agents), and the list of individuals at the entities who are authorized to access the agents or toxins. Information concerning transfer reports; theft, loss, or release reports; identification reports; and exemption requests can be phased into a single database over time.

Recommendation 3

Take immediate steps to establish a national database that includes, at a minimum, names and locations of registered entities, the listed agents and toxins such entities are possessing, using, or transferring, and the list of authorized individuals. Other information can be added to the database at a later time.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *Currently, both * * * HHS-* * * CDC and APHIS have these data in electronic form. APHIS is actively engaged with CDC, the HHS-OCIO, and the USDA-OCIO on creation of "e-SAS" (electronic Select Agent System) which will serve as the National Select Agent Database. E-SAS will be operational by Decemter 31, 2005, (as published in the CDC (42 CFR Part 72) and APHIS (7 CFR Part 331, 9 CFR Part 121) Final Rules on March 18, 2005. A draft copy of the MOU between APHIS and CDC is attached that describes the components of "e-SAS."*

OIG Position. In order to reach management decision, please describe the data that is currently in electronic form.

The Act emphasizes security as a primary focus of the SAP. The Act states that regulations governing select agents "shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a select agent or toxin commensurate with the risk such agent or toxin poses to animal and plant health, and animal and plant products (including the risk of use in domestic or international terrorism)." The Act adds that the Secretary of Agriculture shall ensure compliance with these security requirements as part of the registration system. This system requires registration applicants to submit a security plan detailing the security features of the laboratories and the procedures to follow to safeguard the select agents against unauthorized use or release.

In granting provisional registration to 75 applicants to the SAP, APHIS personnel did not always ensure that the agents would be properly safeguarded against unauthorized use or release. APHIS granted provisional registration even though:

- Documents submitted by 55 of the 66 applicants we reviewed showed deficiencies in the design of the laboratories, the physical security of the laboratories, access to the select agents, accountability, and training;

- APHIS inspection files for 11 of the 13 entities we reviewed did not make clear whether all laboratories housing select agents were actually inspected for security; and

- None of the laboratories whose inspections revealed deficiencies were told that they needed to strengthen their security.

APHIS did not establish procedures for notifying laboratories of security weaknesses. We concluded that none of the 55 applicants we reviewed met the requirements of the law and that none were eligible for provisional registration. APHIS is working with the entities to strengthen security, but as of July 22, 2004, only one entity had been granted full registration. The Act required that the entities have adequate security measures in place by November 2003.

Finding 4 — APHIS Granted Provisional Registration Status Without Ensuring the Registrants Had Adequate Security Plans

APHIS granted provisional registrations to entities without determining whether their security plans provided adequate safeguard and security measures. Regulations allowed for provisional registration if an entity could show by the November 12, 2003, deadline, that it was providing proper

security. However, APHIS officials stated that the regulation's intention to "minimize disruption of research" took precedence over the need to fully comply with security requirements by the deadline. Consequently, APHIS reviewed registration applications only to ensure a security plan had been submitted, not that it met the requirements of the regulations. As a result, the agency had not taken sufficient action to ensure that registered entities have implemented adequate safeguard and security measures to comply with the legislation and regulations.

For entities that were registering their laboratories to use and store select agents, regulations required that a completed registration application (with a security plan) be submitted to APHIS by November 12, 2003. Additionally, the entities were to be in full compliance with the regulations by that date. A security plan is a detailed document concerning the physical security of the select agents and the laboratories that house them. The plan must contain provisions for securing the area (e.g., card access, locks) and protocols for changing access numbers or locks following staff changes; procedures for loss of keys; procedures for reporting suspicious persons or activities, theft of select agents, or alteration of inventory records; procedures for reporting and removing unauthorized persons; and plans to respond to a security breach or a cybersecurity breach.

Recognizing a need to "minimize disruption of research or educational projects…that were already underway," the interim final rule to the regulations established phase-in timeframes for the actions needed to achieve full compliance. The interim final rule set March 12, 2003, as the date to submit the registration package to APHIS; and April 11, 2003, as the date to provide the Attorney General with the names of all the individuals that would be handling or using the select agents. These early dates would allow APHIS time to review the documents for completeness and would give the Attorney General time to perform security risk assessments of the registered individuals before the November 12, 2003, deadline.

On November 3, 2003, the regulations were amended to allow for the issuance of provisional registration certificates for individuals and entities and provisional grants of access to select agents and toxins for individuals. These provisional measures were designed to provide additional time for the Attorney General to complete security risk assessments. The regulations state that "APHIS may issue a provisional registration certificate to current possessors if, as of November 12, 2003, (1) the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity and (2) the entity otherwise meets all of the requirements of the regulations."

APHIS received the required information for the Attorney General's review before granting authorization for individuals to possess, use, or transfer the listed agents or toxins. However, APHIS did not determine whether the entities met all other requirements of the regulations regarding adequate security measures before granting provisional registrations.

On November 12, 2003, APHIS granted provisional certification to 75 entities and denied provisional certification to 3 because they did not send in security plans with their application packages. Of the three entities denied registration, one entity has closed the laboratory and no longer has the select agent, and another has reached full registration. APHIS initially determined that the third entity had not submitted a security plan with its registration package. APHIS later found that it had received, but misplaced, the security plan. Of the 78 entities, 66 possessed animal pathogens and 12 possessed plant pathogens.

For the 66 entities that used or stored animal pathogens, APHIS VS had a contractor review the registration application packages. Initially the contractor screened the applications and checked to make sure that each entity submitted the required material, not that the material met the requirements of the regulations. All registration applications that submitted the required materials were issued a provisional certification. This represented 64 of the 66 applicants. The remaining two applicants were denied a provisional registration because they did not send in the required information.

Once the provisional certifications were issued, the contractor began a review of the application packages to check for adequacy of the materials submitted. The contractor evaluated the entities' security plans, focusing on four areas—inventory control, personnel security, cybersecurity, and incident response. As of January 13, 2004, only 10 entities were deemed to have satisfied all essential security elements, and one entity was exempt from the registration requirements because it fell under special provisions of the regulations.[9] For the security plans of the other 55 entities, the contractor listed problems related to the physical security of the laboratories, access to the select agents, accountability, and training, as shown in the table below.

[9] APHIS regulations (9 CFR 121.4 – 121.5) exempt certain clinical and diagnostic specimens.

Figure 1: Entities With Deficiencies in Their Security Plans

Entity	Deficiencies					
Total Number	**Physical Security**	**Select Agent Access**	**Accounting for the Select Agent**	**Biosafety Level ***	**Security Training**	**Laboratory Design**
55	34	30	31	25	30	4

***** The biosafety level (BSL) of a laboratory indicates the degree to which the laboratory is equipped to handle dangerous pathogens. For example, a laboratory that registers to handle anthrax in an aerosol state must show that it has a BSL-4 level rating. Any lesser rating would disqualify the laboratory from storing or using the pathogen.

Based on these review results, none of the 55 entities met the requirements of the regulations, and consequently none were eligible for a provisional certificate on November 12, 2003.

APHIS PPQ staff reviewed the application packages for 11 of the 12 entities that used or stored plant pathogens, and found that 5 of the security plans were poor, 2 were only fair, 3 were good, and 1 was excellent. Provisional registrations were given to the 11 entities. The 12th entity was transferred to CDC, and therefore was not reviewed. APHIS granted a provisional registration before the transfer.

APHIS personnel stated that the regulations that provided for provisional registration status indicated that that status was intended to accommodate entities engaged in critical research and minimize any disruption of that research. APHIS officials stated that they granted the provisional status in accordance with this intent of the regulations. We noted, however, that the regulation provided a phased-in timeframe to accommodate entities engaged in critical research; it established provisional registrations to give the Attorney General more time to complete the large volume of security risk assessments. Moreover, the regulations specifically allow provisional registrations only in cases where the entity meets all the security requirements set forth in the regulations.

During the audit, APHIS began developing a letter to send to the entities detailing the results of the initial review, the deficiencies, and the further actions that need to be taken by the entities in order to obtain full registration. The letter was to require entities to respond within 10 days. However, as of July 22, 2004, this letter had not been sent to any of the entities.

As of July 22, 2004, only one entity had been granted full registration. Only three indepth reviews (comparing the application package, security plan, inspections, and any additional information that may be available) had been completed.

Recommendation 4

Determine whether entities are in full compliance with all aspects of the regulations and either grant or deny registration.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *As stated in the regulations (Interim Final Rule), "a provisional registration certificate will be effective until APHIS either issues a certificate of registration or suspends or revokes the provisional registration." As set forth in the Interim Rule, issuance of provisional registrations depended on submission by November 12, 2003, of:*
>
> - *a completed application*
> - *a security plan*
> - *all Security Risk Assessment material to FBI*
>
> *Following an indepth review, APHIS has granted full registration to 62 entities (as of April 8, 2005). * * **
>
> * * * * * * * * *

OIG Position. In order to reach management decision, please provide the estimated timeframes for completing the remaining 13 indepth reviews and granting full registrations.

Finding 5 APHIS Had Not Established Policies and Procedures to Ensure Consistent and Thorough Inspections

APHIS had not established policies and procedures to ensure that inspections of the registering entities security measures were consistent and thorough. This occurred because no single office or individual prescribed a consistent format for the inspections or for the presentation of inspection results. Inspections performed by VS and PPQ did not provide clear documentation concerning the nature or extent of deficiencies, and did not always conclude as to whether security measures implemented by the registered entities were adequate. As a result, APHIS inspections were not sufficiently documented to show whether registered entities had implemented adequate safeguard and

security measures to prevent access to select agents and toxins to protect them from use in domestic or international terrorism.

The Agricultural Bioterrorism Protection Act of 2002 requires the Secretary of Agriculture to establish and enforce safeguard and security measures commensurate with the risk such agent or toxin poses to animal and plant health, and animal and plant products, including the risk of use in domestic or international terrorism. Regulations state that APHIS may inspect and evaluate the premises and records of any establishment where biological agents or toxins are used or stored to ensure the establishment's compliance with the regulations and the containment and security requirements. Although the regulations do not require APHIS to inspect facilities with the listed agents or toxins, APHIS has established a protocol to perform such inspections before issuing registrations.

We found that APHIS had not developed written procedures for ensuring that laboratory inspections were consistent and thorough to conclude whether entities implemented security measures commensurate with the risks of the pathogens involved. An APHIS VS official told us that there was no defined methodology for determining whether laboratory security was adequate, and no formal reporting or tracking systems to summarize and track the results of the inspections or corrective actions. APHIS VS had not dedicated staff within the SAP to perform the inspections, so veterinarians from APHIS' various field offices performed the entity inspections.

The official said that, although inspectors were provided with checklists to review security, training given to the inspectors was not adequate to assist in drawing conclusions regarding security.

An APHIS PPQ official said that their staff had not been trained on the security aspects of the inspections because, at the time of the last training in April 2004, there was no security specialist or anyone who knew enough to train the inspectors on security.

We judgmentally selected a sample of 13 entities, based on the type of select agents they had, to determine which laboratories were inspected and what was found during the inspections. CDC or APHIS inspected all but 1 of the 13 entities in our sample. (The entity that was not inspected was closed prior to being inspected.)

APHIS VS employees used the checklists to facilitate their inspections of the registering entities. Although some files contained both biosafety and biosecurity checklists, this was not always the case. In cases where both biosafety and biosecurity checklists existed, they did not always clearly show what was inspected. The most common problem involved the location of the laboratory; either the building or room number of the laboratory was not

listed on either of the checklists or if it was listed, the numbers did not match between the two checklists. For many of the entities, we were unable to determine from the information in the files whether all of the laboratories with select agents had been inspected. In some cases, it was even difficult to determine which of an entity's laboratories had the select agents.

Of the 13 inspection files we examined, 11 did not clearly indicate whether all laboratories housing select agents had actually been inspected for security. We concluded that the case files upon which APHIS employees based their decisions to grant provisional registration contained insufficient evidence of adequate security. For example,

- The inspection file for one research unit contained biosafety checklists for four different laboratories where work was being performed with select agents; however, we only located one biosecurity checklist corresponding to one of the four laboratories.

- The file for one university contained an inspection report from CDC[10] that was accepted by VS even though the report did not make clear which laboratories CDC inspected and what was contained in those laboratories. Consequently, for this university, we were unable to determine that all laboratories with select agents were inspected.

Inspection documents did not provide adequate information for APHIS employees to assess the adequacy of safeguard and security measures. Entity inspections typically only took one day to complete, and there were no instructions or requirements for inspectors to relate their observations of the security measures back to the entities' risk assessments and security plans. Consequently, there was no assurance that the inspections were used to determine if the security measures implemented were in line with the entities plan and commensurate with the risk of the particular pathogens present in the laboratories inspected. There was also no requirement that the results of an inspection be included in an inspection report or summary of findings that identified the severity of any deficiencies. We could not determine from the documents available whether an inspection concluded a laboratory was adequate or inadequate.

Recommendation 5

Establish formal procedures for performing security inspections at the registered entities ensuring that the inspections are consistent and thorough, and that documented and supportable conclusions are made concerning the adequacy of security measures at the registered entities.

[10] CDC inspected this entity prior to the entities registration being assigned to APHIS.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *A joint APHIS/CDC * * * [SAP] Steering Committee was performed in January 2004 to oversee and coordinate operational activities for the U.S. Government * * * SAP. An inspection subcommittee was formed and produced the joint APHIS/CDC security inspection checklist (see attached) which is currently being used to guide all entity inspection activities in APHIS and CDC. Adequacy of security measures is determined by APHIS Headquarters SAP staff after review of inspection results and security plans. Further, in 2004 APHIS hired a full time Select Agent Security Specialist whose primary role is to ensure that registered entities maintain select agents and toxins in a secure manner.*

OIG Position. We do not agree with management decision for this recommendation. The security inspection checklists did not provide sufficient evidence to determine whether security measures implemented by the registered entities were adequate. Also, the checklists prepared did not always clearly show what was inspected. As required by the legislation and regulations, registered entities must implement security measures commensurate with the risks. However, there were no instructions or requirements for the inspectors to relate their observations of the security measures to site-specific risk assessments or security plans. Since the inspectors were not required to make this comparison of their observations to the risk assessments or plans, there is no assurance that the inspectors documentation on the completed checklists would provide sufficient evidence for the APHIS Headquarters staff to determine the adequacy of the security measures.

In order to reach management decision, APHIS needs to formalize procedures for performing the inspections to ensure that supportable conclusions are made concerning the adequacy of security measures. The procedures should include steps to relate the inspectors' observations to the site-specific risk assessments and the security plans. The checklists may serve as a tool in the inspection process. However, the inspections should be comprehensive and provide that conclusions be drawn regarding the adequacy of security measures observed during the site visits.

Recommendation 6

Develop and provide formalized training for staff performing the inspections to address security measures.

Agency Response. In its May 24, 2005, response, APHIS stated: "Plans are currently underway for a joint APHIS/CDC training session for entity

inspectors to be held in the Atlanta area during September 2005. Security will be one area that will be addressed."

OIG Position. It is important to note that the legislation addresses security as one of the key controls over dangerous biological agents and toxins. Therefore, our recommendation was intended to emphasize the need for formalized training for the APHIS inspection staff reviewing security measures implemented at the registered entities. In order to reach management decision, please provide information describing the training to be provided and how the training will aid reviewing security at the registered entities. Also, describe how the training will be incorporated into APHIS' operating procedures (i.e., who will receive the training and how often will the training be given).

Finding 6 APHIS Did Not Have Followup Procedures to Ensure Laboratory Safeguard and Security Deficiencies Were Corrected

Although some inspections revealed deficiencies at laboratories applying to use and store select agents, APHIS did not always notify the establishments of the results of the inspections and address, in writing, the nature of the deficiencies. APHIS had not established an appropriate mechanism for following up on deficiencies found during the inspections. We were unable to determine whether inspected laboratories were aware of inspection results and, if so, whether deficiencies had been corrected. An inspection of one entity determined that a laboratory did not meet the requirements to use or store a select agent it possessed. However, APHIS did not follow up to ensure corrective action was taken.

Of the 13 entities whose inspection documentation we reviewed, at least 5 housed laboratories that had been found deficient by APHIS and 1 had its laboratory closed after it failed an inspection by a State committee established to review laboratory biosafety. Files for the laboratories inspected by APHIS showed no evidence that APHIS performed any secondary review to determine if deficiencies had been corrected. For example:

- For one laboratory, APHIS cited several deficiencies during its inspection, the most notable of which was the absence of a biosafety cabinet in the laboratory. A biosafety cabinet is the principal device used to provide containment of infectious splashes or aerosol generated by many microbiological procedures. We did not find any documentation in the file showing that APHIS notified the entity or followed up on the deficiencies at this laboratory. However, we did find evidence that this facility was granted a provisional registration even though the laboratory was determined to be inadequate to house the select agent.

- APHIS inspected one laboratory that had undergone a prior risk assessment by a contractor who had found security deficiencies. APHIS inspectors merely recorded that the security deficiencies found during the risk assessment were not corrected by the time of the registration inspection. There was no evidence in the file that APHIS cautioned the laboratory about prevalent security deficiencies or performed additional followup. Insofar as this laboratory stored and used BSL-3 agents, such a communication would seem to be warranted.

APHIS' followup regarding laboratory deficiencies was, in general, ineffective. In the case of the laboratory that was closed by the State biosafety committee, APHIS became aware of the condition of the laboratory only after the committee notified APHIS to cancel its scheduled registration inspection. The entity was originally inspected by APHIS in July 2000, under APHIS' authority for issuing permits, and was granted a permit to import Bovine Spongiform Encephalopathy (BSE) samples from the United Kingdom. The State's biosafety committee inspected the entity in January 2003 and found an inoperable autoclave,[11] insect and vermin infestation, containment systems that were compromised, inadequate ventilation and climate control, and other deficiencies. Although the risk of someone acquiring BSE was low, the entity did not meet the safety requirements of a BSL-3 laboratory. In September 2003, APHIS sent a letter to the laboratory scheduling a registration inspection and was notified by the committee that the entity had been closed.

APHIS had not established an appropriate mechanism for following up on deficiencies found during an inspection. APHIS did not have a policy of notifying the facility that its laboratory was deficient in either safety or security features. Consequently, the facility would have no reason to strengthen any security features that it did not consider weak. We, therefore, concluded that APHIS should establish procedures for informing entities of the results of inspections and for preparing followup inspections when deficiencies are found.

Recommendation 7

Establish procedures for informing entities of the results of inspections and for performing followup inspections when deficiencies are found.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *APHIS will standardize a written procedure to notify entities not only of inspection deficiencies, but also deficiencies related to applications and security plans. This will be fully*

[11] An autoclave is a device for sterilizing pathogens to destroy them.

implemented by December 2005. Additionally, APHIS has hired a "Select Agent Security Specialist" at APHIS Headquarters, who reviews all APHIS inspection reports, applications, and security plans.

OIG Position. Based on APHIS' response, we could not determine whether the standardized written procedures will include steps to followup on deficiencies identified. In order to reach management decision, please indicate whether followup will be included in the procedures to be implemented in December 2005.

Finding 7 APHIS Did Not Strengthen Controls in its Permit System to Ensure Listed Agents or Toxins Were Transferred Only to Authorized Individuals

APHIS did not implement controls over permits compatible with the stricter requirements of the listed agents and toxin program. Specifically, APHIS did not strengthen controls within its existing permit systems to adequately ensure that listed agents or toxins were only transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin. This occurred because APHIS personnel believed its permit systems, as currently structured, complemented the requirements under the new regulations and provided additional protections for the transfer of listed agents and toxins. Therefore, APHIS incorporated its existing permit requirements into the regulations for the listed agents and toxins, and required that individuals wishing to transfer listed agents and toxins intrastate also obtain permits.[12] However, we found that existing permits (1) were too broad in scope to distinguish between select and non-listed agents or toxins and (2) did not provide sufficient information to readily determine whether individuals who had obtained permits that could be used for transferring listed agents or toxins were approved through registered entities. As a result, APHIS could not ensure that the existing permit system is not used to transfer listed agents or toxins by individuals who (1) have not been through the registration process and (2) have not been authorized to possess, use, or transfer the agents or toxins.

APHIS' current permit system has been in place for over 40 years. APHIS' two divisions, PPQ and VS, each has its own separate permit system and maintains its own database for tracking the permits. Under VS' system, which covers specified animal-related products, the applicant should state the exact nature of the item to be transferred. Permits are approved by a veterinary medical officer and are normally valid for 1 year. PPQ's permits, by contrast, do not always show the exact nature of the material being shipped and may be valid for multi-year periods.

The current permit system allows applicants to apply by fax, mail, or online and does not require them to undergo a background investigation or be registered to receive the pathogen. Recipients of pathogens shipped within the same State do not require a permit at all. Additionally, an OIG audit[13] of

[12] The existing systems only required permits for importation and interstate transfers, not for intrastate transfers.
[13] See Audit Report No. 33601-4-Ch, "APHIS Controls Over Permits to Import Biohazardous Materials Into the United States," issued March 2003.

this system performed in 2003 found that permits were not adequately tracked.

Federal Regulations written to implement the Agricultural Bioterrorism Protection Act of 2002 provide that a select biological agent or toxin may only be transferred to individuals or entities registered to possess, use, or further transfer that particular agent or toxin.

Because APHIS continued to rely on its existing permit system to control listed agents or toxins in transit between users of those agents, it could not fully ensure that shipments of listed agents or toxins were made only to individuals who had been authorized to possess such agents and toxins, and it could not always determine which permit holders transferred or possessed listed agents or toxins.

a. Permits Were Issued to Unregistered Individuals

Permits were issued to individuals that had not been cleared by the Attorney General and approved to possess listed agents or toxins and who may not even have been affiliated with a registered facility. This occurred because APHIS' permit system issues permits to individuals, not entities, whereas the listed agent or toxin program approves registration to entities, not individuals. APHIS queried their permit databases at our request, and provided us a printout of permits that potentially involved select agents. We identified two researchers out of the first ten on the VS permit printout with permits for Bacillus anthracis and Malignant catarrhal fever virus who were not on their institution's registration application to possess listed agents or toxins. We were not able to perform a complete reconciliation between APHIS permit databases and individuals authorized by APHIS to have access to listed agents and toxins because there were no reliable databases to electronically match and a manual match would have been too time consuming.

In establishing the listed agent or toxin legislation, Congress expected that most registrants would be public and private entities, rather than individuals. In deliberations presented in House Resolution Conference Report No. 107-481, Congress emphasized that the primary responsibility for registering employees is with the entity or employer, not the individual employee. Therefore, APHIS regulations required that each entity designate an appropriate individual as the RO who has the authority and control to ensure compliance with the regulations. As part of his or her responsibilities, the RO must ensure that only approved individuals within the entity have access to listed agents or toxins and toxins and that the agents or toxins are transferred to registered individuals or entities.

APHIS' permit system identifies individuals as permit holders, rather than identifying registered entities or their RO's. Therefore, APHIS cannot effectively ensure that permits for listed agents or toxins are, or were, issued only to individuals who have been authorized to possess, use, or transfer the listed agents or toxins through registered entities. In addition, the RO is not listed on the permit even though that person is responsible for certifying that the permittee is registered and has adhered to all regulatory requirements.

Under the current permit system, individuals who are not designated as the RO can obtain a permit to transport both non-select and listed agents or toxins. APHIS cannot determine which permittees are under the authority of a registered entity and its RO. APHIS reported that there are almost 400 individual permittees with listed agents or toxins. However, APHIS also reported that they cannot directly link permittees to facilities. APHIS officials said they were working on updating all permits to reflect the regulations' requirements. However, we were told that a reconciliation between RO's and permittees has not been performed.

b. Permits Did Not Identify the Strain of the Organism or Distinguish Between Select and Non-Listed Agents or Toxins

APHIS could not perform a reconciliation between RO's and permittees because APHIS issued permits that were too broad in scope to determine whether they were listed agents or toxins. For example, we noted two entries in the VS permit database that described the permits as covering "various microorganisms." Such a broad term would have made it impossible for anyone to recognize the permit as having been issued for a listed agent or toxin, had it not already been categorized in the APHIS database as such. Furthermore, the term clearly makes it impossible to determine whether the agents transferred under the permit were the same as the listed agents or toxins listed on the entity's registration application.

In addition, permits that do identify pathogens do not always specify the specific strain of the pathogen. We determined that APHIS' permit database did not have a data field that showed the specific strains of the agents or toxins. For example, to distinguish between select and non-listed agents or toxins, entries in the APHIS database for Avian influenza virus and for Ralstonia solanacearum race 3, biovar 2 must show the specific strain because all strains of these agents are not listed agents or toxins.

We concluded that because APHIS' existing permit system does not have adequate controls to ensure compliance with the listed agent or toxin program, APHIS should create a permit system that is separate and distinct from the current system and that tracks and controls permits for listed agents or toxins separately from other permits. Such a system should ensure that the permit identifies the specific listed agent or toxin (including strain) being transferred to the registered entity, and that the permit be issued to the individual listed on the registration application as the RO for that entity.

In creating a separate permit system for the listed agent or toxin program; APHIS should take the opportunity to strengthen two critical weaknesses inherent in its current system. Specifically, APHIS should monitor the listed agent or toxin permit after it expires or the research involving the listed agent or toxin is completed, and it should limit access to the database containing listed agent or toxin information. Neither of APHIS' current permit systems (administered by PPQ and VS) have functioning notification processes to alert managers when permits expire, and neither PPQ nor VS have procedures to terminate permits when research has ended. APHIS personnel informed us that the permittees must notify APHIS if they want to renew their permit; APHIS does not track permits or check permit databases to determine which permits have expired. APHIS also does not terminate permits. An entity may notify APHIS that its research is completed and all of the pathogen destroyed, but the permit will not be terminated, and the permittee, who might still be able to obtain the pathogen, will still be on record as the permit holder.

We reported on the permit system control weakness in our March 2003 report. At that time, APHIS officials acknowledged that their system was deficient in tracking and that they planned to replace it with an "ePermits" database. The officials assured us that with this new database, APHIS would terminate all existing permits and reissue them with sufficient information to activate a tracking function that would alert managers to expired permits. APHIS officials repeated these assurances during our current audit. We agree that reissuing all existing permits will allow greater control over them. However, we noted that the ePermits system was still not functioning and concluded that APHIS should not wait for the ePermits system to establish controls over the listed agent or toxin program but rather implement a program that can begin tracking the expiration of listed agent or toxin permits immediately.

Once separated from the current system, any new tracking program for listed agent or toxin permits must have limited access by APHIS employees. The permit databases administered by PPQ and VS contain information about the person, place, use, and storage facilities of biological agents transferred under APHIS' permit, for both listed and non-listed agents or toxins. However, APHIS' standard operating procedures (SOP) identify information under the

listed agent or toxin program as "unclassified but sensitive," requiring safeguards against unauthorized use or disclosure. These safeguards include precautions against oral disclosure, prevention of visual access to the information, and precautions against release of the material to unauthorized personnel. We found that over 60 people have access to the combined listed/non-listed permit databases and do not have security clearances. According to APHIS' SOP's, information about recipients and entities receiving listed agents or toxins should be disseminated on a need-to-know basis only.

The Act was intended to strengthen controls that USDA has over dangerous biological agents. Because APHIS chose to incorporate the existing permit system into the SAP, permits take on even greater importance as a control mechanism. We, therefore, concluded that APHIS needs to separate those permits used to transfer listed agents or toxins from all other permits, and to establish a database that can independently track and account for movements of pathogens in the listed agent or toxin program. To facilitate such a realignment of operations, APHIS should terminate all existing permits, reissue them with information specific enough to distinguish between those issued for listed agents or toxins and those issued for non-listed agents or toxins, and enter information about listed agent or toxin permits only in the independent database. To further facilitate this realignment, APHIS should create a listed agent or toxin permit that is clearly distinguishable from a non-listed agent or toxin permit. Finally, to promote greater control and accountability over the listed agent or toxin program, APHIS should ensure that permits for listed agents or toxins identify the entities and RO's, and restrict access to the listed agent or toxin database to those employees with a need to know.

Recommendation 8

Strengthen controls for permits regarding listed agents or toxins by establishing a separate and secure permit system for the SAP to help ensure that only registered entities and authorized individuals have or obtain permits that can be used for such agents or toxins.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *Currently, APHIS permits for select agents are issued by SAP staff only. Prior to issuance of a permit under 9 CFR Part 122 (the VS permitting regulations) or 7 CFR Part 330 (the PPQ permitting regulations) for organisms listed in 9 CFR 121 or 7 CFR 331 as select agents, APHIS requires that:*
>
> *-the entity is registered for the requested organism*
> *-the permit application has an approved SRA*

-the entity is in full compliance with 9 CFR Part 121 and 7 CFR Part 331

In regards to an electronic system, APHIS is currently developing e-Permits. This system, which is currently in the requirements stage, is expected to be operational in late September 2005. This system will be separate and secure system that both PPQ and VS personnel will access to process and issue permits.

OIG Position. Based on APHIS' response, we could not determine what policies and procedures were established and in place to process permits for select agents. For example, we could not determine what controls were established to ensure that permits for select agents are received, identified, and routed through the SAP staff. APHIS controls should be designed to ensure that permits that could allow the transfer of select agents are not issued to unregistered entities or individuals who have not been authorized to transfer select agents. In order to reach management decision, we will need to obtain copies of the written policies and procedures that describe the process for processing and issuing permits for select agents. We will also need policies and procedures developed or planned for processing select agent permits through the electronic e-permits system once it is implemented in September 2005.

Recommendation 9

Update the permit form to distinguish permits for listed agents or toxins from those for non-listed agents or toxins.

Agency Response. In its May 24, 2005, response, APHIS stated:

Currently, both VS and PPQ permits indicate on the permit if the permit is for a select agent. Thus it is clear to both the permit holder and APHIS staff that select agents are involved. However, neither the VS application form (16-3) nor the PPQ application form (526) distinguish between applications for select agents and non-select agents. Following input from various government agencies (e.g., DOT and DOD), USDA and HHS determined it would be inadvisable to call unnecessary attention to shipments of, or documentation related to, select agents.

OIG Position. Based on APHIS' response, we agree with management decision for this recommendation. No further action is necessary.

Recommendation 10

Issue permits for listed agents or toxins that identify the registered entity and the RO, and update the regulations to include this requirement in order to promote greater control and accountability over the listed agent or toxin program.

Agency Response. In its May 24, 2005, response, APHIS stated:

> *APHIS is evaluating possible contractual modifications that will allow for connections between e-Permits and HCARTS. This will include budget considerations. It should be noted that lack of this link will not prohibit the secure issuance of permits. * * * [SAP] personnel will simply access the hard copy information as they are currently doing.*
>
> * * * * * * * * *

OIG Position. APHIS' response does not address the recommendation. In order to reach management decision, APHIS should address whether it plans to identify the registered entity and the RO on all permits issued for select agents.

Scope and Methodology

This report represents the results of the first phase of our audit work to determine how effectively APHIS has implemented the SAP. Our fieldwork was conducted at APHIS Headquarters in Riverdale, Maryland. The period of review was calendar year 2002 through current operations. Fieldwork was conducted during the period December 2003 through August 2004. During the second phase of the audit, we will examine the registered entities' compliance with select agent regulations and assess APHIS' oversight of the entities.

To accomplish our audit objectives for this first phase, we performed the following audit procedures.

- We interviewed APHIS officials from both VS and PPQ to obtain an overview of the registration, inspection, and security risk assessment process.

- We interviewed APHIS officials in order to determine:

  - the agency's roles and responsibilities regarding the SAP;
  - the agency's use of the notification/possession database;
  - policies and procedures to address theft, loss, or release of agents or toxins;
  - policies and procedures on the registration process including denials of registration;
  - APHIS' process for inspection of laboratories; and
  - training of personnel involved in the SAP.

- We interviewed personnel from APHIS' IES to determine policies and procedures for enforcing provisions of the Act.

- We assessed the accuracy and completeness of APHIS' registration records.

- We reviewed registration documentation sent in by entities to determine whether the packages were complete.

- We reviewed documentation for provisional registration certificates to ensure APHIS' determinations were supported by adequate documentation and were consistent.

- We interviewed APHIS officials in order to determine the coordination between APHIS and CDC ensuring that all persons possessing, using or

transferring select agents are registered. We also gained an understanding of how laboratory registration, certification, inspection and enforcement activities are coordinated between the two agencies.

- We reviewed APHIS' assessment of laboratory security plans.

- We coordinated our work with the U.S. HHS, OIG.

- We prepared a spreadsheet of the entities/sites visited during two previous audits[14] and compared the laboratories' inventory of select agents/toxins with the applications for registration.

- We reviewed APHIS' process for keeping track of persons that have applied for grants of access to select agents.

The audit was performed in accordance with Government auditing standards.

[14] Audit No. 50601-10-At, "Followup on the Security of Biological Agents at USDA Laboratories," and Audit No. 50099-14-At, "Controls Over Biological, Chemical, and Radioactive Materials at Institutions Funded by the USDA."

USDA

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

1400 Independence Avenue SW
Room 317 EW
Washington, DC
20250

TO: Robert W. Young
Assistant Inspector General
for Audit

FROM: W. Ron DeHaven, D.V.M
Administrator

MAY 2 4 2005

SUBJECT: Response to OIG Report: "Evaluation of the Implementation of the Select Agent or Toxin Regulations (Phase I)" (Report No. 33601-2-At)

Thank you for the opportunity for the Animal and Plant Health Inspection Service to comment on the above report. APHIS has responded to each of the report's ten recommendations. We have enclosed seven documents related to the select agent program.

Recommendation No. 1: Designate an official who will be responsible for the select agent program, who can issue policies and procedures, and otherwise coordinate program activities.

APHIS Response

The APHIS Administrator is the official responsible for the APHIS Select Agent Program (SAP). The APHIS Administrator has delegated responsibility for the SAP to managers in the APHIS' Veterinary Services (VS), and Plant Protection and Quarantine (PPQ) Programs. Currently, program activities are coordinated, and policies and procedures are agreed to and issued jointly by managers of the VS and PPQ programs. An example of this would be the recent interactions between the VS and PPQ SAP managers in regards to the creation of the shared select agent system. APHIS will develop SOPs describing the working relationship between the VS and PPQ SAPs. The SOPs are scheduled for completion by May 30, 2005.

Recommendation No. 2: Restrict access to sensitive data (to) only those individuals whose job requires access.

APHIS Response

SAP files are kept secure in a limited-access file room shared by VS and PPQ. Only program staff with a "need to know" have access to the file room. Access/entry into

the file room is controlled by key card. Program staff also must have security clearances before getting access to the file room.

Recommendation No. 3: Take immediate steps to establish a national database that includes, at a minimum, names and locations of registered entities, the listed agents and toxins such entities are possessing, using, or transferring and the list of authorized individuals. Other information can be added to the database at a later time.

APHIS Response

Currently, both Health and Human Services (HHS)-Centers for Disease Control and Prevention (CDC) and APHIS have these data in electronic form. APHIS is actively engaged with CDC, the HHS-OCIO, and the USDA-OCIO on creation of "e-SAS" (electronic Select Agent System) which will serve as the National Select Agent Data base. e-SAS will be operational by December 31, 2005 (as published in the CDC (42 CFR Part 72) and APHIS (7 CFR Part 331, 9 CFR Part 121) Final Rules on March 18, 2005. A draft copy of the MOU between APHIS and CDC is attached that describes the components of "e-SAS".

Recommendation No. 4: Determine whether entities are in full compliance with all aspects of the regulations and grant or deny registration.

APHIS Response

As stated in the regulations (Interim Final Rule), "a provisional registration certificate will be effective until APHIS either issues a certificate of registration or suspends or revokes the provisional registration." As set forth in the Interim Rule, issuance of provisional registrations depended on submission by Nov 12, 2003 of:

- a completed application
- a security plan
- all Security Risk Assessment material to FBI

Following an in-depth review, APHIS has granted full registration to 62 entities (as of April 8, 2005). The evaluation to determine full compliance involves:

- APHIS review of the application package
- entity inspection
- review of entity security plan
- approved Security Risk Assessment for Responsible Official, Assistant Responsible Official, and corporate officers (as applicable)

It was not necessary to revoke any provisional registrations because all were evaluated as compliant.

Recommendation No. 5: Establish formal procedures for performing security inspections at the registered entities ensuring that the inspections are consistent and thorough, and that documented and supportable conclusions are made concerning the adequacy of security measures.

APHIS Response

A joint APHIS/CDC Select Agent Program Steering Committee was formed in January 2004 to oversee and coordinate operational activities for the U.S. Government Select Agent Program. An Inspection Subcommittee was formed and produced the joint APHIS/CDC security inspection checklist (see attached) which is currently being used to guide all entity inspection activities in APHIS and CDC. Adequacy of security measures is determined by APHIS headquarters SAP staff after review of inspection results and security plans. Further, in 2004 APHIS hired a full time Select Agent Security Specialist whose primary role is to insure that registered entities maintain select agents and toxins in a secure manner.

Recommendation No. 6: Develop and provide formalized training for staff performing the inspections to address security measures.

APHIS Response

Plans are currently underway for a joint APHIS/CDC training session for entity inspectors to be held in the Atlanta area during September 2005. Security will be one area that will be addressed.

Recommendation No. 7: Establish procedures for informing entities of the results of inspections and performing follow-up inspections when deficiencies are found.

APHIS Response

APHIS will standardize a written procedure to notify entities not only of inspection deficiencies, but also deficiencies related to applications and security plans. This will be fully implemented by December 2005. Additionally, APHIS has hired a "Select Agent Security Specialist" at APHIS headquarters, who reviews all APHIS inspection reports, applications, and security plans.

Recommendation No. 8: Strengthen controls for permits regarding listed agents or toxins by establishing a separate and secure permit system for the select agent program to help ensure that only registered entities and authorized individuals have or obtain permits that can be used for such agents or toxins.

APHIS Response

Currently, APHIS permits for select agents are issued by SAP staff only. Prior to issuance of a permit under 9 CFR Part 122 (the VS permitting regulations) or 7 CFR Part 330 (the PPQ permitting regulations) for organisms listed in 9 CFR 121 or 7 CFR 331 as select agents, APHIS requires that:

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Recommendation No. 10: Issue permits for listed agents or toxins that identify the registered entity and the RO, and update the regulations to include this requirement in order to promote greater control and accountability over the listed agents or toxin program.

APHIS Response

APHIS is evaluating possible contractual modifications that will allow for connections between e=Permits and HCARTS. This will include budget considerations. It should be noted that lack of this link will not prohibit the secure issuance of permits. Select agent program personnel will simply access the hard copy information as they are currently doing.

Again, APHIS appreciates the opportunity to respond to the key findings and recommendations contained in this review. We believe our actions will address the issues identified with the Select Agent or Toxin Regulations program.

Enclosures

Memorandum of Understanding, Shared Select Agent System, Animal and Plant Health Inspection Service, USDA and Centers for Disease Control and Prevention, HHS
Animal Facility Biosafety Level 2 Checklist (revised April 3, 2003)
Animal Facility Biosafety Level 3 Checklist (revised April 3, 2003)
Lab Biosafety Level 2 Checklist (revised April 3, 2003)
Lab Biosafety Level 3 Checklist (revised April 3, 2003)
Application Checklist for Laboratory Registration under 9 CFR 121 (revised August 11, 2003)
Facility Security Compliance Review (as of August 5, 2003)

Informational copies of this report have been distributed to:

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