UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

U.S. Department of Agriculture

Office of Inspector General
Midwest Region

Audit Report

Animal and Plant Health Inspection Service
Controls Over Permits To Import Biohazardous Materials Into the United States

Report No. 33601-4-Ch
MARCH 2003

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: March 31, 2003

REPLY TO
ATTN OF: 33601-4-Ch

SUBJECT: Controls Over Permits To Import Biohazardous Materials Into The United States

TO: Bobby R. Acord
Administrator
Animal and Plant Health Inspection Service

This report presents the results of our audit of the Animal and Plant Health Inspection Service's (APHIS) controls and procedures over the issuance and monitoring of permits to import regulated pathogens and other materials into the United States. Our primary emphasis in this audit has been to evaluate the agency's controls to ensure that permits are issued only to legitimate users; to safeguard permits, mailing labels, and other related materials associated with the importation of regulated materials; to monitor and track the status of active permits; and to safeguard against the entry of illegal or unauthorized materials in permit packages entering the country.

The APHIS response to the official draft report is included as exhibit A, with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations section of the report. Based on the response, we have reached management decisions on Recommendations Nos. 5, 6, 8, 9, and 10. Please follow your agency's internal procedures in forwarding documentation for final action to the office of the Chief Financial Officer.

Management decisions have not yet been reached on Recommendations Nos. 1, 2, 3, 4, and 7. Management decisions can be reached on these recommendations once you have provided the additional information outlined in the report sections, OIG Position.

In accordance with Departmental Regulation 1720-1, please provide a reply within 60 days describing the corrective actions taken and planned, including timeframes for their implementation. Please note that the regulation requires that management decisions be reached on all recommendations within a maximum of 6 months of report issuance.

/s/
RICHARD D. LONG
Assistant Inspector General
for Audit

Executive Summary

Controls Over Permits To Import Biohazardous Materials into the United States
Audit Report No. 33601-4-Ch

Results in Brief

This audit report presents the results of our audit of APHIS' permit systems for the importation and interstate transfer of regulated materials. APHIS issues permits to colleges, universities, public and private laboratories, and others who wish to import regulated materials, for research and diagnostic work. Permits are issued by two APHIS divisions: Plant Protection and Quarantine (PPQ), which administers permits for plant-related materials, and Veterinary Services (VS), which administers permits for animal-related materials.

Our objective was to determine whether APHIS' controls were adequate to ensure that its permits could not be misused by individuals seeking to import potentially harmful materials into the United States.

We found that although APHIS had reported to the Deputy Secretary in October 2001 that it was quickly addressing identified security concerns with its permit systems, many corrective actions still have not been taken. Such areas include the need for better accountability over permits and increased safeguards.

APHIS' permit system manifests three weaknesses:

Better Selection Criteria is Needed for Onsite Inspections of Applicants. APHIS does not always perform inspections of new applicants for import permits. Although both PPQ and VS have instituted improved inspection procedures following the September 11 attacks, neither division has developed risk-based criteria to determine which applicants need to be inspected.

Permits Are Not Adequately Tracked. PPQ needs to make improvements in its computerized system for tracking the status of active and pending permits. The current system does not automatically flag permits that have expired or are about to expire, and it does not incorporate controls to ensure that personnel input complete information on new permits.

Permit Documents Are Not Accountable. Neither PPQ nor VS requires accountable documentation to accompany shipments of permitted materials, [

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Finally, we found that neither PPQ nor VS [ ] to ensure that regulated materials imported under permit are properly disposed

of when the permit expires. As a result, the agency would have little control over the distribution and use of materials imported under APHIS permit following the expiration of the permits.

We consider the problems described in this report to be material internal control weaknesses and, as such, should be included in the agency's next FMFIA report.

Recommendations in Brief

We recommend that both PPQ and VS: (1) develop written procedures to cover pre-approval and followup inspections of permit applicants; (2) develop a system of accountable, sequentially numbered permit documents and mailing labels which use bar-coded scanning technology to allow them to both monitor incoming permit shipments and verify their validity upon arrival at the ports-of-entry; (3) discontinue the practice of allowing incoming passengers to hand-carry permit materials from the port of entry; and (4) establish controls to ensure that permit-holders properly dispose of imported hazardous materials when their permits expire. Finally, we recommend that PPQ institute new controls and procedures to ensure that its permit tracking system contains complete information on all permit-holders.

Agency Response

In their response to the official draft report, dated March 21, 2003, APHIS officials generally agreed with the findings and recommendations as presented. Actions on some of these recommendations have been completed, while others are in process. In some cases, APHIS officials presented alternative corrective actions to those that were recommended. Portions of the APHIS response are incorporated into the Findings and Recommendations section of the report. The full text of the response is included as exhibit A of the audit report.

OIG Position

We generally agreed with APHIS' responses to the recommendations, although we disagreed with APHIS' position on the need for pre-approval inspections of applicants' facilities. Based on the response to the official draft report, we have reached management decisions on Recommendations Nos. 5, 6, 8, 9, 10, and 11. Management decisions have not yet been reached on Recommendations Nos. 1, 2, 3, 4, and 7. Management decisions can be reached on these recommendations once we receive the information specified in the report sections OIG Position.

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Background and Objectives

Background

APHIS' Plant Protection and Quarantine (PPQ) and Veterinary Services (VS) units have separate permit systems for the importation or domestic transfer of regulated materials. Each unit also maintains its own database for tracking permits. The permit system for PPQ is the Joint Permit System (JPS) and the system for VS is the Permit Issuance Tracking System (PITS).

Applicants for permits issued by either VS or PPQ may apply via fax, mail or on-line. Under VS' system, which covers specified animal-related products, the applicant must state the exact nature of the item to be imported. Permits are approved by a Veterinary Medical Officer (VMO) and are normally valid for 1 year. Laboratories that require a permit from VS may also be required to obtain a permit from the Centers for Disease Control (CDC), since some animal pathogens are also a threat to humans. PPQ's system, by contrast, does not always show the exact nature of the material being imported. PPQ permits may be valid for multi-year periods, and prior to September 11, 2001, could be issued for the import of unknown pathogens for examination by diagnostic laboratories.

OIG's Southeast Region (SER) initiated a review of the APHIS permit system following the September 11 terrorist attacks. PPQ officials informed OIG that on September 21, 2001, they suspended issuance of new permits. As a result, audit work was delayed pending implementation of corrective actions.

Objectives

The objective of our audit was to determine whether APHIS' controls were adequate to ensure that its permits and mailing labels could not be misused by individuals seeking to import regulated materials into the United States for use as terrorist weapons against populations or the Nation's food supply.

For this audit, we reviewed PPQ's database containing 45,000 records of permits and VS' database containing 12,000 records of permits. For full details of the scope of this audit, see the Scope and Methodology section.

Findings and Recommendations

Section 1. Memorandum To The Deputy Secretary

Finding No. 1 APHIS Needs to Inform the Department of Known Vulnerabilities in the Permitting Systems

APHIS reported to the Deputy Secretary in October 2001 that it had ceased issuing new import permits pending the completion of an ongoing review of the agency's existing systems, and that the agency was quickly addressing vulnerabilities noted in this review. However, we found that APHIS [ ] October 2001 memorandum [ ]. As noted in later findings in this report, the use of these systems [ ].

On October 4, 2001, APHIS' Acting Administrator issued an Informational Memorandum to the Deputy Secretary, through the Under Secretary for Marketing and Regulatory Programs. This Memorandum was issued as a result of the terrorist attacks on September 11, 2001. The memorandum stated that APHIS' permitting procedures for importing regulated materials were being reviewed, especially for the potential for misuse of the systems. It further stated that while the ongoing reviews were pending, APHIS had ceased the issuance of new permits to any non-Federal entity.

This memorandum listed a number of corrective actions needed to provide reasonable assurance that the PPQ and VS permit programs could not be improperly used. Because the two permit programs are separate and distinct from one another, different types of corrective actions were identified for each.

Both PPQ and VS officials have been working on corrective measures to address these weaknesses since beginning their review process prior to the issuance of the Informational Memorandum. However, as noted in Findings Nos. 2 through 6 of the report, many serious concerns remain. For instance:

- PPQ's plans to identify and possibly revoke blanket permits issued to diagnostic laboratories were not fully implemented as of the time of our review because PPQ's JPS tracking system could not reliably identify these permits. (See Finding No. 2.)

- The use of tamper-proof paper and a bar code tracking system for incoming shipments has not been implemented.

- The redesign of PPQ's Joint Permit Tracking (JPS) system has not been performed, and our audit revealed significant weaknesses in the system (See Finding No. 3.)

- Followup inspections of facilities have not been implemented to ensure that previously imported materials are being properly disposed of following permit expiration. (See Finding No. 6.)

The Informational Memorandum to the Deputy Secretary indicated that PPQ and VS would maintain their moratoriums on the issuance of new permits until at least the most critical security concerns had been addressed. As noted above and in the other findings of this report, we do not believe that APHIS has satisfactorily addressed these concerns; in addition, our audit disclosed areas of concern that were not brought out in the memorandum.

Despite this, the moratoriums announced in the memorandum were of short duration, and both divisions had fully resumed issuances of new permits by mid-December 2001. Our audit disclosed that even if the moratoriums had continued, equally serious security concerns would remain with respect to existing permits. Until these concerns are addressed, both PPQ's and VS' permit systems remain vulnerable to the type of misuse cited in the memorandum.

In interviews with PPQ and VS officials, we found that no further memorandums or briefings had been provided to Departmental officials since the Informational Memorandum of October 4, 2001. Because of the ongoing possibility that the import permit systems could be misused, we believe it vital that the agency immediately establish timeframes to implement the planned corrective actions.

Recommendation No. 1

Immediately establish appropriate timeframes for the implementation of the corrective actions outlined in the October 4, 2001, memorandum addressed to the Deputy Secretary.

Agency Response.

In the agency's response dated March 21, 2003, PPQ and VS each provided their own responses to the recommendation that addressed the corrective actions applicable to each in the Informational Memorandum to the Deputy Secretary.

PPQ's section of the Informational Memorandum listed eight corrective actions that needed to be taken to provide safeguards against the misuse of the permit system. The agency's response to the draft report provided the status of each of these, stating that corrective actions had been accomplished on five of the cited actions and that timeframes had now been worked out for completing the remaining three. The actions cited as having been completed included the basing of future permit decisions on risk assessments and the lifting of the moratorium on new permit issuances.

VS' section of the informational memorandum cited three corrective actions that needed to be taken. These included assessing the frequency with which multiple shipments entered the United States under individual permits, and increasing the frequency of inspections. VS' response, like PPQ's indicated that timeframes had been established for any actions that had not actually been completed.

OIG Position.

Although we agree that several of the actions proposed in the Informational Memorandum to the Deputy Secretary have been taken, others still require additional review by the agency. Two of the eight actions proposed by PPQ and one of the three proposed by VS are dependent upon the implementation of the new computer-based permit tracking system (ePermits). These include the redesign of PPQ's existing tracking system and the more stringent protocols for tracking and reporting which PPQ intended to implement. VS, after attempting to perform the cited study of incoming permits, also concluded that this would not be feasible until the new system was in place.

In particular, we noted one item from PPQ's response that still needs to be addressed. The Informational Memorandum stated that all future permit decisions would be based on risk assessments, and the response to the draft report stated that this is now being done. However, as noted in the OIG Position section of Recommendation No. 2, we do not believe that PPQ has in fact developed an adequate risk-based system for scheduling inspections. This same concern applies to VS, even though this area was not one of the corrective actions identified in VS' section of the Memorandum.

To reach a management decision on this recommendation, APHIS will need to provide an additional response that addresses the concerns reflected in the OIG Position section of Recommendations Nos. 2 and 3, including timeframes for implementation.

PPQ and VS need to improve their controls and procedures for issuing and tracking permits for importation of regulated materials. PPQ and VS do not always inspect applicants' facilities prior to permit issuance, and the inspections they do make are geared toward evaluating applicants' containment facilities rather than determining whether the applicant is a legitimate user. In addition, PPQ's Joint Permit System needs to be improved to allow adequate tracking of existing permits.

Finding No. 2 APHIS Needs To Strengthen Its Inspections Of Permit Applicants

APHIS does not always inspect applicants' facilities before issuing import permits. Although both PPQ and VS officials stated that they have strengthened their procedures since the issuance of the Informational Memorandum to the Deputy Secretary on October 4, 2001, the current pre-approval inspections performed by VS and PPQ do not address the memorandum's stated goal of reducing the potential for deliberate misuse of the permit programs. The inspection process is inadequate because most of the new procedures are not in writing, and do not provide guidance on risk assessments to help personnel select applicants for inspection. As a result, APHIS' inspection systems are based on the assumption that permit applicants are legitimate users, and the methods of selecting applicants for inspection provide few barriers against those who would exploit the VS and PPQ systems by submitting false information.

Current regulations do not require APHIS to inspect the facilities of applicants for new permits prior to issuance. However, in APHIS' Informational Memorandum to the Deputy Secretary, agency officials acknowledged the need to provide safeguards to address the potential for misuse of their permitting programs. PPQ officials stated in the memorandum that all future permit decisions would be based on risk assessments and that criteria were being developed to determine the level of risk to be applied to each application. VS officials, while stating their belief that their permit system already incorporated significant safeguards, also cited the need to improve the frequency of laboratory inspections.

Plant Protection and Quarantine

PPQ officials stated that prior to the events of September 11, 2001, it was common practice to issue permits without performing an inspection of the applicant's facilities. Since then, PPQ officials have attempted to establish new inspection procedures and trained PPQ officers to conduct inspections. When we began our audit in March 2002, PPQ officials stated that these inspectors would be used to perform inspections of existing permit holders whose facilities had never been inspected, with special emphasis given to certain types of

permits. PPQ's goal was to inspect, prior to permit issuance, all new applicants whose permits would require containment facilities. Eventually, PPQ officials decided to only perform inspections of pre-September 11 permits-holders who applied for renewals of their permits.

Since this time approximately 2,500 new permits have been issued by PPQ. Our review of a sample of permits showed that only a minimal number were inspected.

Veterinary Services

VS issues permits only for animal pathogens requiring containment facilities of BL-2[1] level or higher. However, like PPQ, they do not inspect all applicants as part of the permitting process. VS makes inspection decisions on a case-by-case basis, using factors which include [
]. VS officials stated that the existence of previous inspection reports from an applicant's facility was not necessarily a determining factor in whether an inspection on a new application would be performed. The officials explained that within the same laboratory, a new application may call for containment equipment that is different from the equipment being used for materials imported under a prior permit, even though the pathogens or pests imported under the two permits might be of the same BL-rating. Based on the inspection decisions made by VS officials, one facility might be inspected twice in conjunction with two permits issued over a relatively short period of time, while other facilities might receive permits without being inspected.

Neither PPQ nor VS has developed written risk assessment procedures to assist their personnel to determine when an inspection is needed. Thus, personnel of both units decide whether or not to perform inspections based [
].

The October 4 Informational Memorandum to the Deputy Secretary notes that although there have been no known cases of abuse, the system is potentially vulnerable to misuse. The memorandum further notes that the actions it outlines are intended primarily to safeguard the system against such misuse. We therefore concluded that the corrective actions implemented by both PPQ and VS must incorporate safeguards against program abuse by those who would apply for permits under false pretenses.

When assessing whether an inspection should be made, APHIS needs to take into account whether the applicant has ever been visited either by APHIS personnel or by personnel of another agency such as the Centers for Disease Control (CDC). Permit applicants who have never been visited by APHIS or another agency (including such applicants who are already permit holders),

[1] Biosafety Level (BL) rating, described in Health and Human Services' (HHS) Biosafety Handbook. Biosafety levels are rated from BL-1, for organisms that generally do not cause disease in humans, to BL-4, for high-risk, life-threatening diseases.

should be inspected before new permits are issued. In addition, we believe that both PPQ and VS officials need to establish written policies and procedures to govern their inspection programs to ensure uniform and consistent treatment of new applicants.

Recommendation No. 2

Develop written procedures governing the inspection of facilities for both PPQ's and VS' permit systems, including any risk-related criteria that would exclude a facility from being inspected.

Agency Response.

In their response to the official draft report, dated March 21, 2003, APHIS officials stated that they are using criteria for determining whether or not to perform inspections of applicants' facilities. The procedures cited by both PPQ and VS for selecting applicants to be visited are based on an assessment of the level of risk associated with the pathogen or other organism being imported.

OIG Position.

We continue to believe that both PPQ and VS need to include, as part of their inspection operations each year, a number of onsite inspections to facilities that have not been previously visited, regardless of the apparent risk level indicated by the applications. To reach a management decision on this recommendation, APHIS needs to provide us with a response that indicates that some random inspections will be made to ensure that all facilities have a chance to be inspected.

Recommendation No. 3

Ensure that all permit applicants not previously inspected by APHIS are visited prior to permit issuance or renewal.

Agency Response.

PPQ officials responded that based on the criteria outlined in the response to Recommendation No. 2, no new permits or permit renewals would be issued until a facility that required an inspection had in fact been inspected. VS officials stated that applicants wishing to import high consequence pathogens and toxins of livestock agents are inspected prior to permit issuance. Applicants for permit renewals are inspected every 3 years, and this language is contained on the permits.

OIG Position.

A management decision cannot be reached until Recommendation No. 2 is resolved.

Finding No. 3 PPQ's Joint Permit System Needs Improvement

PPQ's Joint Permit System (JPS) does not contain data fields that would allow it to [ ]. Also PPQ personnel responsible for inputting data to the system frequently omitted information needed to perform certain types of potentially critical data sorting, and the system itself lacked features that would have reduced the need for extensive manual reviews. PPQ officials said the system was seen as adequate to the tasks it was intended to perform in the past, when tracking permits was not given the high priority that it has since acquired. Because of the system's current inadequacies, PPQ [

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APHIS' Informational Memorandum to the Deputy Secretary stated that PPQ's database would undergo a major redesign to allow for [ ] of the pathogen. The memo further stated that a waiver was being sought from the Office of the Chief Information Officer to permit the system redesign.

PPQ maintains its JPS database to track information on permits issued for the importation and interstate transport of regulated plant materials. The database contains over 45,000 permits, with nearly 4,000 new permits having been issued in FY 2001 alone. Over 2,400 import permits have been issued from October 1, 2001, to July 1, 2002.

PPQ officials stated that in the past, PPQ's permit system was operated based on a high level of trust between APHIS and its permit users. At that time (see Finding No. 2) inspections of permit applicants were given less priority because the type of materials imported under PPQ's program were not regarded as highly dangerous. For that same reason, PPQ permits were frequently issued to cover multi-year periods.

The need for greater accountability over the permitting process has placed increased demands upon the JPS. The JPS, however, has not met those demands. In addition, users of the system have not employed its features efficiently and key data fields are often left blank when information on new permits is being input. Consequently, the system cannot be used to reliably identify or sort data as needed.

Among the conditions we noted are:

- Database contains incomplete and inconsistent data;
- Database does not identify [ ];

- JPS system does not identify [ ]; and

- JPS does not contain facility inspection data.

To correct these deficiencies, PPQ intends to replace the JPS with a new system called the "ePermits" database, which it plans to have in service by June 2003. In the interim, PPQ needs to take steps to improve the effectiveness of the existing system. These include timely updates and improved controls to ensure that all critical data fields are being completed at the time new permits are input.

If feasible, upgrades to the existing JPS—such as providing the capability to flag certain permits—would be beneficial. In addition, PPQ should explore the possibility of having the current system reject input for new permits unless certain specified data fields (such as the numerical identifiers for the main table and subsidiary table) are completed.

Recommendation No. 4

Develop procedures and controls to ensure that complete data on new permits is input to the system, and that information on the status of existing permits is timely updated.

Agency Response.

PPQ officials stated that they have added new elements to staff performance plans to correct previous problems of incomplete data entry into the databases. The element requires that all entries into the database be complete and adequate with less than 3 percent omissions per year. The response also stated that the Branch Chief now regularly performs reviews of database records on permits and facilities. All discrepancies and omissions found in these reviews are discussed with the responsible staff member.

OIG Position.

We concur with the proposed corrective action. To reach a management decision, PPQ officials need to provide us with clarification on the type and extent of the reviews being performed by management, and whether the requirements for such reviews have been incorporated into PPQ's written procedures.

Recommendation No. 5

Incorporate additional data elements into the JPS, as necessary, to provide PPQ with the ability to readily determine whether institutions have been inspected and to perform queries based on various data fields.

Agency Response.

APHIS states that they will not incorporate additional data elements into JPS because the database is obsolete and will be replaced by the "ePermit" system. The contract for the "ePermit" system was awarded in December 2002, and deployment of Release 1 is scheduled for June 2003. The new system will incorporate elements that would correct the deficiencies noted in our finding.

OIG Position.

We accept APHIS' management decision. Final action can be reached when the agency provides the Office of the Chief Financial Officer (OCFO) with documentation to show that the new system has been implemented.

Section 3. Accountability Over Permit Documents

APHIS needs to improve its accountability over shipments of permit materials entering the United States. Neither PPQ nor VS requires [ ] incoming packages, and neither [ ] in place [ ] that enter the country under any given permit. Neither PPQ nor VS has adequate controls to ensure that incoming packages reach their intended destination, and both continue to allow individuals to hand-carry permit packages through the ports-of-entry. This lack of accountability and control could leave both of APHIS' permit systems open to misuse by individuals or organizations.

Finding No. 4 APHIS Lacks Controls To Ensure That Only Approved Materials Enter the Country Under Permit

Neither PPQ nor VS [ ]. Such a system is lacking because APHIS regulations and procedures do not require the use of accountable permit forms or shipping labels [ ]. Also, neither PPQ nor VS officials have provided PPQ inspectors at the ports with access to the permit data contained in their respective automated tracking systems.

APHIS' Informational Memorandum to the Deputy Secretary, dated October 4, 2001, noted that among the corrective actions needed to address identified weaknesses in the permit system were the redesign of PPQ's existing permit shipping labels, and a more stringent protocol/process for permitting based on tracking, monitoring, reporting, and disposing of permitted material. VS did not report any problems specifically related to inspecting and tracking incoming permit materials.

Packages entering the United States under PPQ's permit system can be routed through any one of 15 Plant Inspection Stations located among the numerous airports, seaports, border crossings, and mail facilities available to importers. VS permits are not restricted to the plant inspection stations. PPQ's inspectors have the responsibility for examining all incoming permit packages and determining whether they should be allowed to proceed to their destinations within the U.S. However, different procedures are followed for the handling of incoming PPQ and VS permit packages.

PPQ Permit Packages

Packages containing PPQ permit materials are identified by a PPQ-issued mailing label, of which there are two types. Due to the potentially hazardous nature of the regulated materials associated with one type of label, PPQ inspectors at the Plant Inspection Stations are required to verify that the package is coming in under a valid and current permit, and that the address on the mailing label corresponds with that of the registered permittee. However, the PPQ inspectors have only limited means of verifying the validity of the permit, none of which is fully reliable.

Onsite Permit Files. Each Plant Inspection Station maintains copies of permits onsite, which PPQ inspectors can use to verify permit numbers written on the labels of incoming permit shipments. If these numbers can be matched, the inspector can verify that the permit is current and that the mailing address on the package label corresponds to that shown on the permit itself. However, PPQ officials acknowledge that these files are not sufficiently complete or comprehensive for an inspector to conclude that an incoming permit package is always valid.

Online Data. To address this situation, PPQ set up an internet website that the stations could access, listing current permit numbers and other information which PPQ officers at the stations could use to verify the permit numbers on incoming packages. The internet site was fed from the JPS, so that the information at the stations would theoretically be as comprehensive as that in the database. However, we found that the information on the website was not always correct or current. PPQ then took the internet site offline.

Permittee contact. If a PPQ inspector cannot verify the validity of the permit using the paper files, the only other recourse other than following up with PPQ Headquarters is to contact the permittee using information provided in any accompanying paperwork. However, there are no requirements that any specific documentation (such as a copy of the permit or the permittee's name) be included with the shipment. Although in some cases the shipment may include the name of a contact person and telephone number, this is likewise not required.

According to PPQ officials, the mailing label used by PPQ to identify certain permit packages has been used without alteration since 1992. Since it is not an accountable document, there is no record of how many have been sent to various permittees across the country over the past 10 years, and no assurance that the scientists and laboratories receiving them have properly safeguarded them or reported any that could not be accounted for.

PPQ's own earlier review disclosed this problem, as referenced in the October 4, 2001, Informational Memorandum to the Deputy Secretary. The memorandum proposed the redesign of the shipping labels using tamper-proof paper and a bar-coded tracking system, such as that used with Phytosanitary Certificates. Such a system would, if connected electronically to PPQ's central JPS database, allow PPQ officers at the inspection stations to immediately check the validity of permit numbers displayed on the mailing labels, and to verify that the address marked on the inner box of a permit shipment matches the address of the permittee in APHIS' database.

VS Permit Packages

As noted above, VS does not maintain a full-time presence at the ports-of-entry and thus depends upon PPQ inspectors to inspect incoming VS permit shipments. Unlike PPQ packages, those of VS are required to display a copy of the permit itself on the outside of the package. This allows the PPQ officer to immediately inspect the permit rather than having to locate it in a paper file. In the October 4, 2001, Informational Memorandum to the Deputy Secretary, VS did not cite any weaknesses had identified in relation to this aspect of its permit system.

However, we noted that the VS system contains some of the same vulnerabilities as PPQ's, as well as others which are unique to it.

- Like PPQ permit packages, those of VS are not sufficiently reviewed;

- Unlike PPQ permit packages, those of VS can come into the United States through any port of entry rather than being restricted to entering through one of PPQ's Plant Inspection Stations. (Since PPQ inspectors are being transferred to the Department of Homeland Security, VS may need to alter its existing policy and require its permit shipments to enter through the Plant Inspection Stations, as do those of PPQ.) Thus, the PPQ officer inspecting the VS package may be less familiar with the permit process than his or her counterpart at a plant inspection station;

- While the VS permit provides the PPQ inspector with immediate access to information regarding the permittee, like the PPQ label it is not an accountable document and could be susceptible to alteration or forgery; and

- PPQ officers at the ports-of-entry have [

-] information given on the permit affixed to an incoming package.

VS officials agreed that there could be areas of concern related to this system and stated that they planned to use PPQ's bar-coded tracking system and tamper-proof labels when these become available.

The Deputy Administrator of PPQ agreed that this situation needed to be addressed more quickly. He stated that while the full system of envisioned changes could not be quickly implemented, the tamper-proof paper by itself could. This would, at minimum, render the current mailing labels obsolete and eliminate the value of any that are held by unauthorized parties.

We concluded the Department needs to place a higher priority on eliminating or reducing the vulnerability of the permit systems to misuse. APHIS needs to develop an automated system using accountable permit forms and labels, which will allow inspectors at the ports-of-entry to quickly verify that incoming packages bearing APHIS permit markings are in fact legitimate. In addition, the system should allow APHIS Headquarters to maintain readily accessible records to track and account for each shipment that enters the country under APHIS permit.

Recommendation No. 6

Establish reasonable timeframes for the development and implementation of a universal system to track PPQ and VS shipments that enter the country using bar-code technology with accountable labels and permit documents.

Agency Response.

VS and PPQ are working in conjunction on a new electronic permitting "ePermit" system that would incorporate the elements referred to in the recommendation, specifically the use of bar-coding to identify and track shipping labels. The detailed work plan for system development is expected to be completed by December 31, 2003, with the pilot project by December 2004. The finalized system would be implemented and in place by December 31, 2005.

OIG Position.

We concur with APHIS' management decision. Final action can be reached when APHIS provides documentation to OCFO that the "ePermit" system has been implemented.

Recommendation No. 7

Institute procedures to ensure that the new system allows inspectors at the ports-of-entry to quickly and accurately check the validity of incoming permit shipments, and allows APHIS Headquarters to track the status of all issued

labels. In addition, restrict the entry of VS packages to the plant inspection stations.

Agency Response.

PPQ officials stated that the new "ePermit" system, which is expected to be fully operational by December 31, 2005, would provide electronic access of permit data to all personnel at the Plant Inspection Stations. VS officials stated they are implementing procedures to ensure that the system will incorporate the ability for inspectors at ports-of-entry to check the validity of incoming shipments, as well as the ability of APHIS Headquarters to track the status of all incoming labels. VS officials also stated that they are pursuing the feasibility of restricting the ports-of-entry on permits issued for certain high-consequence pathogens. This restriction would be in place by the end of fiscal year 2003.

OIG Position.

We concur with APHIS officials' plans for implementing the "ePermit" system at the Plant Inspection Stations. However, APHIS officials have not yet stated whether incoming VS permit shipments would be required to pass through the Plant Inspection Stations as PPQ shipments are, or whether the procedures associated with them would be the same as for those of PPQ. To reach a management decision, APHIS officials need to provide us with additional information on their planned corrective actions in this area.

Recommendation No. 8

Until the system cited in Recommendation No. 7 is implemented, develop interim measures to provide the needed controls over incoming permit shipments. These measures should include, but not be limited to, the adoption of tamper-proof paper as referenced in the Informational Memorandum to the Deputy Secretary.

Agency Response.

APHIS officials stated that they are redesigning their shipping label to incorporate a new visual design, tamper-proof paper, and bar-coded tracking technology. Although the bar-coding system will not be effective until the "ePermit" system is operational at the end of 2005, APHIS officials stated that new labels utilizing tamper-proof paper would be in use by the end of fiscal year 2003.

OIG Position.

We concur with APHIS' management decision. To reach final action, APHIS needs to provide OCFO with documentation that the new labels using tamper-proof paper have replaced the existing labels.

Finding No. 5 APHIS Continues to Allow Hand-Carried Permit Material to Leave Ports-of-Entry

Both PPQ and VS allow individuals to hand-carry incoming permit packages. PPQ officials have stated that they cannot prohibit this practice without changing the regulations, and while VS has disallowed hand carrying of certain high-risk pathogens, it continues to allow this for other types of permits. In addition, neither VS nor PPQ has any system to ensure that these hand-carried packages reach their stated destination once they leave the port of entry.

Neither PPQ nor VS had clear regulations or instructions governing how or when individuals may hand-carry permit materials into the country. Because there is no system to track hand-carried materials, neither PPQ nor VS officials could cite the number of cases in which permit materials are hand-carried through ports-of-entry by incoming passengers. However, officials of both acknowledge that this does occur.

As a result of our audit, PPQ and VS both issued guidance on the hand-carrying of permit materials into the country. Although we concur with these restrictions, we do not believe that they provide sufficient safeguards. PPQ officials stated, however, that according to the Office of General Counsel, they have no further authority to restrict the practice of hand-carrying permit packages without a regulatory change.

APHIS' Informational Memorandum to the Deputy Secretary, dated October 4, 2001, indicated the need for a "more stringent protocol/process for permitting based on tracking, monitoring, reporting, and disposition of permit material…" While the need for this was identified only by PPQ, we believe that in this area it applies equally to both PPQ and VS. Because neither has a system to ensure that the permit packages actually reach the recipients marked on the shipping labels, the only way to provide assurance that this is done is to require that no permit package be allowed to leave a port of entry except in the custody of a recognized, bonded commercial carrier.

As a result, we believe that APHIS needs to take action as required to eliminate this security risk, including changes in the applicable regulations if these are determined to be necessary.

Recommendation No. 9

Take immediate steps, including regulatory change, to prohibit the practice of hand-carrying permit materials through ports-of-entry by incoming passengers. Further require that all permit packages leaving a port of entry do so in the custody of a bonded commercial carrier.

Agency Response.

Both PPQ and VS have issued new procedures to prohibit the hand-carrying of permit packages from ports-of-entry where appropriate.

OIG Position.

We concur with APHIS' management decision. To reach final action, the agency needs to provide documentation of the above-referenced procedures to OCFO.

Section 4. Monitoring of Material Disposal

Finding No. 6 APHIS Does Not Monitor the Disposal of Materials Imported Under Permit

We found that although APHIS permits require the proper disposal of certain regulated materials when the permits expire, neither PPQ nor VS followed up to ensure that this was in fact being done. We attributed this in part to the lack of written guidance, and also to the difficulty involved in identifying the expiration date of PPQ permits in its JPS system. Neither PPQ nor VS required permittees to certify compliance with this requirement, or performed onsite visits following permit expiration. As a result, materials imported under APHIS permits could remain on hand indefinitely at laboratories or storage facilities maintained by former permittees.

Currently, APHIS does not have operating procedures in place regarding disposal of permit materials upon the expiration of their import permits. As noted in Finding No. 2, PPQ inspections are only performed as part of the permit approval process; and although VS does perform followup visits, these only occur when a permittee requests the renewal of an existing permit. Because in such cases the permittee would retain the material acquired under the original permit, no confirmation of disposition would be involved in such an inspection.

PPQ officials stated that they planned to send letters to permittees explaining that the permitted materials must be destroyed upon expiration of their permits. They also stated that they would monitor compliance through surprise visits to laboratories with recently expired permits.

VS officials stated that they plan to expand their compliance inspections to cover permittees who do not apply for renewal, but could not at that time provide written procedures describing the process by which permittees would be selected for compliance inspections. In addition, they could not provide us with specific information on how disposal of permit materials are covered in these inspections.

Because of the potential dangers associated with the unnecessary retention of certain materials, we believe that APHIS needs to develop procedures to ensure that they are disposed of in a timely manner. Both PPQ and VS should document those materials covered under their permit programs whose risk level requires disposition. In all such cases, the permit-holder should be required to maintain records of the use and disposition of the imported material, and to provide written certification to APHIS that the material has been disposed of following permit expiration. To ensure compliance with this requirement, APHIS needs to implement procedures to track expiration dates and follow up with permittees if the required certifications are not timely received. Finally, both PPQ and VS need to perform onsite inspections of permittees, at least on a

random basis, to ensure that the above requirements are being complied with and that all dangerous materials imported under APHIS permit are properly disposed of.

Recommendation No. 10

Institute procedures to require that holders of permits to import high-risk materials timely certify to APHIS that the imported agents have been properly disposed of when the permits expire.

Agency Response.

PPQ officials responded that they have instituted new procedures to inform holders of expiring permits that they must maintain a valid permit as long as the organisms governed by that permit are viable. The permits themselves now contain language to hold permitees responsible for the disposition of the organisms throughout the duration of the permit. PPQ must also be notified if the permitee leaves the institution where the organism is being kept, and such organisms must either be destroyed or transferred with PPQ concurrence to a new permitee. Permittees are required to apply for a new permit within 2 months of expiration as long as the organism remains viable. Depending on the level of risk of the organism, a PPQ officer may be asked to witness its destruction.

VS officials stated that their permits only cover the importation or movement of pathogens, as opposed to possession and use. However, under the Agricultural Bioterrorism Protection Act of 2002, all facilities holding high-consequence pathogens must register with APHIS or CDC as applicable. Approval or denial of a facility's application is based on the results of reviews performed by both APHIS and the Department of Justice; these reviews would cover the official responsible for the pathogen, the facility, and the individual who owns or controls the facility. APHIS must be notified of all changes of ownership, and if the facility intends to discontinue possessing, using, or transferring a particular agent or toxin, APHIS must be notified within 5 business days prior to this action so that APHIS has an opportunity to observe its destruction.

OIG Position.

Although the actions proposed by APHIS are somewhat different from those recommended, we believe that they satisfactorily address the concerns raised in the finding. As a result, we are reaching management decision on this recommendation. Final action can be reached when APHIS provides written documentation of these new procedures to OCFO.

Recommendation No. 11

Institute written procedures for performing followup inspections, including onsite visits to selected permittees, to ensure that permittees comply with the requirements for proper accounting and timely disposal of dangerous organisms imported under APHIS permits.

Agency Response.

PPQ officials stated that they are in the process of developing and implementing procedures for conducting followup inspections of all facilities receiving high-risk organisms under permit. The agency's objective for 2003 is to implement a system for conducting followup inspections, both announced and unannounced, of all facilities currently holding permits. To accomplish this, PPQ has requested four new specialist positions and one permit compliance officer in PPQ Headquarters. Before the end of calendar year 2003, 25 additional field inspectors will be trained to accomplish oversight duties.

VS officials responded that their followup procedures are in place and have been implemented based on the requirements of 9 CFR Part 121, Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins.

OIG Position.

We concur with APHIS' management decision. Final action can be reached when the agency provides documentation of the new procedures to OCFO. Additionally, for final action, PPQ will need to provide documentation that the new positions have been filled and the cited training of field inspectors has been completed.

Scope and Methodology

We performed our audit at APHIS Headquarters located in Riverdale, Maryland, university laboratories in Chicago, Illinois, and West Lafayette, Indiana, and Plant Inspection Stations at ports-of-entry in Miami, Florida, and New York, New York. We performed our audit fieldwork from March through September 2002.

We performed analyses of the PPQ and VS permit databases. PPQ's JPS database contains over 45,000 records of permits for plant pests, plant pathogens, and noxious weeds. VS' PITS database contains over 12,000 records with data on permits for animal products and pathogens. We analyzed these databases using Accounting Code Language (ACL) software.

We selected two laboratories holding APHIS permits for review, based on the risk level of their permitted materials and their proximity to the regional office. We interviewed the permit holders at the laboratories and reviewed documents associated with the permits.

We selected two ports-of-entry for review, based on the presence of Plant Inspection Stations at the ports. We interviewed APHIS staff at the ports, observed their inspection procedures, and reviewed documents associated with processing and inspecting permitted shipments.

Where possible, we utilized results obtained by the Southeast Region's Audit of USDA-funded laboratories.

We conducted the audit in accordance with Government Auditing Standards established by the Comptroller General of the United States.

To accomplish our audit objectives, we:

(1) reviewed laws, regulations, policies, and procedures at APHIS Headquarters in Riverdale, Maryland;

(2) interviewed responsible APHIS personnel both at Headquarters and at field locations;

(3) analyzed the databases used by APHIS to store permit data; and

(4) visited laboratories in Chicago, Illinois and West Lafayette, Indiana to review procedures for permitted materials.

Exhibit A

APHIS' Response to the Draft Report

USDA

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Washington, DC 20250

MEMORANDUM FOR THE ASSISTANT INSPECTOR GENERAL

FROM: Bobby R. Acord
Administrator

MAR 21 2003

SUBJECT: Audit Report No. 33601-4-Ch
APHIS Controls Over Permits to Import Biohazardous Materials into the United States

This correspondence is the Animal and Plant Health Inspection Service's reply to your draft audit report dated February 20, 2003. Our comments address each of the recommendations identified in the report.

We appreciate the opportunity to respond to recommendations identified in the report. We look forward to receiving the final version of the document.

Enclosure

APHIS - Protecting American Agriculture
An Equal Opportunity Employer

Because the audit report's findings make recommendations specific to Plant Protection and Quarantine (PPQ), and Veterinary Services (VS), APHIS' response is reflected as PPQ and VS for each recommendation.

Recommendation 1:

Immediately establish appropriate timeframes for the implementation of the corrective actions outlined in the October 4, 2001, memorandum addressed to the Deputy Secretary.

APHIS (PPQ) Response:

This recommendation refers to eight bulleted items in the October 4, 2001, memorandum. Each bulleted item is numbered and addressed below:

1. "Upon notification of permit holders and the public, a moratorium is being placed on the issuance of all new import permits for plant pathogens, biological control organisms and noncommercial genetically modified organisms."

The moratorium was lifted after establishing the policies concerning required inspections (see Response to Recommendation No. 2). No new permits that would require a facility inspection have been issued without a facility inspection.

2. "Blanket permits from foreign sources moving into facilities that have not been inspected by PPQ are subject to possible revocation, along with APHIS shipping labels."

As appropriate, PPQ permits have been canceled. When PPQ is aware of permit violations, the appropriate permits will be canceled.

3. "All future permit decisions will be based on risk assessments; criteria are being developed to determine the level of risk to be applied to each application."

All current permit decisions in PPQ are based on risk assessments. Most risk assessments are not documented separately, but the overall risk analysis, which consists of risk assessment, communication, and management, is documented in the data base and the specific conditions are provided with each permit.

4. "A more stringent protocol/process for permitting based on tracking, monitoring, reporting, and the disposition of permitted material will be implemented. Failure to comply will result in permit revocation."

APHIS has invested significant resources to create a completely new permit data base for receiving permit applications, tracking applications, issuing permits, and follow up inspections. The new data base will serve all APHIS permitting functions and is known as ePermits. A waiver was obtained, a contractor has been selected, and as of January, 2003, the contractor has completed certain tasks. A schedule for implementation of ePermits is attached.

5. "In the interim, an alert is being sent to PPQ field employees to reinforce the current policy for verifying labels in more than a cursory way (the current practice)."

The letter sent to ports was provided to OIG on July 10, 2002.

6. "PPQ's Permit Staff will hold a conference call next week with DHL, FedEX and the U.S. Postal Service to acquaint those companies with the labels and the proper forwarding of packages."

The communications with DHL, FedEx and the U.S. Postal Service took place on December 2, 2001 and the information was provided.

7. "Tamper-proof paper and bar code tracking similar to that used with Phytosanitary Certificates will be used in the redesign of the permit shipping labels."

The shipping labels have been redesigned and each label will be identified uniquely using bar-code technology. PPQ is establishing protocols, hardware requirements, and software interfaces to ePermits for the new shipping labels. Tamper-proof paper will be used by the end of Fiscal Year (FY) 2003. A pilot for tracking shipping labels using bar code technology will be completed by December 31, 2004, and full implementation into ePermits will be completed by December 31, 2005.

8. "The current database will undergo a major redesign to allow for the tracking of permits from issuance to arrival, usage and final disposition of the pathogen or organism. A waiver is being sought through the Office of the Chief Information Officer to permit the system redesign."

A waiver has been obtained for development of ePermits. The contractor began development of the system on September 30, 2002. In June 2003, the contractor will provide a preliminary prototype for ePermits.

The timetable for development of ePermits was provided to OIG on June 27, 2002 (a copy is enclosed with this response). Full implementation for all APHIS permitting entities is estimated to be completed during 2006.

APHIS (VS) Response

The October 4, 2001, memorandum to the Deputy Secretary listed three action items VS planned to pursue to address the potential vulnerabilities in the VS procedures for issuing import permits for agents witch pose a significant threat to the US animal health and/or animal products outlined in 9 CFR Part 122.

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The second action item addressed OIG's recommendation that the Parent Committee on Foreign Pathogens and Vectors for importing biological materials formalize the format for addressing items involving risk. The Parent Committee provides APHIS with expert scientific advice related to the import, use, or distribution of animal pathogens and vectors of animal diseases. Monthly communications and agenda items are based on applications for veterinary permits. Parent Committee decisions are based on disease risks, affect whether a particular importation is approved or denied, and establish broader import policies and regulations. There is a clear mechanism for evaluating issues before making recommendations. The guidelines for each item submitted to the Parent Committee consider numerous risk criteria and are cited below:

1. Summary of request
2. Issues involved
3. Background
4. Risk considerations
    a. Morbidity and mortality
    b. Exotic or not
    c. Research purpose
    d. Commercial distribution
    e. Office International des Epizooties (OIE) list or not
5. Risk Management options
    a. Use only in university settings
    b. Require approval of the State Veterinarian
    c. Biocontainment requirements of the facility
    d. Require inspections and recommendations by the Area Veterinarian In Charge (AVIC)
    e. Time limitations for the permit

The third action item addressed OIG's request for VS to improve the frequency of laboratory inspections. In a letter dated June 25, 2002, VS field personnel were requested to make arrangements to reinspect laboratory and animal facilities that had been inspected and approved on or before June 25, 1999. (The National Center for Import and Export (NCIE) provided lists of these facilities to the AVICs).

On June 12, 2002, a new bill ,"The Public Health Security and Bioterrorism Preparedness and Response Act of 2002" was enacted to improve the ability of the United States to prevent, prepare for and respond to bioterrorism. In accordance with the Act, VS established regulations, standards and procedures governing possession, use and transfer of biological agents and toxins that have been determined to pose a threat to animal and or animal products. These procedures are outlined in 9 CFR Part 121 "Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins" (also know as, "High Consequence Pathogens and Toxins of Livestock Agents") dated December 13, 2002.

Recommendation 2:

Develop written procedures governing the inspection of facilities for both PPQ's and VS' permit systems, including any risk-related criteria that would exclude a facility from being inspected.

APHIS (PPQ) Response:

References throughout the audit report state that APHIS inspection systems are based on the assumption that permit applicants are legitimate scientific users; however, APHIS does not have regulatory authority to ensure users are scientific-based.

One of the primary objectives of the moratorium on issuance of permits was to implement more rigorous requirements for facility inspections prior to issuing new permits. These requirements were fully implemented during the spring of 2002 so that the moratorium could be lifted. Concurrence with our management decision is requested because the following criteria are now being used by the permit evaluation scientists to determine if a facility inspection is required:

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INTERSTATE MOVEMENT

Information on permit application that would require receipt by an inspected containment laboratory:

- Subsequent movements of any noxious weed, plant pest or biological control agent (not previously approved for environmental release) that was previously imported and required an inspected facility for receipt.
- Movement of a high-risk, noxious weed or plant pest under official control from a regulated to a nonregulated area (e.g., Karnal Bunt from New Mexico to California).
- Movement of a native or established noxious weed, plant pest or biological control agent (not previously approved for environmental release) to an area where it does not presently occur (e.g., Mexican bean beetle from Indiana to California, brown garden snail from California to Pennsylvania).

Information on permit application that would indicate no inspection is necessary:

- Movement of a native or established plant pest or biological control agent within its current geographical range.

INTRASTATE MOVEMENT

Federal permits and inspection is required for the following situation:

- Movement of organisms that were brought into the State under a Federal permit that required the facility that initially received it to be inspected by USDA.

APHIS (VS) Response

Prior to issuing a registration/permit, VS inspects facilities that apply to receive high consequence livestock pathogens and toxins. VS procedures are in place for the inspection of these facilities. These procedures are provided to VS field in the form of a guidance cover letter, an inspection check list, and a copy of the import permit. Facilities that do not import such agents are not required to be inspected because the risk posed to U.S. animal agriculture is minimal. The agents are commonly found throughout the livestock population.

APHIS requests concurrence with our management decision.

Recommendation 3:

Ensure that all permit applicants not previously inspected by APHIS are visited prior to permit issuance or renewal.

APHIS (PPQ) Response:

Based on the criteria outlined in PPQ's response to Recommendation No. 2, no new permits or permit renewals are issued until a facility that requires an inspection has been inspected by USDA.

APHIS requests concurrence with our management decision.

APHIS (VS) Response:

All permit applicants requesting to import high consequence pathogens and toxins of livestock agents are inspected prior to the issuance of a registration/permit. All applicants requesting to renew a permit are required to receive facility inspections every 3 years. This is written on the permit. All facilities that have been issued permits for any of these agents must be reinspected every 3 years.

APHIS requests concurrence with our management decision.

Recommendation 4:

Develop procedures and controls to ensure that complete data on new permits is input to the system, and that information on the status of existing permits is timely updated.

APHIS (PPQ) Response:

New elements were added to performance plans for all staff involved with permit and facility evaluations to correct previous problems of incomplete data entry into permits and databases. The standard element reads: "All documents, evaluations and assessments for each assigned permit/facility are placed in the permanent file with less than 1% omissions per year. Entries into the database are complete and adequate with less than 3% omissions per year."

The Branch Chief who supervisors the staff, regularly reviews database records on permits and facilities developed by the staff. All discrepancies and omissions found are discussed with the individual staff member. Additional quality control steps may be incorporated into the new ePermits database.

APHIS requests concurrence with our management decision.

APHIS (VS) Response:

The audit did not identify any recommendations for VS.

Recommendation 5:

Incorporate additional data elements into the Joint Permit System (JPS), as necessary, to provide PPQ with the ability to readily determine whether institutions have been inspected and to perform queries based on various data fields.

APHIS (PPQ) Response:

PPQ will not incorporate additional data elements into JPS. The JPS database is obsolete and will be replaced with the ePermits database which will incorporate applicant/permit and facility data. The contract was awarded for this project in December 2002. Staff viewed a working prototype January 24, 2003. PPQ is scheduled for deployment of Release 1 in June 2003. The initial requirements document was modified February 2003 to include an inspection compliance module. In addition to applicable inspection dates, this new system will incorporate facility deficiencies, a facility inventory, Standard Operating Procedures, a list of authorized personnel, blueprints, and a security plan. All fields in ePermits will be "required" fields to eliminate missing data, and ePermits will provide the ability to query all fields. PPQ invested considerable resources and effort into examining current permit processes, cross-training permit staff, working with business process re-engineering leaders to streamline the permit processes and gain International Standards Organization (ISO)-9000 certification for the permit process. These initiatives provided the basis for the Statement of Work and Requirements Documents for ePermits.

APHIS requests concurrence with our management decision.

APHIS (VS) Response:

The audit did not identify any recommendations for VS.

Recommendation 6:

Establish reasonable timeframes for the development and implementation of a universal system to track PPQ and VS shipments that enter the country using bar-code technology with accountable labels and permit documents.

APHIS (PPQ) Response:

Development of a bar-coding system for tracking shipments (by way of a system for tracking shipping labels) is an Information Technology (IT) project. The hardware is computer based, and the information is maintained in a computer data base. This is a significant IT project. The United States Department of Agriculture has specific requirements that must be met before work can begin on significant IT Projects.

Funding for development of a system for tracking permit shipping labels using bar-code technology was received by PPQ during February, 2003. The results of development work completed by PPQ will be incorporated into ePermits and shared with Veterinary Services and

Biotechnology Regulatory Services. Since development of bar-code technology for permits is part of the creation of the new ePermits database, PPQ is using the IT waiver for ePermits for this Information Technology project.

The "Proof of Concept" is a detailed work plan developed by IT personnel as a first step in the development phase of the ePermits system, which will track shipping labels using bar code technology. It is scheduled to be completed by December 31, 2003. After completion of the Proof of Concept, we expect completion of the Pilot for tracking shipping labels using bar code technology by December 31, 2004. Once the Pilot is complete, we expect implementation of ePermits, by December 31, 2005.

APHIS requests concurrence with our management decisions.

APHIS (VS) Response:

VS is working in conjunction with PPQ in the redesign of the permitting tracking system via a newly designed automated e-permitting system. The Agency has placed a high priority on reducing the concerns about VS' permitting system. For details on this recommendation, please review PPQ's comments on the ePermits database.

APHIS requests concurrence with our management decisions.

Recommendation 7:

Institute procedures to ensure that the new system allows inspectors at the ports of entry to quickly and accurately check the validity of incoming permit shipments, and allows APHIS Headquarters to track the status of all issued labels. In addition, restrict the entry of VS packages to the plant inspection stations.

APHIS (PPQ) Response:

Bar code technology will be installed at points of entry (ports) for PPQ permitted plant pests by December 31, 2005. Port personnel already have access to all necessary permit information. Electronic access to ePermits will be available to personnel at all PPQ Plant Inspection Stations. All shipments of live plant pests, imported under PPQ permits into the United States, enter the country at Plant Inspection Stations. Because APHIS is complying with this recommendation, concurrence with our management decision is requested.

APHIS (VS) Response:

VS is implementing procedures to ensure that the new e-permitting system will incorporate the ability for inspectors at the port of entry to check the validity of incoming permitted shipments along with APHIS Headquarters being able to track the status of all issued labels on imported packages. However, these procedures are contingent on the e-permitting system.

VS is pursuing the feasibility of restricting the ports of entry on permits issued for high consequence livestock pathogens and toxins. Once VS coordinates this with PPQ and VS field forces, a restriction will be placed on the permit to limit the ports of entry to a designated number of ports. This corrective action will be implemented by the end of FY 2003.

Recommendation 8:

Until the system cited in Recommendation No. 7 is implemented, develop interim measures to provide the needed controls over incoming permit shipments. These measures should include, but not be limited to, the adoption of tamper-proof paper as referenced in the Informational Memorandum to the Deputy Secretary.

APHIS (PPQ) Response:

PPQ is redesigning its shipping labels for movement of plant pest material shipped under PPQ Permit. The redesign has three primary components. The new shipping labels will 1) have a new visual design, 2) be made of tamper proof paper, and 3) incorporate bar-code technology. During 2002, PPQ tested various types of tamper-proof paper and has identified appropriate material for our new shipping labels. PPQ plans to utilize existing shipping labels by numbering and distributing them to applicants with specific instructions for use (see instructions below). If it is possible to deploy new labels on tamper-proof paper before the system's engineering, Proof-of-Concept, and Pilot for bar-code technology is complete, PPQ will do so. Our decision will be based partly on whether the effort and cost required to deploy only one of our planned changes (*i.e.*, tamper-proof paper) will provide a concomitant reduction in risk. Because shipping labels alone are not sufficient to move material into the United States (a valid permit must also be presented by the importer), the risk presented by using labels that are not on tamper-proof paper is negligible. However, we do expect full use of the new labels to be implemented by the end of FY 2003.

To track shipments until new bar coded shipping labels are available, the following statement is included as a condition on all permits involving importation of plant pests and issuance of existing, numbered shipping labels:

> "We have supplied you with a certain number of individually numbered shipping labels (PPQ Form 599) to enable foreign shipments to enter the U.S. under this permit. A label must be attached to the exterior of each package being imported under this permit. You, as the permittee, are responsible for each import shipping label issued under this permit. You must record the following information for each label: label number; date mailed to supplier; supplier's name, address, and telephone number; date package received by permittee; organisms and contaminants (identified to most specific identification possible) contained in the package. You must provide this information to us in the form of tracking sheets or copies of shipping manifests (with required additional information) by mail, fax or email on at least every annual anniversary date of your permit. Failure to supply this information will result in cancellation of your permit within thirty days following the anniversary date of your permit. To receive additional labels between anniversary dates, you must submit the above information for all labels used since your last report. Upon expiration of your permit, you

must return all unused labels to us and account for any labels that were used since your last report. Failure to return unused labels or to provide a final report within 30 days of permit expiration may result in our denial of future permit applications and/or civil or criminal penalties."

APHIS requests concurrence with our management decisions.

APHIS (VS) Response:

The audit did not identify any recommendations for VS.

Recommendation 9:

Take immediate steps, including regulatory change, to prohibit the practice of hand-carrying permit materials through ports of entry by incoming passengers. Further require that all permit packages leaving a port of entry do so in the custody of a bonded commercial carrier.

APHIS (PPQ) Response:

The following new policy on hand carrying permit materials was implemented last August by a letter to all new and current permit holders stating:

"You may only import organisms by hand carrying or in you baggage if so authorized in the permit conditions. Only organisms that APHIS determines can be safely inspected (i.e., package opened) at the port of entry are eligible for importation by hand carrying. Only individuals with valid U.S. passports may hand carry organisms. Besides the permit holder, all other authorized individuals must be identified in the permit conditions. Individuals may be added to a permit by submitting a letter to us signed by the permit holder. We will then issue new conditions for the permit with the additional names of authorized individuals. At the port of entry, the traveler must declare on the Customs form that they are carrying organisms under permit, present the materials and a copy of the permits with the conditions to the USDA inspecting official, and confirm their identity by presenting a U.S. passport. Upon release from the port of arrival, the traveler must carry the package directly to the receiving facility identified on the permit. If the traveler cannot deliver the package directly to the facility, then the package must be mailed (at the traveler's expense) from the port of entry directly to the permitted destination. If the PPQ Officers at the port of entry determine that the traveler hand carrying the organisms is not authorized on the permit or does not possess a valid U.S. passport, they will confiscate and destroy the package at the traveler's request."

Changes may occur due to the transfer of PPQ Officers at ports of entry to the new Department of Homeland Security (DHS). Therefore, some of these issues may need to be resolve by DHS. All hand-carried packages leaving a port of entry may need to be in the custody of a bonded commercial carrier.

APHIS requests concurrence with our management decisions.

APHIS (VS) Response:

On October 11, 2002, VS wrote importers, researchers, and other interested parties about a change in policy regarding hand-carrying packages. The procedures were effective immediately and disallowed high consequence livestock pathogens and toxins entry into the United States if they are hand-carried. A commercial carrier or other common carrier must be used.

APHIS requests concurrence with our management decision.

Recommendation 10:

Institute procedures to require that holders of permits to import high-risk materials timely certify to APHIS that the imported agents have been properly disposed of when the permits expire.

APHIS (PPQ) Response:

During June 2002, PPQ transmitted expiration letters to all permit-holders with expired permits. Letters are sent 30 days in advance of expiration. This letter informs applicants of their need to reapply, destroy the organisms or face potential penalties. A copy of this letter goes to the PPQ State Plant Health Director and the State Regulatory Official. Permits now state: "The permit holder is responsible for the disposition of the organisms throughout the duration of the permit. If the permit holder leaves the institution where the organisms are kept, all organisms must be destroyed, unless a new individual who assumes responsibility for continued maintenance submits a PPQ 526 application and obtains a permit prior to the permittee's departure. The permittee must maintain a valid permit for as long as the permitted organisms remain viable and must apply for a new permit at least 2 months before the expiration date of this permit." Depending upon the level of risk of the organism, a PPQ officer may be asked to witness the destruction of this material.

APHIS requests concurrence with our management decisions.

APHIS (VS) Response:

VS permits for pathogens are issued when applicants seek permission to import and/or transfer certain materials. Import permits are issued for the movement, not for the possession and use of the agent. Once a VS permit expires, the permittee is no longer eligible to import or transport such material to their facility. This procedure is slightly different from PPQ's requirements.

APHIS has established new safeguards for the possession, use and transfer of high consequence livestock pathogens and toxins. These safeguards are outlined in 9 CFR Part 121 "Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins". It requires facilities to register if they use, possess or transfer such agents or toxins. To comply with the regulation, facilities were required to register with APHIS or the CDC, depending on the agent, by March 12, 2003. Approval /denial is based on APHIS and DOJ's review of the registration materials. APHIS must approve the responsible official, the facility,

and the individual who owns or controls the facility following a database check and the recommendation of the Attorney General. APHIS shall inspect and evaluate the facility and its records, including the Biosafety and Security Plan, to determine the facility§s compliance with the regulations and the biosafety, containment, and security requirements. The facility must notify APHIS of changes of ownership. If a facility will discontinue possessing, using, or transferring a particular agent or toxin, APHIS must be notified within 5 business days prior to the planned inactivation of the agent or toxin. This provides APHIS an opportunity to observe the inactivation of the agents or toxins.

APHIS requests concurrence with our management decisions.

Recommendation 11:

Institute written procedures for performing follow-up inspections, including onsite visits to selected permittees, to ensure that permittees comply with the requirements for proper accounting and timely disposal of dangerous organisms imported under APHIS permits.

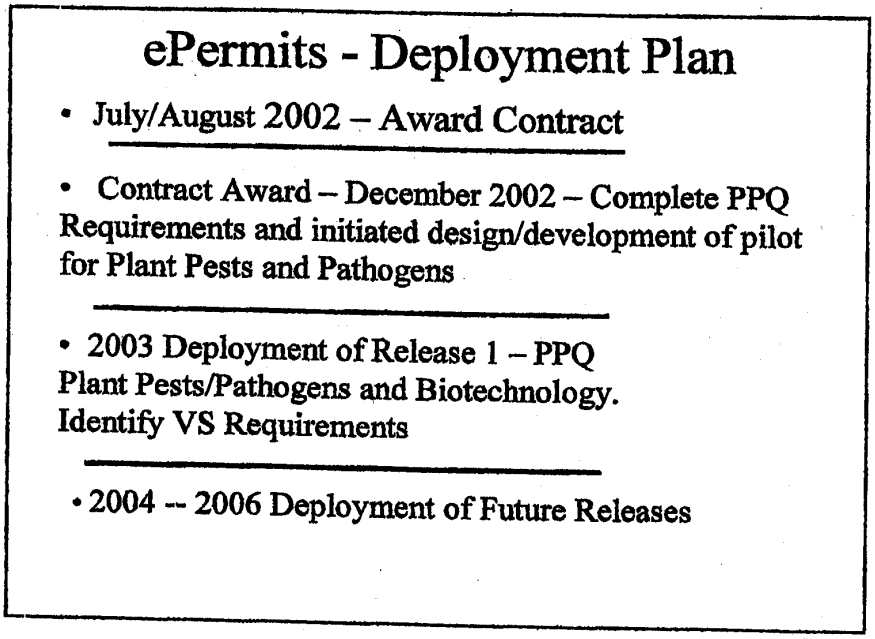
APHIS (PPQ) Response:

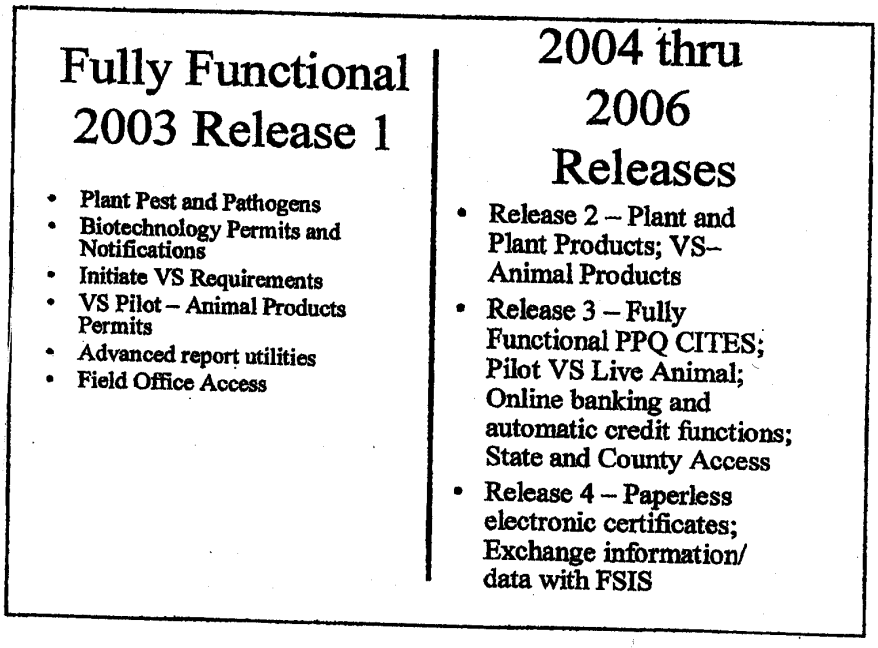
We are in the process of developing and implementing procedures for conducting follow-up inspections of all facilities [redacted]. During 2002, the containment facility inspection staff was reorganized with a new manager and the emphasis was primarily on guaranteeing that all facilities receiving permits requiring inspections actually were inspected. This objective was successfully fulfilled in 2002 with development of new lines of communication among headquarters and field staff, training of field inspectors, and interactions with State regulatory officials. The objective for 2003 is to build on what was accomplished in 2002 by implementing a system for conducting follow-up inspections (announced and unannounced) of all facilities currently holding permits. To accomplish this, we have requested new positions including one Containment Evaluation Specialist, three Organism Evaluation Specialists, and one Permit Compliance Officer in the headquarters' Pest Permit Evaluations Branch. Before the end of calendar year 2003, 25 additional field inspectors will be trained to accomplish oversight duties.

APHIS (VS) Response:

Written procedures for follow-up inspections are in place and have been implemented by VS. These procedures are based on the requirements outlined in 9 CFR Part 121 "Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins" which provide for the proper accounting and timely disposal of dangerous organisms.

APHIS requests concurrence with our management decision.


ePermits - Deployment Plan
• July/August 2002 – Award Contract
• Contract Award – December 2002 – Complete PPQ Requirements and initiated design/development of pilot for Plant Pests and Pathogens
• 2003 Deployment of Release 1 – PPQ Plant Pests/Pathogens and Biotechnology. Identify VS Requirements
• 2004 -- 2006 Deployment of Future Releases


Fully Functional 2003 Release 1
• Plant Pest and Pathogens
• Biotechnology Permits and Notifications
• Initiate VS Requirements
• VS Pilot – Animal Products Permits
• Advanced report utilities
• Field Office Access
2004 thru 2006 Releases
• Release 2 – Plant and Plant Products; VS– Animal Products
• Release 3 – Fully Functional PPQ CITES; Pilot VS Live Animal; Online banking and automatic credit functions; State and County Access
• Release 4 – Paperless electronic certificates; Exchange information/ data with FSIS

Informational copies of this report have been distributed to:

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Director, Planning and Accountability Division (1)