U.S. Department of Agriculture

Office of Inspector General
Southwest Region

Audit Report

Controls Over Plant Variety Protection and Germplasm Storage

Report No. 50601-6-Te
March 2004

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

DATE: March 4, 2004

REPLY TO
ATTN OF: 50601-6-Te

SUBJECT: Controls Over Plant Variety Protection and Germplasm Storage

TO:

Jeremy Stump
Director
Office of Homeland Security

David Hegwood
Special Counsel
to the Secretary

Joseph Jen
Under Secretary
Research, Education, and Economics

William Hawks
Under Secretary
Marketing and Regulatory Programs

This report presents the results of our audit of Controls Over Plant Variety Protection and Germplasm Storage. Responses to the draft report from the Administrators of Agricultural Research Service and Animal and Plant Health Inspection Service, are included in exhibits A and B with excerpts and the Office of Inspector General's (OIG) positions incorporated into the relevant sections of the report.

The agencies' responses expressed concurrence with OIG's findings and recommendations; however, further actions are necessary to reach management decisions on the recommendations. The actions needed to reach management decisions are described in the OIG Position section of the report.

Please furnish the information needed to reach agreement on the management decisions for the recommendations within 60 days. Please note that Departmental Regulation 1720-1 requires a management decision for all recommendations within a maximum of 6 months from the date of report issuance, and final action to be taken within 1 year of each management decision.

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

/s/RWY
ROBERT W. YOUNG
Assistant Inspector General
for Audit

Executive Summary

Controls Over Plant Variety Protection and Germplasm Storage
(Audit Report No. 50601-6-Te)

Results In Brief

Since 2000, when genetically engineered StarLink corn approved only for animal feed appeared in consumer food products, agricultural biotechnology has attracted intense media coverage. The potential for increased adverse reactions to agricultural biotechnology caused us to review the United States Department of Agriculture's (USDA) role in controlling genetically engineered organisms (GEO). Because of USDA's involvement in biotechnology research and its responsibility for regulating the movement of GEOs, we began an audit of the National Plant Germplasm System (NPGS) in June 2002.

As of March 24, 2002, the NPGS consisted of 30 facilities across the U.S and Puerto Rico that store plant germplasm, i.e., living tissue from which new plants can be grown. NPGS curators and scientists evaluate, catalog, and distribute germplasm with the goal of preserving the genetic diversity of crop plants. The Agricultural Research Service (ARS), principal research agency of USDA, coordinates the system.

Two other USDA agencies, the Agricultural Marketing Service (AMS) and the Animal and Plant Health Inspection Service (APHIS), are involved in the control of plant germplasm at NPGS facilities. AMS oversees the Plant Variety Protection Office (PVPO), which issues certificates of protection for newly developed plants and submits germplasm specimens for storage at the NPGS. Through its notification and permit processes, APHIS regulates the movement of certain GEOs and deregulates GEOs that it determines do not pose a plant pest risk.

The objectives of the audit were to determine if the NPGS (1) properly identified, shipped, inventoried, and disposed of GEOs, and (2) implemented adequate security measures at its facilities.

We visited 20 NPGS facilities in the U.S., as well as the PVPO and an APHIS office. We determined that, although two individual germplasm facilities had implemented their own guidelines, the NPGS handbook did not provide national guidance regarding the identification, shipment, inventory, and disposal of GEOs. Furthermore, APHIS policies governing shipment of regulated GEOs were not sufficient.

- Officials at NPGS facilities could not always recognize the germplasm they were storing as genetically engineered because documents arriving with germplasm accessions did not identify the material as such. For example, neither the PVPO application nor the storage application for

NPGS' long-term germplasm collection requires applicants to identify germplasm submissions as genetically engineered. Consequently, GEOs were stored at 2 of the 20 NPGS facilities we visited without the knowledge of facility managers.

- APHIS policies did not adequately ensure that interstate shipments of GEOs complied with approved terms of movement. As a result, one NPGS facility made several unauthorized shipments of regulated genetically engineered seed.

- Because NPGS does not require physical inventories, most facility managers did not conduct inventories on a regular basis. Of the 20 facilities we visited, only 8 performed regularly scheduled inventories. Furthermore, all germplasm was not properly recorded in the NPGS database (Germplasm Resource Information Network (GRIN), which also does not differentiate between regulated and nonregulated GEOs.

- Facilities lacked uniform, written instructions for the disposal of germplasm, including GEOs. Only two of the facilities we visited had written procedures for the disposal of germplasm. At the other facilities, disposal methods ranged from burning germplasm to throwing it in the trash.

We consider the preceding matters to represent material control weaknesses that should be reported in the agencies' Federal Managers' Financial Integrity Act reports.

Additionally, some facilities we visited had not taken reasonable security measures to safeguard the nation's genetic seed stock. Policies governing the entry of foreign visitors and workers were not always implemented, and physical security was not always adequate to deter theft and breaches by eco-terrorists.

Recommendations In Brief

We recommend that ARS develop policies and issue written guidance for the control of GEOs to be implemented at NPGS facilities nationwide. We recommend that these guidelines address:

- Proper identification and documentation of GEOs entering the NPGS;

- routine physical inventories of all germplasm storage facilities; and

- proper germplasm disposal methods, including disposal of GEOs.

We recommend that APHIS revise its requirements for movement of GEOs to prevent unauthorized shipment of genetically engineered germplasm.

We further recommend that ARS revise its national policy dealing with foreign visitors to NPGS facilities, and that it take reasonable measures to enhance physical security at the facilities.

Agency Response

ARS and APHIS officials concurred with the findings and recommendations in our audit report. (See exhibits A and B.)

OIG Position

To reach management decisions for all the recommendations, we need further information. We have explained in the Findings and Recommendations section of the report the actions that are necessary to reach management decisions.

Abbreviations Used in This Report

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CFR	Code of Federal Regulations
CSR	Crop Science Registry
GEO	Genetically Engineered Organism
GRIN	Germplasm Resource Information Network
NPGS	National Plant Germplasm System
PVP	Plant Variety Protection
PVPA	Plant Variety Protection Act
PVPO	Plant Variety Protection Office
REE	Research, Education, and Economics
U.S.	United States
USDA	United States Department of Agriculture
ZmDB	Zea Mays Database

Table of Contents

Executive Summary i

Abbreviations Used in This Report iv

Background and Objectives 1

Findings and Recommendations 4

Section 1. Controls Over GEOs 4

Finding 1 NPGS Needs to Strengthen Controls to Ensure Proper Identification of GEOs 4
Recommendation No. 1, for ARS 7
Recommendation No. 2, for ARS 8
Recommendation No. 3, for ARS 8
Finding 2 APHIS Needs to Strengthen Controls to Prevent Unauthorized Shipment of Regulated GEOs 8
Recommendation No. 4, for APHIS 9
Finding 3 NPGS Needs to Require Physical Inventories of Accessions on a Regular Basis 10
Recommendation No. 5, for ARS 11
Finding 4 NPGS Needs to Establish Written Procedures for Disposal of Germplasm 12
Recommendation No. 6, for ARS 13

Section 2. NPGS Facility Security 14

Finding 5 Policies Governing Entry of Foreigners to NPGS Facilities Need Revision 14
Recommendation No. 7, for ARS 15
Recommendation No. 8, for ARS 15
Finding 6 Physical Security at NPGS Facilities Needs Enhancement 16
Recommendation No. 9, for ARS 16

Scope and Methodology 18

Exhibit A – ARS Response to Draft Report 20

Exhibit B – APHIS Response to Draft Report 23

Glossary of Terms 24

Background and Objectives

Background

The USDA ARS coordinates the NPGS, a network of 30 facilities across the U.S. and Puerto Rico dedicated to maintaining the genetic diversity of crop plants from around the world. NPGS curators and other scientists preserve, evaluate, and catalog plant germplasm, i.e., living tissue from which new plants can be grown, such as leaves, pollen, or cells. NPGS facilities visited include 1 long-term collection of germplasm and 19 working collections to support the day-to-day research needs of scientists. Included in the working collections were six clonal repositories, where germplasm is preserved as living plants rather than in seed form. The NPGS encourages free and unrestricted exchange of germplasm between the U.S and other nations; any individual with valid reason, including plant scientists and breeders, medical researchers, and educators, may make use of NPGS collections, totaling 450,423 accessions[1] as of March 24, 2002.

The National Germplasm Resources Laboratory supports the entire NPGS. A hub for plant exploration activities and a clearinghouse for exchange of plant germplasm with foreign countries, the National Germplasm Resources Laboratory catalogs all incoming accessions, assigns plant introduction identification numbers, and distributes germplasm to the various collections in the system. The GRIN, a computer database maintained at the National Germplasm Resources Laboratory, contains information on genetic resources preserved by the NPGS. GRIN allows users to access the characteristics and location of specific germplasm accessions. NPGS staff members interact with GRIN by entering data, conducting searches, and recording germplasm orders.

The development of agricultural biotechnology has increased the likelihood that the NPGS will obtain and store genetically engineered germplasm. USDA's APHIS, defines genetic engineering as "the genetic modification of organisms by recombinant DNA techniques," which may include the introduction of genes from unrelated species. For the purpose of this report we will refer to these new plant varieties as GEOs.

APHIS classifies GEOs as regulated or nonregulated articles. Regulated articles include any organism that has been altered or produced through genetic engineering if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in Title 7, Code of Federal Regulations (CFR) 340.2 and meets the definition of a plant pest; or any organism or product that APHIS determines or has reason to believe is a plant pest. Prior to introducing a regulated article, which includes importation, interstate movement, or release into the environment, a person must obtain the appropriate APHIS notification or permit. The

[1] An accession is recognized unique genetic material (i.e., a distinct variety of plant) maintained at a collection site. NPGS acquires accessions through collection and by donation from foreign cooperators and international germplasm collections. Accessions include samples from wild populations, plants of a particular cultivar or other improved germplasm, or tissue cultures. NPGS accessions represent more than 10,000 species of plants.

notification/permit processes grant authorization to move, import, or field test regulated GEOs. Regulated GEOs that are candidates for commercialization may achieve deregulated status if the petition process determines that they pose no plant pest risk.

Apart from direct donation by an individual or a company, the three avenues by which genetically engineered germplasm is most likely to enter the NPGS are: the Plant Variety Protection (PVP) process, the Crop Science registration program, and NPGS' associated laboratory research.

- The application for certificate of protection for new varieties of plants, administered by the PVPO in accordance with the Plant Variety Protection Act (PVPA), requires plant breeders to submit a voucher sample of 2,500 seeds, which the PVPO forwards to the NPGS. The PVPA, enacted in December 1970 and amended in 1994, provides legal intellectual property rights to developers of new, sexually reproduced or tuber-propagated plant varieties. After an examination determines that a new variety is distinct from other varieties and genetically uniform and stable through successive generations, the PVPO, part of USDA's AMS, issues a certificate of protection to the owner. The term of protection is 20 years for most crops and 25 years for trees, shrubs, and vines, during which period the owner retains exclusive rights to multiply and market the seed of that variety. The voucher sample submitted to NPGS remains in black-box storage for the length of the certificate. After the certificate expires, the voucher sample becomes part of the NPGS and is transferred to the appropriate working collection, where it may be distributed to valid requesters.

  In addition, the owner of protected germplasm may make a separate, direct donation to a NPGS working collection. Curators at the collections may distribute the donated germplasm for research purposes, even when it is still under certificate.

- Requirements for publication in the scientific journal Crop Science represent another avenue by which GEOs may enter the NPGS. The Crop Science Society of America publishes information on recently released cultivars, parental lines, elite germplasm, and genetic stocks in Crop Science. The Crop Science Registry (CSR), in cooperation with NPGS, handles registration of plant material submitted by breeders seeking publication in the journal. As part of the registration process, the breeder must deposit a sample of each new seed crop in the NPGS' long-term storage facility to ensure preservation. A copy of the storage application form must accompany manuscripts submitted to Crop Science.

- Finally, research activities at NPGS associated facilities, specifically the development of genetically engineered germplasm, present an avenue for GEOs entering the NPGS.

Accounting for GEOs at NPGS facilities assumes increasing importance in light of the mixed reception of genetically engineered crops in the world market.

Objectives

The objectives of the audit were to determine if the NPGS (1) properly identified, shipped, inventoried, and disposed of GEOs, and (2) implemented adequate security measures at its facilities.

We visited 20 of the 30 NPGS facilities, including 14 germplasm collections and 6 clonal repositories. These facilities housed 97 percent of the 450,423 total accessions in the NPGS collections. For full details of the scope of this audit, see the Scope and Methodology section at the end of this report.

Findings and Recommendations

Section 1. Controls Over GEOs

The NPGS handbook, The Manual of Procedures for the National Plant Germplasm System, dated August 1996, provides overall guidance for the operation of the NPGS. However, it includes no national guidelines regarding the identification, shipment, physical inventory, and disposal of GEOs. Because ARS officials consider germplasm produced by genetic engineering to present no greater risk than germplasm produced by traditional breeding methods, they had not anticipated the need for national guidance.

Some curators of NPGS facilities believe additional controls are needed to ensure that GEOs are properly handled. We identified two NPGS facilities that had issued instructions for the control of GEOs at their individual locations. However, only one, facility L, had developed its own written guidelines for the identification and inventory of GEOs. Although officials at facility L indicated that they have not yet received or stored any GEOs, they have procedures in place in the event GEOs are received in the future. In its operational manual, facility L recognizes the importance of identifying genetically engineered germplasm and cautions staff to be aware of genetically engineered material and the complications that would arise if it were inadvertently distributed.

Given some foreign governments' opposition to GEOs, the U.S. could face increased criticism if the NPGS inadvertently distributed genetically engineered germplasm, particularly to scientists in foreign countries, without disclosing its genetically engineered nature.

Finding 1 — NPGS Needs to Strengthen Controls to Ensure Proper Identification of GEOs

The NPGS manual does not contain requirements to ensure that genetically engineered accessions are so identified. As a result, documents accompanying arriving accessions did not directly indicate the accessions were genetically engineered, and curators did not always recognize incoming GEOs and record them as such in the GRIN database.

Of the 20 NPGS facilities we visited, we identified 6 that stored GEOs. Four facilities received GEOs developed elsewhere, and curators at two of those facilities were not aware of all incoming, genetically engineered accessions. Two facilities developed their own genetically engineered accessions. Although we found that the genetically engineered germplasm researched onsite was adequately accounted for at the time of our visits, controls to

prevent the inadvertent distribution of GEOs would be strengthened if NPGS developed written procedures regarding the control of genetically engineered germplasm at its facilities.

Our audit disclosed that, apart from GEOs developed at NPGS associated laboratories, genetically engineered germplasm stored at NPGS facilities originated from at least two sources (the PVPO and company A) and possibly the CSR.

Facility M

In a memorandum of understanding, dated March 11, 2002, between USDA/ARS/facility M and company A, facility M agreed to provide storage of reproducible seed deposits identified by company A and its designated trait licensees as security backup plant materials. Facility M officials informed us that the plant material received from company A is regulated genetically engineered germplasm.

Also, during our visit to facility M in October 2002, the director told us that in a conversation with the PVPO commissioner in the spring of 2002, he was advised that approximately 200 of the PVPO voucher specimens stored at facility M were genetically engineered. All of the accessions were shipped to the facility by the PVPO; however, the PVPO did not identify the accessions as GEOs, nor would the commissioner disclose which PVPO voucher specimens were genetically engineered. Facility M officials identified four accessions they believed were genetically engineered based on the title of the accession.

During our work at the PVPO, officials informed us that the PVPO had identified 223 PVP applications as GEOs, 217 of which had been sent to NPGS. The remaining six GEOs continued to be held by the applicants until PVPO approved their applications. The PVPO based GEO status on an assessment of information contained in the PVP application, which may have included (1) wording indicating that the applicant used genetically engineered material at some point in the development of the variety, (2) a report describing the presence of genetically engineered material (either a transgene[2] or the expression of a transgene), and (3) a combination of the use of a GEO in the pedigree and the description of the GEO-derived trait in the final line. However, officials indicated, it would be possible for a PVP applicant to use a GEO in the pedigree and then remove the GEO-derived trait from the final variety, resulting in a created variety using genetically engineered material but that does not express the GEO-derived trait.

According to PVPO officials, section 56 of the PVPA regarding confidentiality governs applications for certificates of protection listed as

[2] A transgene is a foreign gene inserted by genetically engineering methods.

pending, abandoned, or not otherwise issued. Based on this section, the PVPO had concluded that it could not ask applicants if germplasm is genetically engineered. However, in a subsequent discussion with the commissioner of the PVPO, we learned that PVPO had obtained an Office of the General Counsel opinion allowing it to ask if a variety contained any transgenes; if so, the applicant would be required to provide the USDA-APHIS reference number of the approved petition to deregulate the genetically engineered plant.

In a conversation with the deputy associate administrator for AMS on April 16, 2003, he stated that AMS would be willing to notify facility M of all GEOs shipped from the PVPO to the NPGS.

While officials at Facility M had not identified any of the germplasm submitted by CSR, the organization associated with Crop Science, as genetically engineered, GEOs from CSR or another source could potentially enter the NPGS undetected because facility M's storage applications do not require the applicant to identify genetically engineered germplasm as such. The director of facility M agreed that the storage application should be revised, but the facility could not require donors to identify GEOs until ARS Headquarters issues a policy requiring the identification of GEOs.

In summary, except for the accessions from company A and four PVPO specimens assumed to be GEOs, facility M officials did not know if any of the germplasm stored at the facility was genetically engineered. Although facility M had an internal database for recording GEO information, policies for identifying and storing PVPO samples with genetically engineered traits, and policies for storing and marking genetically engineered company A samples, the policies had not been incorporated in the facility's guidelines, dated April 1, 1998.

Facility K

We visited facility K in July and August 2002, and sampled 145 accessions from the collection's database that were either in the process of obtaining a PVPO certificate or that had been issued a certificate. We identified one genetically engineered accession. In June 2002, facility K received 1,614 seeds of the accession after an applicant abandoned the PVP process. During our initial visit in July, officials indicated they were not storing any GEOs. However, during our followup work in December 2002, we learned that the accession was genetically engineered. Although neither the shipping records nor the inventory records disclosed that the accession was genetically engineered, the title of the sample that included the acronym BG/RR[3] suggested GEO status. The facility staff recorded the accession in the collection's local database after our visits.

[3] BG/RR stands for Boll Guard Roundup Ready and refers to a plant that has been genetically engineered to resist applications of Roundup, a commercial herbicide.

In his response to our written statement documenting the genetically engineered accession, the research leader at facility K wrote, "The fact that a PVP accession was introduced with such a designation (BG/RR), without identification as a potential transgenic, should prompt improved controls and guidelines by the NPGS for handling this type of material."

Facility D

During our visits to facility D in June and July 2002, we were informed that the facility had genetically engineered turf grass in inventory, which it received in two shipments of 22 plants and 26 sprigs on February 14, 2002, and April 8, 2002, respectively. We learned that the facility had housed other GEOs in the past.

Facilities Q and R

During our visit to facilities Q and R[4] in August 2002, we noted that one scientist was performing research on two genetically engineered crops, barley and wheat. Germplasm from these genetically engineered crops was stored with the NPGS collections at the facilities, where it was secured and isolated in storage vaults. However, the genetically engineered germplasm was not officially part of the NPGS and thus was not recorded in GRIN.

Facility G

At the time of our visit in August 2002, the director of facility G estimated that approximately 31,000 transgenic maize stocks were stored at the facility, all of them generated by the National Science Foundation project Maize Gene Discovery, DNA Sequencing and Phenotypic Analysis. Although the transgenic stocks are recorded on the public Zea mays Database (ZmDB), none of the stocks is currently listed in GRIN. According to the director, an ARS-funded project is developing a new database that will merge information in ZmDB with the maize accession listing in GRIN. While the facility will likely send transgenic maize germplasm to facility M for storage in the future, the director explained that the small quantity of kernels per stock has made such a donation impractical.

Recommendation No. 1, for ARS

Develop policy guidelines for effectively obtaining information related to GEO accessions entering NPGS facilities, taking into consideration existing legal and emerging international developments.
nt USDA offices and agencies to address this recommendation, and draft policy guidelines for issuance at the Department level.

[4] The two facilities are located at the same site.

OIG Position. We concur with the proposed actions. To accept a management decision, please provide the details of the new policy guidelines and the estimated date for implementation.

Recommendation No. 2, for ARS

Establish procedures, in cooperation with the PVPO Commissioner, for informing NPGS of GEOs shipped to its facilities by PVPO.

Agency Response. Addressing Recommendation 2 must await policy decisions discussed under Recommendation 1. ARS will work closely with the PVPO to implement such decisions.

OIG Position. We concur with the proposed actions. To accept a management decision, please provide the details of the new policy for PVPO informing NPGS of GEOs shipped to NPGS facilities and the estimated date for implementation.

Recommendation No. 3, for ARS

Establish procedures, consistent with the policy developed in response to Recommendation No. 1, for documenting in GRIN the GEOs entering NPGS facilities.

Agency Response. As OIG recognized, addressing Recommendation 3 must await policy decisions discussed under Recommendation 1.

OIG Position. To accept a management decision, please provide the procedures established for documenting in GRIN the GEOs entering NPGS facilities and the estimated date for implementation.

Finding 2 APHIS Needs to Strengthen Controls to Prevent Unauthorized Shipment of Regulated GEOs

Due to a control weakness in APHIS' requirements for movement of regulated GEOs, interstate shipments of regulated genetically engineered seed were made without APHIS approval. According to APHIS requirements, a permit or notification must be obtained for the interstate movement of a regulated article. However, APHIS does not require the shipper of a regulated article to obtain a copy of the approved notification. APHIS regulation at 7 CFR, section 340.4(c)(1), requires only that the shipper displays the approved notification number on the outside of each shipping container. As a result, the shipper may obtain the APHIS approved notification numbers from the notification's responsible party without

possessing copies of the approved document. Thus, the shipper cannot ensure that shipments of regulated articles comply with the terms of movement specified by APHIS.

From July 27, 2001, to August 6, 2002, staff at facility G made six shipments of regulated genetically engineered seed based on two APHIS approved notifications. Five of the six shipments did not conform to the terms of the APHIS notifications and were therefore made without APHIS approval.

The first APHIS notification authorized interstate movement of regulated seed in the States of California and Hawaii during the period of November 27, 2000, through May 31, 2001. On August 2, 2001, a foreign student working for the party holding the notification requested that regulated seed be shipped to the party's laboratory located at a university in California. The regulated seed was shipped from facility G to California on August 2, 2001. The shipment was made from a State not approved for interstate movement by the APHIS notification and after the end of the approved movement period.

The second APHIS notification authorized the field release (planting) of regulated seed in California for the period April 17, 2001, through April 14, 2003. During the period July 26, 2001, through August 6, 2002, another party in California made four requests for shipment of regulated seed from facility G to California. The four shipments were made under an approved notification for field releases only; therefore, interstate movement of the regulated seed was not authorized.

Recommendation No. 4, for APHIS

Establish procedures requiring shippers of GEOs to obtain a copy of the responsible party's notification/permit and to verify that the notification/permit authorizes the shipment of the requested GEO, to the location designated, during the timeframe the notification/permit authorizes for movement of the GEO.

Agency Response. The audit revealed two instances whereby "regulated articles" were shipped to unauthorized States or destinations. Both movements occurred after permit expiration. APHIS has complied with OIG's recommendation that shippers must be cognizant of movement conditions and restrictions. We modified our formal "letter of acknowledgement" that authorizes such movements. This correspondence now includes a clause requiring the recipient (responsible party) to provide a copy to all cooperators. A copy of a sample "letter of acknowledgement" is enclosed. Dates and sites of authorized movements are included. Shippers of "regulated articles" can now verify compliance with the restrictions identified on movement permits.

OIG Position. Although APHIS' response indicates concurrence with the recommendation, further action is necessary to accept a management decision. The response indicates that APHIS modified its "letter of acknowledgement" by disclosing dates and sites of authorized movement and by requiring a copy of the letter be provided to all cooperators. While this process is workable, further refinements to the "letter of acknowledgement" are needed. The sample letter provided OIG only contained the effective date of the notification and the State to which GEOs may be shipped.

To accept a management decision, the "letter of acknowledgement" needs to be modified to disclose the permit/notification period, both beginning and ending dates. Also, the letter needs to disclose the States from which GEOs may be shipped as well as the States to which GEOs may be shipped. Further, please provide the estimated date for implementation.

Finding 3 NPGS Needs to Require Physical Inventories of Accessions on a Regular Basis

No procedures exist in the NPGS manual to require physical inventories of accessions stored in NPGS facilities. Thus, most facility managers did not take physical inventories on a regular basis. With the potential for increasing numbers of GEOs entering NPGS facilities, it becomes more critical that physical inventories are conducted on a scheduled basis and that all accessions are accurately recorded in GRIN.

Of the 20 NPGS facilities evaluated, only 8 conducted physical inventories of their collections on a regular basis. Managers explained that the facilities have limited resources and cannot devote time to lengthy inventories. At facility E, the curator said the physical inventory consisted of observations recorded periodically on map sheets used to chart the location of trees on the facility's acreage. At facility M, management said that germplasm might be ruined if taken out of refrigerated vaults to be inventoried, and taking inventory in the vaults was difficult due to the cold temperatures.

At facility M, the last physical inventory was taken in 1992, when the facility moved to its current location. The inventory process took 2½ months with a 20-person staff. The inventory discovered about 2,000 accessions that were not recorded in GRIN due to a mix-up at the database management unit. In addition, staff members found accessions they did not know they had and accessions they thought they had but were not there.

Officials at facility M said that physical inventories would be possible if taken on a rotating basis over a period of 10 years. An annual physical inventory of PVPO and genetically engineered germplasm would also be

feasible because those accessions are few in number and would take only one day to inventory, according to officials at facility M.

At facility D, there were material discrepancies in the number of accessions GRIN recorded and the number of accessions stored at the facility. Physical inventories were not taken on a regular basis at the facility, and there were no written requirements to perform them. Before the facility staff corrected the inventory records in GRIN on July 12, 2002, the number of accessions was overstated by 2,019 accessions. On June 20, 2002, the inventory records showed 6,847 accessions. On July 16, 2002, the corrected records showed 4,828 accessions. According to the staff, two reasons accounted for most of the overstatement. First, some receiving NPGS locations did not always correctly record in GRIN the accessions shipped to them by facility D. Second, facility D did not always record in GRIN the accessions shipped to non-NPGS locations. As a result, the facility D inventory in GRIN included some accessions that had been shipped to other locations.

The unit leader at facility D advised that inventories will now be conducted twice a year, and that this task will be included in the performance standards of appropriate staff.

At facility J, there was no written requirement mandating that the facility staff take a physical inventory of the collection's germplasm at specific intervals. The curator said that a physical inventory was taken at least once a year over a period of several months. However, the records generated by this annual physical inventory (map sheets and a field book) did not provide readily available information about the number of accessions stored at the facility.

In addition, the curator told us that the GRIN record of accessions at facility J was not complete. We tested a sample of 32 tree accessions and found that 6 of them were not recorded on GRIN. The accession for another tree was listed on GRIN twice. The curator told us that facility J's Internet website was also incomplete. We tested a sample of eight trees and found that one tree accession was not on the website.

Recommendation No. 5, for ARS

Develop procedures requiring periodic physical inventory of accessions.

Agency Response. As a starting point ARS will develop procedures to ensure a continuous real time record of all inventory uses, i.e., additions, removals, disposals. Furthermore ARS will develop procedures for mandatory, periodic physical inventories of geneback holdings and document them in the Operations Manual for the NPGS and for individual local sites. Procedures will vary greatly among sites, given the dramatically different crops managed, and managerial protocol employed (e.g., orchards of date

palms vs. seed cryopreserved in the base collection). Adherence to procedures will be monitored via periodic reports, spot checks during Annual Resource Management Plan reviews, unit reviews, etc.

OIG Position. We concur with the proposed actions. To accept management decision, please provide the detailed procedures designed to ensure a continuous real time inventory record and the estimated date for implementation.

Finding 4 NPGS Needs to Establish Written Procedures for Disposal of Germplasm

No uniform procedures exist for disposal of germplasm at NPGS facilities, a situation that could allow for the inadvertent release of GEOs into the environment. Our audit found various methods of germplasm disposal, most of which were not documented as written procedures.

Of the 20 NPGS facilities we visited, only 2 had written procedures for disposal of germplasm. The NPGS National manual contains disposal procedures for disposing of quarantined accessions at facility M. After evaluations of germination tests on quarantined accessions have been conducted, all plant materials and accessories used are placed in plastic biohazard waste bags and autoclaved. Officials at facility M said that quarantined and PVPO germplasm are disposed of by autoclaving while other accessions are trashed. At facility D, written procedures indicate that germplasm is destroyed by burning or another method of destruction.

The remaining facilities did not have written procedures for disposal of germplasm. Officials at the facilities advised us that they used various methods for the disposal of germplasm, from simply throwing unwanted germplasm into the regular garbage to incineration. Twelve of the collections' responsible officials, including that of facility G where genetically engineered seed is located, said disposal methods were to throw the germplasm in the trash. The manager of facilities P, Q, and R[5] advised that germplasm from a foreign country would be autoclaved and other germplasm would be placed in the trash. The acting research leader of facilities A and B[6] advised that duplicate germplasm is thrown out with the regular garbage and diseased germplasm is incinerated.

At the six clonal repositories we visited, where germplasm is stored as living plants rather than as seed, methods of disposal included chipping and autoclaving germplasm remnants. Burning was another preferred disposal

[5] The three facilities are located at the same site.
[6] The two facilities are located at the same site.

method. Three of the six repositories disposed of germplasm by throwing it in the trash.

At facility H, the curator advised that there were no written procedures for the disposal of germplasm. According to the curator, the facility policy is to sell seed removed from the collection to a grain elevator.

Recommendation No. 6, for ARS

Develop procedures specifying proper disposal methods for germplasm, including GEOs being refused entry into or removed from NPGS facilities.

Agency Response. ARS will develop procedures specifying proper disposal methods for gemsplasm, and document them in the Operations Manual for the NPGS and for individual local sites. Procedures will vary greatly among sites, given the dramatically different crops managed, and managerial protocol employed (e.g., disposal of 10 m tall date palms vs. nearly microscopic seeds of orchids). Adherence to procedures will be monitored via periodic reports, spot checks during Annual Resource Management Plan reviews, unit reviews, etc.

OIG Position. We concur with the proposed actions. To accept a management decision, please provide the specific procedure for germplasm disposal as documented in the Operations Manual for the NPGS and the estimated date for implementation.

Finding 5 Policies Governing Entry of Foreigners to NPGS Facilities Need Revision

We found that ARS' national policy for reporting noncitizen visitors and workers at NPGS facilities was not followed. NPGS officials were either not aware of the policy or elected not to follow it. These diminished security protocols may have exposed weaknesses in the facilities' ability to safeguard NPGS germplasm collections from countries sponsoring terrorism. Subsequent to our fieldwork, ARS issued a new policy that does not address the risk of allowing foreigners from countries sponsoring terrorism to visit NPGS facilities.

At the time of our audit, NPGS facilities were required to follow the Research, Education, and Economics policy (REE) 121.2, Foreign Research Associate Program and Foreign Visitors at ARS Facilities, dated May 8, 1984. The policy required ARS officials to review requests from foreign sources or foreign visitors, decide if visitation was possible, and send documentation of such visits to ARS Headquarters. NPGS officials had the discretion to permit unannounced visits, however, they were required to provide post facto documentation to ARS.

During our audit, we obtained visitor logs for 10 of the 20 facilities we visited. None of the 10 facilities had fully complied with REE policy 121.2.

From May 1998 to August 2002, we found that 181 foreigners had visited the 10 facilities. Of the 181 visitors, 66 were unannounced and the remaining 115 were scheduled through various research organizations and universities. The facilities submitted the required documents to ARS for only 3 of the 115 planned visitors; the remaining 112 planned visitors were not documented. The facilities submitted the required post facto memo for only 9 of the 66 unannounced visitors.

In our review of the visitor logs, we noted 17 visitors from North Korea, which continues to be 1 of 7 Governments (along with Iran, Iraq, Syria, Libya, Cuba, and Sudan) designated by the U.S. Secretary of State as sponsors of international terrorism. Of the 17 visitors, 11 involved planned visits and the other 6 were unannounced. REE policy 121.2 reporting requirements were not met by any of the three facilities visited by the North Koreans.

We also found a student helper from Iran working at facility O, where she had been employed for the last 2 years. The research leader at the facility said security clearances are conducted in the hiring process for Federal employees, but security clearances for student helpers are not performed.

ARS administration issued new interim procedures for foreign workers and foreign visitors in January 2003. Although the new policy does not place any special emphasis on foreign visitors from countries sponsoring terrorism, the memorandum transmitting the policy specifies that no one from countries on the Department of State's list of State sponsors of terrorism may work at ARS facilities. The new policy requires all facilities to maintain electronic visitor logs.

We are concerned that the new policy does not prohibit individuals from countries sponsoring terrorism from visiting NPGS facilities.

Recommendation No. 7, for ARS

Revise agency policy to prohibit foreigners from countries on the Department of State's list of State sponsors of terrorism from visiting at NPGS facilities without national office clearance.

Agency Response. ARS will reissue and emphasize the Agency policy that prohibits non-citizens from countries on the Department of State's list of State sponsors of terrorism from visiting any ARS facility without approval of ARS Homeland Security.

OIG Position. We concur with the proposed actions. To accept a management decision, please provide the estimated date for implementation.

Recommendation No. 8, for ARS

Follow up to ensure that NPGS facilities, including facility O, are not employing foreigners from countries sponsoring terrorism in accordance with agency policy.

Agency Response. ARS will reissue and emphasize the Agency policy that prohibits non-citizens from countries on the Department of State's list of State sponsors of terrorism from working in any ARS facility.

OIG Position. To accept a management decision, please provide a copy of the reissued policy prohibiting employment of non-citizens from countries on the Department of State's list of State sponsors of terrorism and the estimated date for implementation. Also, provide evidence that ARS has followed up with NPGS facilities, including facility O, to ensure non-citizens from the Department of State's list of State sponsors of terrorism are not employed at the facilities.

Finding 6 Physical Security at NPGS Facilities Needs Enhancement

Many of the 20 NPGS facilities we visited during the summer and fall of 2002 were in need of enhanced security measures as required by ARS guidelines.[7] Managers at 12 facilities said they were waiting for funding and/or vulnerability and threat assessments to be conducted by USDA's Office of Procurement and Property Management, which began inspecting the physical security of all USDA facilities following the events of September 11, 2001.

On November 7, 2003, the director of ARS Homeland Security reported that all assessments had been completed, and needed security enhancements prioritized. Security enhancements were proceeding at four of the highest priority facilities. Security enhancements at 14 facilities are pending receipt of the fiscal year 2004 budget, and security enhancements at the remaining 2 facilities will be funded from area reserve funds or headquarters base funds. Nonetheless, we concluded that some managers waiting for funding could immediately take reasonable security measures to lessen the risk of security breaches by vandals and eco-terrorists at their facilities. Exterior doors at facility K did not have security locks, and the exterior doors at 10 facilities (A, B, E, F, G, H, I, J, K, and L) were not continually locked.

At 5 of the 20 facilities we visited, there had been incidents of a criminal nature, ranging from misdemeanor to felony theft, since 1997. For example, at facility L, three thefts of high-pressure sodium growth lights were reported. An official at the facility speculated that the lights were stolen to grow marijuana indoors; the official said one of the lights was recovered after a drug bust. Also, a purse and day planner were stolen from a desk drawer and later recovered in an unlocked vehicle in the parking lot at the same facility.

Recommendation No. 9, for ARS

Continue security renovations at NPGS facilities based on established priorities and available funding, and direct the facility managers to immediately take reasonable measures, such as locking doors, to strengthen physical security of the facilities.

Agency Response. ARS Homeland Security will reemphasize the need to take reasonable, interim security measures, such as locking doors and wearing badges, pending completion of physical security upgraded at the facility.

[7] ARS security guidelines are based on the U.S. Marshall Service Vulnerability Assessment for Federal Facilities, dated 1995.

OIG Position. We concur with the proposed actions. To accept a management decision, please provide the document reemphasing interim security measures and the date estimated for implementation.

Scope and Methodology

Our audit was conducted at NPGS facilities across the U.S. and at the PVPO in Beltsville, Maryland. NPGS members include Federal, State, and private organizations and research units dedicated to preserving the genetic diversity of crop plants. As of March 24, 2002, the NPGS consisted of 30 facilities holding 450,423 accessions of germplasm across the U.S. and Puerto Rico. NPGS scientists evaluate, catalog, and distribute germplasm to researchers and other valid requesters. Coordinating the system is ARS, principal research agency of USDA.

PVPO issues legal certificates of protection for new, distinct, uniform, and stable varieties of sexually reproduced or tuber-propagated plants. PVPO deposits voucher samples of germplasm at the NPGS' long-term storage facility.

We initiated this audit as a result of an audit survey conducted in 2001 of the Department's controls over the release of GEOs into the environment. Based on our fieldwork, we identified a number of systemic weaknesses in the Department's policies and procedures concerning GEOs. It appeared from our survey that officials at NPGS facilities did not know if the germplasm they received was genetically engineered. Due to foreign governments' refusal to allow some genetically engineered crops into their countries and resistance to expanded use of GEOs in the U.S. by eco-terrorists and other environmental groups, it was imperative that an audit be conducted.

We visited 20 NPGS facilities in the U.S., including 14 germplasm collections and 6 clonal repositories. We reviewed the NPGS manual of procedures for controls over identification, shipment, inventory, and disposal of germplasm. We also reviewed the Department's policies and regulations concerning physical security. Our review covered the period June 2002 through May 2003.

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

- Reviewed applicable laws, regulations, and guidance concerning germplasm;
- reviewed USDA policies, procedures, and administrative controls concerning GEO germplasm;
- reviewed ARS and NPGS policies, procedures, and administrative controls concerning germplasm;
- reviewed PVPO laws, regulations, and rules of practice;

- interviewed USDA Secretarial office staff and officials at ARS Headquarters, AMS, and APHIS;
- visited NPGS facilities; and
- interviewed NPGS personnel.

USDA

United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

FEB 13 2004

SUBJECT: ARS Response of OIG Audit Report 50601-6Te
Controls Over Plant Variety Protection and Germplasm Storage

TO: Robert W. Young
Assistant Inspector General for Audit, OIG
ATTN: 50601-6Te

FROM: for Edward B. Knipling
Acting Administrator

The Agricultural Research Service (ARS) has reviewed the draft audit report. The following is our response to the above Audit:

Finding 1. NPGS Needs to Strengthen Controls to Ensure Proper Identification of GEOs.

Recommendation No. 1, for ARS.

Develop policy guidelines for effectively obtaining information related to GEO accessions entering NPGS facilities, taking into consideration existing legal and emerging international developments.

ARS Response. ARS will collaborate with other relevant USDA offices and agencies to address this recommendation, and draft policy guidelines for issuance at the Department level.

Recommendation No. 2, for ARS.

Establish procedures, in cooperation with the PVPO Commissioner, for informing NPGS of GEOs shipped to its facilities by PVPO.

ARS Response. Addressing Recommendation 2 must await policy decisions discussed under Recommendation 1. ARS will work closely with the PVPO to implement such decisions.

Recommendation No. 3, for ARS.

Establish procedures, consistent with the policy developed in response to Recommendation No. 1, for documenting in GRIN the GEOs entering NPGS facilities.

ars

Office of the Administrator
Jamie L. Whitten Federal Building • Room 302-A • 1400 Independence Avenue, SW.
Washington, D.C. 20250-0300
An Equal Opportunity Employer

ARS Response. As OIG recognized, addressing Recommendation 3 must await policy decisions discussed under Recommendation 1.

Finding 2. APHIS Needs to Strengthen Controls to Prevent Unauthorized Shipment of Regulated GEOs.

Recommendation No. 4, for APHIS.

Establish procedures requiring shippers of GEOs to obtain a copy of the responsible party's permit and to verify that the permit authorizes the shipment of the requested GEO, to the location designated, during the time frame the permit authorizes for movement of the GEO.

Not ARS.

Finding 3. NPGS Needs to Require Physical Inventories of Accessions on a Regular Basis.

Recommendation No. 5, for ARS.

Develop procedures requiring periodic physical inventory of accessions.

ARS Response. ARS agrees. As a starting point ARS will develop procedures to insure a continuous real time record of all inventory uses, i.e. additions, removals, disposals. Furthermore. ARS will develop procedures for mandatory, periodic physical inventories of genebank holdings, and document them in the Operations Manual for the NPGS and for individual local sites. Procedures will vary greatly among sites, given the dramatically different crops managed, and managerial protocol employed (e.g., orchards of date palms vs. seed cryopreserved in the base collection). Adherence to procedures will be monitored via periodic reports, spot checks during Annual Resource Management Plan reviews, unit reviews, etc.

Finding 4. NPGS Needs to Establish Written Procedures for Disposal of Germplasm.

Recommendation No. 6, for ARS.

Develop procedures specifying proper disposal methods for germplasm, including GEOs being refused entry into or removed from NPGS facilities.

ARS Response. ARS agrees, and will develop procedures specifying proper disposal methods for germplasm, and document them in the Operations Manual for the NPGS and for individual local sites. Procedures will vary greatly among sites, given the dramatically different crops managed, and managerial protocol employed (e.g., disposal of 10 m tall date palms vs. nearly microscopic seeds of orchids). Adherence to procedures will be monitored via periodic reports, spot checks during Annual Resource Management Plan reviews, unit reviews, etc.

5. Policies Governing Entry of Foreigners to NPGS Facilities Need Revision.

Recommendation No. 7, for ARS.

Revise agency policy to prohibit foreigners from countries on the Department of State's list of State sponsors of terrorism from visiting at NPGS facilities without national office clearance.

ARS Response. ARS will reissue and emphasize the Agency policy the prohibits non-citizens from countries on the Department of State's list of State sponsors of terrorism from visiting any ARS facility without approval of ARS Homeland Security.

Recommendation No. 8, for ARS.

Follow up to ensure that NPGS facilities, including facility Q, are not employing foreigners from countries sponsoring terrorism in accordance with agency policy.

ARS Response. ARS will reissue and emphasize the Agency policy the prohibits non-citizens from countries on the Department of State's list of State sponsors of terrorism from working in any ARS facility.

Finding 6. Physical Security at NPGS Facilities Needs Enhancement.

Recommendation No. 9, for ARS.

Continue security renovations at NPGS facilities based on established priorities and available funding, and direct the facility managers to immediately take reasonable measures, such as locking doors, to strengthen physical security of the facilities.

ARS Response. ARS Homeland Security will reemphasize the need to take reasonable, interim security measures, such as locking doors and wearing badges, pending completion of physical security upgrades at the facilities.

If you have any questions, or need additional information, please contact Michael Ruff, ARS Homeland Security Director, at 202-720-2452.

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Washington, DC 20250

MEMORANDUM FOR THE ASSISTANT INSPECTOR GENERAL

THROUGH: Bill Hawks JAN 26 2004
Under Secretary
Marketing and Regulatory Programs

FROM: Bobby R. Acord JAN 21 2004
Administrator

SUBJECT: Controls over Plant Variety Protection and Germplasm Storage—Audit No. 50601-6-Te

This correspondence responds to the subject audit issued by your organization. Upon review of the document, we identified one recommendation which pertains to the Animal and Plant Health Inspection Service (APHIS). That item is described below and is followed by our comments.

OIG Recommendation 4: APHIS should require shippers of Genetically-Engineered Organisms (GEO) to obtain a copy of the responsible party's permit. The shippers should then verify that a permit authorizes shipment of the GEO to the location designated during the timeframe the permit authorizes movement of the GEO.

APHIS Response and Action: The audit revealed two instances whereby "regulated articles" were shipped to unauthorized states or destinations. Both movements occurred after permit expiration. APHIS has complied with OIG's recommendation that shippers must be cognizant of movement conditions and restrictions. We modified our formal "letter of acknowledgement" that authorizes such movements. This correspondence now includes a clause requiring the recipient (responsible party) to provide a copy to all cooperators. A copy of a sample "letter of acknowledgement" is enclosed. Dates and sites of authorized movements are included. Shippers of "regulated articles" can now verify compliance with the restrictions identified on movement permits.

APHIS requests OIG concurrence with our corrective actions, and we believe we have satisfied resolution requirements. Thank you for the opportunity to comment.

Enclosures

APHIS - Protecting American Agriculture
An Equal Opportunity Employer

Glossary of Terms

Accession – Recognized unique genetic material (i.e., a distinct variety of a plant) maintained at a collection site. This material includes samples from wild populations, plants of a particular cultivar or other improved germplasm, or tissue cultures. Each accession is given a unique primary identifier in GRIN. It is usually a plant introduction number. There are more than 450,000 accessions (distinct varieties of plants) in the GRIN database. These accessions represent more that 10,000 species of plants.

Genetic engineering – The genetic modification of organisms by recombinant DNA techniques.

Genus/Genera – a taxonomic category of related organisms below a family and above a species.

Germplasm – the raw genetic material required by breeders and researchers for development of improved cultivars and other research. Genetic diversity includes gene heritability and variability and is found in wild species, local landraces, heirloom varieties, and adapted cultivars.

Organism – Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Permit – A written permit issued by the administrator, for the introduction of a regulated article under conditions determined by the administrator, not to present a risk of plant pest introduction.

Plant – Any living stage or form of any member of the plant kingdom including, but not limited to, eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g., pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g., plasmids, ribosomes, etc.) thereof.

Plant Pest – Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

Recombinant DNA Molecules – In the context of the National Institutes of Health guidelines, recombinant DNA molecules are defined as either (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) molecules that result from the replication of those described in (1) above.

Regulated Article –Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 7 CFR, sec 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism,

or any other organism or product altered or produced through genetic engineering which the administrator, determines is a plant pest or has reason to believe is a plant pest.

Vector – Organism or object used to transfer genetic material from the donor organism to the recipient organism.