APR 16 2009

TO: Richard E. Besser, M.D.
Acting Director
Centers for Disease Control and Prevention

FROM: Daniel R. Levinson *Daniel R. Levinson*
Inspector General

SUBJECT: Review of Select Agent Transfers Between Non-Centers for Disease Control and Prevention Entities During the Period January 1, 2006, Through May 31, 2007 (A-02-08-02002)

The attached final report provides the results of our review of select agent transfers between non-Centers for Disease Control and Prevention (CDC) entities during the period January 1, 2006, through May 31, 2007.

CDC's Division of Select Agents and Toxins (DSAT) is responsible for regulating select agents and toxins (referred to as "select agents"), which are biological materials that have the potential to pose a severe threat to public health and safety. Government agencies, research organizations, and legal entities that use, possess, or transfer select agents must register with DSAT and comply with select agent regulations. (We refer collectively to these organizations as "entities.") Entities may authorize access to select agents only to individuals approved by the Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"). Also, entities must develop and implement written security plans designed to safeguard select agents. Entities use the CDC Request To Transfer Select Agents and Toxins form (Form 2) to initiate select agent transfers, obtain DSAT approval, and document receipt of select agents.

During a previous review (A-02-07-02010) of select agent transfers to and from a CDC laboratory, we found that more than half of the transfers reviewed were delivered via common carrier to unapproved individuals. Our report contained several recommendations to ensure that only approved individuals accept delivery of select agent packages.

The objective of this review was to determine whether only approved individuals accessed select agents transferred between non-CDC entities.

Of the 262 select agent transfers between non-CDC entities during the audit period, 165 transfers (63 percent) were accessed only by approved individuals. However, unapproved individuals at

the receiving entities accessed the remaining 97 transfers (37 percent). All 97 transfers were shipped by common carriers. Allowing unapproved individuals to handle select agents increased the risk that the agents could be lost or stolen, thereby potentially posing a severe threat to public health and safety.

We attributed the improperly handled transfers to the following:

- The sending entities did not use a common carrier that offered restricted service and thus did not ensure delivery only to the individual(s) specified on the shipping label.
- Form 2 did not require entities to identify the common carrier used or the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals signed for the package.
- The receiving entities had no or inadequate security plan procedures, or did not follow established procedures, designed to mitigate the risk that unapproved individuals might accept delivery of select agents from a common carrier.
- DSAT's monitoring and enforcement efforts did not focus on procedures for mitigating the risk that unapproved individuals might accept delivery of select agents from a common carrier.

We recommend that CDC direct DSAT to consider the results of this review in its evaluation of our prior recommendation to ensure that only approved individuals accept delivery of select agent packages by requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals.

In its comments on our draft report, CDC concurred in principle with our recommendation and stated that it would carefully evaluate the advantages and disadvantages of implementing the recommendation. In addition, CDC described actions that it had taken or planned to take to address our findings.

This report contains restricted, sensitive information that may be exempt from release under the Freedom of Information Act, 5 U.S.C. § 552. The report will not be posted on the Internet. If information in the report is released pursuant to a request under the Act, the restricted, sensitive information and other information exempt from release will be redacted.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori S. Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through e-mail at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-02-08-02002 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF SELECT AGENT TRANSFERS BETWEEN NON-CENTERS FOR DISEASE CONTROL AND PREVENTION ENTITIES DURING THE PERIOD JANUARY 1, 2006, THROUGH MAY 31, 2007

[redacted]

Daniel R. Levinson
Inspector General

April 2009
A-02-08-02002

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, requires the Department of Health and Human Services (HHS) to regulate select agents and toxins (referred to as "select agents"), which are biological materials that have the potential to pose a severe threat to public health and safety. Within HHS, this responsibility has been assigned to the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT). In collaboration with the U.S. Department of Agriculture, DSAT establishes select agent regulations and monitors and enforces compliance with the regulations.

Any government organization (Federal, State, or local), academic institution, research organization, or other legal entity that uses, possesses, or transfers select agents must register with DSAT and comply with select agent regulations. (We refer collectively to these organizations as "entities.") Pursuant to 42 CFR § 73.10(a), entities may authorize access to select agents only to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"). Also, 42 CFR § 73.11(a) states that entities must develop and implement written security plans designed to safeguard select agents against unauthorized access, theft, loss, or release.

Registered entities may obtain select agents from a CDC laboratory or from any non-CDC entity in the United States. Select agents are transferred between entities via common carrier or via hand delivery by a sending entity employee to a receiving entity employee. Entities use the CDC Request To Transfer Select Agents and Toxins form (Form 2) to initiate transfers, obtain DSAT approval, and document receipt of select agents.

During a previous review (A-02-07-02010) of select agent transfers to and from a CDC laboratory, we found that more than half of the transfers reviewed were delivered via common carrier to unapproved individuals. Our report contained several recommendations to ensure that only approved individuals accept delivery of select agent packages.

OBJECTIVE

The objective of our review was to determine whether only approved individuals accessed select agents transferred between non-CDC entities.

SUMMARY OF FINDINGS

Of the 262 select agent transfers between non-CDC entities from January 1, 2006, through May 31, 2007, 165 transfers (63 percent) were accessed only by approved individuals. However, unapproved individuals at the receiving entities accessed the remaining 97 transfers (37 percent). All 97 transfers were shipped by common carriers. Allowing unapproved individuals to handle

select agents increased the risk that the agents could be lost or stolen, thereby potentially posing a severe threat to public health and safety.

We attributed the improperly handled transfers to the following:

- The sending entities did not use a common carrier that offered restricted service and thus did not ensure delivery only to the individual(s) specified on the shipping label.
- Form 2 did not require entities to identify the common carrier used or the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals signed for the package.
- The receiving entities had no or inadequate security plan procedures, or did not follow established procedures, designed to mitigate the risk that unapproved individuals might accept delivery of select agents from a common carrier.
- DSAT's monitoring and enforcement efforts did not focus on procedures for mitigating the risk that unapproved individuals might accept delivery of select agents from a common carrier.

RECOMMENDATION

We recommend that CDC direct DSAT to consider the results of this review in its evaluation of our prior recommendation to ensure that only approved individuals accept delivery of select agent packages by requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In its comments on our draft report, CDC concurred in principle with our recommendation and stated that it would carefully evaluate the advantages and disadvantages of implementing the recommendation. In addition, CDC described actions that it had taken or planned to take to address our findings.

CDC's comments, except for technical comments, are included as Appendix B.

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INTRODUCTION

BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, requires the Department of Health and Human Services (HHS) to regulate select agents, which are biological materials that have the potential to pose a severe threat to public health and safety. Within HHS, this responsibility has been assigned to the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT). In collaboration with the U.S. Department of Agriculture, DSAT establishes select agent regulations and monitors and enforces compliance with the regulations.[1]

Any government agency (Federal, State, or local), academic institution, research organization, or other legal entity that uses, possesses, or transfers select agents must register with DSAT and comply with select agent regulations. (We refer collectively to these organizations as "entities.")

Select Agent Regulations

Pursuant to 42 CFR § 73.10(a), entities may authorize access to select agents only to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"). Also, 42 CFR § 73.11(a) states that entities must develop and implement written security plans designed to safeguard select agents against unauthorized access, theft, loss, or release. Pursuant to 42 CFR § 73.9, an entity that transfers select agents must designate a Responsible Official who has the authority and responsibility to act on behalf of the entity and ensure compliance with select agent regulations.

Select Agent Transfer Process[2]

Registered entities may obtain select agents from a CDC laboratory or from any non-CDC entity in the United States. Select agents are transferred between entities via common carrier[3] or via hand delivery by a sending entity employee to a receiving entity employee.

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[1]DSAT regulates select agents and toxins that could pose a severe threat to public health and safety. The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), regulates select agents and toxins that could pose a severe threat to animal or plant health. DSAT and APHIS coordinate regulatory activities for those agents that affect both humans and animals (known as overlap select agents and toxins). For purposes of this report, "select agents" refers to all agents and toxins covered under CDC regulations (42 CFR §§ 73.3 and 73.4).

[2]We obtained information on the select agent transfer process from 42 CFR § 73.16 and interviews with officials of DSAT, entities, and common carriers.

[3]Common carriers, which offer transportation services at established rates, are regulated by the U.S. Department of Transportation and are not subject to 42 CFR § 73. Therefore, common carrier employees are not required to be approved individuals.

To initiate a transfer, the receiving entity enters its name and registration number, as well as the name and proposed use of the requested select agent, on the CDC Request To Transfer Select Agents and Toxins form (Form 2).[4] The Responsible Official of the receiving entity signs the form and faxes it to the sending entity. The sending entity then enters its name and registration number and the quantity of the select agent to be transferred on the form. The Responsible Official of the sending entity signs the form and faxes it to DSAT. DSAT verifies the information provided; assigns the transfer a unique approval number, which is valid for 30 days; and faxes the approved form to both the sending and receiving entities. If the transfer does not occur within 30 days, the approval is considered null and void and the transfer may not be completed.

Upon receipt of the approved Form 2, the sending entity packages the select agent in accordance with applicable packaging and shipping laws and places inside the package an updated form containing the date that the select agent is scheduled to leave the facility. If the select agent is to be shipped via common carrier, the sending entity also includes the tracking number on the form and, in accordance with instructions from the receiving entity, enters on the common carrier's shipping label the name and address of the individual(s) designated to accept the package. The common carrier delivers the package to the address indicated and, depending on the level of service used, may or may not ensure delivery to the individual(s) identified on the shipping label.

Within 2 business days of receiving the package, the receiving entity's Responsible Official faxes an updated version of Form 2, containing the date that the select agent was received, to both the sending entity and DSAT. (At the time of our review, the name of the individual at the receiving entity who accepted the package from the common carrier was not included on the form.) The transfer is then considered complete.

Previous Office of Inspector General Review

During a previous review (A-02-07-02010) of select agent transfers to and from the Edward R. Roybal Laboratory[5] during the period January 1, 2006, through March 31, 2007, we found that more than half of the transfers reviewed were delivered via common carrier to unapproved individuals. Our report contained several recommendations to ensure that only approved individuals accept delivery of select agent packages.

CDC concurred in principle with our recommendation to require entities that ship select agents via common carrier to (1) use restricted service to ensure delivery to the approved individual(s) identified on the shipping label and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals. CDC stated that it would study the advantages and disadvantages of implementing that recommendation. CDC fully concurred with our other recommendations to amend Form 2, require all entities to implement security plan procedures

[4]Form 2, which is also used by entities that ship select agents under the authority of APHIS, is often referred to as the "APHIS/CDC Form 2."

[5]The Edward R. Roybal Laboratory is a CDC laboratory located in Atlanta, Georgia.

designed to identify and mitigate the risk that unapproved individuals might sign for and accept delivery of select agent packages from common carriers, and strengthen its monitoring efforts.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our review was to determine whether only approved individuals accessed select agents transferred between non-CDC entities.

Scope

Our audit covered select agent transfers between non-CDC entities during the period January 1, 2006, through May 31, 2007. We focused on access to select agents from the point of delivery to check-in at the laboratory at the receiving entity.

We did not perform an indepth review of DSAT's internal control structure. Rather, we reviewed pertinent DSAT controls relating to the transfer of select agents. In addition, we gained an understanding of procedures governing select agent transfers implemented by entities and common carriers involved in the transfers reviewed.

We performed our fieldwork at DSAT's headquarters in Atlanta, Georgia, from November 2007 through June 2008.

Methodology

To accomplish our objective, we:

- reviewed relevant Federal laws, regulations, and guidance;
- gained an understanding of the role of DSAT, entities, and common carriers in the select agent transfer process;
- reviewed entities' security plan procedures for sending and receiving select agents;
- identified a total population of 453 select agent transfers completed during our audit period;
- eliminated 83 transfers with incomplete or unrecoverable tracking information and 108 hand-delivered transfers with no documentation identifying the individuals who accessed the select agents;
- identified a revised population of 262 select agent transfers and determined that all 262 packages were shipped via common carriers;

- obtained a list of approved individuals at the entities that received the transferred select agents; and

- reviewed the common carriers' electronic tracking data to determine who signed for and accepted delivery of the 262 packages.

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

FINDINGS AND RECOMMENDATION

Of the 262 select agent transfers between non-CDC entities from January 1, 2006, through May 31, 2007, 165 transfers (63 percent) were accessed only by approved individuals.[6] However, unapproved individuals at the receiving entities accessed the remaining 97 transfers (37 percent). All 97 transfers were shipped by common carriers. Allowing unapproved individuals to handle select agents increased the risk that the agents could be lost or stolen, thereby potentially posing a severe threat to public health and safety.

We attributed the improperly handled transfers to the following:

- The sending entities did not use a common carrier that offered restricted service and thus did not ensure delivery only to the individual(s) specified on the shipping label.

- Form 2 did not require entities to identify the common carrier used or the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals signed for the package.

- The receiving entities had no or inadequate security plan procedures, or did not follow established procedures, designed to mitigate the risk that unapproved individuals might accept delivery of select agents from a common carrier.

- DSAT's monitoring and enforcement efforts did not focus on procedures for mitigating the risk that unapproved individuals might accept delivery of select agents from a common carrier.

Appendix A contains details on the number of entities where transfers were received by unapproved individuals and information on DSAT site inspections of those entities.

[6] All 165 properly handled transfers were shipped by [redacted].

RESTRICTED TRANSPORTATION SERVICE NOT USED

All 97 transfers that were accessed by unapproved individuals were shipped via [redacted] or [redacted], which do not provide restricted service requiring delivery only to the individual(s) specified on the shipping label. [redacted] and [redacted] provide delivery to the address on the shipping label and obtain the signature of any individual at that address who will sign for and accept delivery of the package.

Some common carriers, such as [redacted] and [redacted], offer restricted service to ensure delivery only to the individual(s) specified on the shipping label.[7] If the individual(s) specified on the label is not available at the time of delivery, such common carriers retain possession of the package until it can be delivered to the specified individual(s). Thus, until the approved individual(s) is available to accept the package, the select agent remains in the transportation system, outside the authority of the select agent regulations.

Although Federal regulations do not require sending entities to use restricted service, such a requirement would greatly reduce the risk that unapproved individuals might sign for and take possession of select agent packages or that the packages might be shipped to the wrong address, lost, or stolen. Similarly, requiring that the shipping label include the names of at least two approved individuals would minimize the time that select agents remain outside the authority of the select agent regulations. For example:

- A private laboratory shipped a select agent via [redacted] to a university. On the shipping label, the private laboratory entered the address of the entity and the name of the approved individual who should sign for the package. [redacted] delivered the package to the correct address but not to the approved individual specified on the label. Instead, an unapproved individual signed for the package. Subsequently, an approved individual took possession of the select agent from the unapproved individual and checked it into the laboratory.

- [redacted] delivered a select agent shipment between two private laboratories. On the shipping label, the sending entity entered the address of the receiving entity and the name of the approved individual who should sign for the package. However, [redacted] delivered the package as part of a bulk shipment to an unrelated company next door to the intended receiving entity. The Responsible Official of that entity stated that he became aware of the misdelivery when the [redacted] Web site listed the package as having been delivered, but the entity had no record of receiving the package. The official stated that he immediately contacted [redacted] and, within 30 minutes, was notified that the package had been delivered to the company next door. The official

[7]During our prior review (A-02-07-02010), we determined that the average cost to ship a select agent package using [redacted] was [redacted]. The average cost to ship a package using restricted service would have been approximately [redacted] for [redacted] and [redacted] for [redacted]. The actual cost varies by package weight and/or shipping distance. We did not research [redacted] shipping costs.

stated that he immediately went next door to inspect the package for suspicious activity or damage, took possession of the package, and checked it into the laboratory.

Also, during our review, DSAT officials informed us that one vial of Coccidioides immitis (a pathogenic fungus) had been lost while being transferred via [redacted] from a private laboratory to a medical research institute. An investigation concluded that the package had been destroyed on a conveyor belt while being sorted at a [redacted] shipping facility and that the exposure would have been minimal because the layered packaging should have absorbed any leakage of the select agent. If restricted service had been used, the common carrier would have handled the package individually and would not have sent the package to a central sorting facility. Such handling would have greatly reduced the risk of losing the package.

FORM 2 DEFICIENCIES

Form 2 provides DSAT with important information on select agent transfers from the time of the initial request for the transfer through the delivery of the package. However, at the time of our review, the form did not require sending entities to identify the common carrier selected to deliver the package, nor did it require receiving entities to indicate the name of the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals accessed select agent transfers. Specifically, DSAT could have obtained from the common carrier the electronic signature of the individual who signed for the package and compared the name of that individual against the receiving entity's list of approved individuals.

SECURITY PLANNING AND IMPLEMENTATION DEFICIENCIES

Pursuant to 42 CFR § 73.11, entities must develop and implement a written security plan designed to safeguard select agents against unauthorized access, theft, loss, or release. Each entity develops its security plan based on a site-specific risk assessment.

Entities With No Security Plan Procedures

For 50 of the 97 transfers accessed by unapproved individuals, the receiving entities had no written security plan procedures for initial acceptance of select agent packages from common carriers.

For example, a private laboratory's security plan did not contain procedures for receiving and safely opening select agent packages, nor did it address how to handle and limit access to the packages from the time of delivery to the mailroom until check-in at the laboratory. Established receiving dock procedures required receiving dock employees, who were not approved individuals, to sign for all packages upon initial receipt from common carriers and to open the

rigid outer packaging.[8] For one select agent transfer, a receiving dock employee opened the outer package to access the next layer of packaging, which listed the approved recipient's contact information. The select agent, Tetrodotoxin,[9] remained at the receiving dock until receiving dock employees contacted the approved individual. The approved individual then took possession of the package and hand-carried it to the laboratory.

Entities With Inadequate Security Plan Procedures

For 33 of the 97 transfers accessed by unapproved individuals, the receiving entities had inadequate written security plan procedures for initial acceptance of select agent packages from common carriers.

For example, a university laboratory's security plan required that select agent packages be delivered to a building on the university's campus where no approved individuals worked. Consequently, an unapproved individual who worked at the building signed for and took possession of a package containing Botulinum neurotoxin (botulism).[10] The employee subsequently hand-carried the select agent to the Responsible Official, who checked the select agent into the laboratory.

Entities That Did Not Follow Security Plan Procedures

For 14 of the 97 transfers accessed by unapproved individuals, the receiving entities had written security plan procedures for initial acceptance of select agent packages from common carriers. However, employees at these entities did not always follow the procedures.

For example, a private laboratory's security plan stated that when the package arrived at the laboratory's receiving area, the common carrier would be directed to wait until an approved individual could be contacted to take possession of the select agent. However, in one instance, an unapproved receiving dock employee disregarded established procedures and took possession of a package containing Yersinia pestis (plague).[11] An approved individual subsequently went to the receiving area, took possession of the select agent, and checked it into the laboratory.

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[8]Pursuant to 49 CFR §173.196, select agent packages are required to have three layers of packaging: a primary receptacle, a secondary container, and a rigid outer packaging. For the shipment in question, the sending entity indicated the name of the approved individual on the secondary container as well as on the shipping label affixed to the rigid outer packaging.

[9]Tetrodotoxin, which is found in the gonads, liver, intestines, and skin of puffer fish (also known as blowfish), can cause sudden, violent death.

[10]Botulinum neurotoxin is the most potent toxin known, inducing a potentially fatal paralysis known as botulism.

[11]Yersinia pestis is a bacterium that causes plague, an infectious disease of animals and humans.

INADEQUATE MONITORING AND ENFORCEMENT

Pursuant to 42 CFR § 73.18, DSAT conducts periodic site inspections to monitor and enforce compliance with select agent regulations. Site inspections are conducted before an entity is initially registered to send and/or receive select agents and at least every 3 years thereafter.

During its site inspections, DSAT did not adequately monitor or enforce compliance with 42 CFR § 73.11(a), which requires that entities develop and implement written security plans designed to safeguard select agents against unauthorized access, theft, loss, or release. During our audit period, DSAT performed site inspections at 24 entities that received 64 of the 97 select agent transfers accessed by unapproved individuals. However, as shown in Appendix A, DSAT cited only four of these entities for having no or inadequate procedures, or for not following procedures, designed to mitigate the risk that unapproved individuals might sign for and accept delivery of select agent packages upon their initial receipt from common carriers.

According to DSAT officials, its inspectors receive periodic training on how to conduct site inspections and are provided with a checklist for determining whether an entity meets the requirements of the regulations, including security over access to select agents. However, the checklist did not contain specific steps to determine whether the entity had adequate procedures to ensure that only approved individuals signed for and accepted delivery of select agent packages from common carriers. Moreover, DSAT officials acknowledged that inspectors were not required to determine whether unapproved individuals had signed for and accepted delivery of select agent packages.

RECOMMENDATION

We recommend that CDC direct DSAT to consider the results of this review in its evaluation of our prior recommendation to ensure that only approved individuals accept delivery of select agent packages by requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In its comments on our draft report, CDC concurred in principle with our recommendation and stated that it would carefully evaluate the advantages and disadvantages of implementing the recommendation. In addition, CDC described actions that it had taken or planned to take to address our findings.

CDC's comments, except for technical comments, are included as Appendix B.

OTHER MATTER: SENDING ENTITIES' SECURITY PLAN PROCEDURES

Pursuant to CDC regulations (42 CFR § 73.16(i)), an entity that transfers a select agent to another entity must comply with all applicable packaging and shipping laws. Pursuant to Department of Transportation regulations (49 CFR § 172.802), the sending entity's security plan must contain an assessment of possible transportation security risks for select agent shipments and appropriate measures to address the assessed risks, including the risk that unauthorized persons may gain access to select agents and the risks associated with shipments of select agents en route from origin to destination.

For 79 (81 percent) of the 97 transfers delivered via common carrier and accepted by unapproved individuals, the sending entities' security plans did not adequately address these requirements.

APPENDIXES

SELECT AGENT TRANSFERS ACCESSED BY UNAPPROVED INDIVIDUALS

Security Plan Deficiencies	Transfers Received by Unapproved Individuals	Entities	DSAT[1] Inspections	DSAT Citations for Unapproved Access to Transfers
No procedures	50	21	12	2
Inadequate procedures	33	14	7	1
Procedures not followed	14	7	5	1
Total	**97**	**42**	**24**	**4**

[1]DSAT = Division of Select Agents and Toxins of the Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

FEB 20 2009

TO: Daniel R. Levinson
Inspector General
Department of Health and Human Services

FROM: Acting Director
Centers for Disease Control and Prevention

SUBJECT: Office of Inspector General's Draft Report: "Review of Select Agent Transfers Between Non-Centers for Disease Control and Prevention Entities During the Period January 1, 2006 through March 31, 2007" (A-02-08-02002).

The Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report, "Review of Select Agent Transfers Between Non-Centers for Disease Control and Prevention Entities During the Period January 1, 2006 through March 31, 2007."

As stated in the draft, the objective of this review was to determine whether only approved individuals accessed select agent transfers between non-CDC entities. The draft provided the following recommendation to address the identified four findings regarding transfers:

Office of Inspector General (OIG) Recommendation: OIG recommends that CDC direct DSAT to consider the results of this review in its evaluation of OIG's prior recommendation to ensure that only approved individuals accept delivery of select agent packages by requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals.

DSAT Response: DSAT concurs in principle with this recommendation. In accordance with the Select Agent Regulations (42 C.F.R. Part 73, 9 C.F.R. Part 121, 7 C.F.R. Part 331), DSAT strives to ensure that shipments containing select agents and toxins are safeguarded against unauthorized access, as well as against thefts, losses, or releases. It is important to note that of the approximately 2,500 transfers that have occurred since 2003, there has only been one confirmed loss of a select agent that occurred during shipment. This loss was investigated by the Department of Justice/Federal Bureau of Investigation (FBI) and the FBI determined that there was no criminal intent.

Given the concerns identified in this OIG draft report and the previous review (A-02-07-02010), and consideration of the other possible vulnerabilities that may occur during the shipment of select agents and toxins, DSAT is currently reviewing how entities ship select agents and toxins and evaluating ways to improve this process to ensure that the shipment of select agents and toxins is not only safeguarded against unauthorized access, but also against theft, loss, or release. There are three major considerations:

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1) [redacted]: One consideration is whether any additional risks are created by potentially keeping a select agent package in the transportation system longer than usual due to the requirements of a restricted service, such as the package being returned to sender if the identified recipient is unavailable.
2) [redacted]: DSAT must consider whether the implementation of this recommendation would cause any undue financial burdens on the regulated community, given the balance of risks and benefits (in the footnote on page 5 of the draft report, OIG notes that the average cost to ship a package using restricted service would have been approximately [redacted] for [redacted] and [redacted] for [redacted] compared with [redacted] for [redacted]).
3) [redacted]: DSAT also must ensure that implementation of this recommendation will not impede research, as was mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188).

DSAT will carefully evaluate, in collaboration with OIG, the advantages and disadvantages of implementing this recommendation as currently written.

FINDINGS:

The following provides DSAT's response to the four findings identified in this report.

OIG Finding: Sending entities did not use a common carrier that offered restricted service, and thus did not ensure delivery only to the individual(s) specified on the shipping label.

DSAT Response: As described above, DSAT will carefully evaluate, in collaboration with the OIG, the advantages and disadvantages of implementing the report's recommendation to require that select agents be shipped using restricted service. Considerations regarding potential safety and security risks associated with restricted service, additional costs to the regulated community, and possible impediments to research must be researched and evaluated further.

OIG Finding: Form 2 did not require entities to identify the common carrier used or the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals signed for the package.

DSAT Response: The attached "Request to Transfer Select Agents and Toxins" form (APHIS/CDC Form 2) that was approved by the Office of Management and Budget (OMB) on December 7, 2008, now includes a place for the name of the carrier (e.g., [redacted] or "hand-carried" by the sending or receiving entity), the name of the individual who packages the shipment, and the name of the individual who accepts the delivery of the select agent package from the carrier. This will allow DSAT and the U.S. Department of Agriculture/Animal and Plant Health Inspection Service (APHIS) to be aware of any unauthorized access that may have occurred during the packaging and receipt of the select agent shipment.

OIG Finding: The receiving entities had no, or inadequate, security plan procedures, or did not follow established procedures, designed to mitigate the risk that unapproved individuals might accept delivery of the select agents from a common carrier.

DSAT Response: Section 73.11 of the Select Agent Regulations (42 C.F.R. 73.11) requires that an entity develop and implement a written security plan that is sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. The security plan must also be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. This risk assessment should include how the entity ships and receives select agents and toxins.

On April 18, 2007, DSAT provided informational documents to the regulated entities to assist them in complying with the security requirements of the Select Agent Regulations. These documents should assist entities in developing or revising a written security plan and in performing a site-specific risk assessment. The documents are available on the National Select Agent Registry (NSAR) website at http://www.selectagents.gov/complianceAssistance.htm.

Additional guidance is currently being developed in collaboration with the Department of Transportation to provide entities with information on the regulations governing the transportation of select agents and toxins. In addition, DSAT, in coordination with APHIS, has developed two educational workshops with the theme of "Management Oversight" to inform Responsible Officials of their legal responsibilities for implementing the Select Agent Regulations. One of the workshops occurred on December 9, 2008, and the other is scheduled for summer 2009. Information on the December workshop is available on the NSAR website at http://www.selectagents.gov/training.htm.

OIG Finding: DSAT's monitoring and enforcement efforts did not focus on procedures for mitigating the risk that unapproved individuals might accept delivery of select agents from a common carrier.

DSAT Response: DSAT has revised its standard operating procedure (SOP) involving inspections to include an expectation that inspectors review shipping and receiving protocols to determine if unapproved individuals signed for and accepted delivery of select agent packages upon initial receipt from carriers. DSAT also has improved the inspection process by having inspectors review security plans in advance of the inspection to verify that the plans include such protocols. Once on site, the inspectors verify the information through inspection of the facility and querying the staff.

As discussed above, the OMB-approved APHIS/CDC Form 2 now includes: (1) the name of the carrier (e.g., "[redacted]" or "hand-carried" by the sending or receiving entity), (2) the name of the individual who packages the shipment, and (3) the name of the individual who accepts the delivery of the select agent package from the carrier. In addition, DSAT has strengthened its monitoring efforts by developing a quality control checklist for monitoring transfers. Once a transfer is complete, the DSAT reviewer will check the name of the individuals identified on the

APHIS/CDC Form 2 as packaging and receiving the select agent shipment against the list of Security Risk Assessment-approved individuals at the sending and receiving entities. This will allow DSAT to determine if any unauthorized access occurred during the transfer process. The changes to the APHIS/CDC Form 2 and the new follow-up procedures will make DSAT and APHIS aware of any unauthorized access that may have occurred during the packaging and receipt of the select agent shipment.

OTHER MATTER:

The report also identified the following:

Summary of OIG Finding Regarding Sending Entities' Security Plan Procedures: Pursuant to CDC regulations (42 CFR § 73.16[i]), an entity that transfers a select agent to another entity must comply with all applicable packaging and shipping laws. Pursuant to Department of Transportation (DOT) regulations (49 CFR § 172.802), the sending entity's security plan must contain an assessment of possible transportation security risks for select agent shipments and appropriate measures to address the assessed risks, including the risk that unauthorized persons may gain access to select agents and the risks associated with shipments of select agents en route from origin to destination.

DSAT Response: To assist DOT in determining whether entities transferring select agents are complying with DOT regulations, in March 2008, DSAT provided DOT with a list of entities that perform transfers involving select agents. DOT has performed 15 inspections of these entities.

In addition, DSAT is working with DOT to develop guidance for the regulated community on the shipping and packaging of select agents. This guidance will include information on all applicable domestic and international shipping regulations. It will be available to the regulated community via the NSAB website (http://www.selectagents.gov).

Technical comments on the draft report are provided in the attachment. We appreciate your consideration of our general and technical comments as you develop the final report. Please direct any questions regarding these comments to Mr. Shaun Ratliff by telephone at (404) 639-2809 or by e-mail at [redacted].

Thank you for your review of this important matter.

Richard E. Besser

Richard E. Besser, M.D.

Attachment

USDA

GUIDANCE DOCUMENT FOR REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2011

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was distributed to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a combined reporting form for this data collection.

A select agent or toxin may only be transferred under the conditions detailed in 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16 and must be authorized by APHIS or CDC prior to transfer. To request approval, the recipient's Responsible Official (RO) must submit this form (APHIS/CDC Form 2) to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-8662
E-mail: [redacted]

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2000
Email: [redacted]

PURPOSE

The purpose of this form is to request prior authorization of a transfer of select agent(s) or toxin(s) and to provide a method for the documentation of the transfer. The form must be completed for each transfer of select agents or toxins and maintained for three years.

INSTRUCTIONS

1. Prior to transferring a select agent or toxin, the recipient RO must complete section 1, sign and date at the bottom of the page, and send the completed form to APHIS or CDC for transfer approval. For registered entities, the information provided for this form must match the information submitted in the entity's certificate of registration.
   a. Transfer of select agents or toxins may require the intended recipient to obtain a valid USDA and/or PHS permit prior to the transfer (See 7 CFR Part 331.300, 9 CFR Part 122.2, and 42 CFR Part 71.54) The application and instructions for obtaining USDA transport or import permits are available through the APHIS website at [redacted] or the PPQ website at [redacted] or by calling 301-734-[redacted]. The application and instructions for obtaining PHS import permits are available through the CDC website at [redacted] or by calling 404-718-2077. A copy of the APHIS and/or PHS permit should be retained with the transfer request.
   b. Clinical and diagnostic laboratories that transfer select agents and toxins after identification (See 7 CFR 331, 9 CFR 121, and 42 CFR 73) are required to submit this form for approval prior to transferring the select agent or toxin for research purposes to a registered entity (see also APHIS/CDC Form 4, "Report of the Identification of a Select Agent or Toxin").
   c. The agency receiving the form (APHIS or CDC) will review the request and approve or disapprove the transfer. The agency will return the form to the recipient RO and will send a copy of the form to the sender. The transfer must be completed within 30 days of issuance of the Transfer Authorization.
2. When the sender receives the Form 2 with CDC or APHIS authorization for transfer, the sender must complete Section 2 and sign and date at the bottom of Section 2.
   a. For block 28 ("Characterization of agent"), please provide characterization of agent (e.g., strain designation, GenBank Accession number, pertinent strain studies, relevant characterization data, etc). If unknown, indicate "not known" for block.
   b. For block 29 ("Name of carrier"), please indicate the method of shipment (e.g., FedEx delivery or hand delivered by sender, recipient, or federal law enforcement agency). For hand deliveries, please include the name of the individual.
   c. If the sender has a suspicion that the agent may not be used for the proposed purpose, then the sender should consult with APHIS or CDC prior to the transfer. Select agents and toxins must be packaged, labeled, and shipped in accordance with all federal and international regulations. It is highly recommended that the shipper utilize a method for tracking the movement of the select agents and toxins being shipped.
   d. The sender must retain one copy of page 2 of the Form in the shipment and send one copy of page 2 of the form to CDC or APHIS.
3. Upon receipt of the shipment, the recipient's RO must complete Section 3 and send one copy of page 2 of the form to the sender and one copy to APHIS or CDC within 2 business days of receipt. If the select agent or toxin has not been received within 48 hours after the expected delivery time or the package received containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred, the recipient's RO must immediately report to APHIS or CDC and complete APHIS/CDC Form 3, "Report of Theft, Loss, or Release of Select Agents and Toxins." A copy of the completed form must be maintained for 3 years. NOTE: If the transfer does not occur within 30 days of authorization, the recipient RO completes block 39 of Section 3 and sends the completed form to APHIS or CDC.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact APHIS at (301) 734-5960 or CDC at (404) 718-2000. This guidance document and form are also available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.cdc.gov/od/sap.

USDA

REQUEST TO TRANSFER
SELECT AGENTS AND TOXINS
(APHIS/CDC FORM 2)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2011

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. This report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-5992
E-mail: [redacted]

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: [redacted]

1. [redacted]	2. [redacted]		
3. Address (NOT a post office address):	4. City:	5. State:	6. Zip Code:
7. Principal Investigator name First: MI: Last:	8. a. APHIS Permit #: b. CDC Permit #:		
9. Responsible Official name First: MI: Last:	10. Telephone #:		
11. FAX #:	12. E-mail address:		
[redacted]			
13. [redacted]	14. ☐ [redacted] ☐ [redacted] ☐ Other		
16. Address (NOT a post office address):	15. City:	17. State:	18. Zip Code:
19. Responsible Official (RO) or facility director First: MI: Last:	20. Telephone #:		
21. FAX #:	22. E-mail address:		
[redacted]			
23. [redacted]			
A			
B			
C			
D			
E			
F			

I hereby certify that the information contained in Section 1 on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, and 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official: _____ Title: _____

Typed or printed name of Responsible Official: _____ Date: _____

Warning—This report contains restricted information for official use.
Distribution is limited to authorized officials.

USDA

REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2011

Read all instructions carefully before completing this report. This report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road, Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3992
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2000
Email: lrsat@cdc.gov

APHIS/CDC AUTHORIZATION NUMBER: _____ EFFECTIVE DATE: _____

	24. Select agents and/or toxins:	25. Characterization of agent:	26. Number of vials:	27. Form (powder/liquid/ dried):	28. Volume or weight of vial contents (e.g., mL, mg, ng):
A					
B					
C					
D					
E					
F					

29. Recipient Name of Intended Shipment Date:
First: MI: Last:

30. Date of shipment:

31. Type of shipment: ☐ Email ☐ Fax ☐ Telephone

32. Name of individual who packaged shipment:
First: MI: Last:

33. Number of packages shipped:

34. Shipment Date:

35. Package description (box, drum, description of packaging including number and type of inner packages):

36. Name of carrier (If hand-delivered, please indicate and indicate name of individual):

37. Airway bill number(s) of tracking number/tracking number:

I hereby certify that the select agents and/or toxins were packaged, labeled, and shipped in accordance with all federal and international regulations and information contained on in Section 2 of this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, and 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Sender: _____ Title: _____

Typed or printed name of Sender: _____ Date: _____

Section 3 - To be completed by the recipient

38. Name of individual who received shipment:
First: MI: Last:

39. ☐ Transfer Was Not Opened ☐ Transfer Occurred Date of Receipt:

40. The select agents and/or toxins listed in Section were received:
☐ Yes ☐ If no, describe discrepancy in separate attachment:

41. Shipment was packaged, labeled, and shipped in accordance with regulations: ☐ Yes ☐ If no, describe discrepancy in separate attachment.

I hereby certify that the information contained in Section 3 on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, and 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official: _____ Title: _____

Typed or printed name of Responsible Official: _____ Date: _____

Public reporting burden: Public reporting burden of this collection of information is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333, ATTN: PRA (0920-0576).
APHIS/CDC FORM 2 (12/31/2011)

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