



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

**Testimony Before the United States House of Representatives
Committee on Energy and Commerce:
Subcommittee on Oversight and Investigations**

**“Continuing Concerns with the Federal Select Agent Program:
Department of Defense Shipments of Live Anthrax”**

Testimony of:

**Gregory E. Demske
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
Department of Health and Human Services**

July 28, 2015

10 a.m.

Location: Rayburn House Office Building, Room 2123

Testimony of:
Gregory E. Demske
Chief Counsel to the Inspector General
Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. I am Gregory Demske, Chief Counsel to the Inspector General for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). I appreciate the opportunity to appear before you to discuss the Federal Select Agent Program (FSAP).

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002) established FSAP. FSAP is administered by the Centers for Disease Control and Prevention (CDC) and the Agricultural Select Agent Program within the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture. OIG is authorized to conduct investigations and to impose civil money penalties (CMPs) against an individual or entity that has violated FSAP regulations. OIG recognizes the importance of FSAP in promoting public health and safety.

This testimony discusses: (1) OIG's FSAP enforcement, (2) OIG's review of violations at the Department of Defense's Dugway Proving Ground Life Science Test Facility in Utah (Dugway), (3) OIG's audits of FSAP, and (4) opportunities to strengthen FSAP.

OIG Involvement in FSAP Enforcement

When CDC's Division of Select Agents and Toxins (DSAT) identifies a potential FSAP violation, it must first assess whether a potential crime, or a suspicious person or activity is involved. In those urgent situations, DSAT coordinates with the Federal Bureau of Investigation. With respect to FSAP matters, DSAT has broad authority to deny, suspend, or revoke an entity's registration, and may require an entity to enter into a Performance Improvement Plan. When DSAT identifies potential misconduct by an HHS employee, it coordinates with OIG to gather facts. OIG presents its findings to the appropriate agency so that it can determine whether any disciplinary action is warranted.

If, after DSAT's investigation, it concludes that a civil violation might have occurred, DSAT refers the case to OIG for potential enforcement. OIG evaluates the case and, if OIG concludes there is a violation, determines the appropriate disposition of the case.

OIG's Approach to Case Resolution

Since passage of the Bioterrorism Act of 2002, OIG has received 68 referrals involving 53 unique entities from DSAT for potential FSAP enforcement. OIG resolves each referral from DSAT in one of three ways: (1) imposing a CMP, (2) issuing a Notice of

Violation letter; or (3) closing the case. OIG found violations in 30 of the 68 referrals. OIG has imposed CMPs on 20 entities totaling \$2,414,000 and issued 10 Notice of Violation letters to parties OIG determined violated FSAP regulations. OIG has closed 32 cases and has six referrals pending.

Given the seriousness of any FSAP violation, OIG carefully evaluates its enforcement options for each referral, by analyzing the facts and circumstances of the alleged violations. OIG considers the seriousness of the conduct, the security risk posed by the violation, the evidentiary strength of the case, the entity's response to the violation (including whether the conduct was self-disclosed), the number of violations, and any other relevant factors. Rather than applying a formula, OIG relies on its experience and exercises judgment to determine how to resolve a referral and to ensure consistency in our approach.

OIG has observed that violations pose variable levels of risk to the nation's security and the overall safety of entities and individuals possessing, using, or transferring select agents and toxins. In the referrals OIG has reviewed, we have considered the most serious or significant violations to include: actual or potential human exposure to a select agent or toxin, theft or loss of a select agent or toxin, performance of unapproved restricted experiments, and access to select agents or toxins by a restricted person. Other serious violations for which OIG has imposed penalties include: unauthorized transfers of a select agent or toxin, unauthorized access to a select agent or toxin, failure to maintain accurate inventory, and failure to have a biosafety and security plan commensurate with the risks associated with a particular select agent or toxin.

Civil Money Penalties: When OIG imposes CMPs, regulations require OIG to conduct a case-specific analysis to determine the appropriate penalty. OIG does not assign a dollar value to a specific regulatory provision, but rather evaluates factors outlined in the regulations, including: (1) the nature of the wrongdoing, including the length of noncompliance and whether the evidence demonstrates a pattern of noncompliance; (2) the entity's degree of culpability; (3) the entity's history of any prior offenses; (4) the entity's financial condition; and (5) other matters as justice may require.

Notice of Violation Letters: OIG has issued Notice of Violation letters when it has concluded that a violation of FSAP regulations occurred but we decided to exercise our discretion not to impose CMPs. In general, Notice of Violation letters describe the violation(s) and direct the entity to examine its current practices and policies governing select agents, and to implement corrective actions and safeguards to prevent future violations. A copy of each Notice of Violation letter is sent to DSAT. OIG has issued five Notice of Violation letters to Federal entities, three to universities, and two to other private entities.

Referral Closed: If OIG concludes the case does not merit a CMP or Notice of Violation letter, OIG closes the case and informs DSAT of the closure.

Approach to Federal Entities

In FSAP referrals involving violations by Federal entities, OIG has resolved matters by issuing Notice of Violation letters to high-ranking officials with oversight responsibility for the entities. While we believe OIG has the authority to impose a CMP on a Federal entity, we have not done so in prior cases on the basis of several considerations. Any money paid by a Federal entity would simply be moved from a Federal agency's budget to the General Fund of the Treasury. Although there would be no net receipt of money for the Federal Government, the Government would incur the cost of negotiating or disputing the CMP. CMP payments from Federal agencies are unlikely to promote better future compliance and, in fact, may reduce resources for the Federal entity's future compliance efforts. OIG's approach is consistent with other Federal agencies that issue letters, or take other nonmonetary action, in similar situations involving violations by Federal agencies. Since passage of the Bioterrorism Act of 2002, OIG has received 16 referrals regarding Federal entities and sent five Notice of Violation letters.

Dugway: 2007 Anthrax Violation

In April 2007, Dugway shipped anthrax to a research facility. The shipment included a certification that the anthrax was nonviable. The research facility tested the material upon receipt and found the presence of a low concentration of viable anthrax.

DSAT investigated and concluded that Dugway used a scientifically acceptable inactivation method to kill the anthrax, but that method was not part of Dugway's Standard Operating Procedures. DSAT also found that Dugway used a scientifically acceptable viability test, but that Dugway ignored the outcome of the test, which showed that viable anthrax was still present.

DSAT referred the potential violation to OIG for review on November 16, 2007. After considering all the evidence, OIG concluded that Dugway shipped viable anthrax without obtaining prior DSAT approval. On December 2, 2009, OIG issued a Notice of Violation letter to Dugway stating that OIG had determined Dugway had violated FSAP by making an unauthorized transfer of anthrax. The letter also stated that Dugway should examine its current policies and practices, take corrective action, and monitor its safeguards on an ongoing basis.

Dugway: 2008 & 2010 Botulinum Neurotoxin Violations

On November 18, 2010, a Government laboratory received a shipment from Dugway that included a vial of Botulinum neurotoxin. The packing slip indicated that the vial contained a small amount of Botulinum neurotoxin that would be exempt from FSAP regulations. However, when the Government laboratory sought to use the Botulinum neurotoxin, it determined that the vial actually contained a greater amount of Botulinum neurotoxin that is not exempt from FSAP regulations. On April 29, 2011, the Government laboratory reported the unauthorized transfer to DSAT. DSAT concluded that Dugway had shipped Botulinum neurotoxin without obtaining the required DSAT prior authorization. Dugway also self-reported to DSAT two additional unauthorized shipments of Botulinum neurotoxin that occurred in 2008.

DSAT referred this case to OIG on June 16, 2011. OIG concluded that Dugway shipped Botulinum neurotoxin in amounts that were not exempt under FSAP regulations without obtaining prior DSAT approval. Based on these facts, including Dugway's corrective action and Dugway's status as a Federal entity, on November 3, 2011, OIG issued a Notice of Violation letter stating that OIG had determined Dugway had violated FSAP by making three unauthorized transfers of Botulinum neurotoxin. The letter also stated Dugway should examine its current policies and practices, take corrective action, and monitor its safeguards on an ongoing basis.

To date, OIG has not received a referral for any more recent potential violations involving Dugway.

OIG Audits

Over the years, in addition to our enforcement efforts, OIG has audited Government and private entities for FSAP compliance. For example, OIG audited six Federal laboratories' FSAP regulatory compliance. The audit results were provided to the head of the relevant Federal agency, putting it on notice of deficiencies and non-compliance. In 2011, OIG issued a report summarizing these audits. OIG found that DSAT did not effectively monitor and enforce certain FSAP regulatory provisions, resulting in violations that were not identified by DSAT. CDC concurred with OIG's recommendations for improvements to its FSAP oversight. OIG also audited transfers of select agents and found a high incidence of access by unapproved persons, typically at the point of delivery. CDC concurred with OIG's recommendations for enhancing controls on shipping and receipt of select agent packages.

Future OIG Work

OIG is expanding its audit and evaluation assessments of select agent management. Collaborative efforts are underway to define the scope and methodology of this work.

OIG will target its initial efforts on CDC's oversight of FSAP, which will shed light on the scope, magnitude, and potential implications of recent biosecurity breaches, and on HHS agencies' (e.g., National Institutes of Health, Food and Drug Administration) operation of laboratories that handle select agents. Related efforts under active consideration are HHS agencies' decision-making processes and protocols; risk assessments, tracking, and monitoring; the volume, frequency, and nature of laboratory enforcement actions; and the development and implementation of corrective actions. OIG takes a risk-based approach to identify areas for audit or evaluation, so our efforts may be redirected to other areas, as warranted. OIG understands that CDC recently announced plans to conduct a comprehensive review of laboratory safety. OIG will coordinate with CDC and other HHS agencies to ensure that our work complements and advances effective oversight of FSAP through objective assessments and recommendations.

Opportunities to Strengthen FSAP

Through this testimony, OIG offers the following opportunities to strengthen and improve the Government's ability to administer FSAP and improve its ability to enforce violations of the regulations. OIG has identified these opportunities through our investigative and enforcement experience.

FSAP regulations should:

- require laboratories to document inactivation procedures, validation and safety/sterility testing procedures, and outcomes to ensure that a select agent or toxin is rendered nonvirulent;
- require registered entities to video entry/exit points and video specific laboratory select agent and toxin work;
- require registered entities to maintain additional records, including all documents created or maintained in the ordinary course of working with a select agent and toxin;
- expressly prohibit the destruction or alteration of any document that is required to be maintained under the regulations; and
- expand the document retention period for registered entities from three to six years to match the CMP statute of limitation period.

In addition, Federal inspectors' ability to conduct effective and meaningful oversight should be strengthened by:

- requiring any registered entity to make available for interview upon reasonable request by inspectors any individual who has accessed, possessed, used, or transferred a select agent or toxin;
- allowing inspectors to physically inspect, handle, or test material that is believed to be a select agent or toxin, when appropriate (consideration should be given to DSAT's ability to immediately transfer material, in accordance with the regulations, so that independent testing can be performed to determine whether particular material is covered by the regulations); and
- considering the viability of independent third-party testing of select agent or toxin material.

Conclusion

On the basis of our enforcement work, OIG has identified opportunities to strengthen FSAP that CDC should consider as it reviews how FSAP can be improved. In addition, OIG will continue to provide oversight through audits and evaluations of FSAP and use our CMP authority to take enforcement actions.

Thank you again for inviting me to speak about OIG's role in FSAP. I would be happy to answer your questions.