

USDA APHIS Questions for the Record
House Committee on Energy and Commerce
Hearing on Bioresearch Labs and Deactivation of Dangerous Pathogens
September 27, 2016

The Honorable Tim Murphy

Dr. Davidson, APHIS' response to the Committee last night indicated that the Investigative and Enforcement Services (IES), APHIS' law enforcement arm, has levied fines against entities suspected of violating select agent regulations but provided no further information.

**1. How many times has IES levied fines for select agent regulations?
a. What was the nature of these violations and fines?**

Since 2003, APHIS' Investigative and Enforcement Service (IES) has entered into pre-litigation stipulations that included civil penalties for alleged violations of the Agency's select agent regulations 8 times for a total of \$116,750. These fines were assessed to resolve allegations such as failing to register with the Federal Select Agent Program when knowingly in possession of a select agent or toxin, or transferring select agents and toxins without authorization.

2. How many referrals has APHIS provided to IES?

Since 2003, APHIS has referred 49 entities to IES for further investigation.

a. How many referrals has IES provided to USDA's Office of the General Counsel to institute an administrative proceeding, or possible referral to DOJ?

None. However, since 2003, IES or the Agency's Agriculture Select Agent Services (AgSAS) has referred 4 cases to USDA's Office of the Inspector General for further investigation into potential criminal charges.

3. Does IES maintain this data? If so, where is this data maintained?

IES maintains data about the cases referred to the program as part of its standard record-keeping system, which includes a database and document repository.

a. Does APHIS document its oversight on select agent violations and referrals?

APHIS maintains a record of referrals to IES. The records contain case information such as the entity name, IES case number, the date of the possible violation, a description of the possible violation, and enforcement actions taken.

4. Why did the USDA Internal Review recommend documenting case referrals?

APHIS' internal review found that the Agency lacked a formal, written standard office procedure for when to refer cases to IES. To improve consistency of decision-making, the group recommended and the select agent program is implementing a formal written process.

5. The internal review recommended formally documenting policies and procedures related to Theft Loss or Release reporting and case referrals to IES. What was the basis for this recommendation?

APHIS' internal review found that, while there are formal policies on theft, loss, or release reporting for the Federal Select Agent Program as a whole, the Agency lacked its own formal written policy for when to refer incidents involving the theft, loss, or release of select agents to IES. A written policy would ensure consistency in what types of violations are referred from year-to-year, and could help the program identify and monitor trends.