

Federal Select Agent Program Training

Agriculture Select Agent Services (USDA/APHIS)
Division of Select Agents and Toxins (HHS/CDC)
Bioterrorism Risk Assessment Group (FBI/CJIS)



HOW ARE NON-COMPLIANCE ISSUES HANDLED BY THE FSAP? WHY WOULD MY ENTITY GET REFERRED TO OIG/FBI?

Thomas Cremer, Ph.D.

Senior Microbiologist/Inspector

Centers for Disease Control (CDC)

Division of Select Agents and Toxins (DSAT)



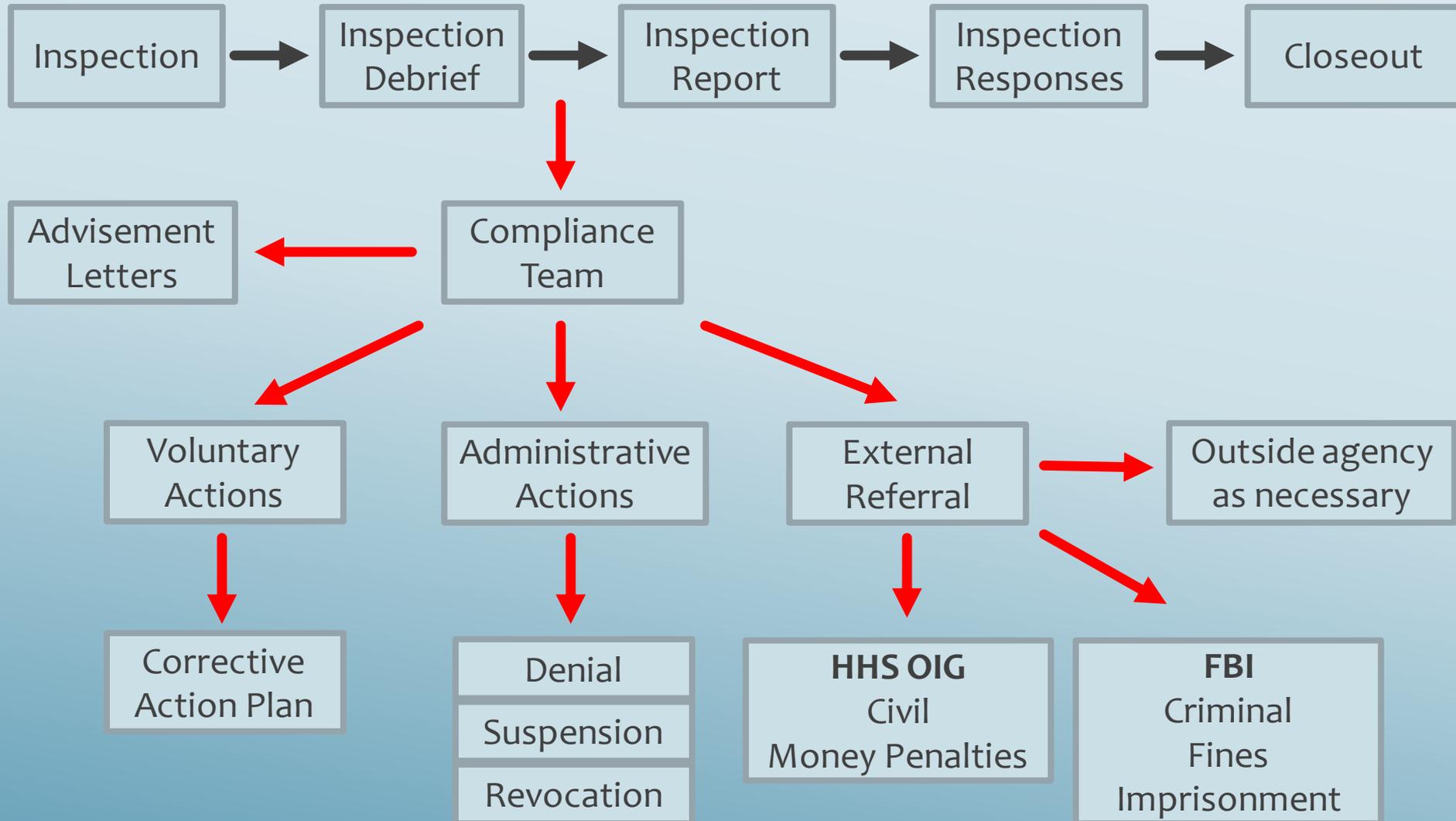
Overview

- ❑ **Review how CDC/DSAT identifies and responds to non-compliance with 42 CFR 73.**
- ❑ **Review non-compliance (12 items) that may result in referral to the Health and Human Services (HHS) Office of the Inspector General (OIG).**
- ❑ **Review non-compliance (8 items) that may result in referral to the Federal Bureau of Investigation (FBI).**

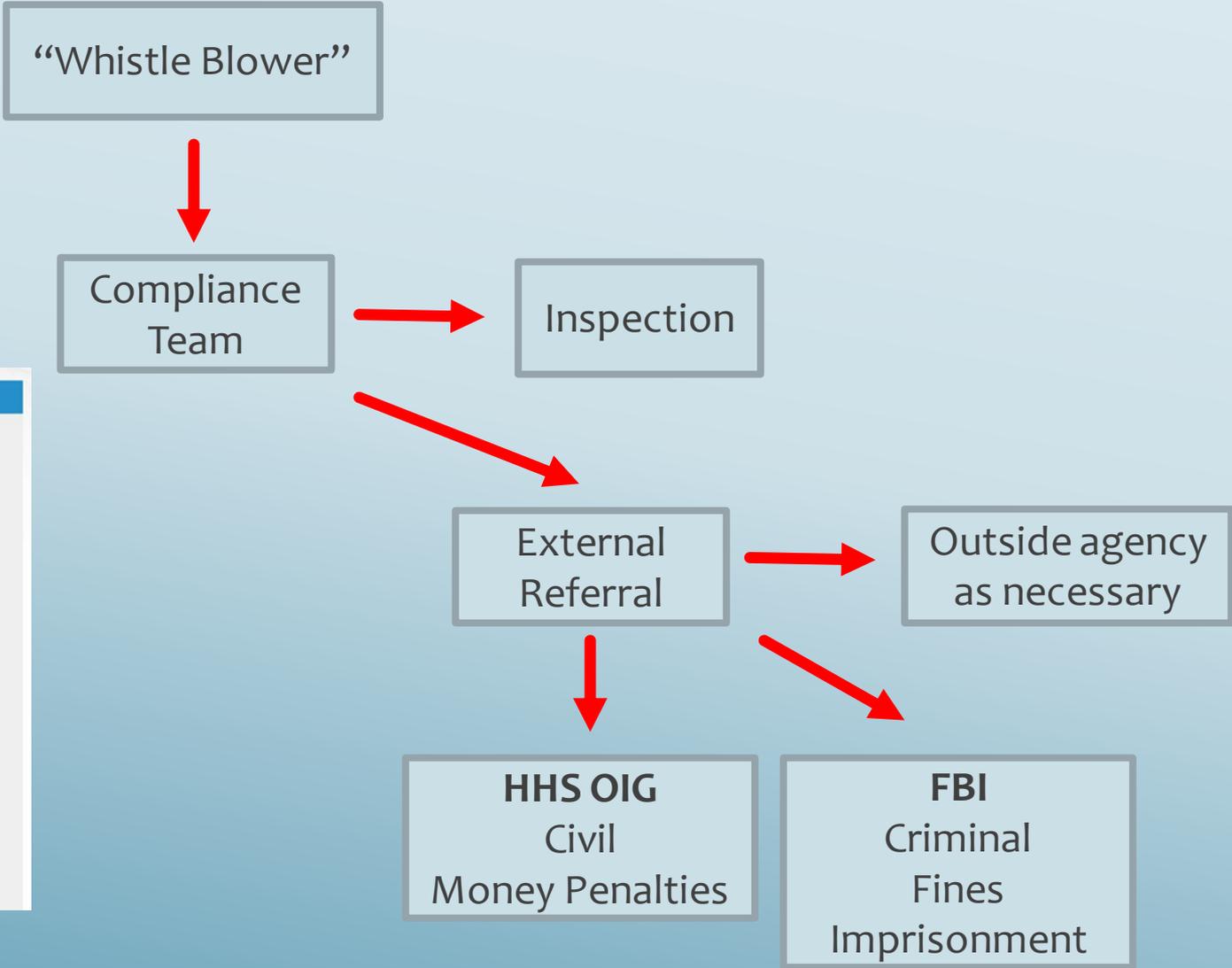
Note:

- ❑ **Referral does always equate to enforcement action.**
- ❑ **Violations involving a U.S. Department of Agriculture's (USDA)-only select agent or must be sent to the USDA Animal and Plant Health Inspection Services (APHIS) Agricultural Select Agent Services (AgSAS) for review.**
- ❑ **Violations involving overlap select agents may be referred for enforcement action under HHS and/or USDA.**

INSPECTIONS & NON-COMPLIANCE



OUTSIDE REPORTS OF NON-COMPLIANCE



Anonymous Reporting

The Department of Health & Human Services, Office of Inspector General (OIG) maintains a confidential hotline for you to report safety, security, or other concerns associated with select agents and toxins. When reporting these issues to OIG, please ensure that you indicate it is a "Select Agent/Import Permit Complaint" issue. Thank you.

OIG Hotline contact information:

Voice: 1-800-HHS-TIPS, (800-447-8477)

Fax: 1-800-223-8164

Web: <https://oig.hhs.gov/fraud/report-fraud/index.asp>

Mail: Office of Inspector General
Department of Health & Human Services
Attn: Hotline
P.O. Box 23489
Washington, DC 20026

DSAT POST INSPECTION ACTIONS



The Operations Branch Chief conducts debriefs for all inspections that include the Inspection Team and respective Team Lead.

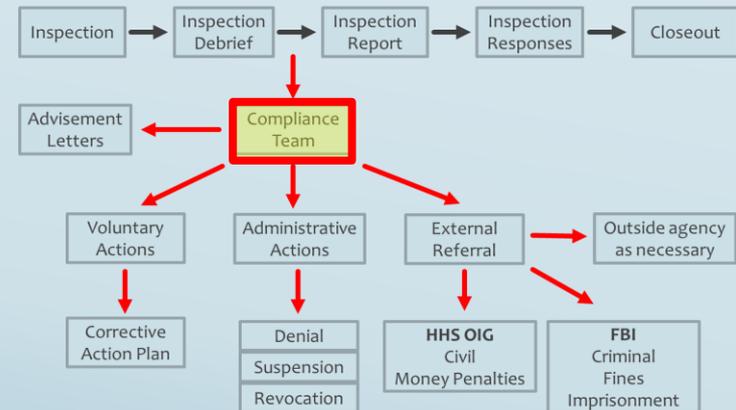
- ❑ **Ensures consistency among teams and findings.**
- ❑ **Inspection team, team lead, operations branch chief security and facility specialist (as needed).**
- ❑ **Reviews inspection observations.**
- ❑ **Assign risk score (0-5) – internal use currently:**
 - **0 – 1.9: Identified compliance matter and requires further action.**
 - **2.0 – 2.9: Identified entity for watch list.**
 - **3.0 – 3.9: Entity is average.**
 - **4.0 – 5.0: Entity is above average.**

DSAT POST INSPECTION ACTIONS

Entities that are identified as having deficiencies of a more serious concern are referred to the DSAT

Compliance Team:

- ❑ **Director**
- ❑ **Deputy Director**
- ❑ **Operations Branch Chief**
- ❑ **Program Services Branch Chief**
- ❑ **Associate Director of Policy**
- ❑ **Associate Director of Science**
- ❑ **Biosafety Manager**
- ❑ **Senior Attorney for the HHS Office of General Counsel**
- ❑ **Team Leads included for issues arising from their respective teams**



DSAT Compliance Team defers to APHIS if USDA-only agent involved.

SELECT AGENT ENFORCEMENT

Voluntary:

- ❑ **Corrective Action Plan (formerly known as Performance Improvement Plan).**

Administrative Actions:

- ❑ **Denial of application.**
- ❑ **Revocation or suspension of registration.**

Civil Money Penalties – Referral to OIG:

- ❑ **Up to \$250K for an individual for each violation.**
- ❑ **Up to \$500K for an entity for each violation.**

Criminal – Referral to FBI:

- ❑ **Imprisonment for up to 5 years, a fine or both.**

VOLUNTARY PROGRAM: CORRECTIVE ACTION PLAN (CAP)

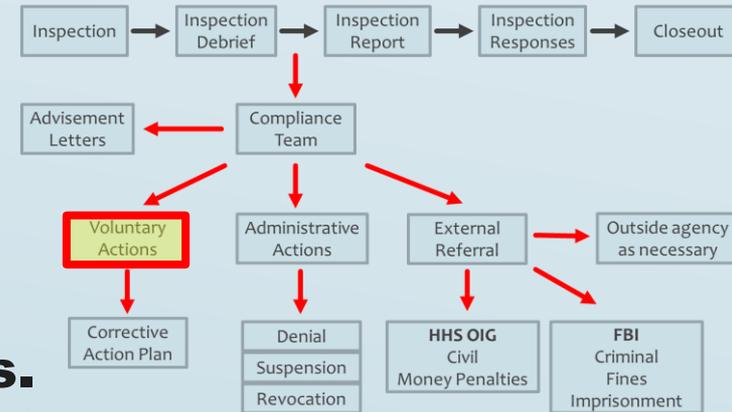
Established March 2008.

Assist entities identified with systemic regulatory departures.

- ❑ Detailed plan to correct departures.
- ❑ Target milestones and completion dates.
- ❑ Entity's progress is monitored.

Participation in CAP:

- ❑ **34** registered entities have agreed to participate in the CAP program.
- ❑ **28** registered entities have successfully completed the CAP program.
- ❑ **5** registered entities are continuing to work with DSAT to meet their CAP goals.
- ❑ **1** entity's registration was revoked due to safety and security concerns.



VOLUNTARY PROGRAM: CORRECTIVE ACTION PLAN (CAP)

Corrective Action Plan– offers the entity the opportunity in lieu of taking steps to immediately suspend or revoke the certificate of registration, to participate in a Corrective Action Plan (CAP) under specified conditions.

Entity must:

- ❑ Submit their written CAP, including milestones for resolution of deficiencies noted in the inspection report; plan must be approved by DSAT.**
- ❑ Provide bi-weekly progress reports detailing the milestones completed.**
- ❑ Notify DSAT immediately of any situation that adversely impacts the plan.**
- ❑ Provide written confirmation as deficiencies are corrected.**
- ❑ Resolve all deficiencies identified in the inspection report.**

VOLUNTARY PROGRAM: CORRECTIVE ACTION PLAN (CAP)

“Show cause” letter accompanies an inspection report containing specific departures from 42 CFR Part 73.

High level summary of non-compliance observed in the latest inspection and/or repeated non-compliance. Tabular example:

	January 2011	January 2014	February 2015
RO oversight/ Registration accuracy	X	X	X
Security plan requirements/ implementation	X	X	X
Biosafety plan requirements	X	X	X
Biosafety plan implementation/ containment practices	X	X	X
Incident response plan requirements	X	X	X
Training	X	X	X
Record Maintenance and Accuracy	X	X	X
Notification of Theft, Loss or Release	X	X	X

Senior leadership of the registered entity may be copied with the correspondence.

VOLUNTARY PROGRAM: CORRECTIVE ACTION PLAN (CAP)

The proposed CAP is reviewed and may or may not be accepted by DSAT. Revisions may be required for proposed action items or milestone.

Unannounced verification inspections are conducted to:

- ❑ Verify progress with the completion of milestones as reported in biweekly updates.**
- ❑ Verify final completion of the CAP.**

New observations during verification inspections may delay closure of the CAP.

DSAT compliance team is given weekly updates of progress.

ADMINISTRATIVE ACTIONS

DSAT Compliance Team may determine that the deficiencies are of grave concern and **allowing the entity to continue work could compromise public health and safety.**

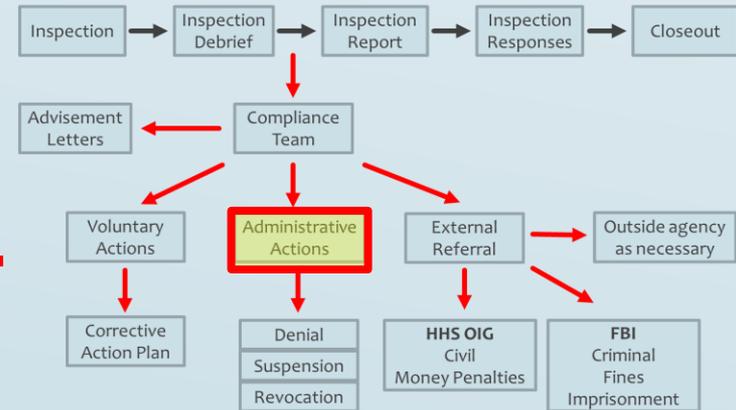
Denial – Registration is not granted.

Suspension – “Cease/desist” letter informs entity to:

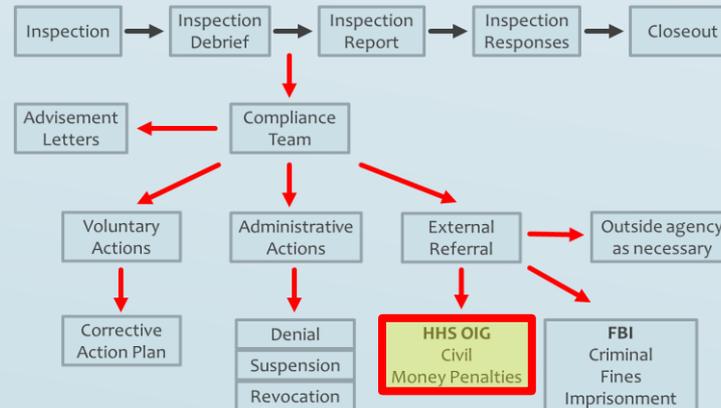
- ❑ **Suspend some or all select agent and/or toxin work.**
- ❑ **Place select agents and/or toxins in a storage only capacity, or transfer to another registered entity.**
- ❑ **Suspension in effect until DSAT/APHIS can determine through further review and inspections that all deficiencies have been satisfactorily resolved.**
- ❑ **Requires approval by the CDC Director.**

Revocation – Termination of a registration:

- ❑ **Requires approval by the CDC Director.**



REFERRALS TO THE HHS OFFICE OF INSPECTOR GENERAL (OIG)



DSAT Compliance Team may determine that the violations of 42 CFR Part 73 constitute a basis for referral to the HHS Office of Inspector General (OIG), based upon the following criteria:

- 1. The possession, use or transfer of a select agent or toxin by a nonregistered individual or entity.**
- 2. The possession, use or transfer of a select agent or toxin by a registered individual or entity where the possession, use or transfer is not reflected on their certificate of registration.**

REFERRALS TO THE HHS OFFICE OF INSPECTOR GENERAL (OIG)

DSAT Compliance Team may determine that the violations of 42 CFR Part 73 constitute a basis for referral to the HHS Office of Inspector General (OIG), based upon the following criteria:

- 3. The possession, use or transfer of a select agent or toxin by an individual or entity who has failed to comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by a revocation or suspension.**
- 4. Allowing a person without approval from the Federal Select Agent Program to have access to a select agent or toxin.**
- 5. Any departure from the select agent regulations that has the result of being a present danger to public health and safety.**

REFERRALS TO THE HHS OFFICE OF INSPECTOR GENERAL (OIG)

DSAT Compliance Team may determine that the violations of 42 CFR Part 73 constitute a basis for referral to the HHS Office of Inspector General (OIG), based upon the following criteria:

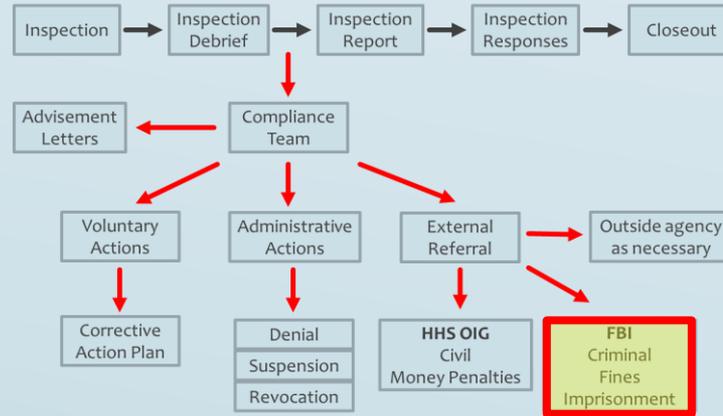
- 6. Allowing the conduct of a restricted experiment without prior authorization.**
- 7. Transferring a select agent or toxin without prior authorization.**
- 8. Failure to maintain complete records with regards to select agents or toxins, as required under Section 17; whoever knowingly possess select agents or toxins or fails to report incidents that could affect public health and safety based on inadequate records.**

REFERRALS TO THE HHS OFFICE OF INSPECTOR GENERAL (OIG)

DSAT Compliance Team may determine that the violations of 42 CFR Part 73 constitute a basis for referral to the HHS Office of Inspector General (OIG), based upon the following criteria:

- 9. Failing to report the identification of a select agent or toxin.**
- 10. Any departure from the select agent regulations that demonstrates a registered individual's or entity's failure to maintain institutional integrity.**
- 11. Failure to adequately resolve repeated inspection deficiencies (i.e., specific observations noted repeatedly on follow-up inspections).**
- 12. Failure to designate a Responsible Official that is approved by the HHS Secretary or Administrator.**

REFERRALS TO THE FEDERAL BUREAU OF INVESTIGATION (FBI)



DSAT Compliance Team may determine that actions by an entity or an individual constitute a basis for referral to the FBI, based upon the following criteria:

- 1. The possession, use or transfer of a select agent or toxin by a nonregistered individual or entity.**
- 2. The possession, use or transfer of a select agent or toxin by a registered individual or entity where the possession, use or transfer is not reflected on their certificate of registration.**

REFERRALS TO THE FEDERAL BUREAU OF INVESTIGATION (FBI)

DSAT Compliance Team may determine that actions by an entity or an individual constitute a basis for referral to the FBI, based upon the following criteria:

- 3. Possession, use or transfer of a select agent or toxin by an individual or entity who has failed to comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by a revocation or suspension.**
- 4. Allowing a person without approval from the Federal Select Agent Program to have access to a select agent or toxin.**
- 5. Any departure from the select agent regulations that has the result of being a present danger to public health and safety.**

REFERRALS TO THE FEDERAL BUREAU OF INVESTIGATION (FBI)

DSAT Compliance Team may determine that actions by an entity or an individual constitute a basis for referral to the FBI, based upon the following criteria:

- 6. Allowing the conduct of a restricted experiment without prior authorization.**
- 7. Evidence of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents.**
- 8. Submitting a false document to DSAT in violation of 42 CFR Part 73.**

DSAT SELECT AGENT ENFORCEMENT ACTIVITIES – SINCE 2003

Administrative Actions:

- ❑ **5** entities were denied registration.
- ❑ **6** entities had their registration suspended.
- ❑ **2** entities had their registration revoked.
- ❑ **Formal appeal process (Section 20).**

Referrals to HHS IG – civil money penalties:

- ❑ **68** entities referred.
- ❑ **20** entities fined (\$2.4M).

Referrals to FBI – criminal penalties:

- ❑ **No criminal prosecutions.**



Federal Select Agent Program Training

**For more information, please contact the Federal Select Agent
Program**

Telephone: 301-851-3300 Option 3 (USDA) or 404-718-2000 (CDC)

E-mail: AgSAS@aphis.usda.gov (USDA) or Irsat@cdc.gov (CDC)

Web: [Federal Select Agent Program](#)

