

FEDERAL SELECT AGENT PROGRAM

2015 Annual Report | Key Statistics

The Federal Select Agent Program (FSAP) published its first annual report of key program data for 2015 as part of its ongoing commitment to increasing transparency and understanding of the program. These data provide insight into work conducted with select agents and toxins at laboratories across the nation, as well as the regulatory functions of the program.

- FSAP is managed jointly by the Centers for Disease Control and Prevention's Division of Select Agents and Toxins & the Animal and Plant Health Inspection Service's Agriculture Select Agent Services
- FSAP regulates the possession, use and transfer of biological select agents and toxins (BSAT) so that important work with potentially dangerous and deadly pathogens is conducted as safely and securely as possible
- BSAT are materials that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products

291
ENTITIES WERE REGISTERED WITH FSAP

32% ACADEMIC
18% COMMERCIAL
15% FEDERAL GOVERNMENT
29% NON-FEDERAL GOVERNMENT
6% PRIVATE
51% of entities are registered for Tier 1* BSAT

TOP REGISTERED AGENTS BY AGENCY

CDC's Division of Select Agents and Toxins

1. *Brucella melitensis*
2. *Brucella suis*
3. *Brucella abortus*
4. *Bacillus anthracis* (Pasteur strain)
5. *Francisella tularensis**
6. *Yersinia pestis**
7. *Bacillus anthracis**
8. *Burkholderia pseudomallei**
9. *Burkholderia mallei**
10. Botulinum neurotoxin producing species of *Clostridium**

APHIS's Agriculture Select Agent Services

1. Avian influenza virus
2. Newcastle disease virus
3. *Brucella abortus*
4. *Bacillus anthracis**
5. *Ralstonia solanacearum*
6. *Xanthomonas oryzae*
7. *Brucella melitensis*
8. *Brucella suis*
9. *Burkholderia pseudomallei**
10. *Burkholderia mallei**

COMPLIANCE & ENFORCEMENT

- 6** entities agreed to participate in a corrective action plan
- 3** entities were put under suspension
- 4** entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services
- 16** entities were referred to FBI (no criminal intents found)

THEFT, LOSS, & RELEASE

- 0** thefts reported
- 12** reports of losses determined to be records management errors or samples mistakenly autoclaved as waste
- 199** potential occupational exposure incidents reported (resulting in monitoring for 908 laboratory workers)
- 0** potential exposures resulting in illness, death, or transmission

TRANSFER APPROVALS: 337 DSAT | 126 AgSAS

- 32%** of these were initiated by unregistered entities, mostly due to identification of BSAT in a diagnostic specimen

216

TOTAL INSPECTIONS CONDUCTED BY FSAP

145 by DSAT
33 by AgSAS
38 joint DSAT & AgSAS

3

AVERAGE DURATION (IN DAYS) FOR INSPECTION

Range of **1 to 8** days

4,426

SECURITY RISK ASSESSMENTS APPROVED IN 2015

Restricted access for **16** individuals

KEY ABBREVIATIONS: **FSAP:** Federal Select Agent Program **CDC:** Centers for Disease Control and Prevention **DSAT:** Division of Select Agents and Toxins **APHIS:** Animal and Plant Health Inspection Service **AgSAS:** Agriculture Select Agent Services **BSAT:** Biological select agents and toxins

*Tier 1 agent, those that pose the greatest risk through misuse