

FEDERAL SELECT AGENT PROGRAM

2016 Annual Report | Key Statistics

The 2016 Annual Report of the Federal Select Agent Program provides continued insight into the work conducted with biological select agents and toxins at laboratories across the nation, as well as the regulatory functions of the Federal Select Agent Program (FSAP). This annual report is FSAP's second report of aggregate program data, and reflects the program's ongoing commitment to transparency and increasing understanding 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

276
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

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES
32% have BSL-2 and/or ABSL-2 labs
80% have BSL-3 and/or ABSL-3 labs
3% have BSL-4 and/or ABSL-4 labs

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**

APHIS's Agriculture Select Agent Services

1. Newcastle disease virus
2. Avian influenza virus
3. *Bacillus anthracis**
4. *Brucella abortus*
5. *Ralstonia solanacearum*

COMPLIANCE & ENFORCEMENT

- 5** entities agreed to participate in a corrective action plan
- 3** entities were put under suspension
- 0** instances of criminal intent found for the 12 matters of which FBI was notified
- 3** entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

- 0** thefts reported
- 8** reports of losses determined to be records management errors
- 177** incidents involving potential occupational exposures reported (resulting in monitoring for 998 laboratory workers)
- 0** potential exposures resulting in illness, death, or transmission

TRANSFER APPROVALS: 188 DSAT | 72 AgSAS

- 38%** of the transfers were from unregistered entities to registered entities, mostly as a result of identification of BSAT in a diagnostic specimen

181

TOTAL INSPECTIONS CONDUCTED BY FSAP

103 by DSAT
29 by AgSAS
49 joint DSAT & AgSAS

3

AVERAGE DURATION (IN DAYS) FOR INSPECTION

Range of **1** to **8** days

3,982

SECURITY RISK ASSESSMENTS APPROVED IN 2016

Denied access for **10** individuals

KEY ABBREVIATIONS:

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

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