FEDERAL SELECT AGENT PROGRAM
2017 Annual Report | Key Statistics

The *2017 Annual Report of the Federal Select Agent Program* continues to provide insight into the regulatory activities of the Federal Select Agent Program (FSAP). The report includes a look at both the regulatory functions of the program, as well as compliance with the select agent regulations at laboratories across the nation. This annual report is FSAP's third 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 and 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

263 ENTITIES WERE REGISTERED WITH FSAP

- **33%** ACADEMIC
- **18%** COMMERCIAL
- **15%** FEDERAL GOVERNMENT
- **29%** NON-FEDERAL GOVERNMENT
- **6%** PRIVATE
- **50%** of entities are registered for Tier 1* BSAT

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

- **31%** have **BSL-2** and/or **ABSL-2** labs
- **79%** 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* *
   Brucella abortus
   Ralstonia solanacearum

COMPLIANCE & ENFORCEMENT

- **8** total entities participated in a corrective action plan (including **1** entity that newly agreed to participate in 2017)
- **4** total entities had suspended registrations (including **2** entities newly put under suspension in 2017)
- **18** matters were shared with the Federal Bureau of Investigation for potential investigation (no action was needed in **17** of those cases, with one pending)
- **7** entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

- **0** thefts reported
- **9** reports of losses determined to be records management errors
- **199** incidents reported involving potential occupational exposure of 1,152 laboratory workers
- **0** potential exposures resulting in illness, death, or transmission

TRANSFER APPROVALS: 177 DSAT | 79 AgSAS

- **29%** of the transfers were from unregistered entities to registered entities, mostly as a result of identification of BSAT in a diagnostic specimen

169 TOTAL INSPECTIONS CONDUCTED BY FSAP
- **106** by DSAT
- **31** by AgSAS
- **32** joint DSAT & AgSAS

2.6 AVERAGE DURATION (IN DAYS) FOR INSPECTION
Range of **1** to **9** days

9,916 ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS
Denied access for **17** individuals

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