

The 2019 Annual Report of the Federal Select Agent Program (FSAP) provides insight into the program's regulatory activities and includes a look at compliance with the select agent regulations at laboratories across the nation. The findings underscore that overall, most laboratories registered with the program are compliant with the regulations, and none of the relatively small number of reported incidents during the year resulted in a risk to public or agricultural health. The report reflects the program's continued commitment to increasing transparency.

## BACKGROUND

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. The program regulates the possession, use, and transfer of biological select agents and toxins – which are materials that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products – so that important work with potentially dangerous and deadly pathogens can be conducted as safely and securely as possible.

# 247

ENTITIES WERE REGISTERED WITH FSAP

**34% ACADEMIC**  
**17% COMMERCIAL**  
**16% FEDERAL GOVERNMENT**  
**28% NON-FEDERAL GOVERNMENT**  
**6% PRIVATE**

Note: Percentages are rounded and do not equal 100%

**51%** of entities were registered for Tier 1\* BSAT

## LAB BIOSAFETY LEVELS (BSL)

### ENTITIES MAY HAVE MULTIPLE TYPES

**30%** had BSL-2 and/or ABSL-2 labs  
**81%** had BSL-3 and/or ABSL-3 labs  
**3%** had 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. *Ralstonia solanacearum*
4. *Xanthomonas oryzae*
5. *Brucella abortus*

## COMPLIANCE & ENFORCEMENT

- 1** total entity participated in a corrective action plan (with **1** entity newly participating in 2019)
- 3** total entities had suspended registrations, either partially or fully (with **1** entity newly put under a full suspension in 2019)
- 18** matters were shared with the Federal Bureau of Investigation for potential investigation (FBI determined no action was needed in **9** of those cases, with **9** pending)
- 1** entity was referred to both the HHS Office of Inspector General and the APHIS Investigative and Enforcement Services

## THEFT, LOSS, OR RELEASE

- 0** thefts reported
- 13** reports of losses determined to be inventory volume discrepancies or record keeping discrepancies
- 0** occupational exposures resulting in illness, death, or transmission, out of the **195** incidents reported involving occupational exposures

## TRANSFER APPROVALS: 136 DSAT | 35 AgSAS

**158** transfers occurred

# 189

TOTAL INSPECTIONS CONDUCTED BY FSAP

**122** by DSAT  
**21** by AgSAS  
**46** joint DSAT & AgSAS

# 2.4

AVERAGE DURATION (IN DAYS) FOR INSPECTION

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

# 8,360

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS

Denied access for **27** 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