

The 2021 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 content underscores that overall, most laboratories registered with the program are compliant with the regulations, and none of the small number of reported incidents during the year resulted in a significant risk to public or agricultural health. The report reflects the program's ongoing commitment to transparency. It provides insight into key ways the program has adapted to carry out its mission during the COVID-19 pandemic and highlights FSAP's efforts to engage with the regulated community throughout the year to ensure regulatory compliance.

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 Division of Agricultural Select Agents and Toxins. 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 dangerous and deadly pathogens can be conducted as safely and securely as possible.

233

ENTITIES WERE REGISTERED WITH FSAP

35% ACADEMIC
17% COMMERCIAL
13% FEDERAL GOVERNMENT
29% NON-FEDERAL GOVERNMENT
6% PRIVATE

55% 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
80% 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 Division of Agricultural Select Agents and Toxins

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

COMPLIANCE & ENFORCEMENT

3 total entities participated in corrective action plans (with **0** entities newly participating in 2021)

2 entities had fully suspended registrations (with **2** new entities put under suspension in 2021)

22 matters were shared with the Federal Bureau of Investigation for potential investigation (FBI determined no action was needed in **8** of those cases, with **14** pending)

0 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 inventory volume or record keeping discrepancies, or loss of experimental material with no evidence that the material left the laboratory

0 releases resulted in illness, death, or transmission among workers or to the outside of a laboratory into the surrounding environment or community (out of **177** reports)

6 webinars for the regulated community on in-depth select agent topics - **1148 total attendees**

2 webinars for the public on regulatory reporting requirements - **411 attendees**

206

TOTAL INSPECTIONS CONDUCTED BY FSAP

139 by DSAT
21 by DASAT
46 joint DSAT & DASAT

19 on-site
106 remote
81 hybrid*

*Combination of on-site and remote

8,367

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS

Denied access for **22** individuals

OUTREACH

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 **DASAT:** Division of Agricultural Select Agents and Toxins

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