

The 2022 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 report also highlights FSAP's efforts to engage with the regulated community throughout the year to enhance regulatory compliance. The content underscores that overall, 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 health or agriculture. The publication, now in its eighth year, reflects the program's ongoing commitment to transparency.

BACKGROUND

FSAP is managed jointly by the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service. 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.

234

ENTITIES WERE REGISTERED WITH FSAP

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

51% of entities were registered for Tier 1* select agents and toxins

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

28% 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

Centers for Disease Control and Prevention

1. *Brucella melitensis*
2. *Brucella suis*
3. *Brucella abortus*
4. *Bacillus anthracis* (Pasteur strain)
5. *Francisella tularensis**

Animal and Plant Health Inspection Service

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 2022)

0 entities had suspended registrations

24 security-related matters were shared with the Federal Bureau of Investigation for potential investigation (none were considered by the FBI for criminal investigation)

0 entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

0 thefts reported

6 reports of losses determined to be related to record keeping issues and not the actual loss of material

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 **170** reports)

197

TOTAL INSPECTIONS CONDUCTED BY FSAP

133 by CDC
18 by APHIS
46 joint CDC & APHIS

8,516

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS

Denied access for **16** individuals

OUTREACH

5 webinars for the regulated community on in-depth select agent topics – **984 total attendees**

43 entities contacted as a result of emergency management activities during which FSAP offered assistance due to events such as severe weather, natural disasters, or other situations with potential impacts to safety or security (**7** events, **0** entities required assistance)

KEY ABBREVIATIONS:

FSAP: Federal Select Agent Program **ABSL:** Animal Biosafety Level
CDC: Centers for Disease Control and Prevention **APHIS:** Animal and Plant Health Inspection Service

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