FEDERAL SELECT AGENT PROGRAM • 2023 ANNUAL REPORT | KEY STATISTICS

INTRODUCTION

The *2023 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 and toxin 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 ninth 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.

226 ENTITIES WERE REGISTERED WITH FSAP

- 36% ACADEMIC
- 29% NON-FEDERAL GOVERNMENT
- 16% COMMERCIAL
- 13% FEDERAL GOVERNMENT
- 5% PRIVATE

Percentages do not add up to 100% due to rounding.

50% of entities were registered for Tier 1* select agents and toxins

TOP REGISTERED AGENTS BY AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

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

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. Newcastle disease virus
2. Avian influenza virus
3. *Ralstonia solanacearum*
4. *Xanthomonas oryzae*
5. African swine fever virus
   *Bacillus anthracis**
   Brucella abortus

Some positions have multiple agents tied.

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

- **29%** had **BSL-2** and/or **ABSL-2** labs
- **79%** had **BSL-3** and/or **ABSL-3** labs
- **3%** had **BSL-4** and/or **ABSL-4** labs

OUTREACH

6 webinars for the regulated community on in-depth select agent and toxin topics
1,483 total attendees

17 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)

TOTAL INSPECTIONS CONDUCTED BY FSAP — 197

- **124** by CDC
- **23** by APHIS
- **50** joint CDC & APHIS

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS — 8,599

Denied access for **17** individuals

COMPLIANCE & ENFORCEMENT

- **1** entity participated in a corrective action plan (with **0** entities newly participating in 2023)
- **1** entity had its registration revoked
- **0** entities had suspended registrations
- **16** security-related matters were shared with the Federal Bureau of Investigation for potential investigation (**7** were considered for criminal investigation)
- **1** entity was referred to the Department of Health and Human Services Office of Inspector General (with **0** entities referred to APHIS Investigative and Enforcement Services)

THEFT, LOSS, OR RELEASE

- **0** thefts reported
- **8** reports of losses determined to be related to record keeping issues and not the actual loss of material
- **0** releases resulted in illness among the general public, death or transmission among workers, or transmission to the outside of a laboratory into the surrounding environment or community (out of **215** reports)
- **1** report of occupational exposure resulted in illness of a worker, but no disease transmission to others

KEY ABBREVIATIONS:

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

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

Source: *2023 Annual Report of the Federal Select Agent Program*, October 2024 | www.selectagents.gov/annualreport2023.html