

# History and Evolution of the U.S. Federal Select Agent Program (FSAP)



# Agenda

- Early Days
- Founding FSAP
- Today's Program
- Then vs. Now
- Looking Forward



# 20 Years of the Federal Select Agent Program (FSAP)!

- Started with the signing of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a) and the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401)
- Regulations phased in throughout the course of 2003
- Federal Select Agent Program established as a joint-agency effort (Centers for Disease Control and Prevention/Animal and Plant Health Inspection Service)
- As a result, FSAP has improved the safety and security of this work in laboratories nationwide
- 2023 marks 20 years!



# Program Metrics



Since 2003, there have been:

- NO confirmed thefts of a select agent or toxin from a registered entity
- NO deaths among laboratory workers
- NO reported cases of illness or death in the general public due to work with select agents and toxins in regulated laboratories
- NO animal or plant disease outbreaks due to work with these agents in regulated laboratories



# Impact

- FSAP helps to ensure the safety and security of work with these dangerous biological agents and toxins – inside and outside of the laboratory
- This essential work leads to important scientific discoveries that can improve detection and prevention of human, animal, and plant diseases, as well as diagnostic and treatment options to address them
- Data from recent years shows that overall:
  - **Most registered laboratories are compliant** with the regulations
  - **No reported incidents have resulted in a significant risk** to public or agricultural health



# Early Days



# Before the Select Agent Regulations



- Throughout the 1980s and 90s, several incidents led to the development of the select agent and toxin regulations
  - 1995 – *Yersinia pestis*, Larry Wayne Harris
- At that time, there were **no registration and limited safety requirements** for laboratories or individuals engaged in the transfer of human disease-causing pathogens or toxins within the United States, and no federal requirements to report the transfer of these agents
- While there were some regulations and interstate permitting for livestock, plant pests, and plant diseases (including limited inspections), these **efforts were less robust**



# Antiterrorism and Effective Death Penalty Act of 1996

- Congress passed Section 511 of the **Antiterrorism and Effective Death Penalty Act of 1996** to address concerns about how easy it was to legally obtain biological agents that could cause disease in humans
- HHS was directed to establish:
  - A list of biological agents and toxins that have the potential to threaten public health and safety (select agents)
  - Register entities and identify procedures governing the transfer of those agents
  - Create safety/training requirements for entities transferring select agents
- As a result, regulatory program was established at CDC
- Served as the foundation for today's program

One Hundred Fourth Congress  
of the  
United States of America

AT THE SECOND SESSION

*Began and held at the City of Washington on Wednesday,  
the third day of January, one thousand nine hundred and ninety-six*

An Act

To deter terrorism, provide justice for victims, provide for an effective death penalty,  
and for other purposes.

*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Antiterrorism and Effective  
Death Penalty Act of 1996".





# Brief Timeline

- 2001 anthrax attacks led to strengthening of the program
- **Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act, October 2001)**
  - Restricts who may have access to select agents – established criteria for those prohibited from having access to select agents and toxins
- **Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Title II)/Agricultural Bioterrorism Protection Act of 2002 (June 2002)**
  - Legal authority for the current Federal Select Agent Program
  - Required security measures in addition to biosafety measures
  - Strengthened the regulatory authorities of HHS
  - Granted comparable regulatory authorities to USDA
  - **Ultimately, required HHS and USDA to publish regulations to strengthen oversight of select agents and toxins that have the potential to pose a severe threat to public health – as well as to animal and plant health, or to animal and plant products**



# Founding FSAP



# Federal Select Agent Program Founded

- HHS delegated its authority to CDC; USDA delegated its authority to APHIS
- Managed jointly by:



- The **Division of Regulatory Science and Compliance** (DRSC), Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS)
- The **Division of Agricultural Select Agents and Toxins** (DASAT), Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA)
- HHS-only, USDA-only, and overlap select agents and toxins
- In addition, the Attorney General was given the authority and responsibility to conduct **security risk assessments** on entities and personnel to identify if they are “restricted” under the USA PATRIOT Act or reasonably suspected of committing Federal crimes of terrorism (delegated to FBI)



# 2003 - Implementation of the Select Agent Regulations: Key Milestones

- Interim Final Rule published in December 2002
- If entity **was** already registered under 42 CFR 72.6\* (biosafety components):
  - By February 7, 2003 – registration application must be submitted (to meet new regulatory requirements, including security provisions)
    - As required under §72.6, they would have already identified a Responsible Official (RO), and met the safety, emergency response, training, and records provisions in the regulations
  - **By November 12 – must be registered with the program to continue to work with select agents/toxins**
- If entity **was not** already registered under §72.6:
  - On February 7, 2003 – open for registration; could begin to submit applications
  - By November 12 – must be registered to work with select agents/toxins and comply with all regulatory requirements
  - **NO work conducted until registration completed**

**\*Note: There was no comparable existing USDA authority at the time**



# Comparison of Program Functions

## Before 2003

- CDC:
  - Laboratory Registration for Select Agents and Toxins (LRSAT)
  - Limited in scope (required program to develop list of agents; register entities; and set requirements related to biosafety, training, and emergency response)
  - Program was more hands-off in terms of oversight
- APHIS:
  - Regulated importation and domestic movement of organisms and vectors of livestock diseases and plant pests

## After 2003

- FSAP established jointly by CDC and APHIS
- Several regulatory requirements were added (e.g., security risk assessments, security measures)
- Program took a much more active role in oversight
- Established active inspection efforts



# Final Select Agent Regulations

- Published in Federal Register on March 18, 2005:
  - 7 C.F.R. Part 331 (plants and plant products)
  - 9 C.F.R. Part 121 (animals and animal products)
  - 42 C.F.R. Part 73 (public health)
- While most of the existing regulatory requirements remained the same, the Final Rule included some clarifications as well as additions in order to ensure the regulations met the purpose of ensuring safety/security in the best way possible

**Federal Register / Vol. 70, No. 52 / Friday, March 18, 2005 / Rules and Regulations**



# Today's Program



# Key Regulatory Functions and Activities

- Promulgate the select agent and toxin regulations
  - Develop, implement, enforce
- Provide oversight of possession, use, and transfer
- Conduct inspections and approve registrations
- Approve individual access to select agents and toxins
- Receive reports of a theft, loss, or release
- Take appropriate enforcement actions
- Serve as a resource on compliance with the regulations





# FSAP 2021: Key Facts

- **233** registered entities
- **206** inspections conducted
- **8,367** active individual security risk assessments
  - Denied access for **22** individuals
- **0** releases resulted in illness, death, or transmission among workers or to the outside of a laboratory into the surrounding environment or community

## FEDERAL SELECT AGENT PROGRAM 2021 ANNUAL REPORT | KEY STATISTICS

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

Source: 2021 Annual Report of the Federal Select Agent Program, September 2022 | [www.selectagents.gov/annualreport2021.html](http://www.selectagents.gov/annualreport2021.html)

Source: 2021 Annual Report of the Federal Select Agent Program,  
<https://www.selectagents.gov/annualreport2021.html>



# Then vs. Now



# Registration Over Time

**7636** Approved  
Individuals  
(2003-2004)

As of 12/31/03,  
**521** registered  
entities (431 DRSC  
and 90 DASAT)

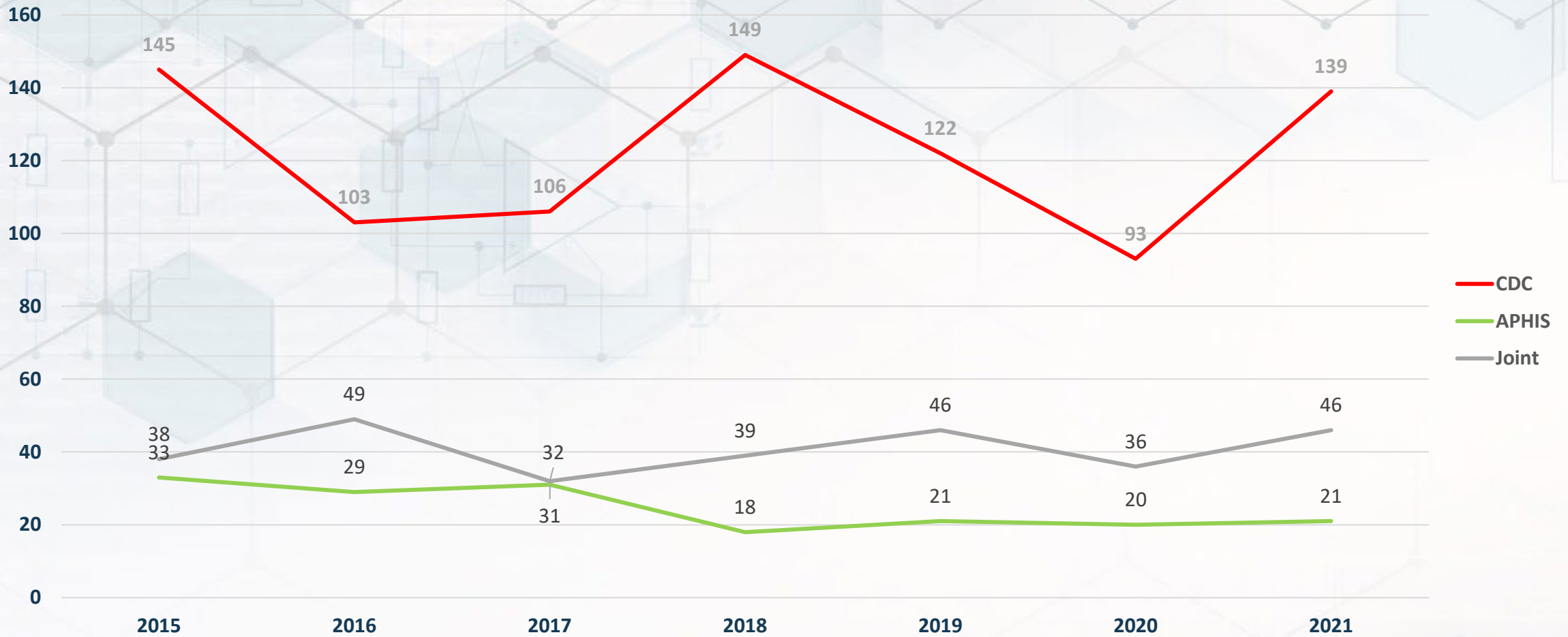
As of 12/31/22,  
**234** registered  
entities (198 DRSC  
and 36 DASAT)

As of 12/31/13,  
**327** registered  
entities (284 DRSC  
and 43 DASAT)

**8516** Approved  
Individuals  
(2023)



# Inspections, by Year (2015-2021)



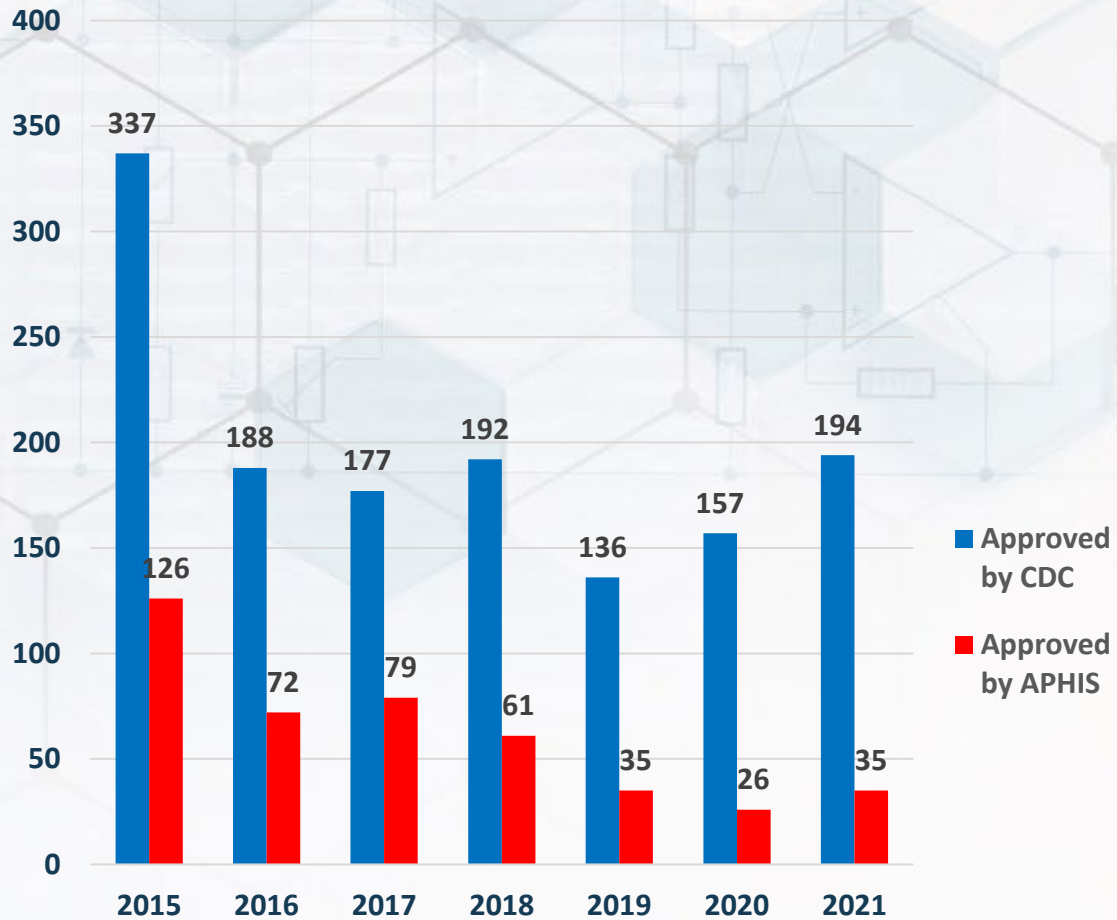
# Limited Occupational Illness

- Since 2003 – out of almost 3,600 reports of releases, **only three** occupational exposures have led to illness
  - Involved *Brucella melitensis* (1) and *Coxiella burnetii* (2)
- **NONE** of the infections were transmitted among workers, nor was there transmission outside of a laboratory into the surrounding environment or community.

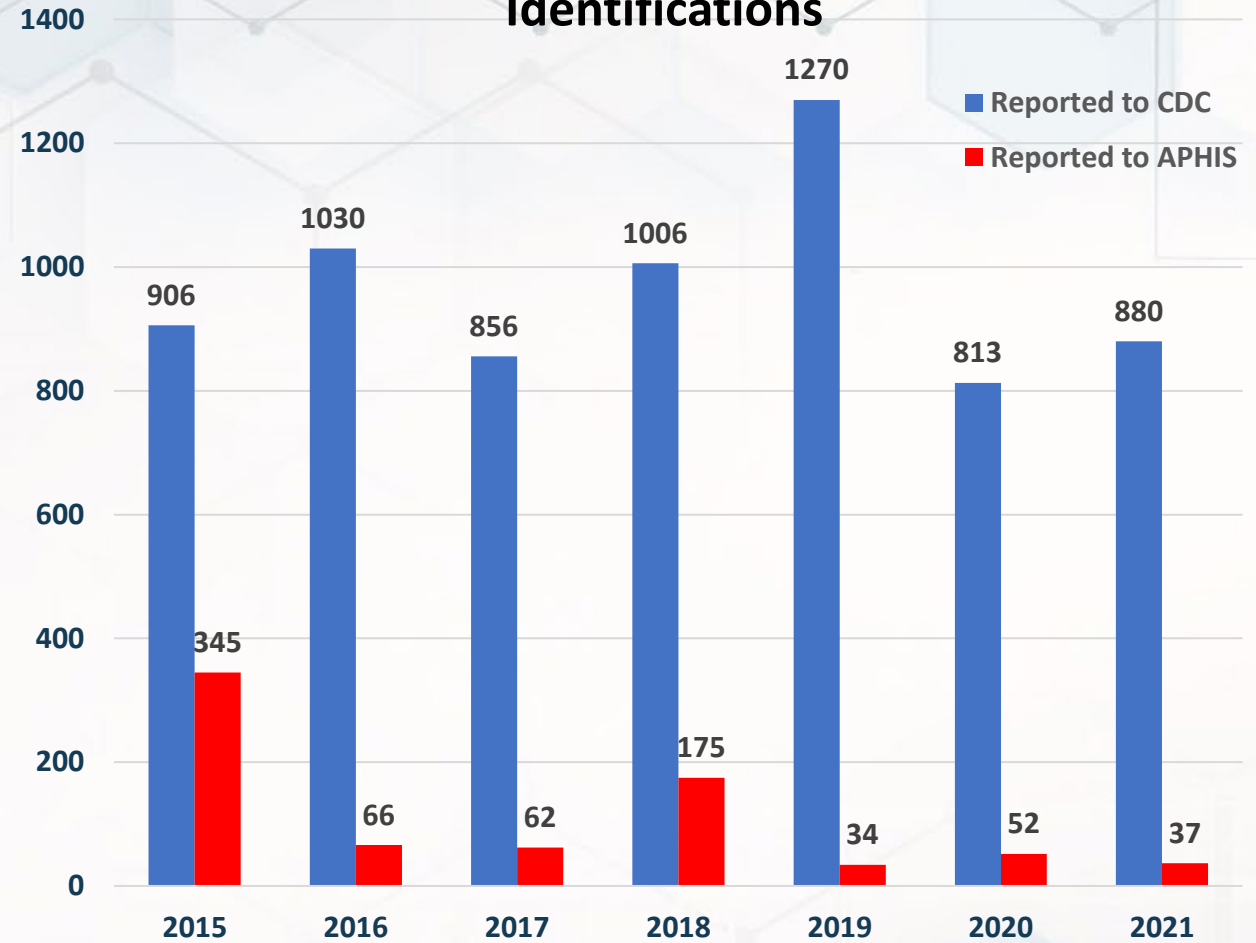


# Transfers and Identifications, by Agency (2015-2021)

## Transfers



## Identifications



# Looking Forward



# Looking Forward – What's Next?

- Continuing to embrace new technology through development and implementation of the eFSAP information system
- Keeping pace with evolving science





[www.selectagents.gov](http://www.selectagents.gov)

CDC Contact Information  
Division of Regulatory Science  
and Compliance  
[LRSAT@cdc.gov](mailto:LRSAT@cdc.gov)  
404-718-2000

APHIS Contact Information  
Division of Agricultural  
Select Agents and Toxins  
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Animal and Plant Health Inspection Service.

