

Federal Select Agent Program Inspection Overview



Agenda

- Background information
 - Regulatory authority, entity types and biosafety levels
- FSAP 2023 inspections
 - Inspections and future projections
- Inspection preparation
 - Inspection types and complexity scores, documents and planning tips
- Discussion



Regulatory
Authority



FSAP Regulatory Authority

- 42 CFR Part 73 (Public Health)
 - HHS Select Agents and Toxins and Overlap
- 9 CFR Part 121 (Animal and Animal Products)
 - USDA Veterinary Services (VS) Select Agents and Overlap
- 7 CFR Part 331 (Agriculture)
 - USDA Plant Protection and Quarantine (PPQ) Select Agents

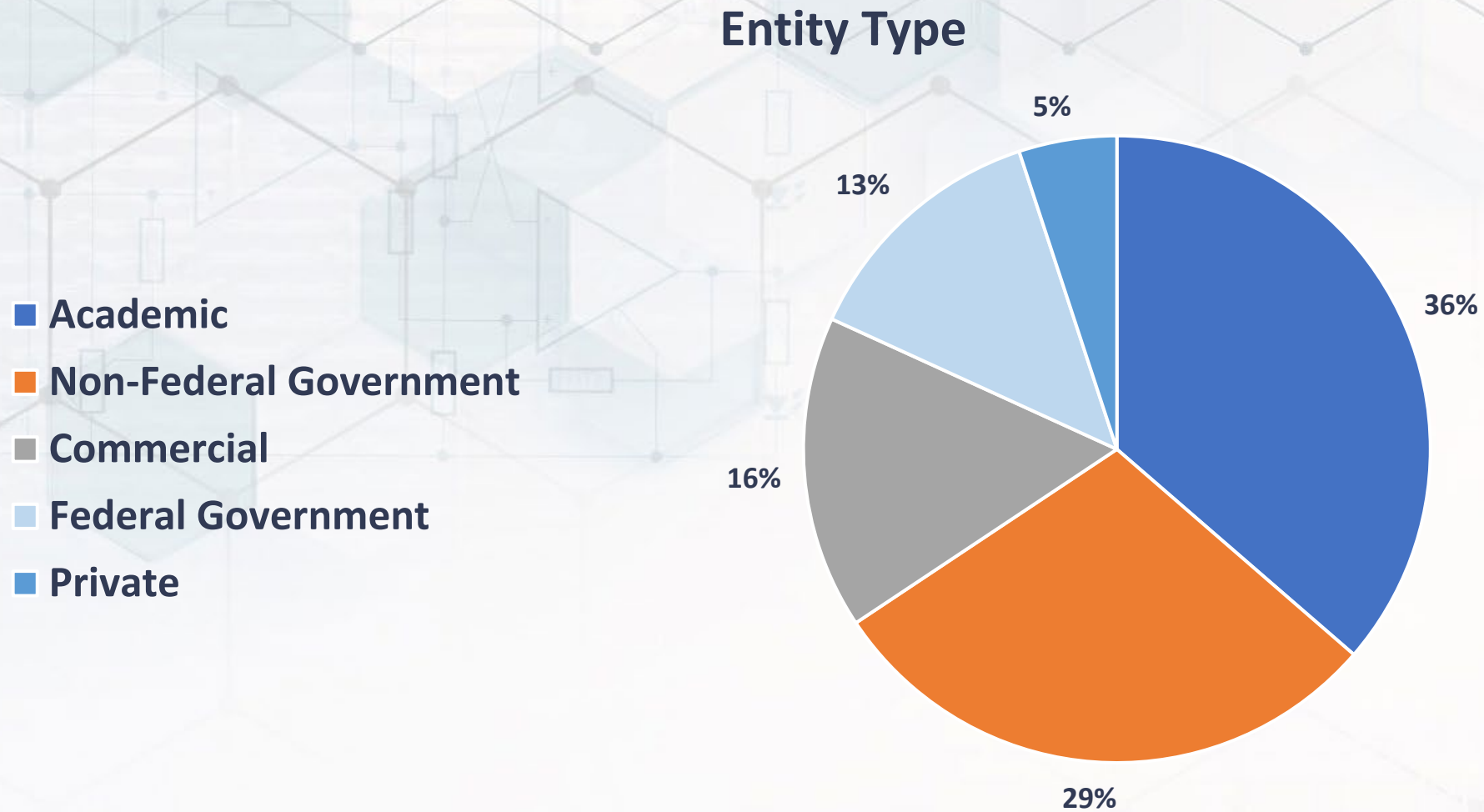


FSAP Lead Agency – 2023

- 226 FSAP-registered entities as of December 31, 2023
 - 25 with DASAT as lead agency
 - 154 with DRSC as lead agency
 - 47 of 226 managed jointly
 - 11 with DASAT as lead agency
 - 36 with DRSC as lead agency



Entity Type – 2023



Entity Biosafety Levels – 2023

Laboratory Type: Biosafety Level	Total Registered Entities	Registered for Tier 1 BSAT	Academic	Non-Federal Government	Commercial	Federal Government	Private
BSL-2/ABSL-2	66	49	21	10	18	13	4
BSL-3/ABSL-3	182	94	69	65	17	20	11
BSL-4/ABSL-4	8	8	2	0	0	5	1



FSAP 2023 Inspections



FSAP Inspections – 2023

- 198 Total Inspections
 - 24 DASAT
 - 124 DRSC
 - 50 Joint:
 - 15 DASAT-led
 - 35 DRSC-led



Inspection Classifications

- Renewals
- Verifications
- Maximum Containment
- Amendment Assessment
- New Registration
- Compliance



Inspection Classifications – 2023

Inspection Type	DASAT	DRSC	Joint
Renewal	7	66	10
Verification	16	55	30
Maximum Containment	0	3	5
Amendment Assessment	1	5	5
New Registration	0	3	1
Compliance	0	0	1



Inspection Types

- On-Site
 - Announced
 - Unannounced
- Remote
 - Announced
- Hybrid
 - Announced remote portion
 - Announced or unannounced on-site portion



FSAP Inspection Projections: CY2024 and Beyond

- Risk-based annual inspections for DRSC entities with a complexity score of 100 or above will continue
- Annual inspections of DASAT entities will continue
- Annual inspections for BSL-4 laboratories



Inspection Updates

- No major updates currently
- Continue to conduct remote, hybrid, and onsite inspections
- More joint inspections with FSAP partners:
 - Other CDC Programs (IPP, NAC)
 - Other Federal Partners (DHS, FDA, DAIG and others)



Inspection Updates—SA Grams

- SA Grams (2024)
 - 6/6/2024 - H5 Avian Influenza Virus Exemption
 - 8/12/2024 - Updated Avian Influenza Virus Guidance
 - 8/22/2024 - Clarification of “Annual” in A/BSL-4 Verification Policy



Inspection Preparation



Entity Complexity Score Criteria

- Complexity scores are based on criteria including:
 - Possession
 - Size
 - Risk group
 - Tier 1
 - Animals
 - Inactivation
 - Large scale growth of agent
 - Compliance



Entity Complexity Scores—DRSC

- Entities divided into:
 - Non-possessors/Storage only
 - Likely to be a remote inspection outside of renewal
 - Below 100
 - Likely to be visited once between renewals
 - 100 and above
 - Likely to be visited annually between renewals



FSAP Inspection Type vs. Entity Complexity—DRSC

- **Renewal: Announced**
 - Not more than three years, announced
- **On-Site Verification: May be unannounced**
 - Annually for higher complexity entities
 - Once per renewal cycle for lower complexity entities
- **Remote Verification: Announced**
 - During renewal cycle for a non-possessor/storage only facility
 - Prelude to on-site portion of hybrid verification



FSAP Inspection Type vs. Entity Complexity—DASAT

- **Renewal: Announced**
 - Not more than three years, announced
- **Verification: May be unannounced**
 - Annually



Inspection Planning – Announced

- Up to 6 months prior to inspection
 - Responsible Official (RO) will be contacted with potential inspection dates
- 1 to 2 months prior to inspection
 - Lead Inspector will reach out to RO to start planning for inspection
 - Documents to be reviewed, interview candidates, tentative agenda
 - Reviewing Form 1 Section 5C
- 1 to 3 weeks prior to inspection
 - Agenda finalized, RO begins plans for escorts and other logistics
 - RO prepares documents and begins to upload to eFSAP



Inspection Planning – Unannounced

- Notification – day before or day of inspection:
 - Lead Inspector contacts RO about upcoming inspection
 - Provides tentative agenda and document request list
 - Inspection team arrives; Section 5C information is referenced
- At start of inspection:
 - Lead Inspector and RO will discuss space and escort logistics
 - Tentative agenda will be planned
 - Additional document requests made



Section 5C Review

- Directions to entity and parking information
 - Parking app? Visitor spaces? Parking passes?
- Identification or security measures
- Personal protective equipment
 - What will an entity provide?
- Medical documentation requests
 - Vaccines, titers or TB testing and timeframe?



eFSAP

- eFSAP is the official information system for FSAP
 - It is preferred that certain documents (plans) be uploaded into eFSAP, even if an alternate file sharing system is used



Documents: eFSAP

- Documents must be:
 - Promptly produced upon request, including any referenced documents or Standard Operating Procedures (SOPs) needed to meet the regulatory requirements
 - Under 25MB if uploaded to eFSAP
- Documents that must be reviewed on site or include large file sizes:
 - Discuss with Lead Inspector



Documents: Organization and Nomenclature

- Upload Biosafety, Security, and Incident Response Plans and other commonly requested files early
- Collate documents such as BSC and HEPA certifications
- Be consistent with file naming practices
 - Include version numbers, if applicable
 - Use short but descriptive file names
 - Use common abbreviations
 - Tip: keep a spreadsheet of files uploaded



Pre-Planning for an Inspection – Tips

- As documents become available throughout the year, upload into eFSAP to save time during inspection
 - Certifications
 - RO inspection checklists
 - Annual reviews/updates of plans
- Keep a spreadsheet or notes to match the organized documents
- Devise a plan for file sharing



Pre-Planning for an Inspection – Additional Tips

- Consider using FSAP checklists for internal inspections, inspection preparations and verification policies
 - Collate/organize ABSL-3/BSL-3 or ABSL-4/BSL-4 verification data with a summary of work and dates
- Be familiar with the regulations and checklists as a reference for inspector requests and required documentation





FSAP Inspection Checklists

- Biosafety
- Security
- Incident Response
- Training
- Records
- Agent Specific
- Others

With regulatory reference

Regulatory Checklists

[ABSL-2](#)  [PDF - 127 KB]

[ABSL-3](#)  [PDF - 151 KB]

[ABSL-3 Ag.](#)  [PDF - 272 KB]

[ABSL-4](#)  [PDF - 145 KB]

[ACL-3](#)  [PDF - 80 KB]

[Agent Special Requirements: 1918 Influenza, Poxvirus, RVFV, SARS CoV, VEEV](#)  [PDF - 94 KB]

[Agent Specific: ASFv, CSFv](#)  [PDF - 54 KB]


[Agent Specific: Avian Influenza Virus](#)  [PDF - 126 KB]

[Agent Specific: FMD and Rinderpest Additional Security](#)  [PDF - 110 KB]

[Agent Specific: Newcastle Disease Virus](#)  [PDF - 107 KB]

[Agent Specific: Rinderpest](#)  [PDF - 110 KB]

[Agent Specific: VEEV, RVFV](#)  [PDF - 104 KB]

[Biocontainment BSL-3](#)  [PDF - 106 KB]

[Biocontainment: Plant Containment](#)  [PDF - 138 KB]

[BSL-3](#)  [PDF - 110 KB]

[BSL-4 Cabinet](#)  [PDF - 123 KB]

[BSL-4 Core](#)  [PDF - 174 KB]

[BSL-4 Suit](#)  [PDF - 180 KB]

[General Biocontainment](#)  [PDF - 223 KB]

[General Biosafety](#)  [PDF - 320 KB]

[Incident Response](#)  [PDF - 99 KB]

[NIH BL4 Animals](#)  [PDF - 355 KB]

[NIH BL4](#)  [PDF - 130 KB]

[Records](#)  [PDF - 138 KB]

[Registration](#)  [PDF - 93 KB]

[Responsible Official](#)  [PDF - 99 KB]

[Security](#)  [PDF - 154 KB]

[Toxin](#)  [PDF - 142 KB]

[Training](#)  [PDF - 88 KB]



Inspection Resources (www.selectagents.gov)

Overview ▾ Select Agents & Toxins ▾ Compliance ▾ Regulations & Policies ▾ Forms ▾ Resources ▾ eFSAP ▾

- FAQs
- Guidance Documents
- Preparing for an Inspection
- Security Risk Assessments
- Severity Spectrum and Enforcement Options
- Compliance Infographics

2023 Federal Select Agent Inspection Report Program Annual Summary

CDC USDA

This screenshot shows the 'Compliance' dropdown menu open. The menu items are: FAQs, Guidance Documents, Preparing for an Inspection, Security Risk Assessments, Severity Spectrum and Enforcement Options, and Compliance Infographics. The background features a blue header with navigation tabs and a main banner with the text '2023 Federal Select Agent Inspection Report Program Annual Summary' and the CDC and USDA logos.

Overview ▾ Select Agents & Toxins ▾ Compliance ▾ Regulations & Policies ▾ Forms ▾ Resources ▾ eFSAP ▾

- Select Agents Regulations
- Policy Statements
- Regulatory Interpretations
- Veterinary Services Memoranda
- Department of Transportation Clarification

2023 Federal Select Agent Inspection Report Program Annual Summary

CDC USDA

This screenshot shows the 'Regulations & Policies' dropdown menu open. The menu items are: Select Agents Regulations, Policy Statements, Regulatory Interpretations, Veterinary Services Memoranda, and Department of Transportation Clarification. The background features a blue header with navigation tabs and a main banner with the text '2023 Federal Select Agent Inspection Report Program Annual Summary' and the CDC and USDA logos.



Flexibility and Communication

- Even in announced inspections, flexibility is a necessity!
- Communication between parties is key for the positive flow of an inspection.



www.selectagents.gov

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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.

