

# Plant Pathogen Select Agents: Inspection Preparation and A Look at 7 CFR Part 331 Departure Trends 2019-2023



# Agenda

- Global Impacts of Plant Pathogens
- Plant Pathogen Select Agents and Modes of Transmission
- Inspection Categories
- Plant Pathogen Select Agent Regulations and Guidelines
- Preparing for a Plant Pathogen Select Agent Inspection
- Preparing for Renewal Inspections
- A look at 7 CFR Part 331 departure trends over 5 years (2019-2023)
- Most Recurrent Unique Identifier Numbers (UID's) Under 7 CFR Part 331 From 2019-2023



# Global Impacts of Plant Pathogens

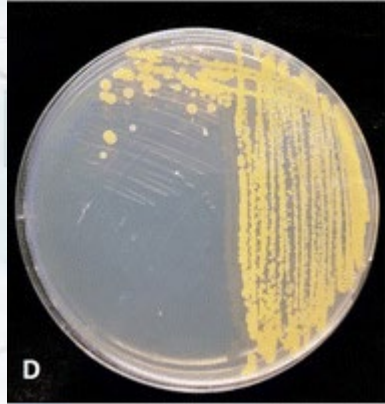
- **Global trade increases the likelihood of new pathogen introductions**
- **Low or no genetic diversity in crops → greater likelihood for significant losses with new/emerging pathogens**
- **Plant pathogen resistance to pesticides**
- **Interdependent global food system**
- **Agro-terrorism**
- **Increase in evolution of trans-kingdom pathogens**
- **Countless significant global environmental impacts**



# Plant Pathogen Modes of Transmission

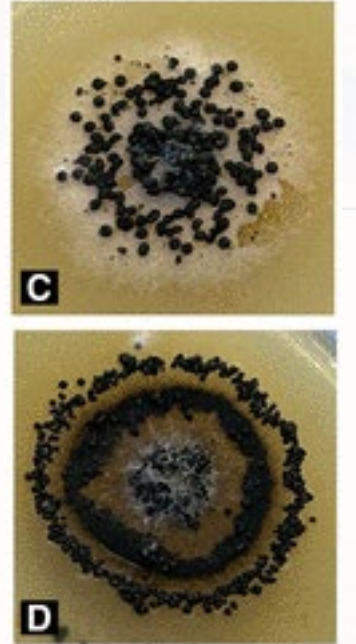
## Bacterial Plant Pathogens

- Not airborne
- Moves via water
- Mechanically transmitted
- Infected seed or plant parts
- Soil



## Fungal Plant Pathogens

- Airborne
- Thick-walled spores
- Moves via water
- Mechanically transmitted
- Seed borne



# Inspection Categories



# Inspection Categories

- **Renewal** inspections generally occur once every 3 years preceding the registration expiration
- Generally, 1-2 **Verification** inspections occur during the 3-year approval
- **Compliance** or **Form 3** inspections are generally triggered by an event
- **Amendment, New Registration, or Request for Assistance** inspections are generally initiated by the entity
- Multiple categories can be assigned to a single inspection



A close-up photograph of a scientist in a laboratory. The scientist is wearing a white lab coat over a blue shirt and a dark tie. They are also wearing clear safety glasses and a white surgical mask. The scientist is holding a clipboard and a pen, looking down at the clipboard. The background is a blurred laboratory setting with various pieces of equipment.

## Plant Pathogen Select Agent Regulations and Guidelines

# Plant Pathogen Select Agent Regulations and Guidelines

- 7 CFR Part 331- Possession, Use, & Transfer of Select Agents & Toxins  
<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-331>
- A Practical Guide to Containment: Plant Biosafety in Research Greenhouses  
<https://vtechworks.lib.vt.edu/items/586974ff-6e77-443a-add5-c881e693b569>
  - *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 6<sup>th</sup> ed
  - NIH Guidelines - <https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2> – April 2024 (Appendix L – Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants)
- FSAP website - <https://www.selectagents.gov/>





A close-up photograph of a person in a laboratory setting. The person is wearing a white lab coat over a light blue shirt and a dark tie. They are also wearing clear safety glasses and a white surgical mask. They are holding a dark clipboard with a white sheet of paper and a pen in their right hand, which is wearing a blue nitrile glove. The background is a blurred laboratory environment with various pieces of equipment and shelves.

## Preparing for a Plant Pathogen Select Agent Inspection

# Preparing for a Plant Pathogen Select Agent Inspection (1/7)

Federal Select Agent Program Website - <http://www.selectagents.gov/>



## Anonymous Reporting

To report safety, security, or other concerns associated with select agents and toxins, please use the Office of Inspector General (OIG)'s confidential hotline. When reporting these issues to OIG, please ensure that you indicate it is a "Select Agent Complaint" issue.

### OIG Hotline contact information

Voice: 1-800-HHS-TIPS (800-447-8477)

Fax: 1-800-223-8164

Web: <https://oig.hhs.gov/fraud/report-fraud/index.asp>

### Mail:

Office of Inspector General  
Department of Health & Human Services  
Attn: Hotline  
P.O. Box 23489  
Washington, DC 20026

### USDA OIG Hotline contact information

Voice: 1-800-424-9121

Fax: 1-202-690-2474

Web: <https://www.usda.gov/oig/hotline>

### Mail:

United States Department of Agriculture  
Office of Inspector General  
P.O. Box 23399  
Washington, DC 20026-3399

Centers for Disease Control and Prevention  
Division of Regulatory Science and Compliance  
1600 Clifton Road, NE, Mailstop H21-4  
Atlanta, GA 30329

Telephone: 404-718-2000  
404-488-7100 (after hours)  
Fax: 404-718-2096  
Email: [LRSAT@cdc.gov](mailto:LRSAT@cdc.gov)

Animal and Plant Health Inspection Service  
Division of Agricultural Select Agents and Toxins  
4700 River Road, Unit 2, Mailstop 22, Cubicle 1A07  
Riverdale, MD 20737

Telephone: 301-851-2070  
Fax: 301-734-3652  
Email: [DASAT@usda.gov](mailto:DASAT@usda.gov)  
HHS Vulnerability Disclosure Policy  
HHS Responsible Disclosure

## Email Updates

Sign up with your e-mail address to receive updates from the Federal Select Agent Program

What's this?



# Preparing for a Plant Pathogen Select Agent Inspection (2/7)

The screenshot shows the top navigation bar with the CDC and USDA logos and the text "FEDERAL SELECT AGENT INSPECTION". Below the logo is a navigation bar with three tabs: "Overview", "Select Agents & Toxins", and "Compliance". A dropdown menu is open under "Overview", listing the following items: Home, About Us, History, What's New, and Leadership. A black oval highlights this dropdown menu.

The screenshot shows the same website as the first image, but with the "Select Agents & Toxins" tab selected. A dropdown menu is open under this tab, listing the following items: Select Agents & Toxins, List, Exclusions, Exemptions, and Permissible Toxin Amounts. A black oval highlights this dropdown menu.



# Preparing for a Plant Pathogen Select Agent Inspection (3/7)

The image shows a screenshot of a website with a navigation menu on the left and a list of regulatory checklists on the right. A black circle highlights the 'Preparing for an Inspection' option in the navigation menu.

**Navigation Menu:**

- Toxins ▾
- Compliance ▾
- Regulations & Policies ▾
- Forms

**Preparing for an Inspection (highlighted):**

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

**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]



# Preparing for a Plant Pathogen Select Agent Inspection (4/7)

<b>Compliance – Guidance Documents Plans and Personnel</b>	Annual Inspections; Biosafety/Biocontainment Plan; Drills and Exercises; Select Agent Regulation Training Requirements; Incident Response Plan; Information Systems Security Controls; Occupational Health Program; Responsible Official Resource Manual; Security Plan
<b>Shipping and Storage</b>	Completing the Shipper's Declaration for Dangerous Goods; Inventory of Select Agents and Toxins; Transfer of Select Agents and Toxins
<b>Select Agent and Toxin Use</b>	Exclusions; Inactivation or Removal of Select Agents and Toxins for Future Use; Regulation of Select Agent and Toxin Nucleic Acids; Restricted Experiments;



# Preparing for a Plant Pathogen Select Agent Inspection (5/7)

## AGENT PROGRAM

Search

Home

Regulations & Policies

Forms

Resources

Select Agents Regulations

Policy Statements

Regulatory Interpretations

Veterinary Services Memoranda

Department of Transportation Clarification

## AGENT PROGRAM

Search

Home

Regulations & Policies

Forms

Overview

APHIS/CDC Form 1

APHIS/CDC Form 2

APHIS/CDC Form 3

APHIS/CDC Form 4

APHIS/CDC Form 5



# Preparing for a Plant Pathogen Select Agent Inspection (6/7)

## T PROGRAM

Regulations & Policies ▾

Forms ▾

Resources ▾

Select Agent (SA) Grams

Legislation

Publications

Program Reviews & Reports

Biosafety in Microbiological & Biomedical Laboratories

NIH Guidelines

Helpful Links

Training

Inspection Checklist App



## FEDERAL SELECT AGENT PROGRAM



Overview ▾

Select Agents & Toxins ▾

Compliance ▾

Regulations & Policies ▾

Forms ▾

Resources ▾

eFSAP ▾

Select Agents > Resources

## Training

[Print](#)

### 2023 Responsible Official Webinar Series

In 2023, the Federal Select Agent Program (FSAP) held a webinar series to provide Responsible Officials and Alternate Responsible Officials with information related to compliance with the select agent regulations, as well as updates from FSAP on a variety of topics. The webinar series presentations are available for download below:

[Analysis of FSAP Inspection Report Departures \(September 21, 2023\)](#) [PDF - 2 MB]

[Enhance](#) [PDF - 1 MB]

[APHIS/CDC Forms 3 and 4 Overview and Updates \(June 29, 2023\)](#) [PDF - 2 MB]

[History](#) [October 2021]

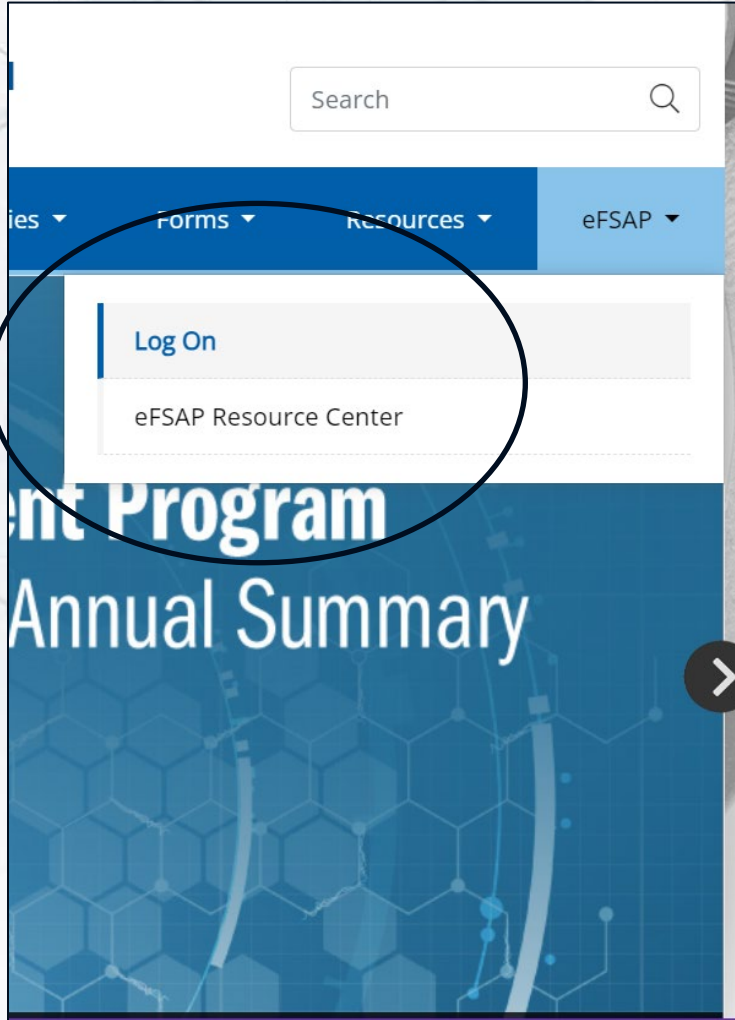
### Plant Biocontainment

Responsible Official Workshop

May 26, 2021



# Preparing for a Plant Pathogen Select Agent Inspection (7/7)



The eFSAP Resource Center homepage features the CDC and USDA logos at the top left, followed by the text 'FEDERAL SELECT AGENT PROGRAM'. A search bar is located at the top right. Below the header is a navigation bar with dropdown menus for 'Overview', 'Select Agents & Toxins', 'Compliance', 'Regulations & Policies', 'Forms', 'Resources', and 'eFSAP'. The main content area is titled 'eFSAP Resource Center' and includes a sidebar with a home icon and a list of links: 'Overview', 'What is eFSAP?', 'Using eFSAP', 'Updates', 'Contact Us', and 'Log On'. The main content area contains an 'Overview' section with a welcome message, a link to log on, and links to 'What is eFSAP?' and 'Using eFSAP'.

**eFSAP Resource Center**

Welcome to the eFSAP Resource Center! Here you will find everything you need to gain access to and use the new electronic Federal Select Agent Program portal, eFSAP.

Click [here](#) to log on to the system.

[What is eFSAP?](#) describes FSAP's new secure information system, eFSAP, and explains how the system will improve communication between FSAP and regulated entities.

[Using eFSAP](#) provides training materials, reference guides, and answers to frequently asked questions to assist eFSAP users.

[Updates](#) provides the latest information about new features and system roll-out.





A man in a white lab coat, safety glasses, and a face mask, holding a clipboard and pen, in a laboratory setting. The background is a blurred laboratory environment with various pieces of equipment.

## Preparing for a Renewal Inspection

# Preparing for Renewal Inspections (1/4)

- Ensure that Form 1 is up to date in eFSAP
- Ensure information in plans and standard operating procedures (SOPs) is accurate and up to date
- Biocontainment plan (or SOPs referenced therein) should include **all biosafety and containment procedures for the entity's approved BSAT work**



# Preparing for Renewal Inspections (2/4)

## Disinfectants

Do you know that the disinfectants you are using will work on your select agent(s) in the way you are using them (contact time, concentration, etc.)?



# Preparing for Renewal Inspections (3/4)

## Documentation

- Inactivation Procedures
- Training
- Drills and Exercises
- RO Inspection Records



# Preparing for Renewal Inspections (4/4)

- Use your RO inspection as a practice inspection
- Use a share drive to keep files accessible
- Reach out to your file manager

## 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]



# Biosafety Levels in Plant Pathogen Select Agent Labs

“The NIH biosafety levels are generally universally accepted as the most relevant for plant work and thus are used in this Guide.”  
- A Practical Guide to Plant Biocontainment, pg. 11-12

**EMERGENCY CONTACT INFORMATION**

Location: **Environmental Health and Safety Services Building - 1210**

Primary Contact: <b>Michelle DeScience</b>	email: <b>mde@barab.edu</b>	Phone: <b>(515) 294-xxxx</b>
Co-Alternate: <b>Kirsty Chemical</b>	email: <b>krc@barab.edu</b>	Phone: <b>(515) 294-xxxx</b>
2nd Alternate: <b>Anne Decker</b>	email: <b>ade@barab.edu</b>	Phone: <b>(515) 294-xxxx</b>
3rd Alternate: <b>Scotty Labs</b>	email: <b>sml@barab.edu</b>	Phone: <b>(515) 294-xxxx</b>

**Personal Protective Equipment**

**Hazards and Warnings**

	
---	---

**Special / Other Hazards**  
**CAUTION, RADIOACTIVE MATERIAL(S)**      **Nuclides: Any**  
Radiation Safety Training is REQUIRED  
**RESTRICTED AREA, NO UNAUTHORIZED PERSONNEL, PLANT BIOHAZARD PESTS**

Bio Safety Level: **P105L**      IDC Log #: **xxxxxx**  
USCA Permit #: **xxxxxx**

**EMERGENCY: DIAL 911**

Last Printed Date: 10/01/2022

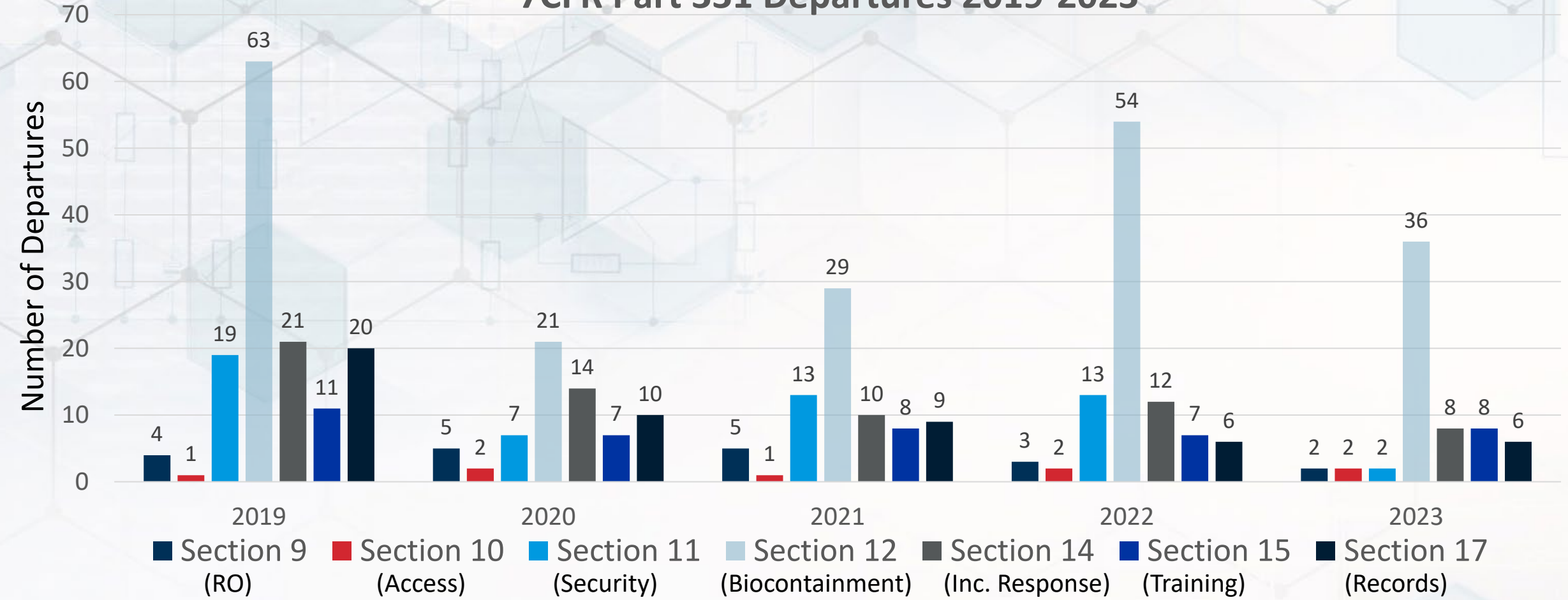


# **A Look at 7 CFR Part 331 Departure Trends Over 5 Years (2019-2023)**



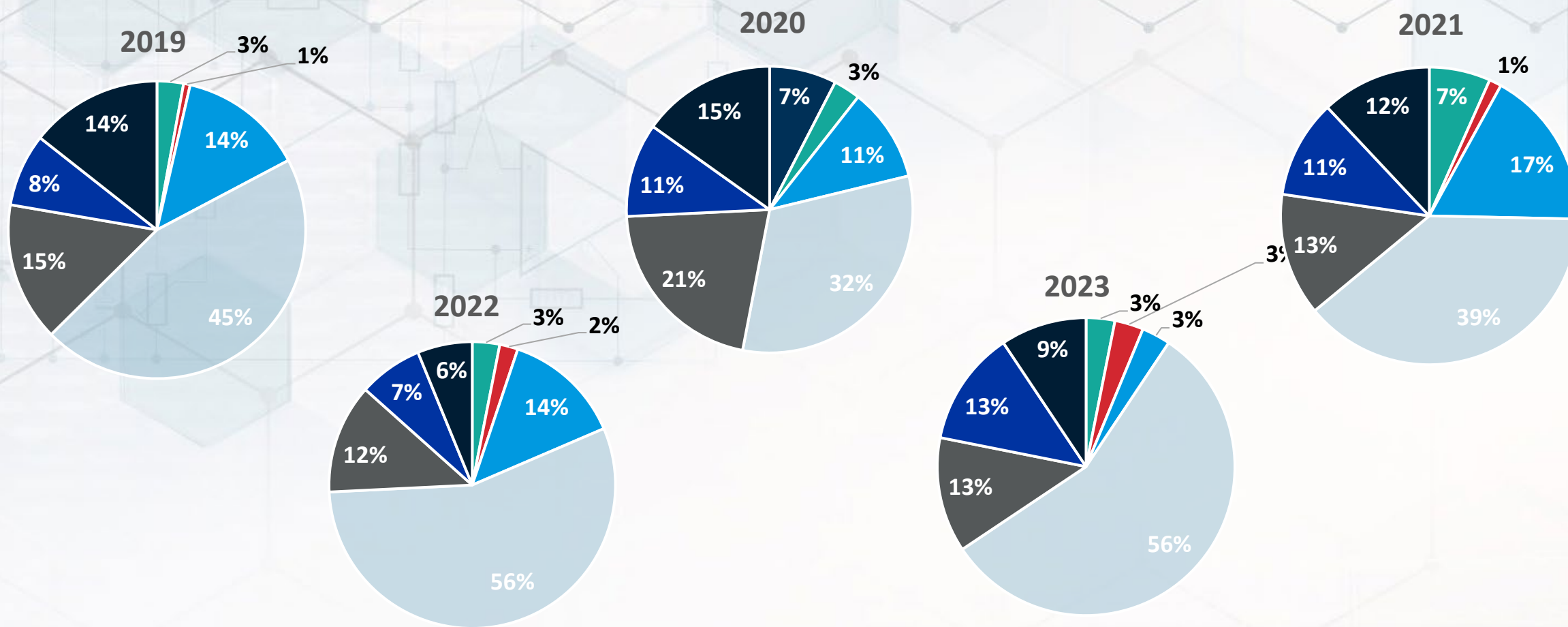
# 7 CFR Part 331 Departure Totals and Trends Over 5 Years (1/2)

## 7CFR Part 331 Departures 2019-2023





# 7 CFR Departure Part 331 Totals and Trends Over 5 Years (2/2)



Section 9 10 11 12 14 15 17



# **Most Recurrent Unique Identifier Numbers (UID's) Under 7 CFR Part 331 From 2019-2023**



# Most Recurrent UID's 2019-2023 (1/5)

1. 7 CFR 331.14(d)(6), 07-14-00900 Planning and coordination with local emergency responders (12 occurrences)
2. 7 CFR 331.15(a)(1), 07-15-00100 Initial training within 12 months of FSAP approval (9 occurrences)
3. 7 CFR 331.17(a)(5), 07-17-02400 Visitor entry into areas containing select agents or toxins (name of individual, name of escort, date, time of entry) (9 occurrences)



# Most Recurrent UID's 2019-2023 (2/5)

4. 7 CFR 331.11(c)(10), 07-11-01700 The security plan must contain policies and procedures for shipping, receiving, and storage of select agents and toxins (8 occurrences)

5. 7 CFR 331.12(a)(3), 07-12-37600 The biosafety plan must include written procedures for each validated method used for disinfection, decontamination, or destruction (8 occurrences)



# Most Recurrent UID's 2019-2023 (3/5)

6. 7 CFR 331.12(b), 07-12-41550 Sign with biohazard symbol is posted at entrance of areas containing BSAT (8 occurrences)

7. 7 CFR 331.14(d)(11), 07-14-01400 The incident response plan must contain procedures for emergency evacuation (8 occurrences)

8. 7 CFR 331.14(f), 07-14-01801 Drills or exercises must be conducted annually to test and evaluate the plan. (8 occurrences)



# Most Recurrent UID's 2019-2023 (4/5)

9. 7 CFR 331.15(a)(2), 07-15-00120 Visitor training (8 occurrences)

10. 7 CFR 331.15(e), 07-15-00600 The RO must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline (7 occurrences)



## Anonymous Reporting

To report safety, security, or other concerns associated with select agents and toxins, please use the Office of Inspector General (OIG)'s confidential hotline. When reporting these issues to OIG, please ensure that you indicate it is a "Select Agent Complaint" issue.

### OIG Hotline contact information

**Voice:** 1-800-HHS-TIPS (800-447-8477)

**Fax:** 1-800-223-8164

**Web:** <https://oig.hhs.gov/fraud/report-fraud/index.asp>

### Mail:

Office of Inspector General  
Department of Health & Human Services  
Attn: Hotline  
P.O. Box 23489  
Washington, DC 20026

### USDA OIG Hotline contact information

**Voice:** 1-800-424-9121

**Fax:** 1-202-690-2474

**Web:** <https://www.usda.gov/oig/hotline>

### Mail:

United States Department of Agriculture  
Office of Inspector General  
P.O. Box 23399  
Washington, DC 20026-3399



# Most Recurrent UID's 2019-2023 (5/5)

11. 7 CFR 331.12(a)(4), 7-12-37700 The biosafety plan must contain procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination (7 occurrences)

12. 7 CFR 331.14(d)(1), 07-14-00400 The incident response plan must contain the name and contact information for the individual or entity (7 occurrences)

13. 7 CFR 331.15(c), 07-15-00400 Refresher training must be provided annually for individuals with access approval (7 occurrences)



# Most Recurrent UIDs Under 7 CFR Part 331 In 2022

## Of the seven most recurrent UID's in 2022, three are plan statements

- 7 CFR 331.12(a)(2), 07-15-00120 The biocontainment plan describes procedures for hand washing or sanitizing when leaving the greenhouse or walk-in growth chamber
- 7 CFR 331,11(c)(10), 07-15-00120 The security plan must contain policies and procedures for shipping, receiving, and storage of select agents and toxins
- 7 CFR 331.12(a)(4), 07-12-48100 The biocontainment plan includes procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.





# Most Recurrent UIDs Under 7 CFR Part 331 In 2023 (3 Occurrences Each)

- 7 CFR 331.12(b) Biocontainment procedures must be sufficient to contain the select agent or toxin
  - 07-12-39100 - Biological Safety Cabinets and/or Chemical Fume Hoods are certified annually
  - 07-12-46201 - Appropriate procedures have been developed and implemented for use of centrifuges
  - 07-12-40901 - The interior surfaces are water resistant (walls, floors and ceilings). Penetrations in floors, walls, and ceiling surfaces are sealed.

