

Electronic Federal Select Agent Program (eFSAP) Information System

2021 Responsible Official Webinar Series

August 18, 2021



Electronic Federal Select Agent Program (eFSAP) Information System

- Highly secure, web-based communication portal
- Provides immediate, real-time information on **who** has access to **which** select agents, how they are being **used**, and **where** they are located
- Built to benefit both the Federal Select Agent Program (FSAP) as well as the regulated community

Building 6

BSL3-Ag room

Tier 1 lab and storage room

Approved Tier 1 Suite 1 Storage BSL3Ag

Approved Tier 1 Suite 1 Storage BSL3

Work Objective: WO001476.023 **Status:** Approved **Date Approved:** 06/02/2020 Active Work

Principal Investigators: Albert Einstein **Work Only** [View](#)

Previous work demonstrated that purified unlipidated Omp19 has protease inhibitor activity against gastrointestinal and lysosomal proteases. Here we are trying to determine if a Brucella omp19 deletion mutant is highly attenuated in mice when infecting by the oral route. We will be testing bacterial susceptibility to host proteases as well as possible cell division defects when exposed to pancreatic proteases. We will also be testing if Omp19 deletion mutants are more susceptible to killing by macrophage derived microsomes than wt strains. We will be testing if preincubation with gastrointestinal proteases leads to an increased susceptibility of Omp19 deletion mutant to macrophage intracellular killing.

Agents/Toxins: Brucella abortus, Brucella melitensis, Brucella suis **Required Attachments:** A B C D E F G

Buildings/Rooms: Building 6 - Tier 1 lab and storage room **Biosafety Levels:** BSL3

Botulinum neurotoxins	Type A	1	Albert Einstein, Linus Pauling
Brucella abortus	biovar 5	4	Kary Mullis, Linus Pauling
Brucella melitensis	16M	1	Linus Pauling
Brucella suis	513	1	Isaac Newton
Brucella suis	biovar 1	7	Albert Einstein, Linus Pauling



Benefits of the eFSAP Information System

- Status of registration amendments, theft-loss-release reports, transfer requests, inspection reports, etc. displayed in real-time and available to the entity 24/7

Real-time Notifications

From	Date And Time	Notification
eFSAP system	1/22/2021 5:20:04 AM	Form 2 transfer authorization T-F2-010324 has expired.
Branch Chief	1/19/2021 3:31:38 PM	Form2 (T-F2-010327) was modified (State: Approved Section2 Pending) by Branch Chief
eFSAP system	12/13/2020 5:10:04 AM	Section 4 - SRA status will expire in 7 days on 12/20/2020 for Gregor Mendel (JJ070277)
fte advanced	12/8/2020 10:33:00 AM	Amendment #332070 - Section 7a/c - Amendment to Modify Work objective (WO001976.003.001) was modified (State:
Branch Chief	8/24/2020 12:17:47 PM	Form3 (TLR-F3-000090) was modified (State: RequestForMoreInformation) by Branch Chief



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Amendment Status

Amendment Type	Number	Date Submitted	Date Approved	Status
Section 7AC - Add Ne...	00332071	12/08/2020		Pending
Section 7AC - Remove...	00332067	12/08/2020	12/08/2020	Approved
Section 6 - Modify Roo...	00332009	09/09/2020	09/18/2020	Approved
Section 1 - Change Ent...	00332022	09/25/2020		RequestFo...

Transfer Status

Agents	Transfer Id.	Sender	Date Create.	Status
Bacillus anthracis	T-F2-010359	eFSAP Test Entity	01/15/2021	Transfer in Review
Ricin	T-F2-010351	eFSAP Test Entity	12/30/2020	Request for Information
Botulinum neurotoxin	T-F2-010343	eFSAP Test Entity	12/15/2020	Approved Section 2 Pending
Burkholderia mallei	T-F2-010333	eFSAP Test Entity	12/05/2020	Approved Section 3 Pending
Yersinia pestis	T-F2-010323	eFSAP Test Entity	11/27/2020	Transfer Complete





Benefits of the eFSAP Information System


- Entity staff can communicate with FSAP staff directly within the system
- Discussions are time-stamped and categorized for later search and retrieval


Discussion Logs

General Discussion

responsible official4 - regarding: Amendment [332071](#) 1/22/2021 4:45:37 PM 
Just submitted this amendment. Please reach out to me if you need any additional information

 1/22/2021 4:46:42 PM **Branch Chief** - regarding: Amendment [332071](#)
Yes sir, just saw it come in. We will take a look and get back to you if any additional information is needed.

responsible official4 - regarding: Form 2 Transfer ID [T-F2-010326](#) 1/22/2021 4:47:58 PM 
Wanted to let you know that we may have to modify this transfer request to add a few more agents. How do I do that?

 1/22/2021 4:49:12 PM **Branch Chief** - regarding: Form 2 Transfer ID [T-F2-010326](#)
That's no problem, I'll return the form to you so that you can modify it.

Type your message here...

Previous **1** 2 Next Send



Benefits of the eFSAP Information System

- eFSAP is FSAP's official system of records
- Entities do not need to maintain separate records
- If entities keep eFSAP up to date, the number of records requested during inspections should be minimal

Entity records library

	Original Name	Unique File Identifier	Uploaded Date	File Category
	<input type="text"/>	<input type="text"/>	Start Date <input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>	End Date <input type="text"/>	
🕒	Human remains application doc.pdf	TLR-F3-000090-20200824-9/2/2020 3:29:05 PM-Other-'other v2'	9/2/2020 3:29:05 PM	Form 3
🕒	test upload pdf	TLR-F3-000074-20200722-9/2/2020 3:20:20 PM-Other-'other v2'	9/2/2020 3:20:20 PM	Form 3
🕒	form 3 upload error.JPG	F2-010338-9/2/2020 1:52:05 PM-Transfer Authorization-'ta v2'	9/2/2020 1:52:05 PM	Form 2
🕒	updated test upload.docx	F2-010338-9/2/2020 1:49:17 PM-Application Request-'ar v2'	9/2/2020 1:49:17 PM	Form 2
🕒	test upload.pdf	F2-010338-9/2/2020 1:48:27 PM-Application Request-'ar v2'	9/2/2020 1:48:27 PM	Form 2
🕒	Upload Test - (9).pdf	F2-010338-9/2/2020 1:28:20 PM-Application Complete	9/2/2020 1:28:20 PM	Form 2
🕒	Upload Test - (9).pdf	F2-010338-9/2/2020 1:27:50 PM-Application Complete	9/2/2020 1:27:50 PM	Form 2

1 - 10 of 162 items

Form 1 (33)	Form 2 (19)	Form 3 (11)	Form 4A (8)	Form 4B (1)	Form 5 (3)
Compliance (8)	Facilities (2)	Inspection (42)	Policy (8)	Entity Select Agent and Toxin Program Documents (13)	Registration Certificate (1)
Security (1)	Training (2)	View All (162)			Restricted Experiments/Exclusions (3)



Impact of the eFSAP Information System

- 79% reduction in time required for entities to resolve regulatory departures
- 92-99% reduction in FSAP approval times versus previous system

Select Agents and Toxins Regulatory Process/Requirement	Median Business Days		Percent (%)	
	Pre eFSAP (2016-2017)	eFSAP (2019-2020)	Increase in Efficiency	Decrease in Time
Days to Resolve Regulatory Departures	202	42	481	79
Days to Approve Amendments:				
a. Replace Responsible Official	26	2	1,300	92
b. Update Entity Personnel	15	*0.02	75,000	99.87
c. Update Entity Safety/Security Information	100	2	5,000	98
d. Add/Update/Remove Registered Areas	93	3	3,100	97
e. Add/Modify/Remove Approved Activities	63	4	1,575	94
f. Add/Modify/Remove Strains	64	*0.02	320,000	99.96

*These amendments are now "self-service" within eFSAP information system. The 0.02 value for business days represents a conservative estimate of these actions requiring 30 minutes to complete.



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eFSAP Information System: Recent Major Updates

- **Principal Investigator (PI) user role**
- **Rapid PI replacement**
- **Redesign of how strains are captured**
- **Integration with the FBI Bioterrorism Risk Assessment Group**
- **Internal “Action Center”**
- **Internal PowerBI-based reporting module**



eFSAP Information System: Recent Major Updates

- **PI user role**

- Specialized user role for entity PIs
- Allows PIs to have direct control to update and edit agent strains in their inventory
- Permits PIs to edit and save, but not submit, draft amendments to their approved work objectives
- Provides PIs a read-only view of their approved work objectives for review of accuracy
- Designed to protect the privacy of research (PIs cannot see the work being conducted or strains possessed by other PIs on the registration)



eFSAP Information System: Recent Major Updates

- **Rapid PI replacement**

- The APHIS/CDC Form 1 requires that all personnel, work objectives, and strains be assigned to at least one PI
- Previously, when a PI left an organization, many hours may have been spent to reassign personnel, work objectives, and strains to another PI
- eFSAP now provides a way for entities to rapidly replace a PI via an automated script that reassigns personnel, work, and strains to a new PI in just minutes



eFSAP Information System: Recent Major Updates

- **Redesign of how strains are captured**
 - Historically, and initially in eFSAP, agent strains were captured as free text fields
 - The program was not able to rapidly query and identify which entities/PIs possessed specific strains of an agent
 - With a redesign to enable input of strains from a drop-down list, the program can now identify in minutes the entities and PIs that possess any specific select agent strain
 - The program can now provide immediate support to law enforcement



eFSAP Information System: Recent Major Updates

- **Integration with the FBI Bioterrorism Risk Assessment Group (BRAG)**
 - BRAG provides FSAP with the results of the security risk assessment for entity personnel seeking to work with select agents and toxins
 - BRAG has a user role allowing system access to directly update information on the over 9000 active users for security risk assessments
 - Allowing BRAG access to eFSAP has led to faster processing of security risk assessments
 - BRAG only has access to personnel records to protect entity privacy



eFSAP Information System: Recent Major Updates

- **Internal “Action Center”**

- Home page and hub for internal eFSAP users
- Multiple grid tables providing real-time notifications of events requiring action/attention
- Hyperlinks allowing instant navigation to the amendment, form, inspection response, etc.
- Internal FSAP users can filter the information to their team or personal level



eFSAP Information System: Recent Major Updates

- **Internal PowerBI-based reporting module**
 - Built upon the Microsoft PowerBI platform
 - Pulls real-time information from different system data points
 - Limited to internal system users (FSAP staff)
 - Allows rapid analysis of metrics, trends, and data anomalies/outliers
 - Current information is readily available and accurate



Total Amendments

310

Entity Name

Entity

Entity Type

- Academic - Private
- Academic - State
- Commercial - Profit
- Government - Federal
- Government - State/Local
- Private - Non-Profit

Lead Agency

- APHIS
- CDC

Submitted Date

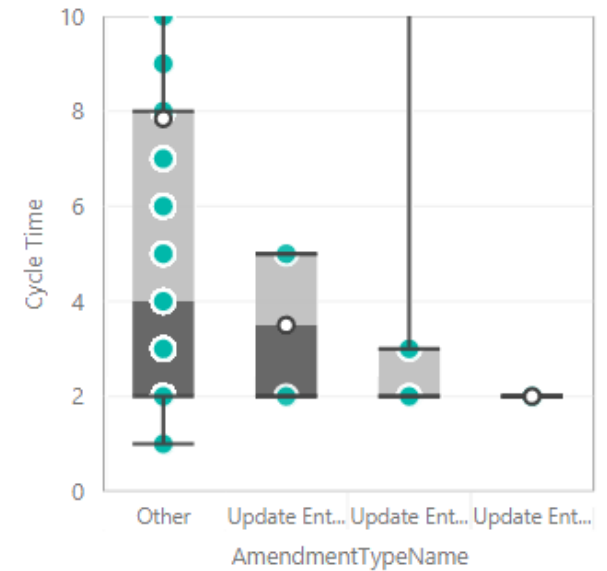
Approved Date

Amendment Cycle Times

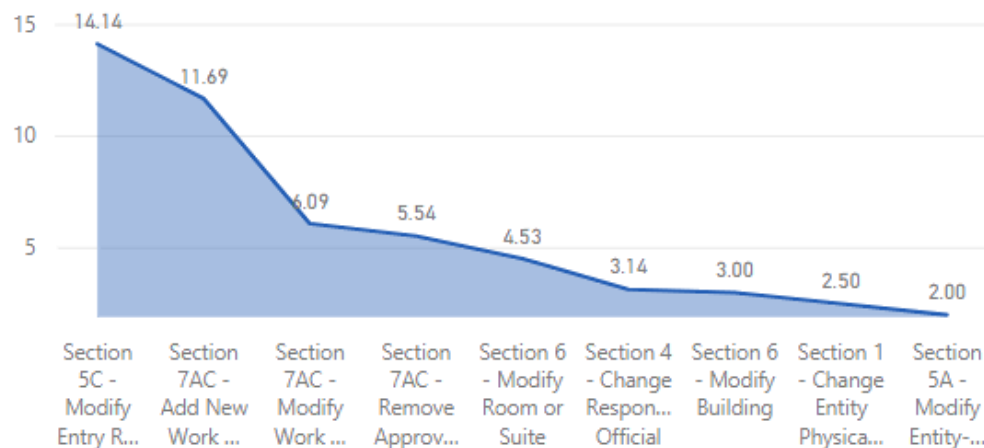
Amendment Cycle Times by Entity and Category

Entity	Number	Submitted Date	Approved Date	Amendment Category	Total Days	Work Days
	3682	4/6/2020	4/7/2020	Section 7AC - Remove Approved Work Objective	2	2
	3684	4/6/2020	4/8/2020	Section 7AC - Remove Approved Work Objective	3	3
	3685	4/6/2020	4/9/2020	Section 6 - Modify Building	4	4
	3690	4/7/2020	4/8/2020	Section 7AC - Modify Work Objective and/or Attachment(s)	2	2
	3693	4/7/2020	4/9/2020	Section 7AC - Modify Work Objective and/or Attachment(s)	3	3
	3875	6/4/2020	6/8/2020	Section 6 - Modify Room or Suite	5	3
	3689	4/6/2020	4/7/2020	Section 7AC - Modify Work Objective and/or Attachment(s)	2	2
	3969	6/30/2020	7/7/2020	Section 7AC - Add New Work Objective	8	6
	3881	7/8/2020	7/9/2020	Section 7AC - Remove Approved Work	2	2

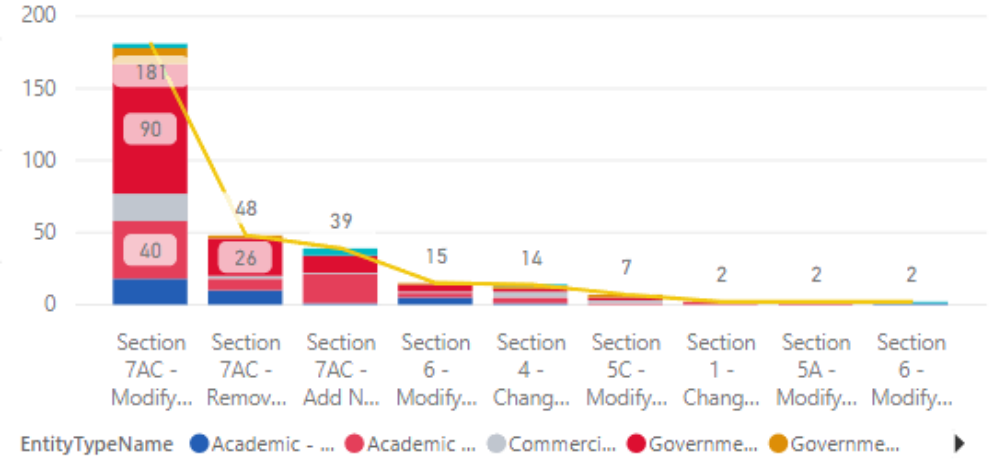
Cycle Time by Amendment Type



Avg. Cycle Time by Amendment Category



Amendment Category Count by Entity Type



Total Amendments

310

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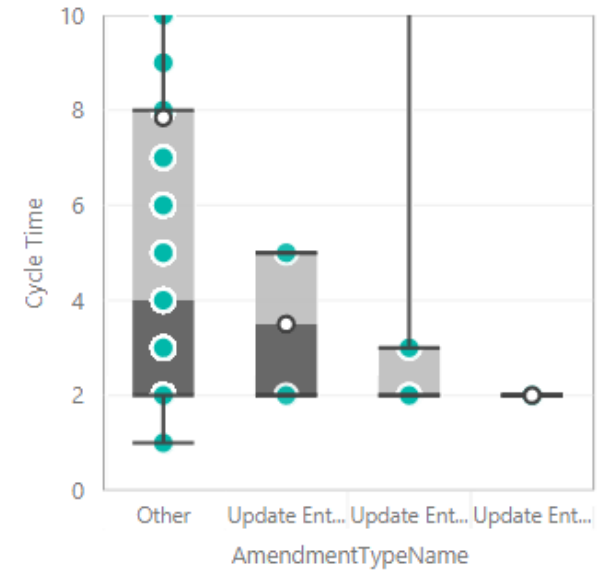
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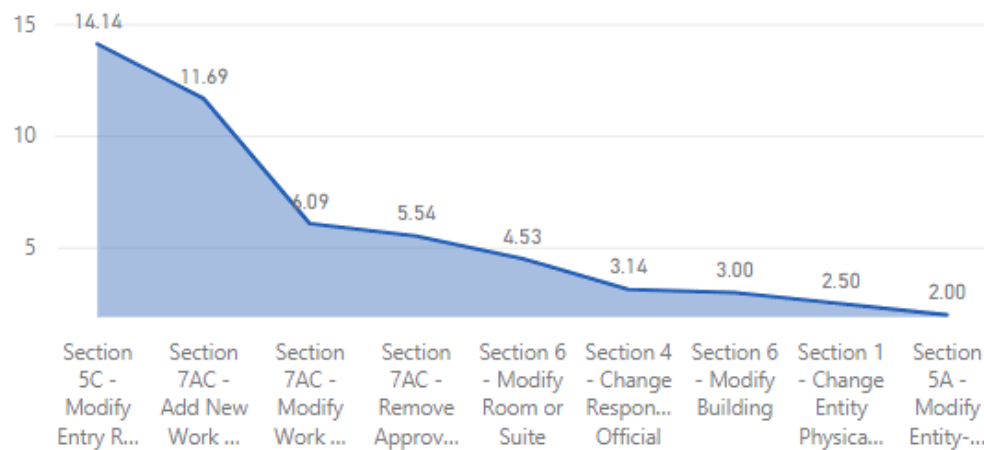
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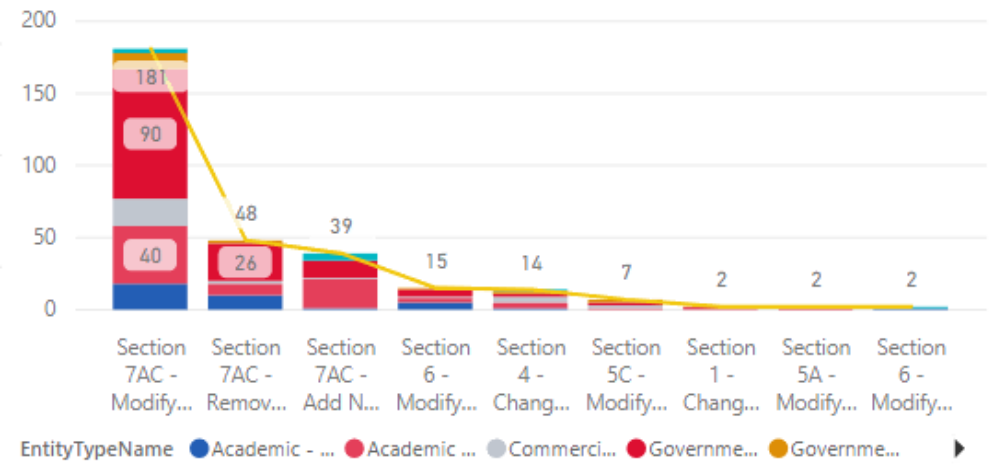
Cycle Time by Amendment Type



Avg. Cycle Time by Amendment Category



Amendment Category Count by Entity Type



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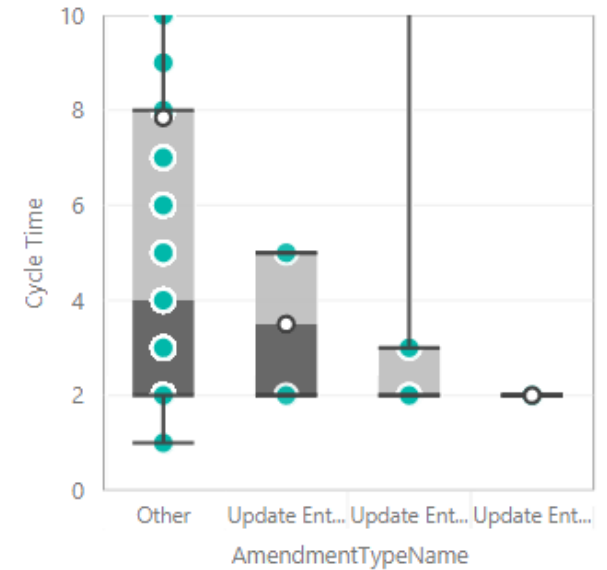
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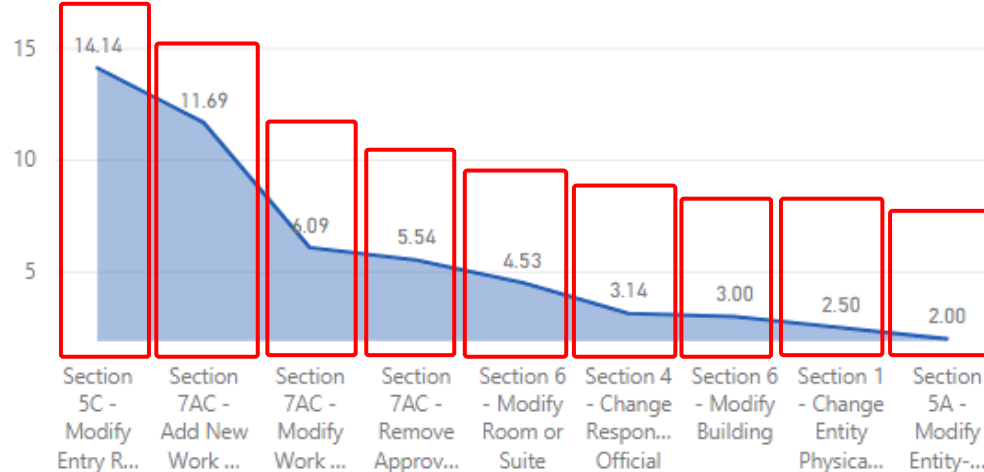
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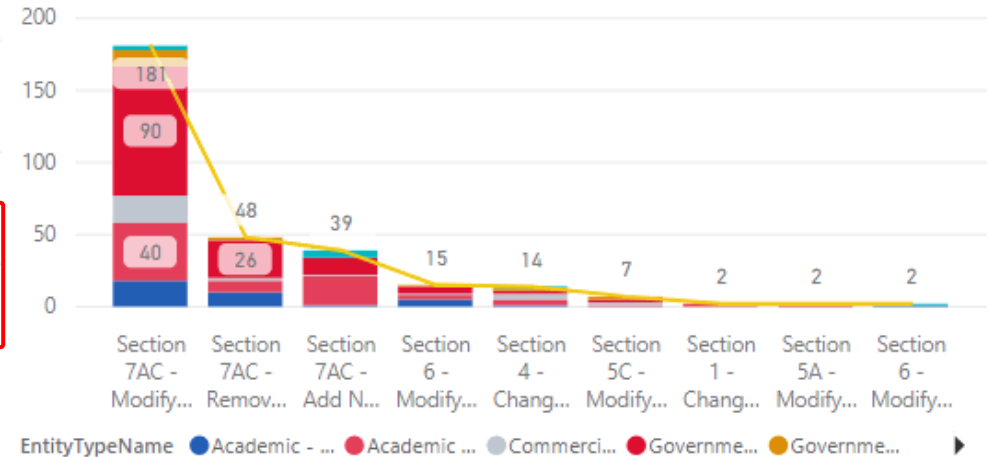
Cycle Time by Amendment Type



Avg. Cycle Time by Amendment Category



Amendment Category Count by Entity Type



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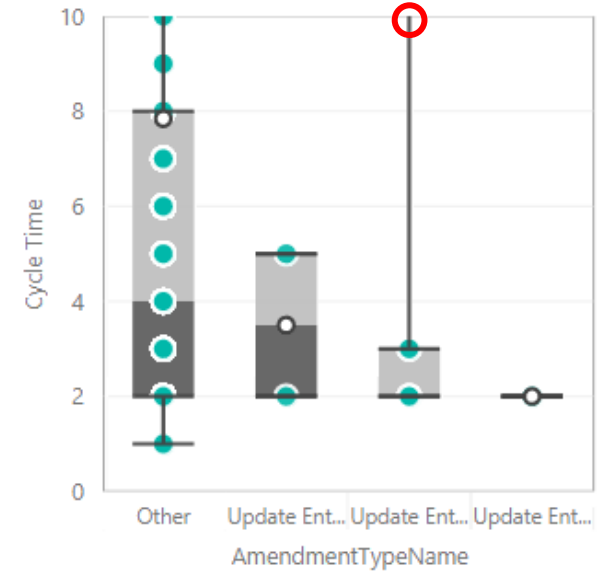
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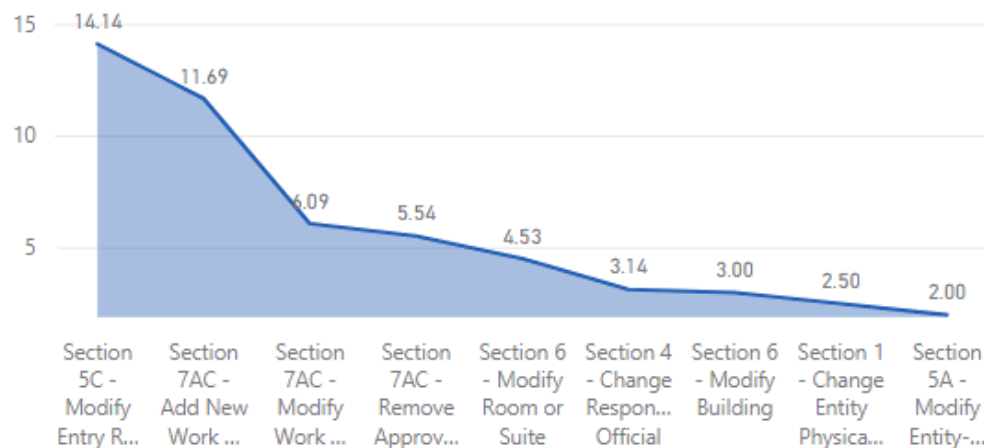
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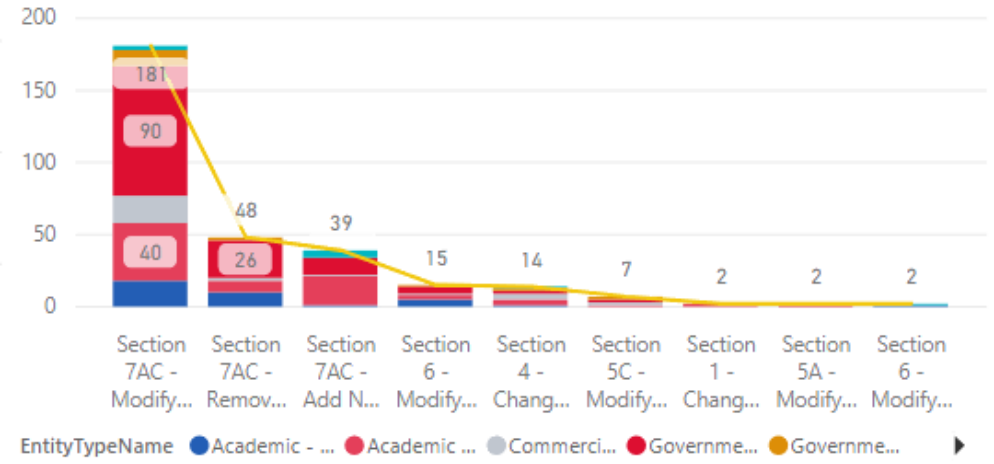
Cycle Time by Amendment Type



Avg. Cycle Time by Amendment Category



Amendment Category Count by Entity Type



Team

Search

Lead Agency

CDC

Team

CDC
 USDA

Joint Inspection

False
 True

Inspection End Date

1/1/2020 6/18/2020

Final Findings Released

1/1/2020 7/8/2020

Inspection Processing Time

Total Inspections

42

Median Final Process Time (Days)

26

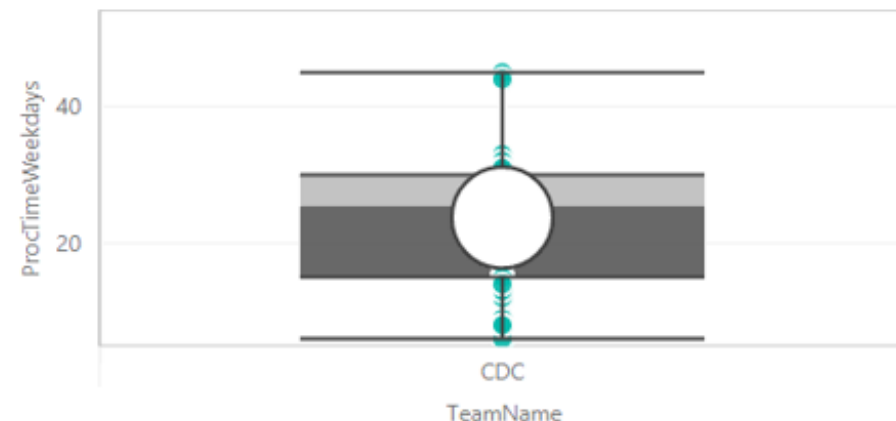
Median Amended Process Time (Days)

89

Processing Time by Agency and Team

Lead Agency	Team Name	Median Final Process Time	Median Amended Process Time
CDC	CDC	26	89

Total Processing Time by Team & Inspection



Details by Agency, Entity and Team

Lead Agency	Inspection Number	Entity	Team	Joint Inspection	Process Start Date	Final Findings Released	Processing Time	Amended Findings Released	Amended Processing Time
CDC	7353		CDC	False	04/20/2020	04/29/20	8		
CDC	7280		CDC	False	03/09/2020	04/15/20	28		
CDC	7284		CDC	False	03/09/2020	04/16/20	29		
CDC	7306		CDC	True	03/09/2020	04/15/20	28		
CDC	7249		CDC	False	03/02/2020	03/24/20	17		
CDC	7271		CDC	False	03/02/2020	04/06/20	26	06/18/2020	79
CDC	7248		CDC	False	02/24/2020	03/10/20	12		

Team

Search

Lead Agency

CDC

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CDC
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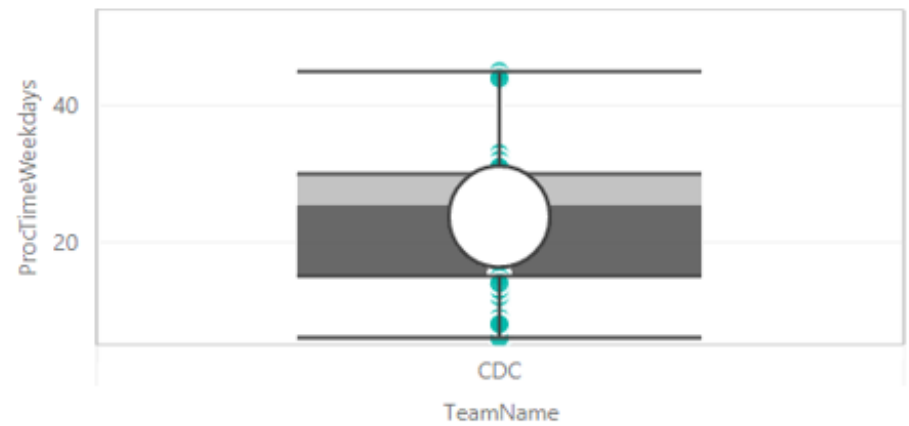
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Search

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Final Findings Released



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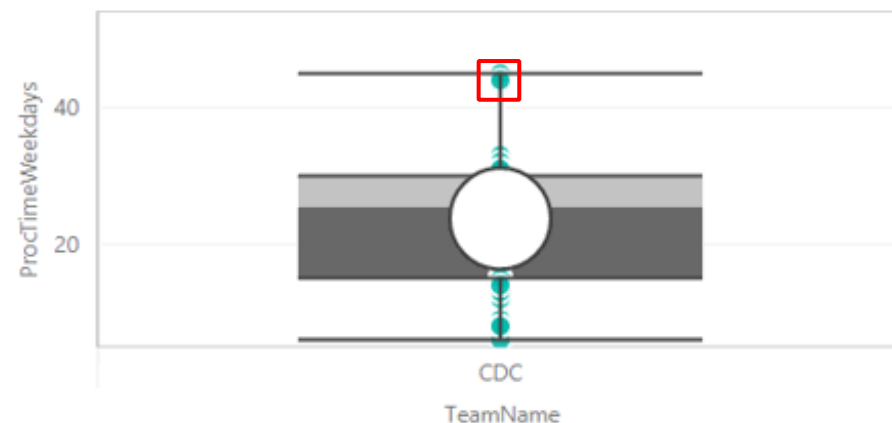
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FY 2021 Focal Points



FY 2021 Focal Points

- **eFSAP Database Updates**

- Conversion of eFSAP CRM-based database to SQL database
- Streamlined access to data for reporting
- Enhanced efficiencies through removal of excess data layers

- **eFSAP Infrastructure Updates**

- Transition to Microsoft Azure Government Cloud-based hosting
- Continental Redundancy (Arizona / Virginia) vs. Regional Redundancy (Atlanta, GA / Lawrenceville, GA)

- **eIPP system updates**

- Human Remains Importation Application
- eIPP inspection module



eFSAP Information System: Coming Features



eFSAP Information System: Future Features

- **Document Review Center / 1-click uploading**
- Document reclassification
- Enhancements to Inspection Module to better support “hybrid” inspections
- Science Module - expedited review and approval of exclusions and restricted experiments
- Internal routing of entity information for faster review and approval
- The ability to “recycle” previously submitted forms
- Form 1 Section 7a/c attachment sharing
- Inspection “Report Cards”



eFSAP Information System: Future Features

- **Document Review Center / 1-click uploading**
- **Document reclassification**
- Enhancements to Inspection Module to better support “hybrid” inspections
- Science Module - expedited review and approval of exclusions and restricted experiments
- Internal routing of entity information for faster review and approval
- The ability to “recycle” previously submitted forms
- Form 1 Section 7a/c attachment sharing
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eFSAP Information System: Reminders

- eFSAP provides notifications when individuals are 90, 45, and 7 days from expiring
- Please ensure that FD-961s are submitted after receiving the first notification

Notifications

Filter:

Current Archived

From	Type	Date And Time	Notification
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="sra"/>
eFSAP system	Form1 View	9/7/2021 5:10:10 AM	Section 4 – SRA status has expired for J. Edgar Hoover (JH070426)
eFSAP system	Form1 View	8/30/2021 5:10:03 AM	Section 4 – SRA status will expire in 7 days on 9/6/2021 for J. Edgar Hoover (JH070426)
eFSAP system	Form1 View	7/23/2021 5:10:07 AM	Section 4 – SRA status will expire in 45 days on 9/6/2021 for J. Edgar Hoover (JH070426)
eFSAP system	Form1 View	6/08/2021 5:10:05 AM	Section 4 – SRA status will expire in 90 days on 9/6/2021 for J. Edgar Hoover (JH070426)



eFSAP Information System: Reminders

- **The Federal Select Agent Program provides several mechanisms to receive assistance with using the system.**

Primary and secondary points of contact are listed at the top of each entity's home page

eFSAP Test Entity

 LEAD AGENCY: CDC

 REGISTRATION STATUS: Approved

REGISTRATION EXPIRES: 03/23/2022

Facility Address: 1020 Valley Drive, Atlanta, GA 30329-1234

Registration #: 20200401-103033

Responsible Official Name: Alexander Bell

Responsible Official Business #: 444-121-1236

Responsible Official Emergency #: 444-121-1236

Primary FSAP POC: Albert Einstein

Primary POC Office #: 012-345-6789

Primary POC Mobile #: 012-345-6789

Secondary FSAP POC: George Carver

Secondary POC Office #: 123-456-7890

Secondary POC Mobile #: 999-124-7891

The bottom right of every page in the system provides links to our resource center, support request form, and contacts for our help desk

Help and Support

eFSAP Resource Center
eFSAP Customer Support Request Form
Telephone: 877-232-3322
Email: eFSAPsupport@cdc.gov



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301- 851-2070

