# 2019 Federal Select Agent Program Inspection Report Processing Annual Summary

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The *2019 Federal Select Agent Program (FSAP) Inspection Report Processing Annual Summary* presents an analysis of FSAP's responsiveness in providing feedback, via inspection reports, to FSAP-registered entities after on-site inspections during Calendar Year (CY) 2019. FSAP uses this data to improve program performance in providing timely feedback to registered entities that have received an on-site inspection. The target timeframe to process a final inspection report and issue it to an entity is 30 business days following the Monday after the conclusion of the inspection. **In CY2019, FSAP issued 193 inspection reports with 97% issued within the target timeframe of 30 business days.**

# Section 1. Introduction

The Federal Select Agent Program (FSAP) regulates the possession, use, and transfer of biological select agents and toxins (BSAT)—such as *Bacillus anthracis,* avian influenza viruses, *Ralstonia solanacearum,* and botulinum neurotoxin—that have the potential to pose a severe threat to human, animal or plant health, or to animal or plant products. FSAP is managed jointly by the U.S. Department of Health and Human Services (HHS)/ Centers for Disease Control and Prevention (CDC)/ Division of Select Agents and Toxins (DSAT) and the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)/Agriculture Select Agent Services (AgSAS). HHS provides oversight for biological agents and toxins that have the potential to pose a severe threat to public health and safety. USDA provides oversight for biological agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. HHS and USDA jointly oversee biological agents and toxins which have the potential to pose a severe threat to both public health and safety and animal health and products, also known as overlap select agents and toxins.

The select agent regulations include biosafety/ biocontainment, security, and incident response requirements that registered entities must follow to ensure the safety and security of those working in laboratories and living in surrounding communities. An entity required to register with FSAP (i.e. an entity that possesses, transfers, or works with BSAT) is subject to the select agent regulations and on-site inspections to ensure that appropriate biosafety/ biocontainment and security measures are in place.

The *2019 Federal Select Agent Program Inspection Report Processing Annual Summary* is the second joint program analysis of inspection report timeliness data. It is the fifth annual analysis of timeliness data for DSAT, and the second for AgSAS. Previous reports are available on the FSAP website at https://www.selectagents.gov/publications.html.

# Section 2. Methods

## *Data Gathering and Analysis*

FSAP calculated the processing time for providing a final inspection report to registered entities based on the number of federal government business days, beginning from the Monday following the last day of the inspection (allowing for travel time) to the issuance of the inspection report. If the report was sent prior to the Monday following the last day of inspection (such as when the entity was notified that there were no observations on the inspection), zero days was assigned as the processing time. FSAP extracted this data from the program's electronic information system (eFSAP) as well as scheduling and inspection tracking spreadsheets.

FSAP analyzed the processing times by inspection type, which includes six categories:

1. **Compliance**—Review of entity's registration, including laboratory spaces and documents (e.g. plans, records, facility verification documentation), with a focus on compliance issues.

2. **Maximum Containment**—Review of entity's registered maximum containment program, including laboratory spaces and documents specific to work that requires the highest levels of containment (e.g. biosafety level 4, or BSL-4).

3. **New Entity**—Review of information provided in an entity's application to register with FSAP, as well as all laboratory spaces and documents, to support approval or denial of a new entity registration application.

4. **New Space**—Review of laboratory space and documents for adding laboratory space to an existing entity's registration.

5. **Renewal**—Review to make a determination regarding the renewal of an existing entity's registration, including all registered laboratory spaces and documents; typically occurs every 3 years.

6. **Verification**—Review of selected portions of an entity's registration, including laboratory spaces and documents; this often includes an assessment of responses to previous inspection findings and may be conducted before allowing an entity to withdraw from FSAP.

## *Inspection Report Process and Target Time Frames*

The process for generating a final inspection report is complex and involves, at minimum: review of observations and documents collected during inspection; determination of departures from regulatory requirements and associated severity levels; debrief and discussion with program leadership, ensuring consistency between inspection teams; and writing, editing, and delivering the observations through the eFSAP information system to the entity. The target timeframe for the entire inspection report process is 30 business days. In 2016, FSAP also began issuing immediate action reports when inspections identified serious regulatory violations that required urgent action by an entity. FSAP sends these reports within 10 business days to allow the entity to address urgent concerns as soon as possible.[1] The target timeframe for the entire final inspection report remains at 30 business days even when an immediate action report is issued. FSAP considers final reports issued after 30 business days to be delayed reports.

Since this report is focused on inspection report processing and not inspections, the reports issued in CY2019 do not reflect the total number of inspections conducted in CY2019. This report includes inspection reports that were issued in CY2019 but for which the inspections occurred at the end of CY2018, and similarly, does not include reports for inspections that occurred at the end of CY2019 but the reports were not issued until CY2020.

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1    For significant inspection findings that compromise safety or security, FSAP shares those findings with the entity immediately to ensure action is taken to address the concern as soon as possible.

# Section 3. Results

## *Final Inspection Reports*

FSAP issued 193 final inspection reports in CY2019 (Table 1). This number includes 23 reports for inspections that occurred in CY2018, but the reports were sent to the entities in CY2019. The target timeframe to process a final inspection report and issue it to an entity is 30 business days following the Monday after the conclusion of the inspection. **Of those 193 final inspection reports, 97% were sent within the target timeframe of 30 business days.** To further break down the results:

- AgSAS issued 95% of its 37 final inspection reports within 30 business days during CY2019. For comparison, AgSAS issued 84% (21/25) of the reports in CY2018 within the target timeframe of 30 business days (Figure 1).

- DSAT issued 98% of its 156 final inspection reports within the target timeframe of 30 business days. For comparison, DSAT issued 95% (160/169) of the reports in CY2018, 96% (136/142) of the reports in CY2017, 73% (88/120) of the reports in CY2016, and 64% (99/154) of reports in CY2015 within 30 business days (Figure 2).

As of December 31, 2019, inspection reports from 19 inspections performed either in November or December of 2019 were still pending. FSAP issued all 19 of those inspection reports in early 2020—within the target timeframe of 30 business days; that data will be included as part of the data analysis in next year's *2020 FSAP Inspection Report Processing Annual Summary*.

*Table 1. FSAP Final Inspection Report Processing Time, CY2019*

| Agency | Total Number of Final Reports | Number of Final Reports Sent Within Processing Target | Processing Time to Final Report (in Federal Government Business Days) Average / Range |
|---|---|---|---|
| AgSAS | 37 | 35 | 17.8 / 3–41 |
| DSAT | 156 | 153 | 21.7 / 0–37 |
| **FSAP Total** | **193** | **188** | **21.0 / 0–41** |

Figure 1. Two-year Comparison of Final Inspection Report Processing Times for AgSAS
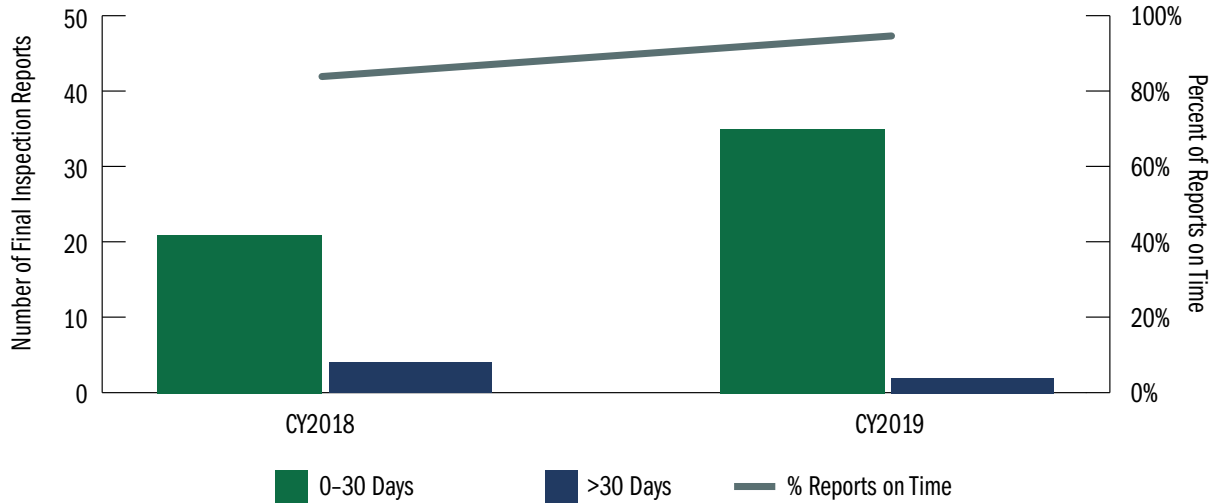
*Figure 1. The bar graph shows the number of final inspection reports AgSAS issued over the past two years. The solid line shows the percent of final inspection reports sent within 30 business days.*



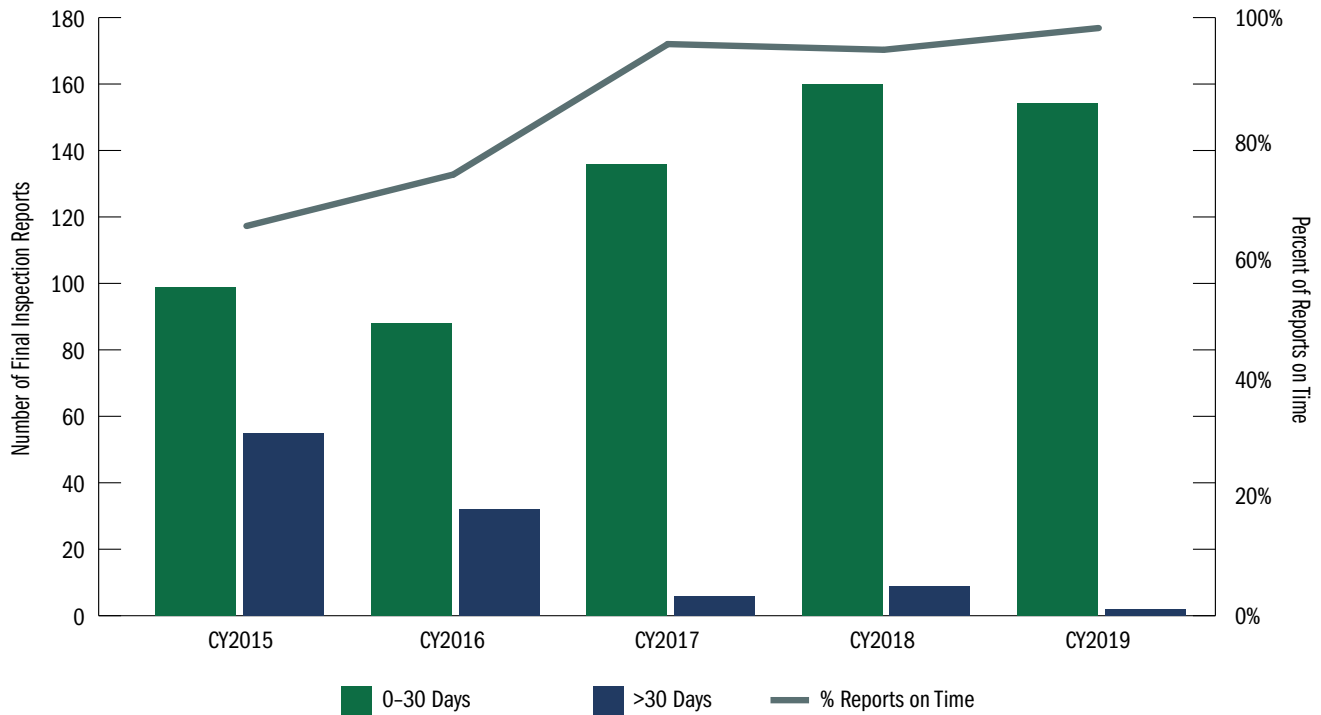Figure 2. Five-year Comparison of Final Inspection Report Processing Times for DSAT

*Figure 2. The bar graph shows the number of final inspection reports DSAT issued over the past five years. The solid line shows the percent of final inspection reports sent within 30 business days.*

## Immediate Action Inspection Reports

In CY2019, FSAP issued seven immediate action reports (five sent by DSAT and two sent by AgSAS), all within the target timeframe of 10 business days following the Monday after the conclusion of the inspection (Table 2). The average processing time for immediate action reports was 8 business days. For comparison, FSAP issued four immediate action reports in CY2018, all sent within the target timeframe of 10 business days. The average processing time for immediate action reports in CY2018 was 6 business days.

*Table 2. FSAP Immediate Action Inspection Report Processing Time, CY2019*

| Report Type | Number of Reports | Number of Reports Sent Within Processing Target | Processing Time (in Federal Government Business Days) Average / Range |
|---|---|---|---|
| Immediate Action Report | 7 | 7 | 8 / 0–10 |

## Relationship of Inspection Report Type to Processing Times

FSAP observed that Verification Inspection reports were the most common type of report sent in CY2019 for both AgSAS and DSAT; these reports accounted for two of the five delayed reports (Table 3). The second most common inspection report type was Renewal Inspection reports, which also accounted for two of the five delayed reports. The remaining delayed report was for a Compliance Inspection. For comparison, the most commonly delayed report in CY2015 was for New Space Inspections, in CY2016 and CY2017 it was for Renewal Inspections, and in CY2018 it was for Verification Inspections.

*Table 3. FSAP Final Inspection Report Processing Time by Inspection Type, CY2019*

| Agency | Verification ≤30 Days | Verification >30 Days | Renewal ≤30 Days | Renewal >30 Days | Maximum Containment ≤30 Days | Maximum Containment >30 Days | New Space ≤30 Days | New Space >30 Days | New Entity ≤30 Days | New Entity >30 Days | Compliance ≤30 Days | Compliance >30 Days |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DSAT | 75 | 1 | 64 | 1 | 6 | 0 | 4 | 0 | 0 | 0 | 4 | 1 |
| AgSAS | 17 | 1 | 14 | 1 | 0 | 0 | 1 | 0 | 1 | 0 | 3 | 0 |
| **FSAP Total** | **92** | **2** | **78** | **2** | **6** | **0** | **5** | **0** | **1** | **0** | **6** | **1** |

*Table 3. The table shows the number of final inspection reports sent either within (≤30 Days) or after 30 business days (>30 Days) by inspection type for CY2019.*

## Reasons for Delayed Reports

In CY2019, 188 of the 193 final inspection reports were sent to entities within 30 business days. Five final inspection reports were delayed across both AgSAS and DSAT. Of those five reports:

- DSAT issued two reports at 32 business days and one report at 37 business days.
- AgSAS issued two reports, one each at 33 and 41 business days, respectively.

FSAP closely monitors reasons for delayed final inspection reports so that it can implement process changes as needed to decrease issuance time. Reasons for delayed reports included the following:

- Staff leave and availability around federal holidays (1)
- Staff shortages due to competing priorities and staff availability (1)
- Complex observations that required extensive discussion and review (1)
- IT and process issues related to sending notification to an entity if there were no adverse observations (2)

# Section 4. Discussion

CY2019 is the second year FSAP conducted a joint DSAT/AgSAS analysis of inspection report timeliness data. FSAP continues to demonstrate its strong commitment to increasing inspection report timeliness, issuing 97% of final inspection reports, and all immediate action reports, within the target timeframes. During CY2019, FSAP issued nearly all of its final inspection reports within the target of 30 business days; DSAT issued 98% and AgSAS issued 95% of their inspection reports within the target timeframe. CY2019 is the third consecutive year for DSAT, and the first year for AgSAS, in which at least 95% of the final inspection reports were issued within this timeframe. FSAP will continue to track and review inspection report processing time data to ensure that entities receive timely feedback.

This was the fourth year that FSAP issued immediate action reports to hasten communication of serious regulatory departures in order to enable rapid entity response. FSAP issued seven immediate action reports in CY2019, all within the target of 10 business days: five for DSAT-led inspections and two for AgSAS-led inspections. FSAP will continue to provide entities prompt notification of serious regulatory departures.

FSAP also analyzed the data by inspection type to identify which type resulted in delayed final inspection reports. In CY2019, there were two Verification Inspection reports and two Renewal Inspection reports that were delayed. These two types of inspections were the most commonly conducted during the year, accounting for a combined 90% of the inspection reports released by FSAP in CY2019. The one other delayed report was for a Compliance Inspection.

In CY2019, FSAP leadership analyzed detailed reasons for each late report to adjust work processes to reduce future delays. In early 2019, FSAP implemented a new method for issuing inspection reports to entities using the eFSAP information system. FSAP anticipated that this new process would reduce delays. Inspection observations and comments are now captured and tracked in the system: the lead author directly inputs observations noted in the draft reports; inspection report reviewers edit the observations for clarity and accuracy within the eFSAP information system; this is followed by legal review; and the final report containing inspection observations is sent directly to the entity, all serving to increase review efficiency and customer service. Of the five late reports, two of those reports had no adverse observations, and therefore no action was required by the entity, but process issues were identified where notifications of such results were not sent to the entities within the target timeframe. The IT and process issues identified during this review did lead to additional refinements being made to the eFSAP information system to correct these issues. In this report, no systemic deficits were identified to merit institution of further corrective actions at this time, but process reviews are ongoing and corrective actions will be undertaken should the need arise. FSAP will continue to track reasons for inspection report delays to identify additional processes (including improvements to the eFSAP information system) that may improve the timeliness of all reports.

Inspection reports are an important tool for providing critical feedback to entities that possess, use, or transfer BSAT. These reports contain FSAP's inspection observations and, often, required corrective actions, or if there were no adverse observations, are used to inform the entity that no corrective actions are needed. The timely issuance of inspection reports allows an entity to address the observations expeditiously to improve the safety and security of their work with select agents and toxins, their employees, facilities, and surrounding communities. FSAP is continually striving to improve the inspection report issuance process by using data from analyses to address any concerns that may be identified throughout the year.

For questions, please contact DSAT at LRSAT@cdc.gov or AgSAS at AgSAS@usda.gov.