



2018 Federal Select Agent Program Inspection Report Processing Annual Summary

Published October, 2019



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

The 2018 Federal Select Agent Program Inspection Report Processing Annual Summary presents an analysis of the time frame for an entity registered with the program to receive a report after an on-site inspection during calendar year 2018 (CY2018). The Federal Select Agent Program (FSAP) uses this data to improve program performance in providing timely feedback to those registered entities that have received an on-site inspection. The target time frame to process and issue a final inspection report to an entity is 30 business days. **Of the 194 final inspection reports issued in CY2018, 93% overall were within the 30-business day time frame.**

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 (SAR) include biosafety/biocontainment, security, and incident response requirements that all 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 SAR and on-site inspections to review laboratory programs to ensure that appropriate biosafety/biocontainment and security measures are in place.

This report analyzes FSAP's responsiveness in providing feedback to entities after an on-site inspection. **While DSAT has issued annual summaries in the past three years, this is the first year the annual summary includes AgSAS timeliness data.** Previous reports specific to DSAT activities are available on the FSAP website at <https://www.selectagents.gov/publications.html>.

Section 2. Methods

Data Gathering and Analysis

FSAP calculated processing time 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. FSAP extracted these dates 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 an 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 an entity's registered maximum containment program, including laboratory spaces and documents specific to work that requires the highest levels of containment—such as Biosafety Level (BSL)-4.
3. **New Entity**—Review of information provided in an entity's application to register with the 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 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; often includes an assessment of responses to previous inspection findings and may be conducted prior to allowing an entity to withdraw from FSAP.

Inspection Report Process and Target Time Frames

The final inspection report process is complex and typically involves, at minimum, the following:

- A review of observations and documents collected during inspection
- Determination of any departures from regulatory requirements and associated severity level
- Debrief and discussion with program leadership of consistency between other inspection team members
- Writing, editing, and delivering the final report to the entity

The target time frame for the entire inspection report process is 30 business days. In 2016, FSAP also began issuing immediate action reports when serious regulatory violations were identified requiring 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 time frame 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.”

This analysis includes all reports issued by FSAP in CY2018 but does not reflect the total number of inspections conducted in CY2018.

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

Section 3. Results

Final Inspection Reports

FSAP issued 194 final inspection reports in CY2018 (Table 1). This number includes 11 reports for inspections that occurred in CY2017 but the reports were sent to the entities in CY2018. **Of the 194 final inspection reports, 93% overall were within the 30-business day time frame.** (This is the first year that AgSAS data is included and year-to-year comparative data for both agencies will be included in future reports.) To further break down the results,

- AgSAS issued 84% of its 25 final inspection reports within 30 business days during CY2018.²
- DSAT issued 95% of its 169 final inspection reports within the 30 day target time frame.
 - ◆ For comparison, DSAT issued 96% (136/142) of the reports in CY2017, 73% (88/120) of the reports in CY2016, and 64% (99/154) of the reports in CY2015 within the 30-business day metric (Figure 1).

As of December 31, 2018, inspection reports from 23 inspections performed either in November or December of 2018 were still pending. FSAP issued 22 of those 23 inspection reports within the 30-business day metric in early 2019; that data will be included as part of the data analysis in next year’s 2019 FSAP Inspection Report Processing Annual Summary. There are no outstanding final reports for inspections performed in CY2017.

Table 1. FSAP Final Inspection Report Processing Time, CY2018

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
DSAT	169	160	22.3 / 3–51
AgSAS	25	21	26.2 / 4–99
FSAP Total	194	181	23.6 / 3–99

² One final inspection report sent to an entity in CY2018 combined two AgSAS inspections conducted in CY2017. The processing time for this report was calculated from the Monday following the first inspection.

Figure 1. Four-year Comparison of Final Inspection Report Processing Times for DSAT

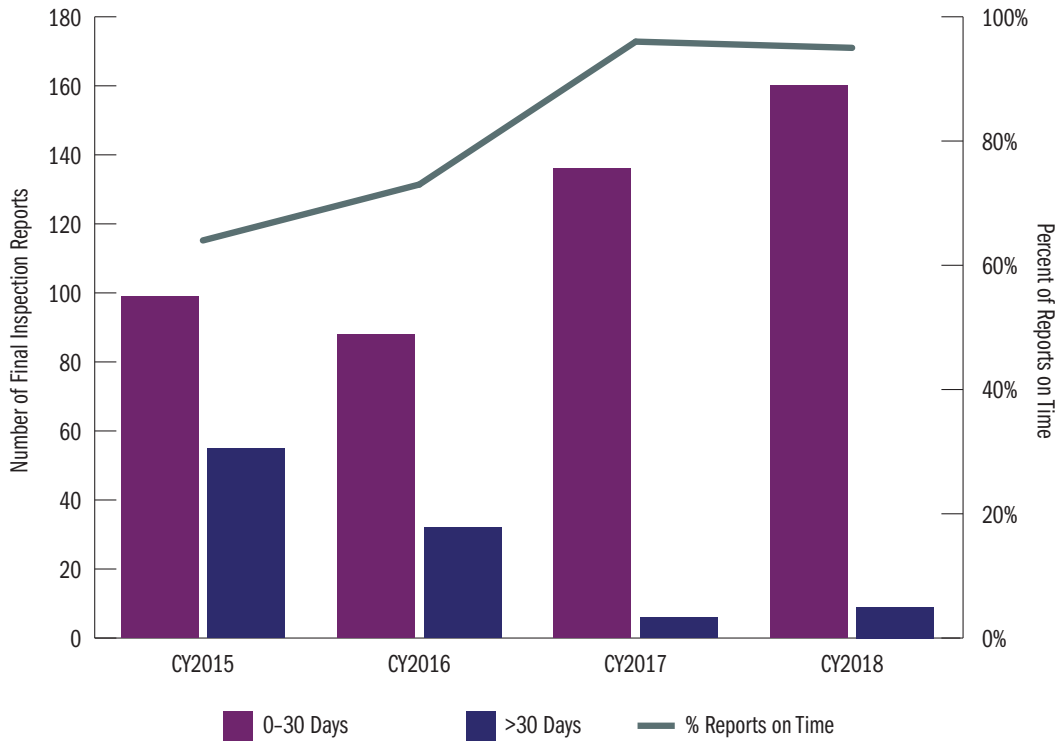


Figure 1. The graph shows the number of final inspection reports DSAT issued over the past 4 years. The line shows the percent of final inspection reports sent within 30 business days. The percent increased from 64% in CY2015, to 73% in CY2016, and peaked at 96% in CY2017 before decreasing slightly to 95% in CY2018.

Immediate Action Inspection Reports

In CY2018, FSAP issued four immediate action reports (two sent by DSAT and two sent by AgSAS), all within the 10-business day time frame (Table 2). The average processing time for immediate action reports was 5.8 business days. For comparison, DSAT issued three immediate action reports in CY2017 and 13 immediate action reports in CY2016. All three immediate action reports were sent within the 10-business day time frame in CY2017, and 7 of the 13 immediate action reports were sent within this same metric in CY2016.

Table 2. FSAP Immediate Action Inspection Report Processing Time, CY2018

Report Type	Number of Reports	Number of Reports Sent Within Processing Target	Processing Time (in Federal Government Business Days) Average / Range
Immediate Action Report	4	4	5.8 / 4-9

Relationship of Inspection Type to Processing Times

FSAP observed that Verification Inspections were the most common report sent in CY2018 for both AgSAS and DSAT, and accounted for 8 of the 13 delayed reports (Table 3). The second most common inspection type was Renewal Inspections, which accounted for 4 of the 13 delayed reports. The remaining delayed report was for a Maximum Containment Inspection. For comparison, the most commonly delayed report in 2015 was for New Space Inspections, and the most commonly delayed report in both 2016 and 2017 was for Renewal Inspections.

Table 3. FSAP Final Inspection Report Processing Time by Inspection Type, CY2018

Agency	Verification On Time	Verification >30 Days	Renewal On Time	Renewal >30 Days	Maximum Containment On Time	Maximum Containment >30 Days	New Space On Time	New Space >30 Days	New Entity On Time	New Entity >30 Days	Compliance On Time	Compliance >30 Days
DSAT	81	6	60	3	7	0	9	0	1	0	2	0
AgSAS	11	2	9	1	1	1	0	0	0	0	0	0
FSAP Total	92	8	69	4	8	1	9	0	1	0	2	0

Reasons for Delayed Reports

In CY2018, 181 of the 194 final inspection reports were sent to entities within 30 business days. Only 13 final inspection reports in total were delayed across both AgSAS and DSAT. Of those 13 reports:

- DSAT issued 8 within 40 business days, and 1 report at 51 business days.
- AgSAS issued the remaining 4 delayed reports at 50, 56, 96, and 99 business days; 3 of these reports were for inspections that occurred in CY2017.

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:³

- Proximity of inspection dates to federal holidays (1)
- Staff turnover or training of new staff (4)
- Implementation of a new process to issue inspection reports that resulted in a learning curve for both agencies (3)
- Misunderstanding of the need to issue a report even when no observations were found on inspection (2)
- Entity did not provide requested information in a timely manner (1)
- Complex observations that required extensive discussion and review (2)
- Miscommunication on status in review process (2)

FSAP addressed these delays through inspector training, the inspection scheduling process, and full implementation of a new electronic system (eFSAP) for tracking the review and issuance of inspection observations.

³ The number of delayed reports for each reason is greater than the total number of delayed reports due to multiple reasons being cited for some reports.

Section 4. Discussion

CY2018 is the first year FSAP conducted a joint DSAT/AgSAS analysis of inspection report timeliness data, because AgSAS began formally tracking their data in CY2018. FSAP continues to demonstrate its strong commitment to increasing report timeliness, issuing 93% of final inspection reports and all immediate action reports within the target time frames. FSAP will continue to track and review inspection report processing time data to ensure that entities receive timely feedback to improve their programs.

During CY2018, FSAP issued the majority of its final inspection reports within the 30-business day target; DSAT issued 95% and AgSAS 84% of their reports on time. CY2018 is the second consecutive year in which DSAT issued at least 95% of their final inspection reports on time (Figure 1). This stable performance is notable since the number of final inspection reports issued by DSAT increased by 27 reports in CY2018.

This was the third year that FSAP issued immediate action reports to hasten communication of serious regulatory departures in order to enable rapid entity response. FSAP issued four immediate action reports in CY2018, all within the 10-business day target: two for DSAT-led inspections and two for AgSAS-led inspections. FSAP will continue to provide entities prompt notification of serious regulatory departures, and strive to reduce the average time frame even further.

Starting in January 2016, FSAP began issuing preliminary reports to provide inspection feedback to entities within 20 days only when the final report would not be issued within 30 business days. FSAP discontinued the use of preliminary reports because of increased efforts to issue final inspection reports on time, as reflected in the high percentage of reports issued within the 30-business day metric. If FSAP observes an increase in delayed final inspection reports, the program may reinstate the use of preliminary reports.

FSAP also analyzed the data by inspection type to identify and mitigate root causes that may lengthen reporting cycle time. Previously, Maximum Containment Inspection reports were the most delayed, largely due to staffing limitations. During CY2017, additional inspectors were trained to conduct Maximum Containment Inspections and were available to inspect these complex laboratories in

CY2018. As a result, only one Maximum Containment Inspection report was among the delayed reports (Table 3). CY2018 data shows that Verification Inspection reports are now the most commonly delayed, accounting for 8 of the 13 delayed reports. However, Verification Inspections were also the most common inspection type conducted in CY2018 (52% of all inspections). FSAP will continue to monitor Verification Inspection report processing times to identify ways to improve the timeliness of these reports.

In CY2018, 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. All inspection observations and comments are now captured and tracked in the system as follows:

- The lead author directly inputs draft reports
- Inspection report reviewers edit the observations in the system
- The inspection observations are sent directly to the entity, all serving to increase review efficiency

FSAP anticipates that this new process will greatly reduce delays regardless of the type of inspection conducted. FSAP will continue to track reasons for inspection report delays to identify additional processes 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 required corrective actions. The timely issuance of inspection reports allows an entity to address the observations expeditiously in order to improve the safety and security of their employees, facilities, and surrounding communities. FSAP is continually striving to improve the inspection report issuance process by using data from analyses throughout the year to address issues.

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

