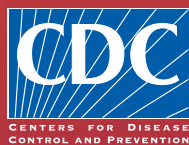


# 2020 Federal Select Agent Program Inspection Report Processing Annual Summary

Published August, 2021



# Acronyms

Acronym	Description
APHIS	The <b>Animal and Plant Health Inspection Service</b> , located within the United States Department of Agriculture, is a multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities.
BSAT	<b>Biological select agents and toxins</b> are pathogens or toxins that have been determined to have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products.
CDC	The <b>Centers for Disease Control and Prevention</b> , located within the Department of Health and Human Services, conducts science and provides health information to protect people from health, safety, and security threats.
DASAT	The <b>Division of Agricultural Select Agents and Toxins</b> , located within the Animal and Plant Health Inspection Service of the United States Department of Agriculture, regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products.
DSAT	The <b>Division of Select Agents and Toxins</b> , located within the Center for Preparedness and Response at the Centers for Disease Control and Prevention, regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to human health.
eFSAP	eFSAP is the <b>Federal Select Agent Program's electronic information system</b> which allows for registered entities to manage their registrations and directly interact with the Program.
FSAP	The <b>Federal Select Agent Program</b> is jointly comprised of CDC/DSAT and APHIS/DASAT. FSAP oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products.
USDA	The <b>United States Department of Agriculture</b> provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management.

The *2020 Federal Select Agent Program (FSAP) Inspection Report Processing Annual Summary* presents an analysis of FSAP's responsiveness in providing feedback to FSAP-registered entities after inspections during Calendar Year (CY) 2020. The target time frame 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 CY2020, FSAP issued 157 final inspection reports. **Of those, 100% were sent within the target time frame of 30 business days.**

## Section 1. Introduction

FSAP regulates the possession, use, and transfer of biological select agents and toxins (BSAT) – such as *Bacillus anthracis*, highly pathogenic 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)/Division of Agricultural Select Agents and Toxins (DASAT)<sup>1</sup>. HHS provides oversight for BSAT that have the potential to pose a severe threat to public health and safety. USDA provides oversight for BSAT 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 overlap BSAT that have the potential to pose a severe threat to both public health and safety, and to animal health or to animal products. An entity that possesses, transfers, or works with BSAT is required to register with FSAP, and is subject to the select agent regulations. FSAP verifies compliance with the regulations through entity inspections.

In April 2020, due to the Coronavirus Disease 2019 (COVID-19) pandemic, FSAP developed and implemented remote inspections due to travel restrictions and for the safety of inspectors and entity staff. The remote inspections focused primarily on the recordkeeping aspects of the regulations, plans, and training, but still enabled FSAP to continue oversight of registered entities. Also for the first time, FSAP conducted a small number of hybrid inspections, which included both on-site and remote inspections of the registered entity. FSAP performed hybrid inspections when there was a need to inspect on site (such as previous compliance problems or complex facility issues), while document review was conducted remotely to minimize the inspectors' time at the entity.

The *2020 Federal Select Agent Program Inspection Report Processing Annual Summary* is the third program analysis of inspection report timeliness data. It is the sixth annual analysis of timeliness data for DSAT, and the third for DASAT. Previous reports are available on the FSAP website at <https://www.selectagents.gov/resources/publications/index.htm>.

---

<sup>1</sup> Name change effective January 12, 2021

## Section 2. Methods

### *Data Gathering and Analysis*

FSAP calculated the inspection report processing time based on the number of business days, beginning from the Monday following the last day of the inspection (allowing for travel time) to the release of the inspection findings to the entity. Data was extracted for the report from the FSAP electronic information system (eFSAP). eFSAP is a highly secure information platform allowing for real-time bi-directional communication between FSAP and the regulated community.

### *Inspection Report Process and Target Time Frames*

The process for generating an 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; discussion with program leadership and legal counsel to ensure consistency in regulatory interpretations; and writing, editing, and releasing the observations through the eFSAP information system to the entity. The target time frame to produce a final inspection report and issue it to an entity is 30 federal business days following the Monday after the conclusion of the inspection.

If necessary, within 10 business days, FSAP also issues immediate action observations when inspections identify serious regulatory violations that require urgent action by an entity (i.e., violations that represent an immediate threat to human, plant, or animal health; animal or plant products; and/or security of biological select agents and toxins; as well as those that indicate a need for systemic improvements).<sup>2</sup> The target time frame for the issuance of a final inspection report remains at 30 business days even when immediate action observations are issued. FSAP considers final inspection reports issued after 30 business days to be delayed reports. FSAP uses this data to improve program performance in providing timely feedback to registered entities that have received an inspection.

This report is focused on inspection report processing and not the overall number of inspections. Therefore, the number of reports issued in CY2020 does not reflect the total number of inspections conducted in CY2020. Inspections conducted at the end of CY2019 but for which the inspection reports were not issued until CY2020 are included in this report, and inspections conducted at the end of CY2020 but for which the inspection reports were not issued until CY2021 will be included in next year's report.

---

<sup>2</sup> 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 157 final inspection reports in CY2020 (Table 1). This number includes 19 reports for inspections that occurred in CY2019, but the reports were sent to the entities in CY2020. **Of those 157 final inspection reports, 100% were sent within the target time frame of 30 business days.** To further break down the results:

- DASAT issued 100% of its 32 final inspection reports within 30 business days during CY2020. For comparison, DASAT issued 95% (35/37) of the reports in CY2019, and 84% (21/25) of the reports in CY2018, within the target time frame of 30 business days (Figure 1).
- DSAT issued 100% of its 125 final inspection reports within the target time frame of 30 business days. For comparison, DSAT issued 98% (153/156) of the reports in CY2019, 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, 2020, final inspection reports from 11 inspections performed either in October, November, or December of 2020 were still pending. FSAP issued 10 of those 11 final inspection reports in early 2021 within the target timeframe of 30 business days; that data will be included as part of the data analysis in next year's *2021 FSAP Inspection Report Processing Annual Summary*.

Table 1. FSAP Final Inspection Report Processing Time, CY2020

Total Number of Final Reports by Agency		Number of Final Reports Sent Within Processing Target	Processing Time to Final Report (in Federal Government Business Days) Average / Range
DASAT	32	32	13.3/2-30
DSAT	125	125	21.1/2-30
<b>FSAP Total</b>	<b>157</b>	<b>157</b>	<b>19.5/2-30</b>

Figure 1. Three-year Comparison of Final Inspection Report Processing Times, DASAT

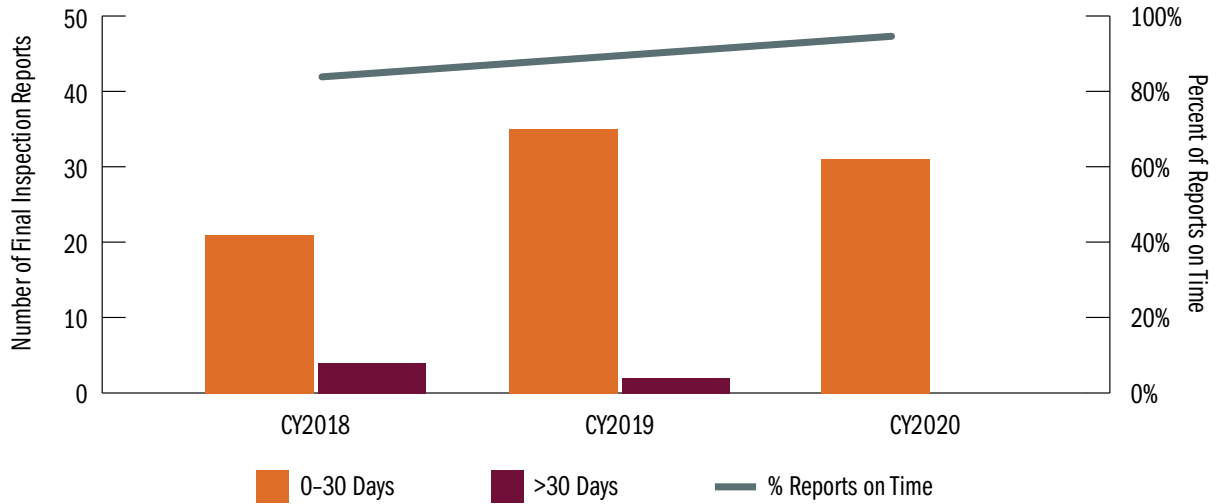


Figure 1. Three-year Comparison of Final Inspection Report Processing Times for DASAT. The bar graph shows the number of final inspection reports DASAT issued over the past three years. The solid line shows the percent of final inspection reports sent within 30 business days.

Figure 2. Six-year Comparison of Final Inspection Report Processing Times, DSAT

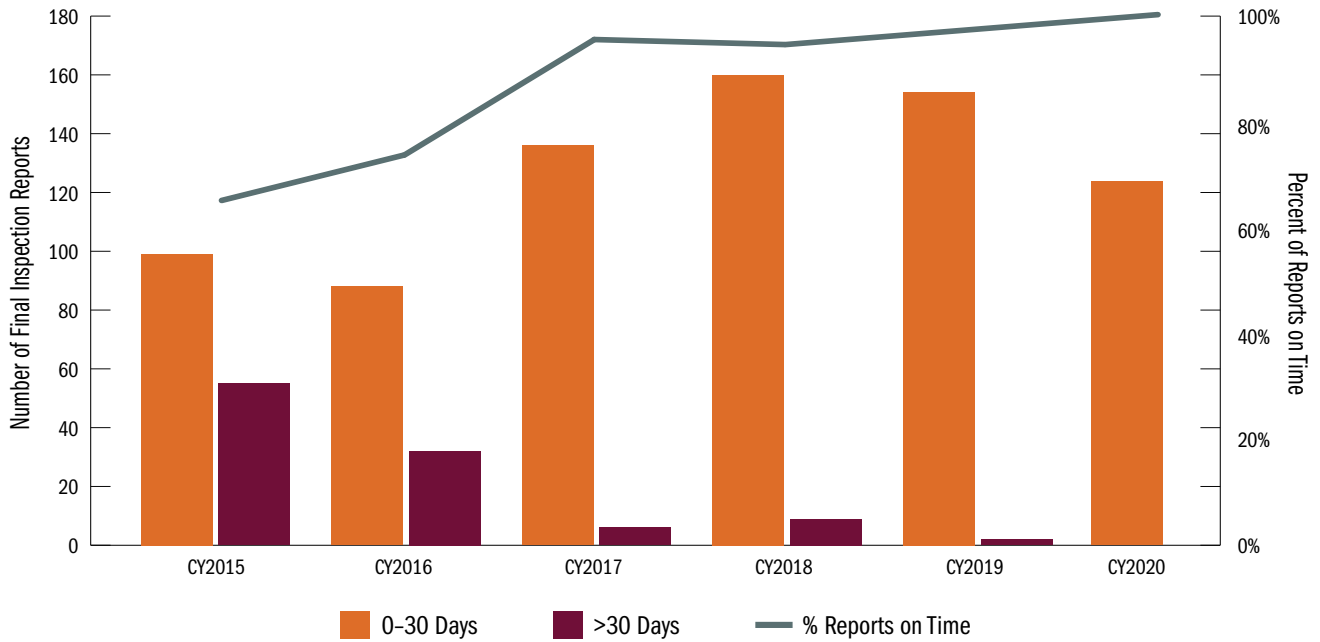


Figure 2. Six-year Comparison of Final Inspection Report Processing Times for DSAT. The bar graph shows the number of final inspection reports DSAT issued over the past six years. The solid line shows the percent of final inspection reports sent within 30 business days.

## Immediate Action Observations

In CY2020, FSAP issued eight immediate action observations (two sent by DSAT and six sent by DASAT), with seven out of the eight issued within the target timeframe of 10 business days following the Monday after the conclusion of the inspection (Table 2). The remaining immediate action observation was issued at 13 business days, and was delayed due to complex inspection observations that required extensive discussion and review. However, the final report for that inspection was issued on time at 28 business days.

The average processing time for immediate action observations was 7 business days. For comparison, FSAP issued eight immediate action observations in CY2019 and four in CY2018, all within the target timeframe of 10 business days. The average processing time for immediate action observations in CY2019 was 8 business days, and the average processing time for immediate action observations in CY2018 was 6 business days.

Table 2. FSAP Immediate Action Observation Processing Time, CY2020

	Number of Observations Sent to Entities	Number of Observations Sent to Entities Within Processing Target	Processing Time (in Federal Government Business Days) Average / Range
Immediate Action Observation	8	7	7/1-13

## Comparison of On-site, Remote, and Hybrid Inspection Report Processing Times

In CY2020, due to the COVID-19 pandemic, FSAP conducted remote inspections for the first time. Therefore, FSAP wanted to understand the effect of remote inspections on inspection report processing times. Table 3 details the number of final inspection reports and processing time for the reports issued either by DASAT or DSAT during CY2020 according to type of inspection: on-site, remote or hybrid. The on-site inspections primarily occurred in CY2019 (but the final inspection reports were issued in CY2020) or prior to April 2020. Average processing times for DASAT and DSAT final inspection reports for the remote inspections were shorter than processing times for on-site inspections. DASAT and DSAT were issuing final remote inspection reports earlier by 8.5 days and 1.2 days, respectively. The final hybrid inspection reports issued by DSAT took on average 28.7 business days and ranged from 26 to 30 business days; these were higher than the averages and ranges for remote or on-site inspections. These were complex inspections that required a high degree of coordination between the on-site and remote inspection teams. However, all final inspection reports were issued within the 30 business days, regardless of the inspection type.

Table 3. FSAP Comparison of Final Inspection Report Processing Times for On-site, Remote, or Hybrid Inspections, CY2020

Agency and Inspection Type	Number of Final Reports	Processing Time (in Federal Government Business Days) Average / Range
DASAT On-site	8	19.6/10-30
DASAT Remote	24	11.1/2-25
DSAT On-site	54	21.6/2-30
DSAT Remote	68	20.4/3-30
DSAT Hybrid*	3	28.7/26-30

\*DASAT did not lead or issue any final inspection reports for hybrid inspections during CY2020

## Section 4. Discussion

CY2020 is the third year FSAP conducted a joint DSAT/DASAT analysis of inspection report timeliness data. FSAP continues to demonstrate its strong commitment to increase inspection report timeliness by issuing 100% of final inspection reports within the target timeframes. CY2020 is the fourth consecutive year for DSAT, and the second consecutive year for DASAT, 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.

FSAP issued eight immediate action observations to entities in CY2020, with seven of those issued within the target of 10 business days. The one delayed immediate action observation was issued at 13 business days, and the final report for that inspection was still issued on time at 28 business days. FSAP will continue to provide entities prompt notification of serious regulatory departures.

In early 2019, FSAP implemented a new method for issuing inspection reports to entities using the eFSAP information system. The use of eFSAP to issue inspection reports has reduced delays and contributed to meeting the 100% timeliness metric.

Due to the COVID-19 pandemic, FSAP had to adjust its inspection processes by adopting remote or hybrid inspections to ensure compliance with the select agent regulations. The capability to conduct remote inspections was aided by the direct interaction with the entities through the use of the eFSAP information system. The shift to remote inspections in CY2020 did not result in any delay in issuing inspection reports. Rather, average processing times for remote inspection reports were shorter than the average processing times for reports issued for on-site inspections.

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, require an entity to take 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 select agents and toxins. FSAP is continually striving to improve the inspection report issuance process by using data to address any problems that may be identified throughout the year.

For questions, please contact DSAT at [LRSAT@cdc.gov](mailto:LRSAT@cdc.gov) or DASAT at [DASAT@usda.gov](mailto:DASAT@usda.gov).



