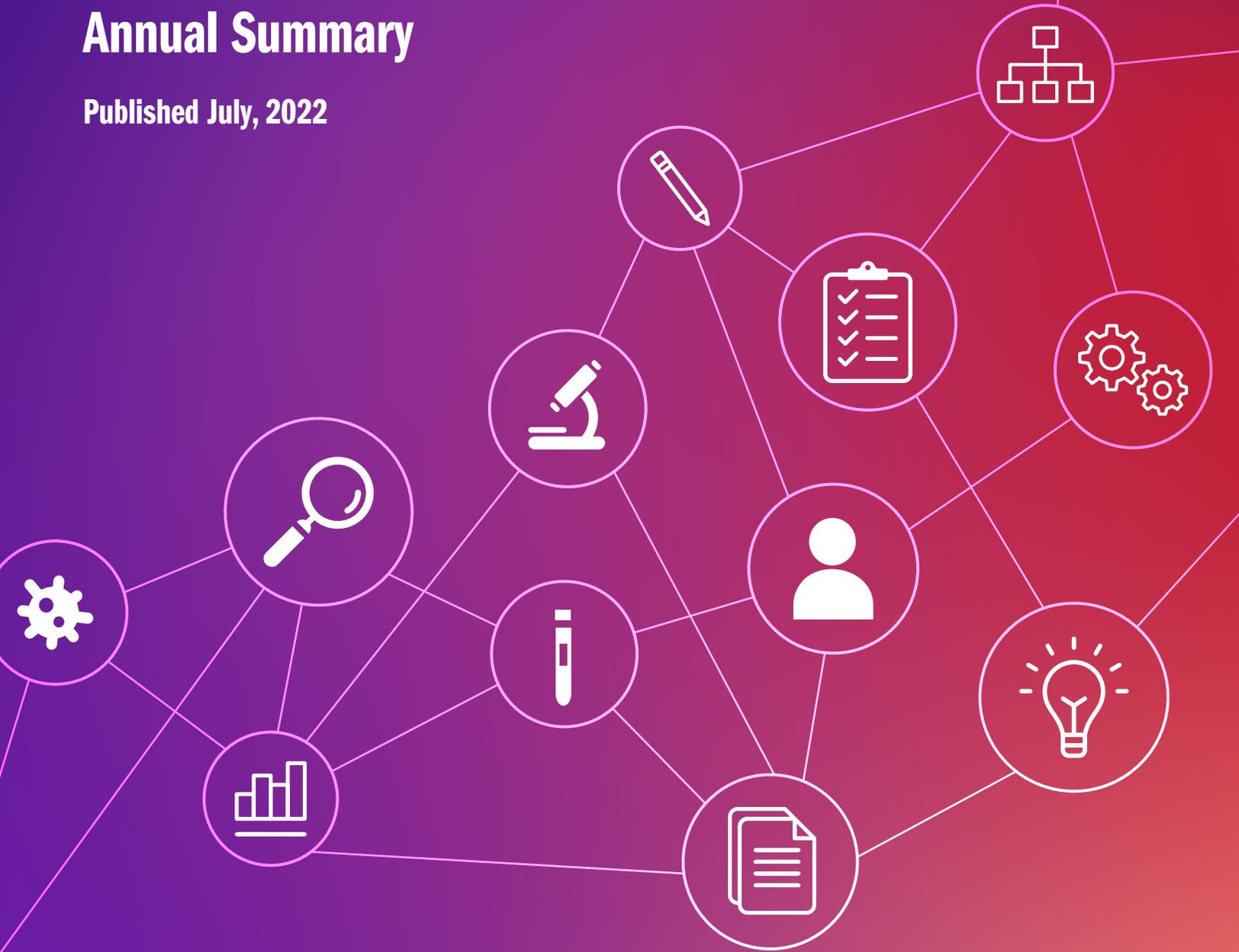


2021 Federal Select Agent Program Inspection Report Processing Annual Summary

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



Acronyms

Acronym	Description
APHIS	The Animal and Plant Health Inspection Service , 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	Biological select agents and toxins 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 Centers for Disease Control and Prevention , 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 Division of Agricultural Select Agents and Toxins , 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 Division of Select Agents and Toxins , 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 Federal Select Agent Program's electronic information system which allows for registered entities to manage their registrations and directly interact with the Program.
FSAP	The Federal Select Agent Program 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 United States Department of Agriculture 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 2021 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) 2021. 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 CY2021, FSAP issued 201 final inspection reports with 99% of those reports issued within the target timeframe 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)¹. 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, which 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.

Throughout CY2021, the majority of FSAP inspections continued to be conducted remotely due to concerns about travel during the Coronavirus Disease 2019 (COVID-19) pandemic and to ensure the safety of inspectors as well as entity staff. However, some on-site and hybrid inspections were conducted. The hybrid inspections included both on-site and remote inspection components. The remote inspection component primarily included review of the recordkeeping aspects of the regulations, including but not limited to entity plans and training records. Staff interviews and occasionally opening and closing inspection meetings were also component parts of the remote inspections. The on-site portion of the hybrid inspections enabled a physical review of the facilities as well as records that entities did not provide in advance of the inspection start date.

Previous inspection report processing annual summaries are available on the FSAP website at <https://www.selectagents.gov/resources/publications/index.htm>.

¹ Name change effective January 12, 2021

Section 2. Methods

Data Gathering and Analysis

As with past reports, 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 to the release of the inspection findings to the entity. Data were 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 timeframe 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).² The target timeframe 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 these 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 CY2021 does not reflect the total number of inspections conducted in CY2021. Inspections conducted at the end of CY2020 but for which the inspection reports were not issued until CY2021 are included in this report. Also, inspections conducted at the end of CY2021 but for which the inspection reports were not issued until CY2022 will be included in next year's report.

² 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 201 final inspection reports in CY2021 (Table 1). This number includes 12 reports for inspections that occurred in CY2020, but the reports were sent to the entities in CY2021. Of those 201 final inspection reports, 99% were sent within the target timeframe of 30 business days. To further break down the results:

- DASAT issued 97% (32/33) of its final inspection reports within 30 business days during CY2021. For comparison, DASAT issued 100% of the 32 reports in CY2020, 95% (35/37) of the reports in CY2019, and 84% (21/25) of the reports in CY2018, within the target timeframe of 30 business days (Figure 1).
- DSAT issued 99% (167/168) of its final inspection reports within the target timeframe of 30 business days during CY2021. For comparison, DSAT issued 100% of the 125 reports in CY2020, 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 the reports in CY2015 within 30 business days (Figure 2).³

As of December 31, 2021, final inspection reports from 17 inspections performed either in November or December of 2021 were still pending. FSAP issued 100% of those 17 final inspection reports in early 2022 within the target timeframe of 30 business days. Those data will be included as part of the data analysis in next year's 2022 FSAP Inspection Report Processing Annual Summary.

Table 1. FSAP Final Inspection Report Processing Time, CY2021

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	33	32	17/5-31
DSAT	168	167	20/1-49
FSAP Total	201	199	20/1-49

³ DSAT began tracking inspection report processing times in CY2015, while DASAT began tracking inspection report processing times in CY2018.

Figure 1. Comparison of Final Inspection Report Processing Times by Year, DASAT

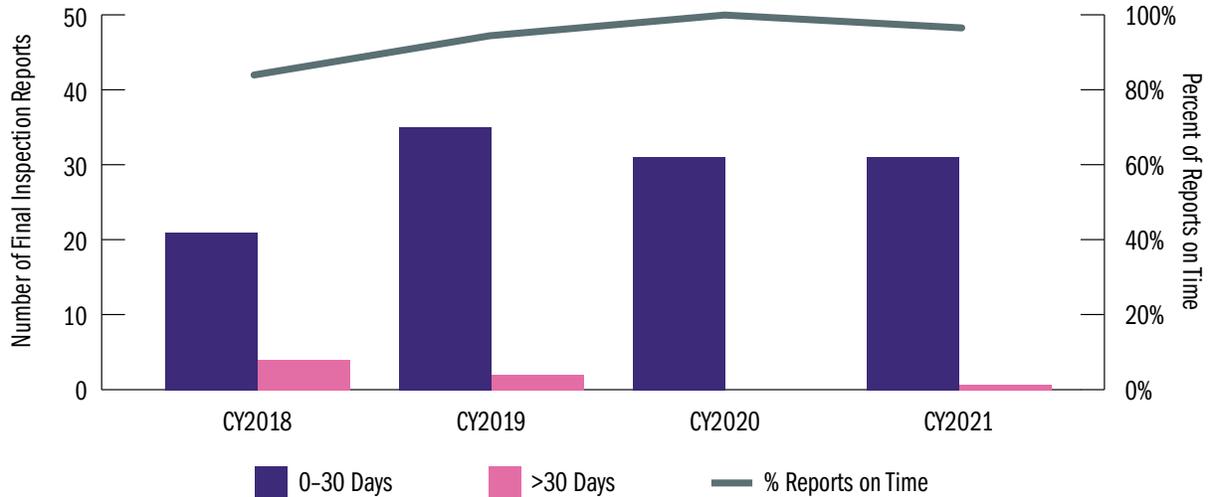


Figure 1. Comparison of Final Inspection Report Processing Times by Year for DASAT. The bar graph shows the number of final inspection reports DASAT issued over the past four years. The solid line shows the percent of final inspection reports sent within 30 business days.

Figure 2. Comparison of Final Inspection Report Processing Times by Year, DSAT

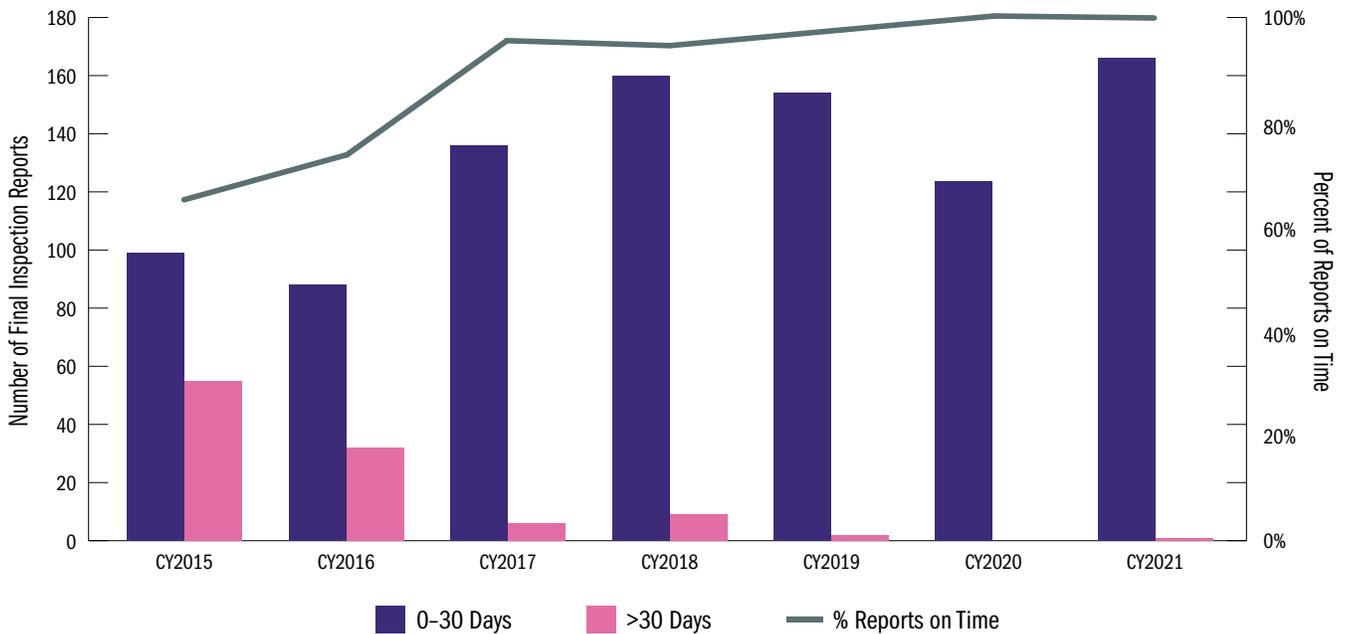


Figure 2. Comparison of Final Inspection Report Processing Times by Year for DSAT. The bar graph shows the number of final inspection reports DSAT issued over the past seven years. The solid line shows the percent of final inspection reports sent within 30 business days.

Reasons for Delayed Reports

All but two of the 201 final inspection reports were issued within the 30 business days.

- One delayed final inspection report for a remote inspection was due to miscommunication between DSAT and DASAT regarding the agency responsible for releasing the findings, which led to the report being issued at 49 business days.
- The other delayed final inspection report for an on-site inspection was released at 31 business days, only one day past the 30 business day metric. The reason for the delayed report was that the inspection was a complicated new space and new agent inspection, and it included adding new high containment space to a registration.

Immediate Action Observations

In CY2021, FSAP issued six immediate action observations (two sent by DSAT and four sent by DASAT), and 100% of the observations were issued 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 observations in CY2021 was seven business days. For comparison, FSAP issued eight immediate action observations in CY2020, eight in CY2019, and four in CY2018. In CY2020, seven out of the eight immediate action observations were issued within the target timeframe. The observations in CY2019 and CY2018 were all issued within the target timeframe of 10 business days. The average processing time for immediate action observations in CY2020 was seven business days, eight business days in CY2019, and six business days in CY2018.

Table 2. FSAP Immediate Action Observation Processing Time, CY2021

Observation Type	Number of Entities Sent Observations	Number of Entities Sent Observations Within Processing Target	Processing Time (in Business Days) Average / Range
Immediate Action Observation	6	6	7/5-9

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

In CY2021, FSAP continued remote as well as hybrid inspections, which were established in CY2020 due to the COVID-19 pandemic. On-site inspections were also conducted. Table 3 details the number of final inspection reports and processing time for the reports issued either by DASAT or DSAT during CY2021 according to type of inspection: on-site, remote or hybrid. Average processing times for DASAT final inspection reports for the remote and on-site inspections were 17-19 business days. DSAT issued final remote, hybrid, and on-site inspection reports with an average of 19-20 business days.

Table 3. FSAP Comparison of Final Inspection Report Processing Times for On-site, Remote, or Hybrid Inspections, CY2021

Agency and Inspection Type	Number of Final Reports	Processing Time (in Business Days) Average / Range
DASAT On-site	12	19/5-31
DASAT Remote	21	17/1-30
DSAT On-site	6	19/1-30
DSAT Remote	93	20/2-49
DSAT Hybrid*	69	20/1-30

*DASAT did not issue any final inspection reports for hybrid inspections during CY2021

Section 4. Discussion

CY2021 is the fourth year that FSAP conducted a joint DSAT/DASAT analysis of inspection report timeliness data. FSAP continues to demonstrate its strong commitment to issuing final inspection reports within the target timeframe of 30 business days by issuing 99% of the reports on time. CY2021 is the fifth 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. Also in CY2021, FSAP issued immediate action observations to six entities, with 100% of those issued within the target of 10 business days. FSAP will continue to provide entities prompt notification of serious regulatory departures. FSAP will also continue to track and review inspection report processing time data to ensure that entities receive timely feedback.

Two (one remote and one on-site) out of the 201 final inspection reports were considered delayed because they were released after the 30 business day metric. One report was for an inspection conducted by DSAT, but for a DASAT-registered entity, which led to a miscommunication between the agencies about which would be responsible for issuing the final report. After discovery of this delayed report, a procedure was implemented to ensure it was clear that the agency responsible for the inspection would also be responsible for releasing the report to the entity. For the second delayed final inspection report, this report was issued one day past the 30 business day metric. This was a complicated inspection involving both DSAT and DASAT, and the final inspection report was issued by DASAT. Both DSAT and DASAT will strive to ensure future reports are issued on time.

Since the start of the COVID-19 pandemic, FSAP has had to continue to adjust its inspection processes by conducting 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 continued to allow for thorough reviews of records and necessary interviews with entity staff, while helping to ensure the safety of inspectors and entity staff during the COVID-19 pandemic. FSAP anticipates further implementing the hybrid inspection module for most future 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 calendar year.

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

