

# 2022 Federal Select Agent Program Inspection Report Processing Annual Summary

Published July, 2023



# Inspection Report Processing By The Numbers



**198**

Final  
Inspection  
Reports

**100%**

**On Time**  
Within Target of  
30 Business Days

**17**

**Business Days**  
Average to Issue  
Final Report

# Acronyms

Acronym	Description
<b>APHIS</b>	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.
<b>BSAT</b>	<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.
<b>CDC</b>	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.
<b>DASAT</b>	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.
<b>DSAT</b>	The <b>Division of Select Agents and Toxins</b> , located within the Office of Readiness 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.
<b>eFSAP</b>	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 Federal Select Agent Program.
<b>FSAP</b>	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.
<b>USDA</b>	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 2022 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) 2022. 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 CY2022, FSAP issued 198 final inspection reports with 100% 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 the botulinum neurotoxins – 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). 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 and toxin regulations. FSAP verifies compliance with the regulations through entity inspections.

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

## 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 to the release of the final 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 Timeframes

The process for generating an inspection report involves: 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, as needed, 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 business days following the Monday after the conclusion of the inspection.

If necessary, within 10 business days, FSAP would issue an immediate action observation when an inspection identifies a serious regulatory violation that requires 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>1</sup> The target timeframe for the issuance of a final inspection report remains 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 CY2022 does not reflect the total number of inspections conducted in CY2022. Inspections conducted at the end of CY2021, but for which the inspection reports were issued in CY2022, are included in this report. Also, inspections conducted at the end of CY2022, but for which the inspection reports were not issued until CY2023, will be included in next year's report.

## Section 3. Results

### Inspection Reports

FSAP issued 198 final inspection reports in CY2022 (Table 1). This number includes 15 reports for inspections that occurred in CY2021, but the reports were sent to the entities in CY2022. Of those 198 final inspection reports, 100% were sent within the target timeframe of 30 business days. Additional details and analyses from past reports can be found [here](#).<sup>2</sup>

As of December 31, 2022, final inspection reports from 16 inspections performed in December 2022 were still pending. Those data will be included as part of the data analysis in next year's *2023 FSAP Inspection Report Processing Annual Summary*.

**Table 1.** FSAP Final Inspection Report Processing Time, CY2022

Agency	Total Number of Final Reports	Number of Final Reports Sent Within Processing Target	Processing Time to Final Report (in Business Days) Average/Range
DASAT	32	32	14/1-27
DSAT	166	166	17/1-29
<b>FSAP Total</b>	<b>198</b>	<b>198</b>	<b>17/1-29</b>

### Immediate Action Observations

In CY2022, FSAP issued one immediate action observation (sent by DSAT) within the target timeframe of 10 business days following the Monday after the conclusion of the

inspection (Table 2). Additional details and analyses from past reports can be found [here](#).

**Table 2.** FSAP Immediate Action Observation Processing Time, CY2022

Agency	Number of Entities Sent Observations	Number of Entities Sent Observations Within Processing Target	Processing Time (in Business Days)
<b>Immediate Action Observation</b>	<b>1</b>	<b>1</b>	<b>10</b>

<sup>1</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.

<sup>2</sup> DSAT began tracking inspection report processing times in CY2015, while DASAT began tracking inspection report processing times in CY2018.

---

## Section 4. Discussion

Inspection reports are an important tool for providing critical feedback to FSAP-registered entities. 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 entity's safety and security measures.

CY2022 is the fifth 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 100% of the reports on time in CY2022. CY2022 is the sixth consecutive year for DSAT, and the fourth 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.

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