

# 2025 Federal Select Agent Program Inspection Report Processing Annual Summary



# Inspection Report Processing By The Numbers



**164**

Final  
Inspection  
Reports

**88%**

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

**19**

**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 Emergency and Regulatory Compliance Services of the Animal and Plant Health Inspection Service in 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>DRSC</b>	The <b>Division of Regulatory Science and Compliance</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>	<b>eFSAP</b> is the Federal Select Agent Program’s electronic information system 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/DRSC 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 <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 *2025 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) 2025. 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 CY2025, FSAP issued 164 final inspection reports with 88% of those reports issued within the target timeframe of 30 business days.**

## Section 1. Introduction

FSAP oversees 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 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 Regulatory Science and Compliance (DRSC) 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 electronic

FSAP 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 issues 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

<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.

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 CY2025 does not reflect

the total number of inspections conducted in CY2025. Inspections conducted at the end of CY2024, but for which the inspection reports were issued in CY2025, are included in this report. Also, inspections conducted at the end of CY2025, but for which the inspection reports were not issued until CY2026, will be included in next year's report.

## Section 3. Results

### Inspection Reports

FSAP issued 164 final inspection reports in CY2025 (Table 1). This number includes 7 reports for inspections that occurred in CY2024, but the reports were sent to the entities in CY2025. Of those 164 final inspection reports, 88% were sent within the target timeframe of 30 business days.

As of December 31, 2025, final inspection reports from 12 inspections performed in December 2025 were still pending. Those data will be included as part of the data analysis in next year's *2026 FSAP Inspection Report Processing Annual Summary*.

**Table 1.** FSAP Final Inspection Report Processing Time, CY2025

Agency	Total Number of Final Reports by Agency	Number of Final Reports Sent Within Processing Target	Processing Time to Final Report (in Business Days) Average/Range
DASAT	32	29	17/3-45
DRSC	132	115	20/1-57
<b>FSAP Total</b>	<b>164</b>	<b>144</b>	<b>19/1-57</b>

### Reasons for Delayed Reports

Twenty of the 164 final inspection reports were issued outside of the 30 business days timeframe. Most of these reports were delayed as a result of the lapse of appropriations for HHS and USDA that occurred in fall 2025.

Due to a lapse in appropriations at HHS and USDA, staffing and operations were limited between October 1, 2025 to

November 12, 2025. As a result of the limited operations, 19 reports were subsequently issued within 38 to 57 business days from the Monday following each inspection, exceeding the 30-day timeframe.

One final inspection report was issued at 31 days (one day beyond the 30 business day timeframe) due to a delay in the review process.

### Immediate Action Observations

In CY2025, FSAP issued 2 immediate action observations (1 sent by DRSC and 1 sent by DASAT), all within the target

timeframe of 10 business days following the Monday after the conclusion of the inspection (Table 2).

**Table 2.** FSAP Immediate Action Observation Processing Time, CY2025

Observation Type	Number of Observations Sent	Number of Entities Sent Observations	Number of Entities Sent Observations Within Processing Target	Processing Time (in Business Days) Average/Range
<b>Immediate Action Observation</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>6/4-8</b>

## 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.

CY2025 is the eighth year that FSAP conducted a joint DRSC/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. In CY2025, despite a lapse in

appropriations that resulted in limited program functions for a period of 43 days, FSAP still issued the majority (88%) of reports on time. Although these circumstances affected the timeliness metrics, FSAP anticipates a return to its standard level of performance in the coming year. FSAP has maintained a strong historical record of meeting or exceeding timeliness goals (with 100% of reports on time in 2022, 2023, and 2024) and will continue to monitor and improve report processing times to ensure entities receive timely feedback.

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