

2023 Federal Select Agent Program Inspection Report Processing Annual Summary

Published June, 2024



Inspection Report Processing By The Numbers



208

Final
Inspection
Reports

100%

On Time
Within Target of
30 Business Days

19

Business Days
Average to Issue
Final Report

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.
DRSC	The Division of Regulatory Science and Compliance , formally known as the Division of Select Agents and Toxins (DSAT), 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. Effective October 1, 2023, the Division of Select Agents and Toxins (DSAT) is known as the Division of Regulatory Science and Compliance (DRSC).
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 Federal Select Agent Program.
FSAP	The Federal Select Agent Program 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.
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 *2023 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) 2023. 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 CY2023, FSAP issued 208 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 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 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 FSAP’s

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 will 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).¹ 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

¹ 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 CY2023 does not reflect

the total number of inspections conducted in CY2023. Inspections conducted at the end of CY2022, but for which the inspection reports were issued in CY2023, are included in this report. Similarly inspections conducted at the end of CY2023, but for which the inspection reports were not issued until CY2024, will be included in next year's report.

Section 3. Results

Inspection Reports

FSAP issued 208 final inspection reports in CY2023 (Table 1). This number includes 16 reports for inspections that occurred in CY2022, but the reports were sent to the entities in CY2023. Of those 208 final inspection reports, 100% were sent within the target timeframe of 30 business days.

As of December 31, 2023, final inspection reports from 9 inspections performed in December 2023 were still pending. Those data will be included as part of the data analysis in next year's *2024 FSAP Inspection Report Processing Annual Summary*.

Table 1. FSAP Final Inspection Report Processing Time, CY2023

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	38	38	13/1-27
DRSC	170	170	20/1-30
FSAP Total	208	208	19/1-30

Immediate Action Observations

In CY2023, FSAP issued one immediate action observation (sent by DASAT) 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, CY2023

Observation Type	Number of Entities Sent Observations	Number of Entities Sent Observations Within Processing Target	Processing Time (in Business Days)
Immediate Action Observation	1	1	7

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.

CY2023 is the sixth year that FSAP conducted a joint DRSC/DASAT analysis of inspection report timeliness data². 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 CY2023. CY2023 is the seventh consecutive year for DRSC, and the fifth 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 DRSC at LRSAT@cdc.gov or DASAT at DASAT@usda.gov.

² DRSC began tracking inspection report processing times in CY2015, while DASAT began tracking inspection report processing times in CY2018.