Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

DATA BRIEF

June 2025 | OEI-02-23-00300

FDA Food Safety Inspections of Domestic Food Facilities

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Why OIG Did This Review

- Each year, roughly 48 million people in the United States get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.
- To protect against foodborne illnesses, the Food and Drug Administration (FDA) inspects food facilities to ensure compliance with regulations and the safety of the Nation's food supply.
- FDA must inspect facilities within required timeframes, either 3 or 5 years depending on the food safety risk of the facility.

What OIG Found

We found gaps in FDA's efforts to inspect domestic food facilities, particularly in meeting required timeframes.

- FDA is conducting **fewer inspections of food facilities** compared to the number prior to the pandemic.
- FDA did not inspect many facilities within the required timeframes and **is not inspecting enough facilities to meet the timeframes in the future.**
- FDA **attempted to inspect thousands of facilities that were not in operation**, which created an inefficient use of resources.
- FDA **uncovered significant violations** in 1 to 2 percent of facilities inspected each year. FDA's identification of significant violations has decreased steadily over time.
- For the majority of significant violations, FDA **did not conduct timely followup inspections**.

What OIG Recommends

These findings underscore the need for FDA to increase its efforts to inspect food facilities and meet required timeframes. If FDA does not address these concerns, it cannot identify harmful conditions and prevent facilities from producing and distributing unsafe food. OIG recommends that FDA:

1. Increase the number of facilities inspected each year and ensure that all facilities are inspected within the required timeframes;
2. Improve methods for identifying facilities that are not in operation to make better use of resources;
3. Assess reasons for the decrease in number of facilities inspected by FDA with significant violations and take action as appropriate; and
4. Conduct timely followup inspections of facilities with significant violations.

FDA concurred with all four of our recommendations.

Primer: FDA Inspections of Domestic Food Facilities

Inspection Process

- FDA conducts food facility inspections to assess a facility's compliance with Federal food safety regulations. Overall, FDA is required to inspect more than 75,000 facilities, including approximately 22,000 high-risk facilities and 53,000 non-high-risk facilities.[1]
- The FDA Food Safety Modernization Act (FSMA) requires FDA to inspect food facilities at regular intervals, based on risk.[2] FDA determines whether a facility is high-risk based on a variety of factors, including whether the facility is associated with outbreaks or recalls, or has prior violations of food safety standards.
- FDA generally conducts unannounced inspections. FDA inspections are conducted by FDA investigators, or by State, Local, Tribal, or Territorial Government investigators under contract with FDA. In this report, we refer to these as FDA inspections.
- FDA relies on two main internal tracking systems to maintain information on inspections and their results, including whether a facility is in operation. FDA's registry of food facilities also contains information on whether the facility is in operation.[3]
- FDA limited the number of domestic food facility inspections it conducted during the COVID-19 pandemic starting in March 2020; it resumed standard inspection operations in July 2021.[4] FDA continued throughout the pandemic to conduct inspectional and oversight work determined on a case-by-case basis to be critical to FDA's public health mission.
- FDA has recently reorganized its oversight of food facility inspections.[5] In October 2024, FDA created the Human Foods Program which, among other actions, dedicates inspection resources—including investigators—to focus specifically on food facilities.

Facilities with Significant Violations

- When FDA inspects a facility and finds a significant violation, FDA classifies the violation as official action indicated (OAI).[6] An OAI classification indicates that an establishment failed to meet either regulatory or administrative requirements and may pose a hazard to public health.[7]
- When it identifies a significant violation, FDA typically conducts followup inspections to ensure that the facility is in compliance with applicable FDA requirements and has corrected the violations found during the initial inspection.[8]
- For the purposes of this report, we considered a timely followup inspection as one that occurred within 6 months after a facility received an OAI classification.[9] Appropriate and timely followup inspections within 6 months help to ensure prompt compliance and limit the threat of potentially harmful products entering the U.S. food supply.

Scope of Review

We based this review on an analysis of FDA's data for all domestic food facilities that are required to be inspected under FSMA.[10] We analyzed FDA's data to determine the number of food facilities that FDA inspected each year from fiscal year (FY) 2017 through FY 2023 (October 1, 2016, through September 30, 2023) and the extent to which FDA conducted inspections within the required timeframes. We also analyzed the extent to which FDA identified facilities with significant violations and conducted timely followup inspections of these facilities.

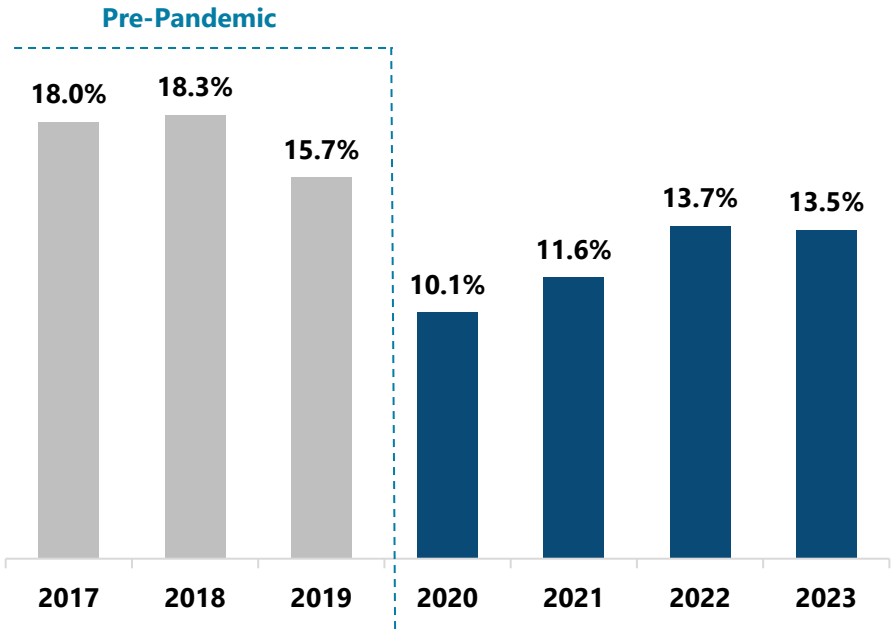
FINDINGS

FDA is conducting fewer inspections of food facilities compared to the number prior to the pandemic

Although the COVID-19 pandemic significantly curtailed FDA's ability to conduct inspections in 2020 and 2021, FDA's inspections have not returned to pre-pandemic levels.[11] In 2017, FDA inspected 12,595 facilities; in 2023, this number dropped to 10,151 facilities—a 19-percent decline.[12] This decline occurred even as the number of food facilities increased. Over this period, the number of food facilities that required inspection increased by more than 5,000 facilities.

The percentage of facilities FDA inspected has also not returned to pre-pandemic levels. In the 3 years prior to the pandemic, FDA inspected an average of 17.3 percent of domestic food facilities each year. In 2022 and 2023, after standard inspection operations had resumed, FDA inspected only 13.7 and 13.5 percent of all food facilities, respectively. For additional information on the percentage and number of food facilities FDA inspected each year, see Exhibit 1 and Appendix A.

Exhibit 1: The percentage of food facilities inspected by FDA has not returned to pre-pandemic levels.



Source: OIG analysis of FDA data, 2024.

A decrease in FDA's funding may have contributed to the decline in food facility inspections. Over the same timeframe, spending for FDA's domestic food facility inspections decreased by 6 percent from about $166 million in 2017 to $156 million in 2023.[13] In addition, there was a 9-percent decline in FDA's overall budget for the Human Foods program. See Appendix C for more information on FDA spending levels.

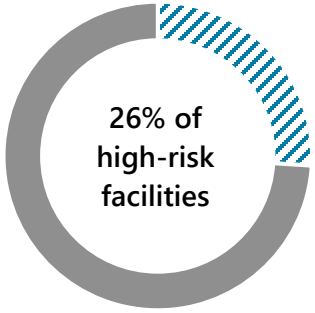
FDA did not inspect many facilities within the required timeframes

FSMA requires FDA to inspect high-risk facilities within 3 years and non-high-risk facilities within 5 years. To determine if FDA inspected facilities within the required timeframes, we analyzed the high-risk facilities in continuous operation in the 3-year period from 2021 through 2023 and the non-high-risk facilities in continuous operation in the 5-year period from 2019 through 2023. We found that FDA did not inspect many of these facilities within the required timeframes.

FDA did not inspect a quarter of high-risk facilities within the required 3-year timeframe

FDA did not inspect 26 percent of the high-risk facilities in continuous operation within the required 3-year timeframe (see Exhibit 2).[14] Since more than a quarter of these high-risk facilities have gone 3 or more years without an inspection to assess compliance, FDA may not have sufficient information to determine whether these high-risk facilities—where the threat of foodborne illness is greatest—posed a hazard to the public.

Exhibit 2: FDA did not inspect 26 percent of the high-risk facilities as required.



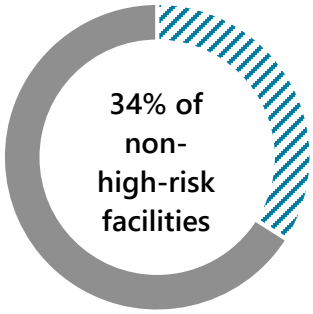
Source: OIG analysis of FDA data, 2024.

If a facility inspection is not completed in the year it is due to be inspected, FDA will prioritize the facility in the following year. However, FDA did not establish a timely target date for 19 percent of the high-risk facilities that were not inspected within the 3-year timeframe. For eight facilities, FDA rescheduled them more than 5 years out.

FDA did not inspect 34 percent of non-high-risk facilities within the required 5-year timeframe

FDA did not inspect 34 percent of the non-high-risk facilities in continuous operation within the required 5-year timeframe (see Exhibit 3).[15] Since more than a third of all non-high-risk facilities have gone more than 5 years without an inspection, FDA may not have sufficient information to determine whether these facilities —which make up most of all food facilities—are operating under harmful conditions.

Exhibit 3: FDA did not inspect 34 percent of the non-high-risk facilities as required.



Source: OIG analysis of FDA data, 2024.

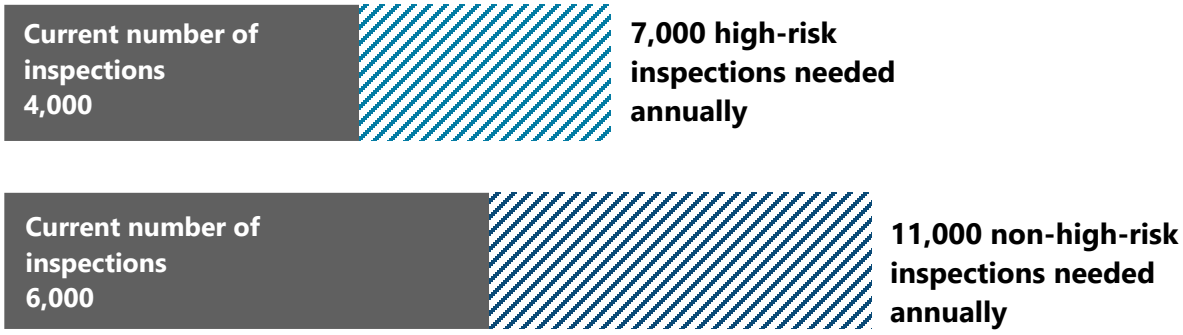
Even accounting for the impact of the pandemic, FDA would still not meet the FSMA mandated timeframe for non-high-risk facilities. To assess the impact of the pandemic, we calculated the extent to which FDA would meet the timeframes if given an additional year, expanding from 5 years to 6 years (2018 through 2023). We found that 21 percent of non-high-risk facilities in continuous operation were not inspected at least once during this expanded timeframe.

FDA is not inspecting enough facilities to meet required timeframes in the future

If FDA is to inspect all high-risk and non-high-risk facilities in the required timeframes in the future, it will need to substantially increase its rate of inspections. Overall, FDA is required to inspect more than a total of 75,000 facilities, comprising approximately 22,000 high-risk facilities and 53,000 non-high-risk facilities. For FDA to meet the inspection timeframes moving forward, it would need to inspect approximately 7,000 high-risk facilities each year.[16] However, FDA inspected only about 58 percent of that amount, or an average of 4,326 high-risk facilities each year.[17] As a comparison, FDA inspected 6,942 high-risk facilities in 2017, prior to the pandemic. To meet the required timeframes, FDA will have to increase inspections of high-risk facilities by more than 3,000 each year.

Similarly, for FDA to meet the inspection timeframes moving forward, it would need to inspect approximately 11,000 non-high-risk facilities each year. However, FDA was only inspecting about 56 percent of that number, or an average of 5,913 non-high-risk facilities each year. FDA inspected only 5,653 non-high-risk facilities in 2017, prior to the pandemic. To meet the required timeframes, FDA will have to increase inspections of non-high-risk facilities by approximately 5,000 each year. See Exhibit 4.

Exhibit 4: FDA is not inspecting enough facilities to meet the FSMA mandate.



Source: OIG analysis of FDA data, 2024.

FDA attempted to inspect thousands of facilities that were not in operation, which created an inefficient use of resources

At the same time that FDA inspected fewer facilities, it used resources to attempt to inspect facilities that were not in operation. These attempted inspections may occur when an investigator visits a facility, but the facility is either seasonal or temporarily not in operation, or the facility is permanently out of business.[18] Attempted inspections of facilities that are not in operation create inefficiencies and bypass opportunities to use inspection resources more efficiently.

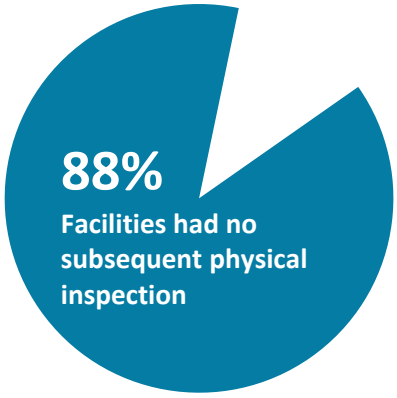
These attempted inspections of facilities not in operation are an ongoing concern. In an earlier report, OIG found that inaccuracies in FDA's domestic food facility data resulted in FDA attempting to inspect numerous facilities that were either out of business or otherwise not in operation at the time of the visit.[19]

FDA attempted to inspect many seasonal or other facilities temporarily not in operation and often failed to return to these facilities to conduct a physical inspection

Between 2017 and 2023, FDA attempted to inspect more than 8,732 seasonal facilities or other facilities temporarily not in operation.

Of these facilities, 88 percent (7,668) never received a subsequent physical inspection. Specifically, 7,237 facilities had an attempted inspection but never received a subsequent physical inspection. The remaining 431 facilities had at least two attempted inspections but had no subsequent physical inspection during the study period 2017 through 2023.

Exhibit 5: Most seasonal or other facilities temporarily not in operation that had an attempted inspection had no subsequent physical inspection.



Source: OIG analysis of FDA data, 2024.

Only 12 percent (1,064) of facilities had an attempted inspection and then received a physical inspection (see Exhibit 5). However, a physical inspection was conducted sometimes 5 years or more after the attempted inspection.

In 2020, FDA reported that it had developed and implemented IT system changes to record the dates when a facility is in operation, e.g., if the facility's business is seasonal; however, visits to non-operational facilities still remained high.

FDA also attempted to inspect facilities that were permanently out of business, which further consumed inspection resources

From 2017 to 2023, FDA attempted to inspect 3,237 facilities that were permanently out of business. In many instances, investigators went out to inspect the facility but discovered that the facility was no longer operating and was permanently closed.[20]

FDA has systems in place to identify facilities that are out of business, but these systems did not inform FDA's inspection scheduling decisions. FDA's food facility registry includes information about when a facility cancels its registration and is no longer in business.[21] FDA periodically aligns the registration cancellations with its inspection tracking system used to schedule inspections.

FDA uncovered significant violations in 1 to 2 percent of the facilities it inspected; this percentage has been decreasing steadily over time

From 2017 to 2023, FDA identified significant violations in a total of 861 facilities, indicating that conditions in these facilities may pose a hazard to public health. When FDA uncovers significant violations, it assigns an OAI (official action indicated) classification.

FDA most commonly classified inspections as OAI when investigators identified insanitary conditions, unsafe manufacturing practices, or poor employee practices. See Exhibit 6 below for examples of facilities that received notice of significant violations, including the presence of insects and rodents and positive tests for pathogens such as listeria.

Exhibit 6: Examples of significant violations FDA identified at food facilities

Example 1. Lack of basic cleanliness: FDA found poor employee practices at a doughnut manufacturer in South Carolina. Specifically, investigators observed employees not washing hands between touching dirty and clean equipment. Investigators also observed an employee taking off soiled gloves and placing them on the conveyor line where the doughnuts were, and then removing them from the conveyor line to put them back on. Investigators also noted flies throughout the production area and landing on dough during production.

Example 2. Evidence of dead birds and rodents: FDA found insanitary conditions at a discount store in Arkansas. Investigators observed two dead birds within the facility, and one live bird was caught in netting hung above pallets of breakfast cereals. Investigators also found live rats and rat carcasses in multiple areas of the store, and over a 6-month period, the store documented over 2,300 rodent captures.

Example 3. Pests throughout the warehouse: FDA found insanitary conditions at a food distribution warehouse in California. Investigators found widespread pest activity that included cockroaches, rodents, animal feces, and animal paw prints on dusty boxes of food products. Investigators also observed a live bat in the warehouse.

Example 4. Contamination by pathogens: FDA found insanitary conditions at a food facility in Florida. Investigators observed live insects throughout the facility, bird excrement on food trays, and the use of unclean utensils in food preparation. FDA investigators also took environmental samples at the facility, which came back positive for *Listeria monocytogenes* (*L. monocytogenes)*. Consuming foods contaminated with *L. monocytogenes* can lead to a severe, sometimes life-threatening illness called listeriosis. FDA found *L. monocytogenes* during the facility's three preceding inspections; however, the facility failed to take the necessary corrective actions to eradicate the organism.

Source: OIG analysis of FDA 2022 inspection reports, 2024.

FDA's identification of significant violations has decreased steadily over time, with an even sharper decline since the COVID-19 pandemic

FDA's identification of significant violations has been decreasing over the last 20 years. The number of facilities with significant violations decreased from a high of 614 in 2004 to a low of 56 in 2023.[22] See text box and Exhibit 7.

Prior OIG Analyses of Facilities with

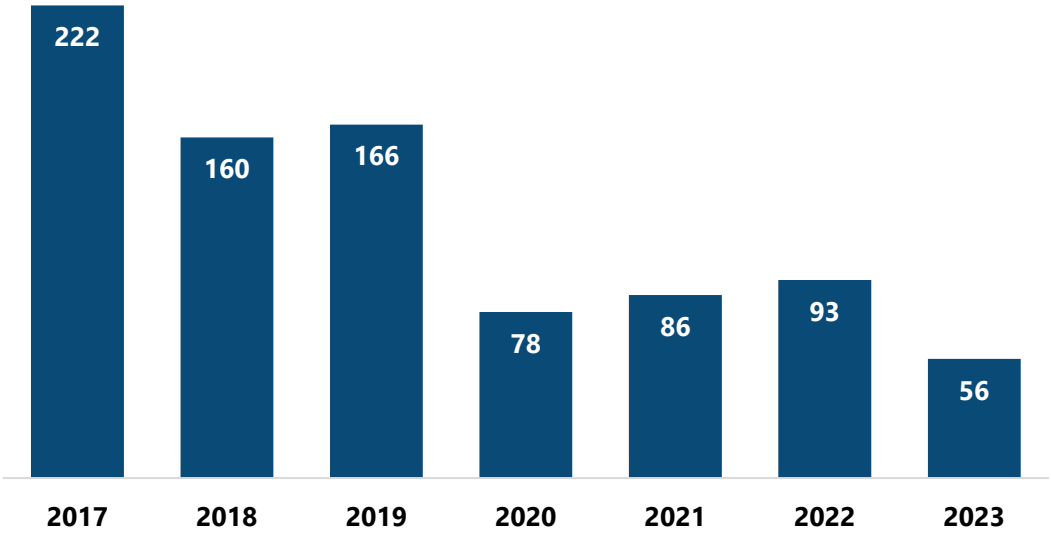
Between 2004 and 2008, the number of facilities with **significant violations decreased from 614 to 283.**

Between 2011 and 2015, the number of facilities with **significant violations decreased from 401 to 164**.

A drop in the number of facilities with significant violations occurred during the pandemic, and this number has not returned to pre-pandemic levels. The number of facilities with significant violations decreased significantly during the first year of the pandemic. The number of facilities with significant violations later increased slightly but decreased again in 2023 to a level below that during the pandemic.

The percentage of facilities inspected with significant violations also decreased, from 1.8 percent in 2017 to 0.6 percent in 2023. See Appendix B for the numbers and percentages of facilities with significant violations.

Exhibit 7: The number of food facilities with significant violations decreased from 2017 to 2023.



Source: OIG analysis of FDA data, 2024.

For the majority of significant violations, FDA did not conduct timely followup inspections

FDA is expected to conduct followup inspections of facilities with significant violations to verify that the facilities have corrected the violations and to ensure that the facilities do not have any new violations. Appropriate and timely followup is critical when FDA identifies unsafe conditions in a facility to ensure prompt corrective actions and limit the threat of potentially harmful products entering the U.S. food supply. However, the pandemic may have impacted FDA's ability to conduct timely followup inspections.

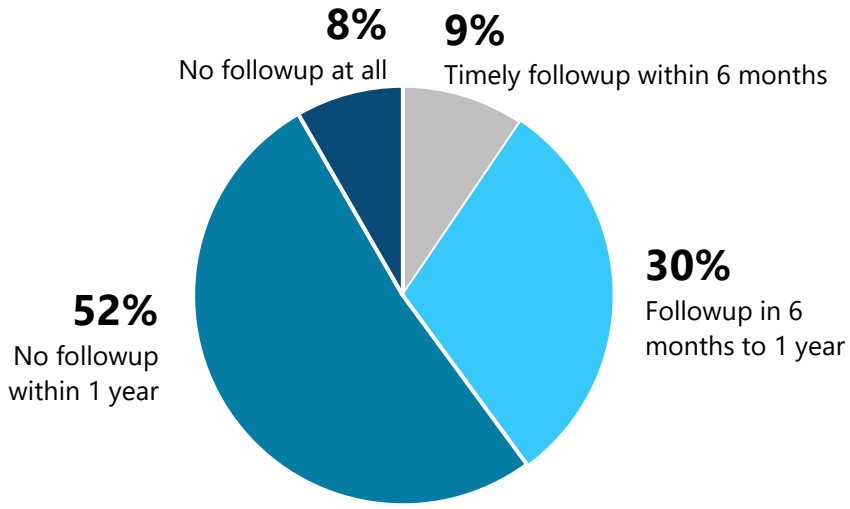
Of the significant violations:

8% had no followup inspection at all

82% had no followup inspection within 6 months

OIG considered a timely followup inspection as one that occurred within 6 months after the completion of an inspection that resulted in an OAI classification.[23] We found that for 91 percent of the inspections with significant violations from 2017 to 2023, FDA did not conduct a timely followup inspection—an inspection within 6 months—limiting its ability to ensure that the facility had corrected the problem. See Exhibit 8.

Exhibit 8: FDA did not conduct timely followup inspections within 6 months for 91 percent of significant violations.



Note: We based this analysis on 769 significant violations. We excluded 47 violations that occurred in 2023 because FDA did not have at least 1 year from the inspection date to conduct a followup inspection. We also excluded 77 violations because the facility went out of business before a followup inspection was conducted. Percentages may not sum to 100% due to rounding.

Source: OIG analysis of FDA data, 2024.

RECOMMENDATIONS

Our findings show that FDA needs to improve its efforts to meet food safety requirements. Although the COVID-19 pandemic significantly curtailed FDA's ability to conduct inspections in 2020 and 2021, FDA is not meeting inspection requirements. From 2017 to 2023, FDA did not inspect facilities within the required timeframes, made attempts to inspect facilities that were not in operation, and did not conduct timely followup inspections of facilities with significant violations that may have posed a hazard to the public.[24]

These findings underscore the need for FDA to increase its efforts to inspect food facilities and meet required timeframes. FDA needs to continue to ensure that it identifies violations and conducts timely followup to ensure that violations are corrected. If FDA does not address these concerns, it cannot identify harmful conditions and prevent facilities from producing and distributing unsafe food.

FDA has recently reorganized its oversight of food facility inspections. In October 2024, FDA created the Human Foods Program which, among other actions, dedicates inspection resources—including investigators—to focus specifically on food facilities. As a part of this reorganization effort, FDA has an opportunity to address the concerns raised in this report and to prioritize food facility inspections and strengthen its oversight on the Nation's food supply.

We recommend that FDA:

Increase the number of facilities inspected each year and ensure that all facilities are inspected within the required timeframes

FDA should increase the number of food facilities it inspects so that it can ensure that all food facilities are inspected within the timeframes required by FSMA. FDA should continue to prioritize inspections of high-risk facilities, where the threat of foodborne illness is greatest, to meet requirements. It should also address the number of non-high-risk facilities that go years beyond the required timeframe without an inspection. Both high-risk and non-high-risk facilities that were not inspected within the required timeframes should be inspected the following year. Ensuring that both high-risk and non-high-risk facilities are inspected within the required timeframes is critical to the safety of the food supply.

FDA should consider a range of approaches to increase the number of facilities inspected. To the extent possible, FDA could explore alternatives to use its resources to increase the number of inspections. For example, FDA could complement physical inspections by ensuring that off-site reviews of products, registration, or other documentation are conducted prior to arrival at the facility.

Improve methods for identifying facilities that are not in operation to make better use of resources

FDA should take additional steps to improve the methods for identifying facilities that are either temporarily not in operation or permanently out of business. Improving the accuracy of its information about these facilities will reduce the number of attempted inspections.

FDA should improve its identification of facilities temporarily not in operation. FDA could increase its efforts to conduct preliminary research of facilities to determine whether a facility is in operation, prior to investigators arriving at the facility to discover that it is inactive. FDA should also improve its ability to indicate when facilities that are temporarily not in operation will reopen so that a future physical inspection can occur on a timely basis.

FDA should also improve its identification of facilities that do not need to be inspected because they are permanently out of business and remove them from its schedule of facilities to inspect. By identifying these facilities that are permanently out of business, FDA will be able to ensure that it does not go back to inspect these facilities. Inspections of facilities known to be out of business consume resources that could be used elsewhere.

Assess reasons for the decrease in number of facilities inspected by FDA with significant violations and take action as appropriate

FDA should investigate the reasons for the decrease in facilities with significant violations and, if needed, take appropriate steps to address the decline. The decrease in significant violations may be partially explained by the decrease in the number of facilities inspected; however, additional information is needed.

FDA should assess other possible reasons for the decrease, which could be related to the process of conducting inspections and reporting which conditions warrant an OAI classification. For example, investigators may need clarity when determining which conditions or practices observed during an inspection should be reported, and which could call for additional training. Other reasons could be inspection protocols that are not updated to assess risks for new products or production techniques.

Conduct timely followup inspections of facilities with significant violations

FDA should conduct timely followup inspections of facilities with significant violations. It is critical that FDA follow up with these facilities and ensures that significant violations are corrected. FDA has identified the conditions that warrant these violations as the greatest threats to the food supply, making timely followup a priority for protecting consumers.

AGENCY COMMENTS AND OIG RESPONSE

FDA concurred with all four of our recommendations.

FDA concurred with our recommendation to increase the number of facilities inspected each year and ensure that all facilities are inspected within the required timeframes. FDA stated that it continues to explore ways to modernize its inspection processes and that maintaining a sufficient workforce of investigators and support staff continues to be a challenge. FDA will consider OIG's recommendation and input as part of the wider context shaping current discussions.

FDA concurred with our recommendation to improve methods for identifying facilities that are not in operation to make better use of resources. FDA stated that it will review its current policies and procedures and explore additional strategies to reduce the number of attempted inspections.

FDA concurred with our recommendation to assess reasons for the decrease in the number of facilities inspected by FDA with significant violations and take action as appropriate. FDA agrees that further assessment is necessary.

FDA concurred with our recommendation to conduct timely followup inspections of facilities with significant violations. FDA stated that it will continue to review its policies and procedures and evaluate the timeliness of followup inspections.

FDA also noted that it does not believe the report accurately represents the agency's timeliness in conducting followup inspections. It is important to note that OIG's methodology differs from FDA's internal calculations of timeliness, as FDA's method excludes the time it takes for FDA to complete advisory and enforcement actions. In this report, we opted to use the completion of the inspection as the basis for calculating the timeliness of FDA's followup. This is, in part, because prior OIG work found that FDA's advisory and enforcement actions were not always timely, and we recommended that FDA should initiate those actions promptly.[25] We think the descriptive data presented in this report provide a critical measure of how long it takes FDA to reinspect facilities with significant violations. OIG continues to stress the importance of improving the timeliness of FDA's followup inspections so that facilities do not persist in operating under harmful conditions.

For the full text of FDA's comments, see Appendix D.

METHODOLOGY

We based this study on an analysis of FDA's data for all domestic food facilities that are required to be inspected under FSMA.

We based the analyses on FDA's data from the following two sources.

1. FDA's FSMA Tracker database: FDA uses this database to schedule inspections for domestic food facilities subject to FSMA and to track the progress of inspections completed or attempted.[26]
2. FDA's Field Accomplishments and Compliance Tracking System (FACTS): This database includes all FDA inspections of domestic food facilities subject to FSMA. FDA uses this database to track current and past inspections, results, and outcomes of inspections completed, including significant violations.

Data Collection and Analysis

We requested from FDA data on domestic food facilities from FY 2017 through FY 2023 (October 1, 2016, through September 30, 2023).[27] From the FSMA Tracker, we requested all the facilities in FDA's inventory; the risk designation (high-risk or non-high-risk) for each facility; and the number of facilities with completed or attempted inspections for each year. From FACTS, we obtained the results and classification of each inspection for each year. In addition, we requested the Establishment Inspection Reports from FY 2022, which was the most recent year available at the time of our review, to provide detailed examples of the nature and conditions that warranted an OAI classification.

Analysis of inspected facilities. We first analyzed data from the FSMA Tracker to determine the number and percentage of food facilities that FDA inspected each year from FY 2017 through FY 2023.[28] We considered FYs 2017, 2018, and 2019 (October 1, 2016, through September 30, 2019) to be the pre-pandemic period. As a benchmark, we determined the number of high-risk and non-high-risk facilities that FDA inspected in 2017, prior to the pandemic.

Next, we analyzed the data from the FSMA Tracker to determine the number of facilities that FDA inspected within the required timeframes. We identified all high-risk and non-high-risk facilities that were in continuous operation for the 3-year or 5-year timeframe.[29] For high-risk facilities, we included facilities that were in continuous operation from FYs 2021 through 2023.[30] For non-high-risk facilities, we included facilities that were in continuous operation from FYs 2019 through 2023.[31] To assess the impact of the pandemic on the non-high-risk cycle, we also calculated the extent to which FDA would meet these timeframes if given an additional year, from FYs 2018 through 2023.

Next, we determined the number of facilities that FDA would need to inspect each year to meet the required timeframes. To do this, we first estimated FDA's current rate of inspections based on the average number of facilities that FDA inspected in FYs 2022 and 2023.[32] We then estimated the number of inspections that FDA would need to inspect to meet the required timeframes. To do this, we divided the total number of high-risk facilities FDA needs to inspect by three and the total number of non-high-risk facilities it needs to inspect by five to approximate the number of facilities FDA would need to inspect each year. We then determined the difference between the current rate of inspections and the number FDA needs to inspect each year to meet the required timeframe.

Analysis of attempted inspections. We analyzed data from the FSMA Tracker to determine the number of facilities that FDA attempted to inspect.[33] We identified all facilities that were not in operation because they were seasonal, temporarily not in operation, or permanently out of business.

We first determined the number of facilities that FDA attempted to inspect that were designated as seasonal or temporarily not in operation. We also determined how many facilities with an attempted inspection never received a subsequent physical inspection.

Next, we determined the number of facilities that FDA attempted to inspect that were designated as permanently out of business. This means that FDA attempted to inspect these facilities after it determined they were permanently closed.

Analysis of facilities with significant violations. We analyzed the FACTS data to determine the number and percentage of facilities with significant violations over the 7-year period from FYs 2017 through 2023.[34] We considered a facility to have a significant violation if it received a final classification of OAI.

We determined the number and percentage of facilities that had significant violations each year. The facility was counted only once per year for every year it received an OAI.

Next, we reviewed FDA's Establishment Inspection Reports from FY 2022 to provide detailed examples of the nature and conditions that warranted an OAI classification. We reviewed these reports and grouped the violations into categories.

Analysis of followup inspections. Lastly, we determined the extent to which FDA conducted timely followup inspections. To conduct this analysis, we reviewed the FACTS data to identify significant violations and determined the length of time it took FDA to conduct a followup inspection. The analysis is based on the number of significant violations; some facilities had more than one violation. We measured the number of days from the date the earlier inspection ended to the date the followup inspection ended. We then determined whether FDA conducted a followup inspection within 6 months from the date the earlier inspection ended. We also determined whether the followup inspection occurred within 6 months to 1 year of

the date the earlier inspection ended, the followup inspection occurred more than 1 year later, or no followup inspection occurred.[35]

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Investigators General on Integrity and Efficiency.

APPENDIX A

Food Facilities Inspected by FDA, 2017 to 2023

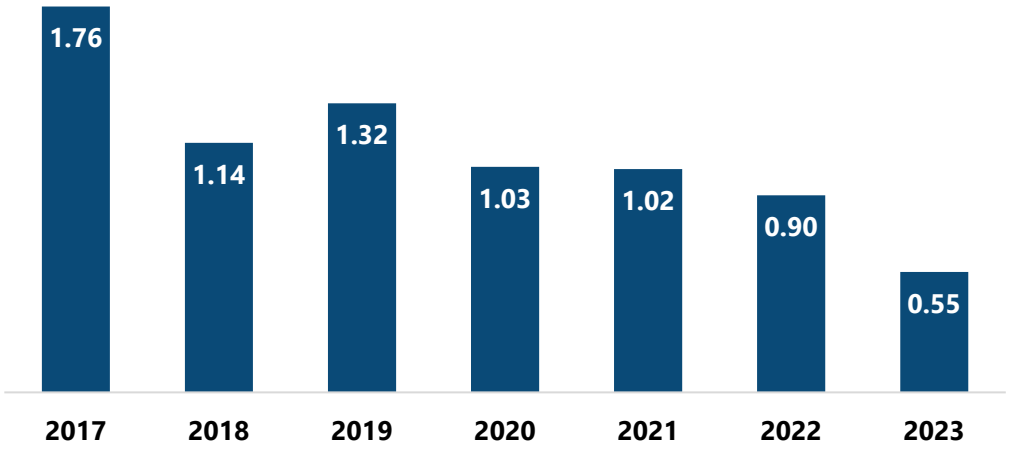
	Number of Facilities Inspected	Total Number of Facilities	Percentage of Facilities Inspected
2017	12,595	70,020	18.0%
2018	14,083	77,080	18.3%
2019	12,603	80,362	15.7%
2020	7,593	74,835	10.1%
2021	8,396	72,578	11.6%
2022	10,325	75,427	13.7%
2023	10,151	75,044	13.5%

Note: All years presented are fiscal years.

Source: OIG analysis of FDA data, 2024.

APPENDIX B

B-1: Percentage of Food Facilities with Significant Violations, 2017 to 2023



Note: All years presented are fiscal years.

Source: OIG analysis of FDA data, 2024.

B-2: Food Facilities with Significant Violations, 2017 to 2023

	Number of Facilities with Significant Violations	Number of Facilities Inspected	Percentage of Facilities Inspected with Significant Violations
2017	222	12,595	1.8%
2018	160	14,083	1.1%
2019	166	12,603	1.3%
2020	78	7,593	1.0%
2021	86	8,396	1.0%
2022	93	10,325	0.9%
2023	56	10,151	0.6%

Note: All years presented are fiscal years.

Source: OIG analysis of FDA data, 2024.

APPENDIX C

FDA Spending for Domestic Food Facility Inspections, 2017 to 2023

	Domestic Food Facility Inspection Budget
2017	$166,035,729
2018	$164,732,837
2019	$161,364,433
2020	$159,990,695
2021	$159,296,714
2022	$151,520,555
2023	$155,616,000

Source: OIG analysis of FDA data, 2024.

All spending is in 2023 dollars.

APPENDIX D

Agency Comments

Following this page are the official comments from FDA.

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

DATE: May 1, 2025

TO: Juliet T. Hodgkins, Acting Inspector General

FROM: Director, Public Health Strategy and Analysis

SUBJECT: Food and Drug Administration's General Comments to Office of Inspector General's Draft Data Brief, "FDA Food Safety Inspections of Domestic Food Facilities"

Enclosed are the Food and Drug Administration's general comments to the Office of Inspector General's OIG Draft Data Brief "FDA Food Safety Inspections of Domestic Food Facilities."

We appreciate the opportunity to review and comment on this draft report prior to publication.

Lisa Rovin, J.D.
Director, Public Health Strategy and Analysis

Attachment

Food and Drug Administration General Comments to
Office of Inspector General's Draft Data Brief
"FDA Food Safety Inspections of Domestic Food Facilities"
OEI-02-23-00300

The Food and Drug Administration (FDA) appreciates the Office of the Inspector General (OIG) for its ongoing work on the topic of domestic food safety inspections.

FDA emphasizes the important role inspectional activities play in helping ensure consumers have access to foods that are produced or manufactured safely and according to applicable FDA requirements. When planning and conducting food inspections, FDA utilizes a risk-based surveillance strategy which takes into account the Food Safety Modernization Act (FSMA) statutory inspection mandates.

Given the large number of food facilities and FDA's limited resources, meeting the existing inspection mandates has been challenging. Since 2017, our ability to fulfill its public health mission is increasingly constrained by reduced inspectional capacity. We continue to face significant obstacles in recruiting and retaining qualified investigators, particularly in the foods program, where nearly 90 investigative positions remain vacant.

In 2024, the Office of Inspections and Investigations (OII) launched an effort to review these challenges in building inspectional capacity in the Operational Workforce Assessment and related work. Outcomes from this analysis include initiatives to improve hiring and retention by placing investigators in more flexible pay bands under Title 21, enhancing succession planning, streamlining workforce data management, shortening the gap between hiring and readiness for independent work, and reducing administrative burdens on investigators.

To help optimize resource allocation to maximize public health impact, FDA is focusing on further building out its risk-based surveillance strategy.

To maximize the impact of the Agency's resources, FDA also leverages additional surveillance and regulatory tools, such as import screening, importer requirements, remote regulatory assessments[1], and regulatory partnerships with domestic state, local, territorial and tribal partners and foreign competent authorities to monitor and ensure the safety of the human food supply.

Response to OIG Recommendations

Recommendation 1: Increase the number of facilities inspected each year and ensure that all facilities are inspected within the required timeframes.

FDA concurs with this recommendation.

[1] See FDA draft guidance for industry: Conducting Remote Regulatory Assessments Questions and Answers (February 2024), available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers.

FDA continues to explore ways to modernize its inspection processes to improve both effectiveness and efficiency. Maintaining a sufficient workforce of investigators and support staff capable of carrying out inspectional work remains a key challenge. Currently, a range of broader policy, resource, and organizational directions are actively being reviewed and assessed. While FDA is not able to provide a detailed update on actions to address these recommendations, OIG's recommendation and input will be considered as part of the wider context shaping current discussions. FDA recognizes the importance of ongoing dialogue and remains committed to a careful and deliberate approach to this recommendation.

Recommendation 2: Improve methods for identifying facilities that are not in operation to make better use of resources.

FDA concurs with this recommendation and will continue to implement procedures and enhancements to address this issue.

The FSMA inspection frequency mandate applies to food facilities that are required to register with FDA. FDA's food facility registration system provides essential information about a facility's operations and is a critical tool for maintaining an up-to-date inventory of firms subject to inspection. Domestic food facilities that manufacture, process, pack, or hold food for consumption in the United States are required to register or renew registration with FDA and consent to FDA inspections.

The domestic food facility inventory experiences a high level of turnover with firms frequently entering and exiting the market. Additionally, the industry is affected by normal business cycles such as seasonality and other less predictable, facility-specific factors. Firms are required to update their facility registration within 60 calendar days of any change to any of the required information (21 CFR 1.234(a)). In the case of a change in ownership, the former owner must cancel the facility's registration within 60 calendar days, and the new owner must submit a new registration for the facility before the facility begins to manufacture/process, pack, or hold food for consumption in the United States (21 CFR 1.234(b)).

However, ongoing challenges affect the accuracy of FDA's registered facility inventories, largely due to industry noncompliance with registration requirements and FDA's limited enforcement tools. As a result, attempted inspections—i.e., inspections FDA initiates but cannot complete, are sometimes unavoidable. While these attempted inspections yield valuable information about a facility's current operations for future inspection targeting and investigations, FDA should continue to make every effort to minimize any negative impacts associated with them.

FDA has the primary responsibility for validating its food facility inventory. Existing procedures aim to reduce attempted inspections by managing updates to new and existing domestic facilities through the food facility registration and biennial registration renewal process. These procedures include verifying key data elements and documenting facility operational activities that inform the FDA's inspection workplan.

In addition to the Food Facility Registration Database, FDA maintains the Official Establishment Inventory (OEI), which includes some facilities whose registrations have expired or that have never registered. Using the OEI in conjunction with the registration database helps FDA inspect unregistered or lapsed facilities and avoids inspecting firms that were incorrectly registered as food facilities.

FDA agrees that the number of attempted inspections should be further minimized. FDA will review its current policies and procedures and explore additional strategies to reduce them. For example, FDA is exploring how to leverage supplementary datasets and quantitative analytical techniques to improve the accuracy of its facility inventory, thereby reducing the number of attempted inspections.

Recommendation 3: Assess reasons for the decrease in number of facilities inspected by FDA with significant violations and take action as appropriate.

FDA concurs with OIG that further assessment is necessary.

Recommendation 4: Conduct timely follow up inspections of facilities with significant violations.

While FDA concurs with the recommendation to conduct timely follow-up inspections of facilities with significant violations, FDA does not agree with the basis for some of the calculations reflected in the OIG report and does not believe the report accurately represents the agency's timeliness in conducting these follow-up inspections.

Follow-up inspection timeframes may be impacted by a variety of different situations, such as when the firm is actively working with the FDA on corrective actions that require more time to implement, when resources are limited, or when higher-priority assignments take precedence. FDA's Regulatory Procedures Manual (RPM) and ORA's Field Management Directive (FMD) 86 were the governing procedures for follow-up inspection timeframes during the period covered in the report. The FDA RPM, Chapter 4, states for warning letter follow-up, "follow-up inspections should be conducted promptly after the agreed upon date of completion of the promised corrections." FMD 86, dated December 14, 2022, states, "ORA's goal is for these follow-up inspections to be conducted at domestic establishments within six months after an Official Action Indicated (OAI) classification has been finalized and any actions taken." FDA's timeliness for follow-up within six months—calculated after OAI classification has been finalized and any actions taken—was 41.1% for FY21 to FY23, which is significantly higher than the 9% reported. Additionally, FDA's timeliness for follow-up within one year was 92.5% for the same period, compared to the 39% depicted in Exhibit 8 of the report.

FDA understands that the methodology used by OIG calculated timeliness based on the last date of the initial inspection. This approach differs substantially from FDA's internal procedures, which focus on a compliance officer's final inspection classification and any subsequent actions taken (e.g. issuance of a Warning Letter to the firm). OIG's own methodology, as stated on page 14, reflects the need for a final classification to establish a significant violation: "We considered a facility to have a significant violation if it received a final classification of OAI." The final

classification is made by a compliance officer in the Human Foods Program (HFP)—not the investigator—and is entered after the regulatory action has been taken.

A key goal of FDA's reorganization in October 2024[i] was to merge compliance functions formerly managed within OII into HFP's existing compliance functions to streamline operations and expedite decision-making. FDA will continue to review and evaluate its policies and procedures and evaluate the timeliness of follow-up inspections.

[i] https://www.fda.gov/about-fda/fda-organization/fda-modernization-efforts-establishing-unified-human-foods-program-new-model-field-operations-and

ENDNOTES

[1] 21 U.S.C. § 374; 21 U.S.C. § 372. We based these facility numbers on data FDA provided on its total inventory of facilities.

[2] Section 421(a)(1) of the FD&C Act (21 U.S.C. § 350(j)(a)(1)). If necessary, inspections can be conducted more frequently. See also FDA, *Inspections to Protect the Food Supply*. Accessed at https://www.fda.gov/food/compliance-enforcement-food/inspections-protect-food-supply on August 29, 2024.

[3] Food facilities are required to register with FDA and cancel their registration within 60 days of any change in status. See FDA, *Registration of Food Facilities and Other Submissions*. Accessed at https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions on August 29, 2024. Food facility registration requirements are established in 21 U.S.C. § 350(d).

[4] FDA, *An Update to the Resiliency Roadmap for FDA Inspectional Oversight*, November 2021. Accessed at https://www.fda.gov/media/154293/download on August 29, 2024.

[5] See *Federal Register: Statement of Organization, Functions, and Delegations of Authority*, June 2024. Accessed at https://www.federalregister.gov/documents/2024/06/03/2024-11893/statement-of-organization-functions-and-delegations-of-authority on August 29, 2024. Prior to this reorganization, FDA investigators were responsible for all facilities under FDA jurisdiction, such as facilities that produced medical devices. This reorganization establishes inspection staff dedicated to human food products. See also *FDA Modernization Efforts for Establishing a Unified Human Foods Program, New Model for Field Operations and More*, October 2024. Accessed at https://www.fda.gov/about-fda/fda-organization/fda-modernization-efforts-establishing-unified-human-foods-program-new-model-field-operations-and on December 23, 2024.

[6] For the purposes of this report, we use "significant violations" to reflect the conditions found during a food facility inspection that FDA classified as OAI. See FDA, *Inspection Classification Database*, September 2024. Accessed at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database on December 23, 2024.

[7] Facilities may be inspected under more than one product/assignment code (PAC), such as dairy or juice, and more than one establishment type, such as warehouse or manufacturer. When a facility is inspected, each PAC and establishment type receives an inspection classification, and each may have a different classification. When an investigator finds objectionable but less significant violations, an investigator can classify the inspection as voluntary action indicated (VAI), which indicates that the violations are serious enough to record but do not meet the threshold for regulatory action. An investigator can also classify an inspection as no action indicated (NAI), which indicates that the investigator found no objectionable conditions or practices, or that their significance does not justify further action.

[8] See FDA, *Inspections to Protect the Food Supply*, March 2024, accessed at https://www.fda.gov/food/compliance-enforcement-food/inspections-protect-food-supply on August 29, 2024; and FDA, *How Does FDA Prioritize Domestic Human Food Facility Inspections?*, December 2024, accessed at https://www.fda.gov/food/inspections-protect-food-supply/how-does-fda-prioritize-domestic-human-food-facility-inspections on December 23, 2024.

[9] At the time of our review, FDA's goal was to conduct followup inspections within 6 months after a facility received an OAI classification, assuming that no other actions were taken. This goal was stated in FDA's policy directive *FMD 86: Establishment Inspection Report Conclusions and Decisions*. FMD 86 was later canceled. See *Canceled FMDs*. Accessed at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/field-management-directives/canceled-fmds on May 22, 2025. FMD 86 can be accessed at an archived site. Accessed at https://web.archive.org/web/20250205200018/https://www.fda.gov/media/87643/download on May 22, 2025.

[10] We based this analysis on facilities that were subject to FDA Food Safety Modernization Act (FSMA) requirements throughout the entire year.

[11] All years presented in the report are fiscal years. FDA limited the number of domestic food facility inspections during the COVID-19 pandemic starting in March 2020; it resumed standard inspection operations in July 2021. For purposes of this analysis, we defined the pre-pandemic period as October 2016 through March 2020, the pandemic period as March 2020 through July 2021, and the post-pandemic period as July 2021 through September 2023.

[12] In this report, we considered inspections conducted by FDA or by State, Local, Tribal, and Territorial Governments on behalf of FDA as FDA inspections. We based this analysis on facilities that were subject to FSMA requirements throughout the entire year.

[13] Spending is in 2023 dollars.

[14] To determine the extent to which high-risk facilities were inspected within the FSMA timeframes, we looked at the 3-year period from 2021 through 2023. We did not look at a facility's last inspection date. The 26 percent of facilities that were not inspected within the timeframes were not inspected at any point during these 3 years and therefore were out of compliance with the 3-year FSMA timeframe.

[15] To determine the extent to which non-high-risk facilities were inspected within the FSMA timeframes, we looked at the 5-year period from 2019 through 2023. We did not look at a facility's last inspection date. The 34 percent of facilities that were not inspected within the timeframes were not inspected at any point during these 5 years and therefore were out of compliance with the 5-year FSMA timeframe.

[16] To determine the inspections needed annually, we averaged the high-risk and non-high-risk FSMA inventory from 2017-2023.

[17] To account for the disruptions from the pandemic, we averaged the number of facilities inspected in 2022 and 2023.

[18] Attempted inspections may also include efforts by investigators to determine the status of a facility, such as internet searches, without visiting the facility.

[19] OIG, *Challenges Remain in FDA's Inspections of Domestic Food Facilities* (OEI-02-14-00420), September 2017.

[20] In some cases, investigators may go out to the facility to verify that it was not in operation, for example, to confirm that the facility was not operating under another name.

[21] FDA maintains a registry of all food facilities and requires facilities to register and to cancel their registrations if they go out of business. FDA uses this registry to identify facilities that are no longer in business. See FDA, *Food Facility Registration and Registration Cancellation by Paper (Mail or FAX)*. Accessed at https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-and-registration-cancellation-paper-mail-or-fax on August 29, 2024

[22] See OIG, *Challenges Remain in FDA's Inspections of Domestic Food Facilities* (OEI-02-14-00420), September 2017, and *FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080), April 2010.

[23] At the time of our review, FDA's goal was to conduct followup inspections within 6 months after a facility received an OAI classification, assuming that no other actions were taken. This goal was stated in FDA's policy directive *FMD 86: Establishment Inspection Report Conclusions and Decisions*. FMD 86 was later canceled. See *Canceled FMDs*. Accessed at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/field-management-directives/canceled-fmds on May 22, 2025. FMD 86 can be accessed at an archived site. Accessed at https://web.archive.org/web/20250205200018/https://www.fda.gov/media/87643/download on May 22, 2025. OIG did not assess compliance with FDA's internal policies, but rather assessed whether an inspection occurred within 6 months of a significant violation. There may be situations in which a food facility can resolve an OAI that lessens the urgency for FDA to physically inspect the facility.

[24] Recent work by the Government Accountability Office (GAO) also found gaps in FDA's ability to meet inspection mandate requirements and recommends that FDA identify and implement additional procedures to minimize incidences of attempted inspections of domestic food facilities. See *Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply*, GAO-25-107571, January 2025. Accessed on January 22, 2025.

[25] See OIG, *Challenges Remain in FDA's Inspections of Domestic Food Facilities* (OEI-02-14-00420), September 2017.

[26] The FSMA Tracker is the foods component of FDA-TRACK, the agency-wide performance management program that tracks measures and key projects.

[27] The study period includes 2017 through 2023. All years presented in the report are fiscal years. Note that FDA provided data for FY 2017 in a separate file.

[28] We based this analysis on the count of all facilities inspected each FY rather than facilities with a "cover by date" assigned in the FSMA tracker. FDA assigns a cover by date as a means of establishing each year's scheduling priorities; however, in some cases, facilities are missing a cover by date or FDA has revised the dates to later years outside the required timeframes for inspection. In addition, we based this analysis on facilities that were subject to FSMA requirements throughout the entire year. In some instances, the status of the facility changed for part of the year. For example, facilities that were previously subject to FSMA due to the types of food they produced stopped production and no longer required a FSMA inspection. Such facilities are excluded from our analysis.

[29] Some facilities in 2017 were designated both high-risk and non-high-risk. For our analysis, we considered these high-risk facilities.

[30] We identified 9,622 facilities that were in continuous operation from 2021 through 2023. In total, 2,535 did not receive an inspection. For 280 of these facilities, an investigator made an attempt to inspect the facility, but was not able to complete an actual inspection.

[31] We identified 38,751 facilities that were in continuous operation from 2019 through 2023. In total, 13,155 did not receive an inspection. For 702 of these facilities, an investigator made an attempt to inspect the facility, but was not able to complete an actual inspection.

[32] To account for the disruptions from the pandemic, we averaged the number of facilities inspected in 2022 and 2023.

[33] We used the FSMA Tracker to identify facilities that were not in operation (Operation 13) and which of these facilities were out of business.

[34] We considered the inspection to be an OAI if at least one product/assignment code (PAC) or establishment type was classified OAI. Facilities may be inspected under more than one PAC, such as dairy or juice, and more than one establishment type, such as warehouse or manufacturer. When a facility is inspected, each PAC and establishment type receives an inspection classification, and each may have a different classification.

[35] We did not include 47 OAI classifications that occurred in 2023 and did not receive a followup inspection because FDA did not have at least 1 year from the date the inspection ended to conduct a followup inspection during our study period. We also excluded 77 OAI classifications because the facility went out of business before a followup inspection occurred.

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