U.S. Government Accountability Office

Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply

GAO-25-107571
Q&A Report to Congressional Addressee
January 8, 2025

Why This Matters

The Food and Drug Administration (FDA) is responsible for ensuring the safety of nearly 80 percent of the nation's food supply, including fruits, vegetables, processed foods, dairy products, and most seafood. Although the U.S. food supply is generally considered safe, foodborne illness remains a common and costly public health problem. Each year, foodborne illnesses sicken tens of millions of Americans. Of these, tens of thousands are hospitalized and thousands die, according to the most recent estimate from the Centers for Disease Control and Prevention.

Foodborne illnesses may result from multistate outbreaks from pathogens in foods regulated by FDA. For example, in October 2024, the nation experienced an outbreak of the dangerous foodborne pathogen *E. coli* that, as of December 3, 2024, had sickened at least 104 people and caused one death. FDA worked to identify the source of that outbreak and determined it likely was slivered onions in burgers sold by a major national fast-food chain. A separate outbreak of the foodborne pathogen *Listeria* occurred earlier in 2024 when 23 people were hospitalized and two died. In that case, an FDA investigation resulted in a manufacturer recall of cheese products that had been contaminated at a production site in California.

We have long reported on FDA's efforts to safeguard the nation's food supply. Improving federal oversight of food safety has been on GAO's High-Risk List since 2007. To accomplish its food safety mission, FDA uses a range of tools, including conducting routine surveillance inspections of domestic and foreign food facilities. Such inspections are intended to monitor a facility's compliance with regulatory requirements and serve as a proactive tool aimed at preventing food safety problems rather than reacting to outbreaks after they happen, according to agency officials. The FDA Food Safety Modernization Act (FSMA), signed into law in 2011, includes targets for the domestic and foreign food inspections that FDA is to conduct annually.

We performed our work at the initiative of the Comptroller General to assist Congress with oversight of FDA's efforts to conduct food safety inspections. This report provides information on FDA's role in conducting domestic and foreign food safety inspections and examines how FDA inspections compare with mandated targets established by FSMA, what challenges FDA faces in conducting food safety inspections, and how FDA assesses the results of its inspection efforts.

Key Takeaways

- FDA has not met FSMA's mandated targets for domestic food facility inspections since fiscal year 2018. In addition, FDA has consistently fallen short of meeting its annual targets for foreign food facility inspections. While

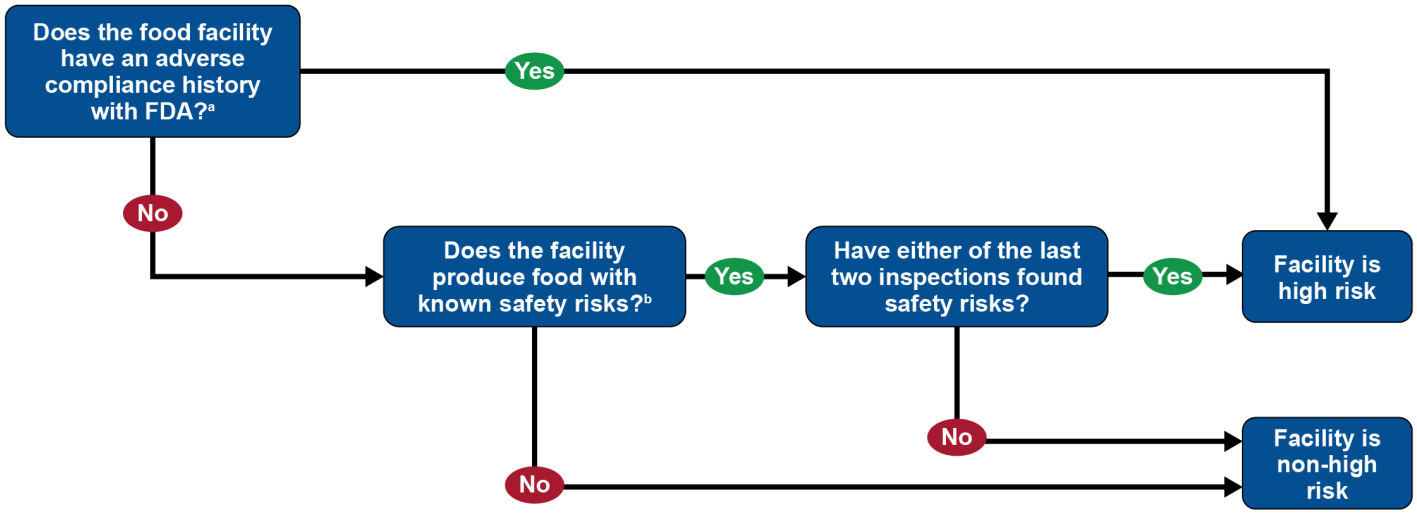
FDA officials told us that FDA's existing foreign inspection targets are unrealistic and unachievable, the agency has not identified an alternative annual target or communicated with Congress regarding this issue.

- FDA has taken steps to address significant and long-standing workforce capacity challenges but has not determined the appropriate size or workload of its foreign investigator cadre.
- FDA has not identified and implemented additional procedures for minimizing incidences where FDA investigators attempt but are unable to complete a domestic food facility inspection. Further, while FDA takes some steps to assess its performance, the agency does not yet have a formal performance management process focused on food safety inspection efforts. Such a process could include, for example, developing goals and measures for FDA's use in assessing its progress in recruiting and retaining investigators.
- We recommend that Congress consider directing FDA to conduct an analysis to determine the annual number of foreign food facility inspections sufficient to ensure the safety of imported food, and communicate this information to Congress. Upon receiving this information from FDA, Congress should consider updating FDA's annual target for conducting these inspections.
- In addition, we recommend that FDA take steps to determine the appropriate size and workload of its foreign investigator cadre necessary to safeguard the U.S. food supply. We also recommend that FDA identify and implement procedures to minimize incidences where FDA investigators attempt but are unable to complete a domestic food facility inspection. Lastly, we recommend that FDA develop a performance management process for assessing the results of the agency's food safety inspection efforts.

What is FDA's role in inspecting domestic food facilities?

FSMA requires FDA to identify the risk level of domestic facilities that manufacture, process, pack, and store food based on two broad categories (high risk and non-high risk) and to conduct inspections according to the facilities' known safety risks.[1] FSMA also establishes factors for FDA to use in identifying high-risk facilities, including known safety risks of the food, a facility's compliance history, and the rigor and effectiveness of a facility's hazard analysis and risk-based preventive controls. According to FDA officials, the agency used these statutory factors to develop a specific process to identify domestic high-risk facilities (see fig. 1).

Figure 1: Food and Drug Administration's (FDA) Process for Categorizing Domestic Food Facilities by Risk



Source: GAO presentation of FDA information. | GAO-25-107571

[a]An adverse compliance history refers to a facility for which a prior inspection identified a food safety violation as well as to a facility associated with a recent food safety recall or outbreak.

[b]Food with known safety risks includes products that have been associated with recalls or outbreaks, such as infant formula.

At the end of fiscal year 2023, about 75,000 domestic food facilities were subject to FDA inspection under FSMA. This included more than 17,000 high-risk facilities (about 23 percent) and nearly 58,000 non-high-risk facilities (about 77 percent).

Under FSMA, domestic high-risk facilities must be inspected more frequently than non-high-risk facilities. FDA uses a risk-based approach to select and conduct unannounced inspections at domestic food facilities, according to FDA officials. FDA investigators from the agency's 19 district offices conduct the inspections and take other actions to safeguard the food supply. In addition, FDA contracts with states and Puerto Rico to conduct food safety inspections on behalf of FDA.[2]

What is FDA's role in inspecting foreign food facilities?

FDA is responsible for identifying foreign facilities for food safety inspections and conducting these inspections to better ensure the safety of food imported into the U.S. for public consumption.[3] As of March 2023, approximately 125,000 foreign food facilities were subject to FDA inspection. Unlike domestic facilities, FDA does not explicitly categorize individual foreign food facilities as high-risk or non-high-risk. However, agency officials told us that FDA uses a risk-based approach to prioritize inspections at facilities determined to have a higher risk profile. In determining a foreign facility's risk profile, FDA considers the type of food at the facility and the facility's compliance history. For example, if a facility's products have been denied entry into the United States, FDA may identify the facility as having a higher risk profile.

While FDA does not notify domestic facilities in advance of an inspection, the agency generally notifies foreign facilities before inspecting them.[4] FDA officials we interviewed told us that providing notification is necessary because foreign facility inspections require more planning and are more costly to conduct than most domestic inspections. Notifying foreign facilities in advance increases the likelihood that they will be operating at the time of the planned inspection.

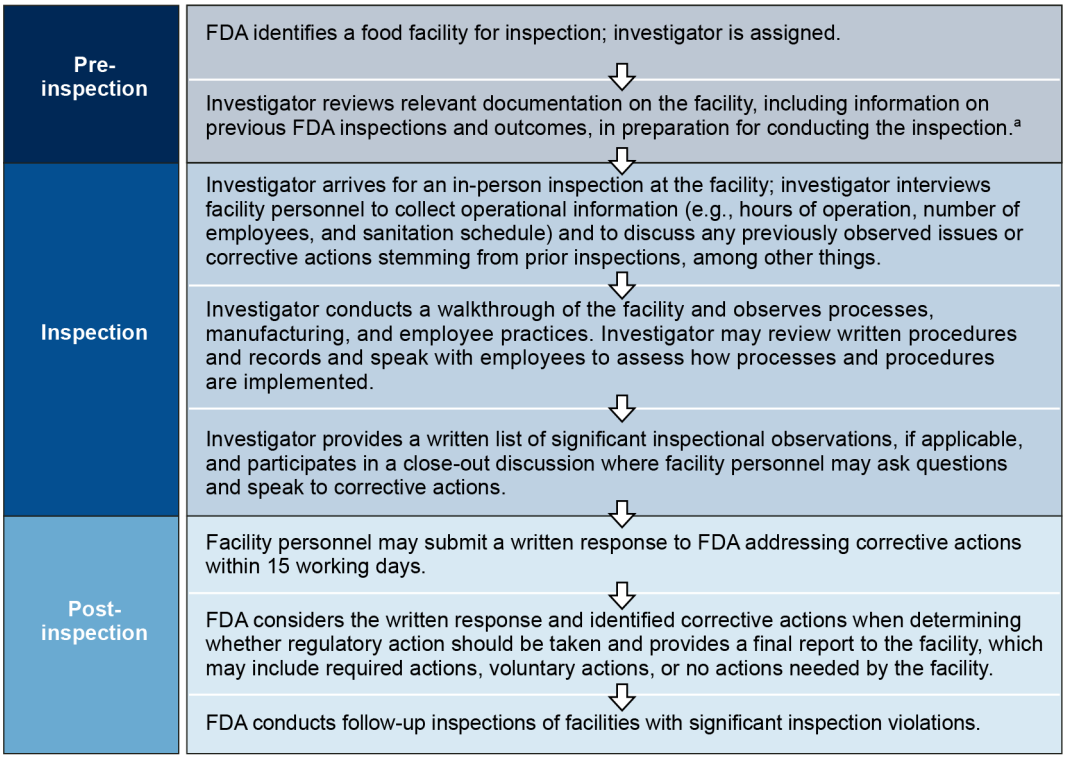
FDA foreign inspections aim to identify potential food safety problems before products arrive in the United States and to determine whether foreign facilities

comply with FDA requirements and food safety standards. FDA may conduct foreign food safety inspections using its own investigators or rely on officials from foreign countries with whom FDA has relevant agreements in place.

What is FDA's process for conducting food safety inspections?

During a typical food safety inspection, an FDA investigator reviews information about the selected facility and conducts a walkthrough. The investigator observes processes, manufacturing, and employee practices to identify potential safety risks to the public (see fig. 2).[5]

Figure 2: Food and Drug Administration's (FDA) General Process for Conducting a Typical Domestic or Foreign Food Safety Inspection



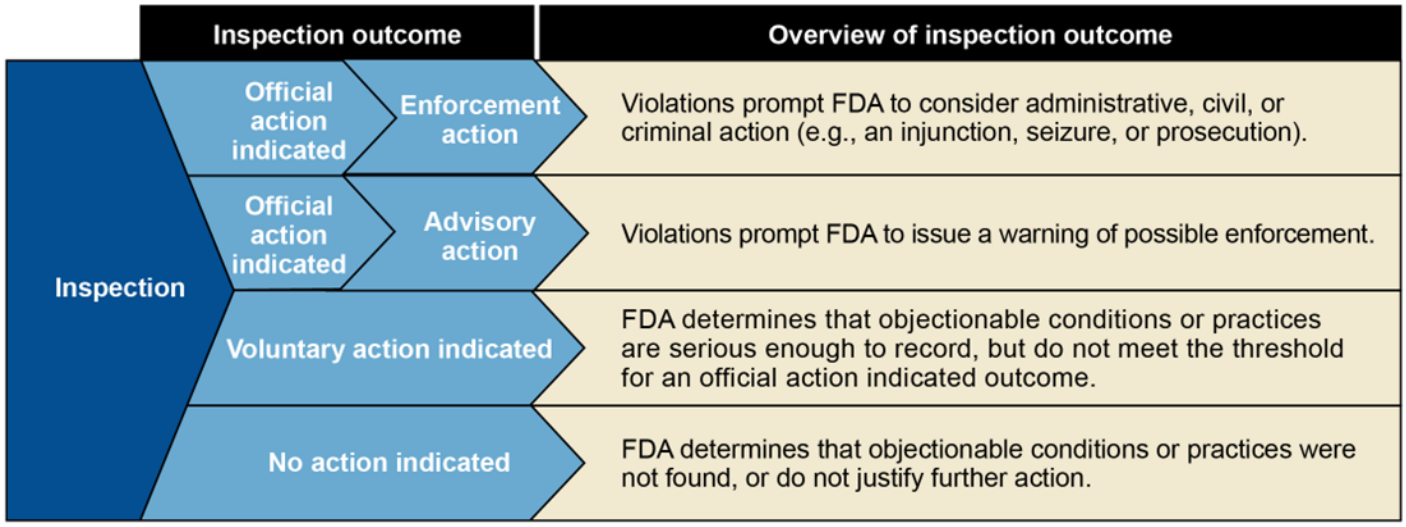
Source: GAO analysis of FDA documentation and officials' statements. | GAO-25-107571

[a]FDA does not notify domestic food facilities in advance of an inspection, and targeted facilities are therefore not aware prior to the arrival of an investigator that an inspection will take place. In contrast, FDA generally notifies foreign facilities in advance of an inspection because such inspections require more planning and are more costly to conduct. Specifically, FDA officials told us that notifying foreign facilities is necessary to increase the likelihood that the facilities are operating at the time of the planned inspection.

According to FDA officials we interviewed, a routine domestic inspection typically takes from 1 to 4 days to complete depending on the facility's size, the type of food at the facility, and the investigator's familiarity with the facility. FDA officials stated that, as of August 2024, the average cost of inspecting a domestic high-risk facility was about $28,600 while the average cost of inspecting a domestic non-high-risk facility was about $14,900. Further, FDA officials told us that, on average, each foreign inspection typically takes from 2 to 5 days to complete and costs about $38,700.

FDA food safety inspections result in four potential outcomes that range in severity (see fig. 3).

Figure 3: Food and Drug Administration (FDA) Domestic and Foreign Food Safety Inspection Outcomes



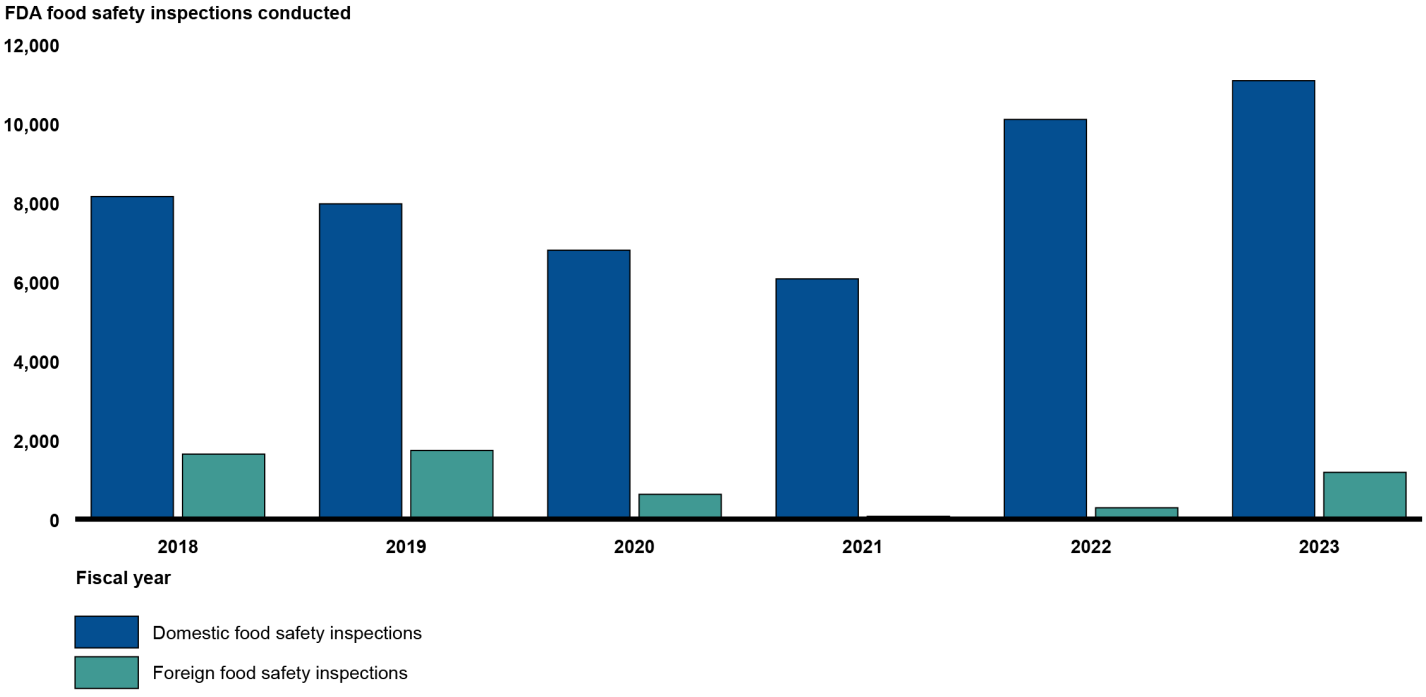
Source: GAO analysis of FDA documentation and officials' statements. | GAO-25-107571

Notes: According to agency officials, FDA encourages facilities to voluntarily correct objectionable conditions and practices identified during an inspection for all voluntary action indicated and official action indicated outcomes. FDA uses the term "classification" to refer to these inspection outcomes.

What do data show about FDA food safety inspections conducted since 2018?

FDA conducted thousands of routine surveillance food safety inspections of domestic and foreign food facilities from fiscal year 2018 through fiscal year 2023, according to our analysis of FDA data.[6] Specifically, these data show that FDA conducted an average of 8,353 domestic food facility inspections per year and an average of 917 foreign food facility inspections per year (see fig. 4).

Figure 4: Number of Food and Drug Administration (FDA) Domestic and Foreign Food Facility Inspections Conducted, Fiscal Years 2018–2023



Source: GAO analysis of FDA data. | GAO-25-107571

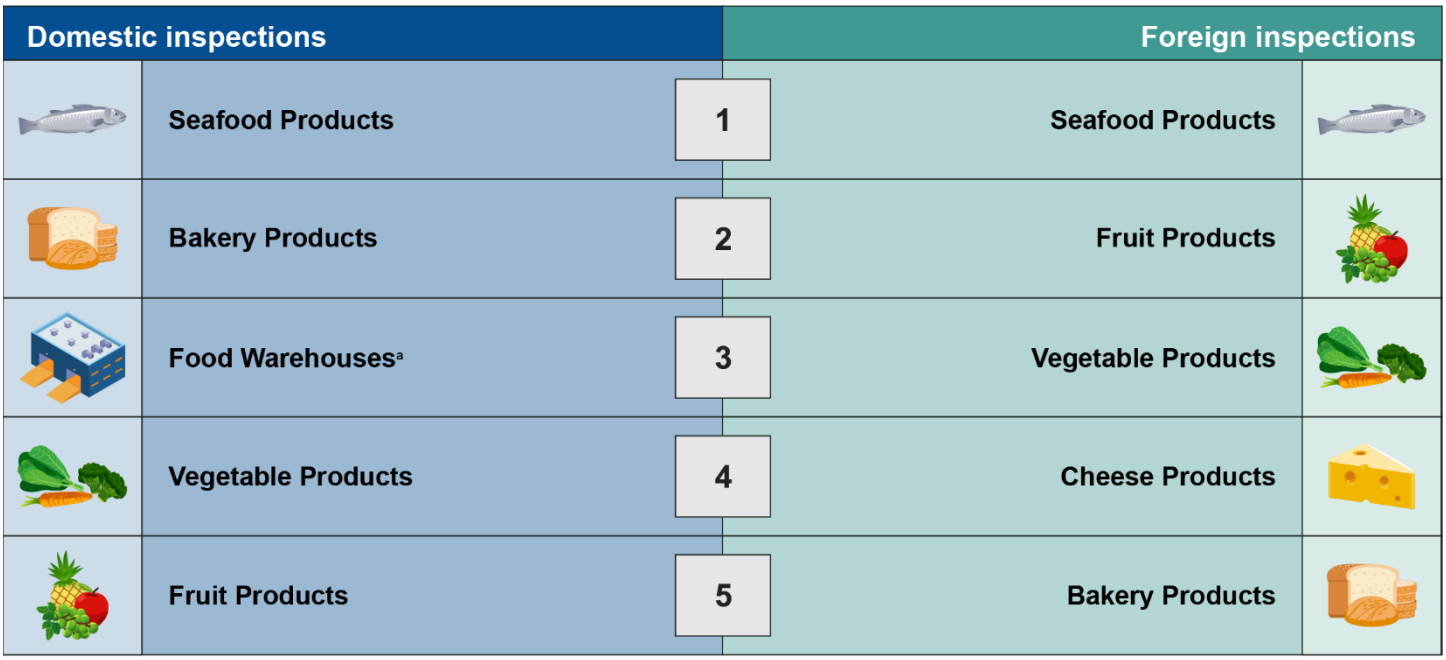
Notes: This figure presents information on FDA's routine surveillance food safety inspections intended to monitor domestic and foreign food facilities' compliance with regulatory requirements. This figure does not include other types of FDA inspections outside the scope of this report, such as inspections conducted to investigate a specific problem. In addition, FDA includes both completed and attempted inspections in its fiscal year totals to track its progress covering the domestic and foreign food facilities in FDA's inventory that are due for inspection. Attempted inspections occur when FDA investigators attempt to conduct an inspection of a food facility, but the

inspection cannot be completed. For example, the facility may not be operating on the day of inspection or may have gone out of business.

FDA includes both completed and attempted inspections in these fiscal year totals to track its progress covering domestic and foreign food facilities in FDA's inventory that are due for inspection. Attempted inspections occur when FDA investigators attempt to conduct an inspection of a food facility, but the inspection cannot be completed. For example, the facility may not be operating on the day of inspection. In such cases, FDA will document the attempted inspection and generally plan to return within 1 year to conduct the inspection.[7] An FDA investigator may also arrive and find that a food facility has gone out of business. In these cases, FDA removes the facility from its inventory.

FDA food safety inspections target a range of foods, including seafood and cheese products, and certain foods may be inspected more than others (see fig. 5). For example, approximately one in six domestic and foreign inspections conducted from fiscal year 2018 through fiscal year 2023 targeted seafood products, according to our analysis of FDA data.

Figure 5: Top Five Types of Food Inspected by the Food and Drug Administration (FDA), Fiscal Years 2018–2023



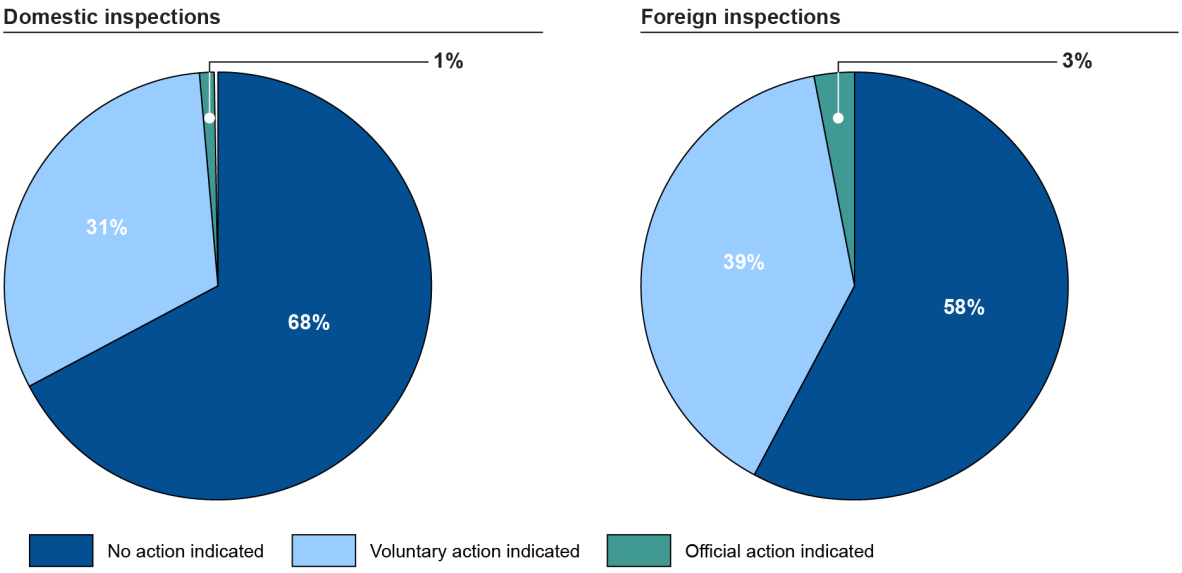
Source: GAO analysis of FDA data; jattumongkhon/stock.adobe.com (icons); creativeteam/stock.adobe.com (warehouse). | GAO-25-107571

Note: FDA is responsible for ensuring the safety of a wide range of food products sold in the United States. However, the U.S. Department of Agriculture is responsible for ensuring the safety of meat, poultry, some egg products, and all fish of the order Siluriformes (e.g., catfish).

[a]FDA's Food Warehouses category includes facilities, such as distribution centers, that store a variety of foods, or store specific foods FDA considers high risk such as dairy products and seafood, according to FDA officials.

Our analysis of fiscal year 2018 through fiscal year 2023 FDA data shows that FDA's domestic and foreign food safety inspections resulted in varied outcomes (see fig. 6). As detailed above, an official action indicated is the most severe inspection outcome and can occur, for example, when a facility does not have a food safety plan in place, when required, or fails to adequately train employees on proper food hygiene. A voluntary action indicated represents a less severe outcome in which FDA formally records a violation for corrective action. For example, according to agency data, an FDA investigator observed a roof leak, dust in a refrigeration unit, and deteriorated concrete during an inspection of a domestic seafood manufacturing facility in fiscal year 2022, which resulted in a voluntary action indicated.

Figure 6: Food and Drug Administration (FDA) Food Safety Inspection Outcomes for Domestic and Foreign Food Facilities, Fiscal Years 2018–2023



Source: GAO analysis of FDA data. | GAO-25-107571

Note: FDA food safety inspections may include inspecting more than one type of food product at a single facility. As a result, an FDA inspection at one food facility may result in multiple inspection outcomes. For the purposes of our analysis, the information above reflects the most severe outcome identified for each food facility FDA inspected. FDA uses the term "classification" to refer to these inspection outcomes.

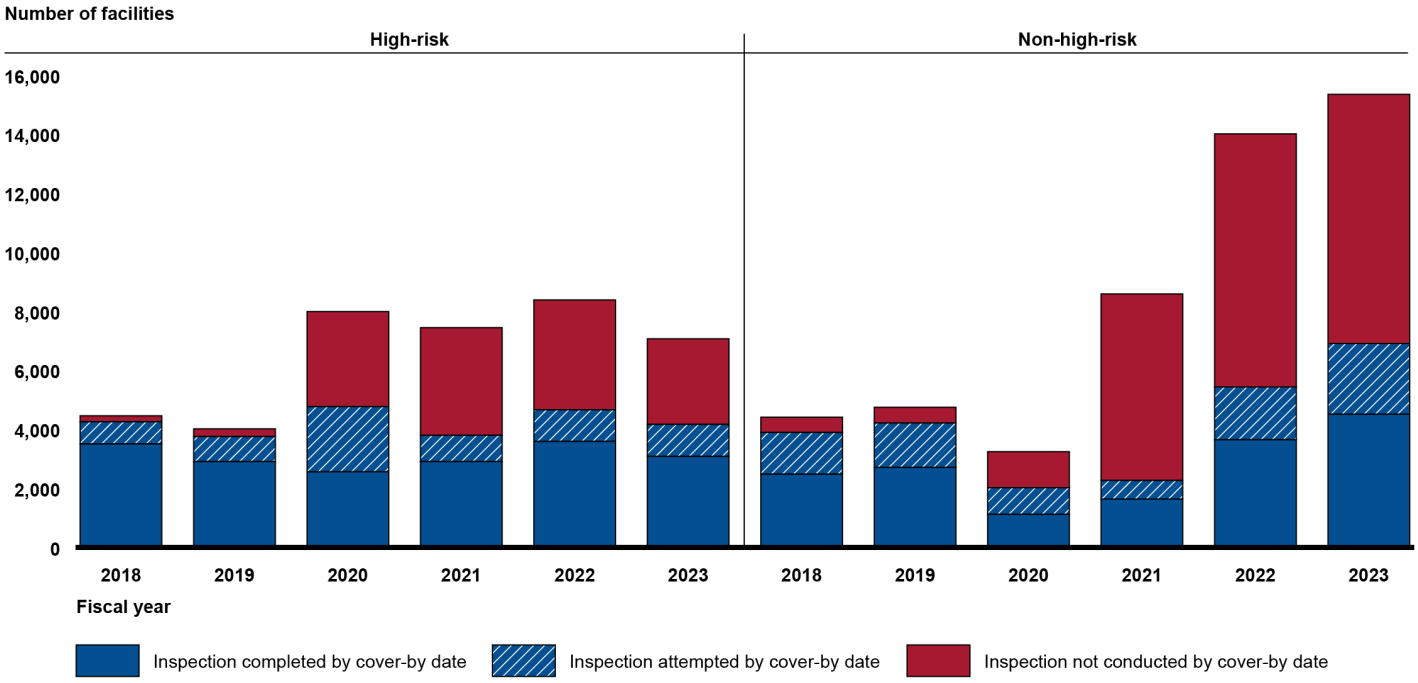
Has FDA met FSMA's mandated targets for domestic inspections?

No. FDA has not met FSMA's mandated targets for domestic inspections since fiscal year 2018, according to FDA data. FSMA directs FDA to inspect each domestic high-risk food facility at least once every 3 years and each non-high-risk food facility at least once every 5 years.[8] Given this recurring inspection cycle, FDA is responsible for inspecting a subset of its full inventory of approximately 75,000 domestic food facilities each fiscal year.

To track its progress toward meeting this target, in fiscal year 2018 FDA implemented the FSMA Tracker—a software system that tracks inspection "cover-by" dates for each high-risk and non-high-risk domestic facility. The FSMA Tracker assists FDA with identifying the subset of domestic facilities in FDA's full inventory that are due for an inspection (i.e., have cover-by dates) in a given fiscal year. This subset represents FDA's mandated targets for that fiscal year. For example, a high-risk facility inspected on October 1, 2022, would be updated in the FSMA Tracker as requiring at least one inspection by the cover-by date of October 1, 2025—exactly 3 years later. Facilities that FDA does not inspect by their cover-by date become past-due.[9]

According to agency data, FDA has not met its mandated targets under FSMA for fiscal year 2018 (the first year FDA used the FSMA Tracker) through fiscal year 2023 (the most recent year with complete data). As shown in figure 7, FDA nearly met its mandated targets for both high-risk and non-high-risk facilities in fiscal years 2018 and 2019, but faced significant challenges in meeting mandated targets beginning in fiscal year 2020. In addition, as the number of past-due facilities increased in fiscal year 2020, a backlog was created for each successive fiscal year. Specifically, the total number of facilities FDA was to inspect each year increased after fiscal year 2020 since it included both past-due facilities and facilities with upcoming cover-by dates.

Figure 7: Food and Drug Administration's (FDA) Performance in Meeting Mandated Targets for Domestic Food Facility Inspections According to FDA Data, Fiscal Years 2018–2023



Source: GAO analysis of FDA data. | GAO-25-107571

Notes: FDA must inspect each high-risk domestic facility at least once every 3 years and each non-high-risk domestic facility at least once every 5 years. FDA uses "cover-by" dates for each facility to ensure it meets these mandated targets. For example, a high-risk domestic facility inspected on October 1, 2022, would have a cover-by date of October 1, 2025—exactly 3 years later. The figure depicts FDA's performance in meeting mandated targets for domestic food facilities with cover-by dates in a given fiscal year. Specifically, the fiscal year totals presented in the figure do not represent FDA's full inventory of approximately 75,000 domestic food facilities subject to FDA inspection. Instead, the fiscal year totals represent a subset of FDA's full inventory. This subset includes domestic facilities that are due for an inspection (i.e., have cover-by dates) in a given fiscal year as well as facilities that are past-due for an inspection (i.e., had cover-by dates in the prior fiscal year, but were not inspected). Therefore, domestic facilities that are not past-due or do not have a cover-by date in a given fiscal year are not included in the data for that fiscal year.

Further, FDA includes both completed and attempted inspections in its fiscal year totals to track its progress covering the domestic food facilities in FDA's inventory that are due for inspection. Attempted inspections occur when FDA investigators attempt to conduct an inspection of a domestic food facility by the cover-by date, but the inspection cannot be completed. For example, the facility may not be operating on the day of inspection or may have gone out of business.

According to FDA data, in fiscal year 2019 FDA did not inspect—or attempt to inspect—about 7 percent of high-risk domestic food facilities by their cover-by date, as required by FSMA. However, the data show that in fiscal years 2020 and 2021, this percentage increased to 40 percent and 49 percent, respectively. According to FDA data, an even greater increase occurred for non-high-risk facilities. For example, from fiscal year 2020 through fiscal year 2021, the percentage of non-high-risk facilities that FDA did not inspect by their cover-by dates increased from about 38 percent to nearly 74 percent.

FDA officials told us these increases were due to the 35-day government shutdown in fiscal year 2019 and the COVID-19 pandemic soon after in 2020. They added that the pandemic significantly impaired FDA's ability to conduct in-person inspections of domestic facilities. The officials also told us in August 2024 that FDA was continuing to address the backlog of inspections created during the pandemic.

As shown in figure 7 above, incidences of attempted inspections represent nearly one in three domestic inspections FDA counted toward meeting its annual FSMA targets since fiscal year 2018. FDA officials told us that attempted inspections often serve to confirm that a given facility is no longer in operation. In doing so, they help FDA maintain an accurate inventory of domestic food facilities, which is in constant flux. According to a senior FDA official responsible for the Human

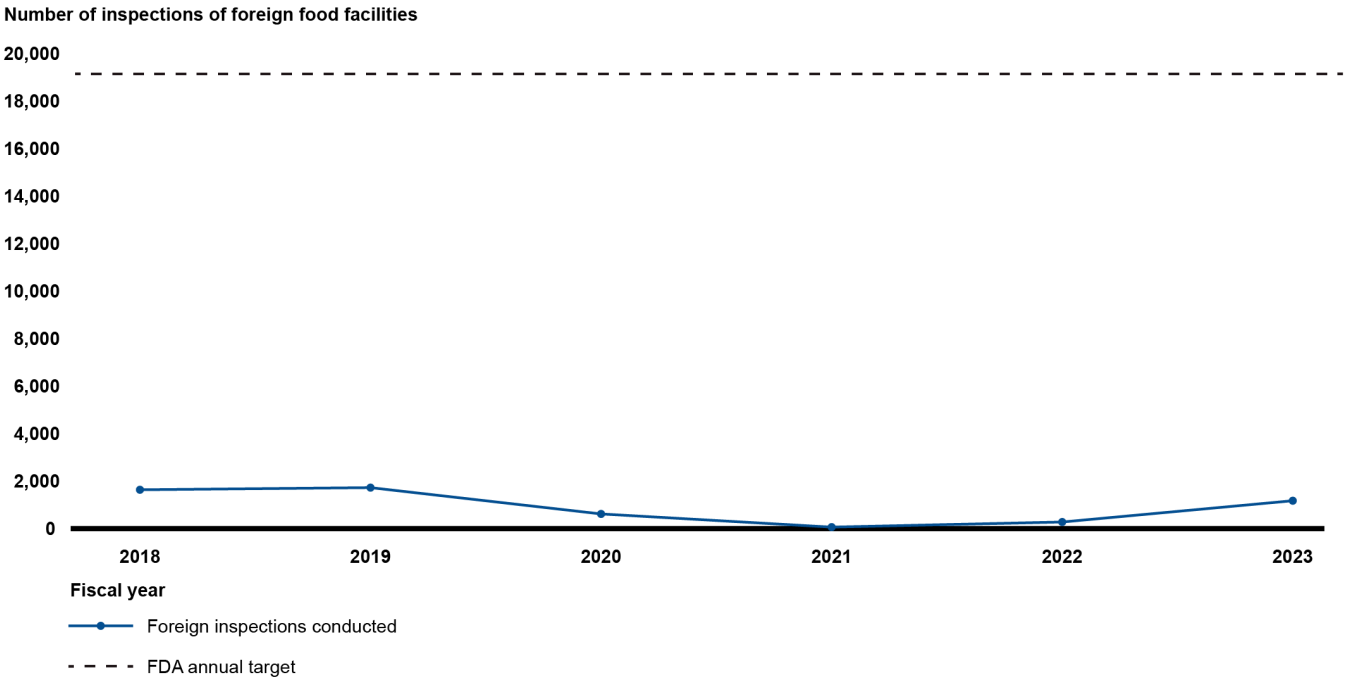
Foods Program, however, minimizing the occurrence of attempted inspections is important to ensure the efficient use of FDA's limited resources.

Has FDA met annual targets for foreign inspections?

No. Since fiscal year 2018, FDA has conducted far fewer foreign food safety inspections than its annual target of 19,200 inspections, according to FDA data. When signed into law in 2011, FSMA directed FDA to conduct an increasing number of foreign inspections each year, culminating in an annual target of 19,200 inspections in 2016.[10] According to FDA officials and agency documents, FDA has interpreted this annual target as remaining in effect for subsequent fiscal years.

According to our analysis of FDA data, the number of foreign inspections FDA conducted annually from fiscal year 2018 through fiscal year 2023, the most recent year with complete data, represents a fraction of its target.[11] Specifically, the data show that FDA conducted an average of 917 foreign food safety inspections each year—about 5 percent of its target of 19,200 inspections for this period (see fig. 8).[12]

Figure 8: Food and Drug Administration's (FDA) Performance in Meeting Annual Targets for Foreign Food Facility Inspections According to FDA Data, Fiscal Years 2018–2023



Source: GAO analysis of FDA data. | GAO-25-107571

Notes: FDA has interpreted FSMA to require that, beginning in 2016, the agency inspect 19,200 foreign facilities per year. Further, FDA includes both completed and attempted inspections in its fiscal year totals to track its progress covering foreign food facilities in FDA's inventory that are due for inspection. Attempted inspections occur when FDA investigators attempt to conduct an inspection of a food facility, but the inspection cannot be completed. For example, the facility may not be operating on the day of inspection or may have gone out of business. Since FDA's foreign inspections generally are announced—FDA notifies each foreign facility about an upcoming inspection—foreign inspections are less likely to result in attempted inspections than domestic facility inspections. For example, from fiscal year 2018 through fiscal year 2023, attempted inspections represented less than 2 percent of all foreign food safety inspections conducted, according to FDA officials.

FDA officials we interviewed consistently stated that inspecting 19,200 foreign facilities annually is not a realistic target given FDA's existing workforce and resources. For example, the most foreign inspections FDA has completed in a single year was in fiscal year 2019, when the agency inspected 1,727 foreign facilities—about 9 percent of the annual target under FSMA.

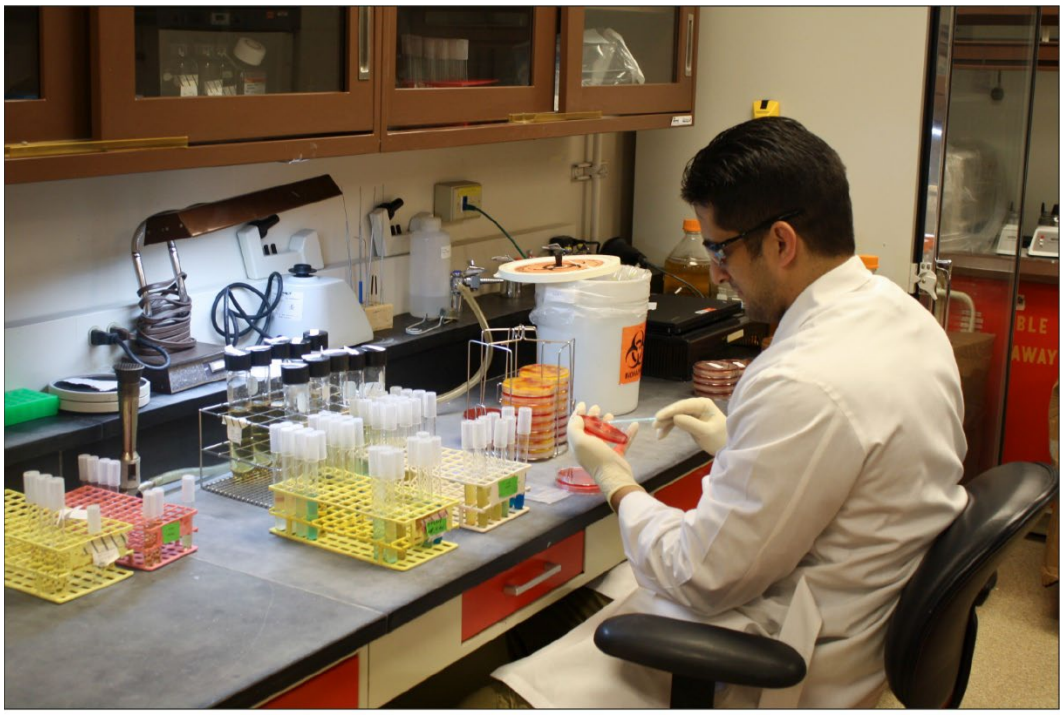
FDA officials also stated that the COVID-19 pandemic significantly affected the agency's ability to conduct foreign inspections. As shown in figure 8 above, the number of foreign inspections FDA conducted decreased in fiscal years 2020 and 2021. For example, FDA conducted a total of 64 foreign inspections in fiscal year 2021. However, FDA data also show the number of foreign inspections FDA conducted increased in fiscal years 2022 and 2023.

What did FDA identify as its primary challenge to meeting its inspection targets?

FDA officials we interviewed told us that limited workforce capacity is FDA's primary challenge to meeting food safety inspection targets and FDA's investigator cadre has remained understaffed for years. For example:

- FDA faces significant challenges in recruiting, hiring, and retaining both domestic and foreign investigators, according to FDA documentation. Agency officials stated that, although FDA has consistently hired new staff, the hiring rate has not outpaced losses and FDA has struggled to fill its full-time equivalent positions in recent years.[13] For example, in July 2024, FDA had a total of 432 investigators—90 percent of the full-time equivalent ceiling—for conducting both domestic and foreign inspections, according to FDA officials.
- FDA officials identified retirement eligibility as an element of the workforce challenge. The officials told us that nearly one-quarter of the 432 investigators on board as of July 2024 were eligible to retire and even more will become eligible to retire within 1 year. Further, FDA officials estimated that it takes about 2 years to fully train a new investigator.
- FDA officials told us the need to prioritize the agency's resources to respond to emergencies—such as a foodborne illness outbreak (see fig. 9)—directly affects FDA's ability to conduct routine food facility inspections.

Figure 9: A Food and Drug Administration Scientist Tests Recalled Peanut Butter for Salmonella



Source: U.S. Food and Drug Administration. | GAO-25-107571

How has FDA addressed workforce capacity challenges?

FDA has taken or is planning to take several actions to increase staffing levels and recruit and retain qualified investigators responsible for ensuring the safety of the U.S. food supply. For example:

- FDA has identified food safety investigators as a prioritized, mission-critical occupation and inspections as a needed capability.[14] FDA plans to make expanded training and development for these positions a top priority in fiscal year 2025.
- FDA plans to implement a recruiting process to attract qualified candidates and use retention incentives to retain investigators in specialized areas, including those that conduct foreign inspections.
- FDA officials told us the agency focuses on offering competitive compensation and incentive packages to its investigator cadre, including time-off awards, bonuses, and a student loan reimbursement program. Further, the officials said FDA recently received additional hiring authorities to assist in identifying and quickly hiring food safety investigators.
- FDA officials we interviewed told us the agency's reorganization of its Human Foods Program—which was completed in October 2024 and includes FDA offices responsible for inspections—will help to address, in part, FDA's workforce capacity and resource challenges. For example, a senior FDA official told us the reorganization will help FDA prioritize its efforts and make better decisions on how best to use the agency's limited resources.[15]

While these actions represent positive steps, FDA continues to face long-standing and significant workforce capacity challenges. FDA officials acknowledged that the agency was not capable of meeting its domestic or foreign inspection targets given its existing workforce capacity and resources. FDA has taken steps to identify the staff and resources it needs to meet its domestic inspection targets, but has not done so for its foreign inspection efforts. Specifically, as of July 2024, FDA's foreign cadre—the group of investigators dedicated to conducting foreign inspections—totaled 20 individuals. FDA officials stated these 20 investigators conduct approximately 35 percent of annual foreign inspections while investigators in FDA's domestic cadre conduct the remaining 65 percent. FDA officials added that investigators typically begin their careers in the domestic cadre and, with experience and time, transition to the foreign cadre. Further, investigators in FDA's foreign cadre are also responsible for responding to emergencies abroad, such as foodborne illness outbreaks, according to FDA officials.

FDA officials were not able to tell us whether 20 investigators is an appropriate size for its foreign cadre, or whether the current workload ratio between the foreign and domestic cadres is optimal for conducting the highest possible number of annual foreign inspections.

The Office of Personnel Management's Human Capital Framework directs agencies on how to, among other things, plan for and manage current and future workforce needs.[16] Taking steps to determine the appropriate size of its foreign investigator cadre would help FDA better plan its foreign inspection efforts and, in turn, better ensure the safety of imported food for U.S. consumers. Further, identifying the optimal workload ratio between its foreign and domestic cadres would better position FDA to holistically manage its workload across both foreign and domestic food safety inspections.

How has FDA addressed other key challenges?

FDA has taken steps to address other key challenges that it identified, including the COVID-19 pandemic and logistics associated with foreign inspections, according to FDA documentation and officials.

COVID-19 pandemic. FDA was not able to meet its targets for inspecting domestic and foreign food facilities during the COVID-19 pandemic. Specifically, the pandemic made in-person inspections of facilities and foreign travel difficult, and sometimes impossible, for FDA investigators.

To help address this challenge, FDA officials told us they sometimes used "remote regulatory assessments" when in-person inspections were logistically challenging or not feasible. These assessments, which FDA investigators conduct remotely, can include the review of facility records and procedures, virtual meetings, and the use of live or prerecorded video of facility operations. According to agency data and FDA officials, FDA investigators completed 96 remote regulatory assessments of domestic facilities and 219 such assessments of foreign facilities from fiscal year 2020 through fiscal year 2023.

The officials explained that while remote regulatory assessments do not count toward meeting FDA's targets under FSMA, they were useful in obtaining information about the operation of domestic and foreign facilities in cases where in-person inspections were not feasible. Further, FDA officials stated the agency plans to continue using remote regulatory assessments in a limited manner—for instance, to follow-up on corrective actions identified during a prior FDA inspection or when safety concerns prohibit an FDA investigator from traveling to a foreign facility.

In addition, while it is unclear when FDA will be able to clear the backlog of past-due inspections created during the pandemic, FDA officials told us they are taking steps to address it. For example, FDA officials stated that the reorganized Human Foods Program will allow FDA to better prioritize high-risk facilities for inspection. Further, for domestic inspections, FDA made a one-time, risk-based adjustment to the inspection schedules for non-high-risk facilities beginning in fiscal year 2024. According to FDA documentation, this adjustment is designed to ensure FDA investigators can prioritize inspections of high-risk facilities that are past-due. Even so, FDA officials stated they will continue to use the FSMA-mandated 5-year inspection schedule for non-high-risk facilities when tracking FDA's performance in meeting FSMA targets.

Foreign inspection logistics. FDA officials stated that conducting food safety inspections outside the United States presents a range of challenges for FDA and investigators. These challenges include planning foreign travel, obtaining visas, and overcoming language barriers. To address these and other challenges, FDA officials said they offer investigators competitive compensation and incentives. Officials also stated that they provide monetary bonuses to investigators in FDA's domestic cadre for each trip they take abroad to conduct foreign inspections.

Another challenge with foreign inspections, according to FDA officials, involves situations in which foreign facilities do not respond to FDA's Notice of Inspection, which prevents FDA from being able to move forward with scheduling and planning the inspection. FDA convened a working group and issued new guidance in October 2022 for FDA and industry partners on how to address this issue, according to agency officials. The officials told us that not responding to an FDA Notice of Inspection—or outright refusing an inspection—can result in a foreign firm being placed on an Import Alert Red List. Products from a firm on the red list are flagged for refusal and may not be allowed entry into the United States.[17] FDA officials noted that foreign firms can formally request removal from this list if they agree to an inspection.

How does FDA assess the performance of its food safety inspection efforts?

FDA takes some steps to assess the performance of its domestic and foreign inspection efforts, but has not defined an annual performance target for conducting foreign inspections. Specifically, FDA uses various methods to assess its performance, including the following:

- Tracking whether it conducted appropriate follow-up activities on facilities that previously received an enforcement action—the most severe outcome of an inspection. According to FDA documentation, the agency exceeded its target of 80 percent during fiscal year 2023 by reviewing 98 percent of such violations.
- Providing information through the use of the FDA-Track website—a publicly available tool for sharing key program performance information, such as efforts associated with food safety inspections. For example, the website provides information on the number and outcomes of food facility inspections FDA conducted by fiscal year.
- Collaborating with the Centers for Disease Control and Prevention to establish new performance measures to estimate the impact of food safety inspections on safeguarding imported foods, according to FDA documentation.

FDA officials also told us the agency uses FSMA's 3- and 5-year mandate for inspecting domestic facilities in developing an annual target for assessing FDA's performance. However, FDA has not identified a similar target for foreign inspections.

Congress, through FSMA, directed FDA to conduct an increasing number of foreign inspections each year, culminating in an annual target of 19,200 inspections in 2016. While FDA interprets FSMA to require FDA to continue conducting 19,200 foreign inspections each year, the agency considers this annual target to be unrealistic and unachievable given FDA's existing resources. To address this issue, we recommended in January 2015 that FDA conduct an analysis to determine the annual number of foreign inspections sufficient to ensure the safety of imported food.[18] We also stated that if the number FDA identified is different from the 19,200 annual target, FDA should report the results to Congress and recommend appropriate legislative changes. Further, we have highlighted this recommendation as a priority for FDA on an annual basis since 2017 because we believe implementing it will help the agency to improve its operations and make progress in addressing a long-standing high-risk issue area—improving federal oversight of food safety.[19]

In response, in May 2023, FDA completed an analysis that determined 4,695 annual foreign inspections represented an optimal performance target for ensuring the safety of imported food when combined with multiple other safety efforts and programs. However, FDA officials explained they do not have the workforce or resources needed to achieve this target. Further, officials told us they did not provide this analysis to Congress and do not use the target number in any way as part of FDA's planning process for conducting foreign inspections.

FDA officials stated they have taken steps in recent years to identify the number of foreign inspections the agency can realistically conduct each year as part of its annual planning process. For example, FDA projected it would be able to conduct 1,008 total foreign inspections in fiscal year 2024 based on its existing capacity and resources. While useful for FDA's planning purposes, this process focuses on the number of inspections FDA has the capacity to conduct rather than, more importantly, the number FDA should be conducting to best ensure the safety of imported food.

FDA officials told us in August 2024—nearly 10 years after we made our recommendation—that they do not intend to take any further action to address it. We maintain that identifying an appropriate annual target for conducting foreign inspections and using it to assess FDA's performance in safeguarding imported food is important. To do so, FDA could use the existing 4,695 target, or the agency could revisit its May 2023 analysis and use updated information and assumptions to identify a new annual target. However, without pursuing either option, FDA will remain unable to measure the performance of its overall foreign inspection efforts or assess whether such efforts are achieving intended results—protecting U.S. consumers.

Finally, since FDA does not plan to take further action to address our recommendation, Congress lacks the information it needs to assess FDA's foreign inspection efforts. Until FDA determines the annual number of foreign food safety inspections sufficient to ensure the safety of imported food and communicates this information to Congress, Congress will not have the information it needs to determine whether FDA's existing target of 19,200 inspections per year should be updated. As a result, FDA will continue to rely on an unrealistic foreign inspection target that the agency cannot achieve and is not useful in measuring FDA's performance in ensuring the safety of imported food.

What additional actions can FDA take to improve its food safety inspections?

We identified two additional actions FDA could take to improve its food safety inspection efforts—establish a process to minimize incidences of attempted domestic inspections and implement a formal performance management process for use in assessing FDA's performance. FDA officials agreed that taking these actions could help to improve FDA's inspection efforts.

Minimize incidences of attempted domestic inspections. In September 2017, the Department of Health and Human Services' Office of Inspector General found that incidences of attempted inspections of domestic facilities expended FDA resources that might be better used on other activities.[20] The Office of Inspector General recommended that FDA improve how it handles attempted domestic inspections to ensure better use of FDA's resources. In March 2020, the Office of Inspector General closed this recommendation as implemented, citing FDA's use of the FSMA Tracker in documenting facilities' dates of operation for planning purposes and other improvements as positive steps toward minimizing attempted inspections.

Although FDA has taken positive steps in this area, attempted domestic inspections have remained common since fiscal year 2020.[21] Specifically, such inspections represented nearly one-third of those FDA counted toward meeting its FSMA mandate from fiscal year 2018 through fiscal year 2023. One senior FDA official we interviewed acknowledged the challenge posed by attempted inspections, stating that minimizing them is important to ensure the efficient use of FDA's limited resources. The official added that there are steps FDA can take to address this issue in the future. However, the official did not identify any specific steps or actions FDA can take to do so, or provide a timeline for when the agency plans to have additional procedures in place to address this issue.

Standards for Internal Control in the Federal Government state that agencies should take action to reduce the likelihood or magnitude of risks related to achieving defined objectives.[22] In this case, FDA risks expending resources on attempted inspections that could be better used for completing inspections. FDA officials told us they were already taking steps to address incidences of attempted domestic inspections and reiterated that such inspections are important in maintaining an accurate inventory of currently operating domestic facilities. We acknowledge that a certain number of attempted inspections are

inevitable given that domestic inspections, by design, are unannounced and that the facilities that compose FDA's inventory are in constant flux.

However, identifying and implementing additional procedures to minimize incidences of attempted domestic inspections would benefit FDA. Specifically, doing so would provide FDA with greater assurance it was efficiently expending its resources in support of safeguarding the U.S. food supply.

Implement a formal performance management process. FDA takes some steps to assess its performance, but does not yet have a formal performance management process focused on its food safety inspection efforts. FDA officials told us they plan to develop such a process in the near future.

FDA takes some steps to assess its performance, including by collecting key performance information on its inspection efforts. For example, as described above, FDA collects and organizes information on the number and outcomes of domestic and foreign inspections conducted each fiscal year, and shares these data on the agency's public FDA-Track website.

FDA officials said they intend to develop a comprehensive plan that focuses on FDA's inspection efforts beginning in fiscal year 2025. They said that this plan will include specific performance goals to identify desired results and associated measures to collect relevant information for use in assessing FDA's progress toward achieving them. FDA officials added that in developing this performance management process, the agency will leverage and build upon existing performance information and inspections data, including those described previously. However, FDA did not provide a specific time frame for developing this performance management process or for identifying specific performance goals or associated measures that will be included. Officials told us it was too early in FDA's planning process to do so.

We have previously defined "performance management" as a three-step process by which organizations (1) set goals to identify the results they seek to achieve, (2) collect performance information to measure progress, and (3) use that information to assess results and inform decision-making.[23] Developing a performance management process focused on inspections as well as a time frame for implementing it would provide FDA with greater assurance the agency is achieving its goals. Specifically, systematically collecting performance information and using it to assess progress and inform decision-making would assist FDA in its critical efforts to reduce instances of foodborne illness.

For example, FDA could develop goals and measures to assess its progress in addressing a key challenge cited by FDA officials—recruiting and retaining investigators. In addition, FDA could develop a performance goal specifying the percentage decrease the agency should strive to achieve in reducing incidences of domestic attempted inspections each year. Without such performance information, it may be difficult for Congress to oversee FDA's inspection efforts and understand how these efforts are contributing to FDA's mission of protecting U.S. consumers.

Conclusions

FDA has a critical mission to ensure the safety of the food that Americans consume. Food safety inspections are an essential proactive tool in meeting this mission. FDA has taken steps to ensure its inspections effectively safeguard the U.S. food supply, including prioritizing high-risk food facilities for inspection and reorganizing its Human Foods Program to better support agency personnel responsible for conducting inspections. However, FDA has not determined the appropriate size or workload of its current foreign investigator cadre, which inhibits FDA's ability to plan its overall foreign inspections.

Further, while FDA has taken some actions to identify a realistic annual target for conducting foreign inspections, as we recommended in January 2015, the agency does not use this target in any way and has not communicated this information to Congress. Further, FDA officials do not plan to take additional actions to address our recommendation. Therefore, legislative action by Congress would help ensure that FDA provides Congress with the information it needs to assess FDA's foreign inspection efforts and decide whether FDA's annual target for conducting these inspections should be updated.

In addition, FDA could take further action to improve its food safety inspection efforts. First, incidences of attempted domestic inspections represent nearly one-third of FDA inspections since fiscal year 2018, according to agency data. However, FDA has not identified and implemented additional procedures to ensure the agency is minimizing incidences of attempted domestic inspections. Doing so would better ensure FDA was using its limited resources efficiently when conducting domestic food safety inspections. Second, FDA does not yet have a formal performance management process focused on its food safety inspection efforts. Developing and implementing such a process would provide FDA with greater assurance the agency is achieving its goals. For example, FDA could develop goals and measures for use in assessing agency progress in recruiting and retaining investigators. Systematically collecting such performance information and using it to assess progress and inform decision-making would assist FDA in its efforts to safeguard the U.S. food supply and protect the Americans who rely on it.

Matters for Congressional Consideration

We are recommending the following two matters for congressional consideration:

Congress should consider directing FDA to conduct an analysis to determine the annual number of foreign food facility inspections sufficient to ensure the safety of imported food, and communicate this number and FDA's underlying analysis to Congress. (Matter for Consideration 1)

Congress should consider, upon receiving the relevant information and analysis from FDA, updating the annual target for the number of foreign food facility inspections FDA should conduct to ensure the safety of imported food. (Matter for Consideration 2)

Recommendations for Executive Action

We are making the following three recommendations to FDA:

The Commissioner of FDA should take steps to determine the appropriate size and workload of its foreign investigator cadre for the purpose of meeting FDA's foreign inspection goals and ensuring FDA's ability to safeguard imported food. (Recommendation 1)

The Commissioner of FDA should identify and implement additional procedures to minimize incidences of attempted inspections of domestic food facilities. (Recommendation 2)

The Commissioner of FDA should develop and implement a performance management process that includes defining the desired results of FDA's food safety inspection efforts, collecting performance information on these efforts, and using this information to assess performance, inform FDA decision-making, and communicate to Congress and the public about results. Specific elements of this process could include, but not be limited to, data and information on FDA's progress in recruiting and retaining food safety investigators and in minimizing incidences of attempted inspections. (Recommendation 3)

Agency Comments

We provided a draft of this report to the Department of Health and Human Services, of which FDA is a component agency, for review and comment. In its comments, reproduced in appendix I, FDA concurred with our recommendations. FDA also provided technical comments, which we incorporated as appropriate.

How GAO Did This Study

We reviewed the FDA Food Safety Modernization Act (FSMA) and FDA policies, procedures, and documentation. Through documentation and interviews with FDA officials, we identified relevant mandated targets and associated FDA goals for conducting food safety inspections for both domestic and foreign facilities. We also analyzed FDA data on the total number of domestic and foreign food safety inspections conducted from fiscal year 2018 through fiscal year 2023.

Specifically, on the domestic side, we analyzed assorted FDA data on domestic food safety inspections from fiscal year 2018 (the first year FDA used its FSMA Tracker software system) through fiscal year 2023 (the most recent year with complete data at the time of our review). We analyzed the data to assess FDA's performance in meeting FSMA's mandated targets for inspecting each high-risk domestic facility at least once every 3 years and each non-high-risk domestic facility at least once every 5 years. On the foreign side, we analyzed assorted FDA data on foreign food safety inspections from fiscal year 2018 through fiscal year 2023 to be consistent with the time frame used for our analysis of FDA domestic data, and therefore provide similar information on foreign inspections conducted during the same 6-year period.

We assessed the reliability of these data by interviewing FDA officials about their data management practices, reviewing agency data and relevant documentation, and following up with FDA to clarify our questions about the data as needed. We determined that the data were sufficiently reliable for our purposes, including to describe the number and frequency, according to FDA's cover-by dates, of domestic food safety inspections and the number of foreign food safety inspections FDA conducted each year since fiscal year 2018.

We assessed FDA documents and interviewed FDA officials responsible for both domestic and foreign food safety inspections to understand the inspection process and FDA's efforts to measure the performance of its food safety inspection efforts. We also assessed FDA documents and interviewed agency officials to understand the challenges FDA faces in conducting domestic and foreign food safety inspections and FDA's efforts to address them.

We conducted a site visit to observe an FDA investigator conduct a routine surveillance inspection of a domestic food facility to inform our understanding of FDA's inspection process. We selected the site for this inspection based on the following four criteria: The inspection had to (1) represent a typical FDA domestic food facility inspection, (2) be planned in July or August of 2024 to match our audit's time frame, (3) be located near an audit team member, and (4) include the approval of the inspected firm. We also interviewed representatives from a non-generalizable selection of two stakeholder groups representing state officials involved in food safety to gather their perspectives on FDA's role in conducting domestic and foreign food safety inspections. Views from stakeholder group representatives we interviewed are not generalizable to other stakeholder groups.

We conducted this performance audit from May 2024 to January 2025 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence

obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix I: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 18, 2024

Steve Morris
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"FOOD SAFETY: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply"** (GAO-25-107571).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - FOOD SAFETY: FDA SHOULD STRENGTHEN INSPECTION EFFORTS TO PROTECT THE U.S. FOOD (GAO 25-107571)

The Department of Health & Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

FDA's inspectional activities play a crucial role in helping ensure consumers have access to foods that are produced or manufactured safely and according to applicable FDA requirements. When it comes to planning and conducting food inspections, FDA's approach involves deploying a risk-based surveillance strategy that takes into account FDA's statutory inspectional mandates. Given the agency's resource constraints, FDA also leverages additional surveillance and regulatory tools—such as import screening, importer requirements, and regulatory partnerships with foreign competent authorities—to monitor and ensure the safety of imported food. We also recognize there is tremendous opportunity for the agency to collect and analyze information from new data sources to form a more complete picture of the risk of foods, including imported foods. By incorporating this information into work planning and screening models, FDA can allocate its limited inspectional resources in a more targeted way.

As FDA has discussed with GAO, given the large number of food facilities and the agency's limited resources, meeting the existing inspection mandates has been challenging for the agency. FDA is excited for the work underway. FDA is focusing on further building out its risk-based surveillance strategy to help optimize resource allocation to maximize public health impact.

Recommendation 1
The Commissioner of FDA should take steps to determine the appropriate size and workload of its foreign investigator cadre for the purpose of meeting FDA's foreign inspection goals and ensuring its ability to safeguard imported food.

HHS Response
FDA concurs with this recommendation. Currently, FDA's foreign inspection goals are determined by available foreign investigator cadre resources. FDA will consider the appropriate size and workload of its foreign investigator cadre in light of the full range of regulatory oversight activities aimed at ensuring the safety of imported foods, building on the FDA analysis that was provided to GAO in May 2023.

Recommendation 2
The Commissioner of FDA should identify and implement additional procedures to minimize incidences of attempted inspections of domestic food facilities.

HHS Response
FDA concurs with this recommendation and will continue to implement procedures and enhancements to address this issue. The domestic food facility inventory is subject to normal business cycles, including seasonality of operations; therefore, incidences of attempted inspections cannot be entirely avoided. FDA's existing procedures manage updates to new and existing domestic facilities during Food Facility Registration and bi-annual re-registration. These procedures reduce the number of attempted inspections by verifying key data elements and documenting facility operational activities that inform the workplan. FDA agrees that the number of attempted inspections should be further minimized. FDA will review and evaluate its existing

policies and procedures and explore additional avenues to reduce attempted inspections.

Recommendation 3
The Commissioner of FDA should establish a performance management process that includes defining the desired results of FDA's food safety inspection efforts, collecting performance information on these efforts, and using this information to assess performance, inform FDA decision-making, and communicate to Congress and the public about results. Specific elements of this process could include, but not limited to, data and information on FDA's progress in recruiting and retaining food safety investigators and in minimizing incidences of attempted inspections.

HHS Response
FDA concurs with this recommendation. As part of the new, unified Human Foods Program (HFP), FDA has established an Office of Strategic Programs, with a staff dedicated to strategic planning, performance, and evaluation of the HFP and related inspections and investigations activities. An office with this explicit charge has not previously existed. This new office will develop outcome-based performance measures and indicators for the HFP, in coordination with the Office of Inspections and Investigations (OII), and will monitor, analyze, and report progress, accomplishments, and challenges. In FY 2025, HFP will review existing metrics to understand where they have insightful program data and where they will need to further develop key performance indicators. This work will also support development of an HFP strategic plan for FY 2026 – FY 2030 and supporting outcome-based performance management framework. FDA agrees with the recommendations from GAO and will incorporate them into this process.

List of Addressees

The Honorable Richard Blumenthal
United States Senate

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Commissioner of the Food and Drug Administration, and other interested parties. In addition, the report will be available at no charge on the GAO website at https://www.gao.gov.

GAO Contact Information

For more information, contact: Steve D. Morris, Director, Natural Resources and Environment, MorrisS@gao.gov, (202) 512-3841.

Sarah Kaczmarek, Managing Director, Public Affairs, KaczmarekS@gao.gov, (202) 512-4800.

A. Nicole Clowers, Managing Director, Congressional Relations, ClowersA@gao.gov, (202) 512-4400.

Staff Acknowledgments: Nkenge Gibson (Assistant Director), Bryan Bourgault (Analyst in Charge), Adrian Apodaca, Rebecca Conway, Frank Garro, Barbara Lancaster, Benjamin T. Licht, Skip McClinton, Norma-Jean Simon, Amber Sinclair, and Paras Sharma.

Endnotes

[1]FDA is responsible for ensuring the safety of a wide range of food products sold in the United States, including fruits, vegetables, processed foods, and most seafood. The U.S. Department of Agriculture is responsible for ensuring the safety of meat, poultry, some egg products, and all fish of the order Siluriformes (e.g., catfish). This report focuses on FDA's routine surveillance inspections of domestic and foreign facilities that manufacture, process, pack, and store food. This report does not address inspections and oversight of restaurants, grocery stores, cafeterias, and other facilities that handle food, which are the responsibility of state, local, and tribal agencies.

[2]From fiscal year 2018 through fiscal year 2023, states conducted about one-third of routine surveillance food safety inspections on behalf of FDA, according to agency data.

[3]According to FDA documentation, as of March 2023, the U.S. imported about 15 percent of its overall food supply. Specifically, more than 200 countries or territories supply approximately 32 percent of the fresh vegetables, 55 percent of the fresh fruit, and 94 percent of the seafood that Americans consume annually.

[4]Under the Food and Drug Omnibus Reform Act of 2022, FDA is to conduct annual inspections, including unannounced inspections, of both foreign and domestic facilities that manufacture infant formula. Pub. L. No. 117-328, tit. III, subtit. D, § 3401(i)(3), 136 Stat. 5807, 5843 (2022).

[5]This report focuses on FDA's routine surveillance food safety inspections intended to monitor a food facility's compliance with regulatory requirements. This report does not cover other types of FDA inspections, such as those conducted when there is reason to believe a facility has serious manufacturing problems or to investigate a specific problem or complaint that has come to FDA's attention.

[6]We analyzed FDA data on the total number of domestic and foreign food safety inspections conducted from fiscal year 2018 (the first year FDA used its new software system to track its progress covering domestic facilities due for inspection) through fiscal year 2023 (the most recent year with complete data at the time of our review).

[7]If an FDA investigator attempts to inspect a domestic food facility that has more than 1 year remaining until it is due for an inspection, FDA retains the facility's existing inspection due date, according to FDA officials.

[8]Section 201 of the FDA Food Safety Modernization Act, Pub. L. No. 111-353, tit. II, § 201, 124 Stat. 3885, 3923-24 (2011) (codified at 21 U.S.C § 350j), required FDA to increase the frequency of inspection of all facilities. The statute defines "facility" as a domestic or foreign facility that is required to register under 21 U.S.C. § 350d, which encompasses any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States. Under 21 U.S.C. § 350d(c)(3), foreign facilities are required to register only when food from the facility is exported to the United States without further processing or packaging outside the United States. FSMA directed FDA to inspect each domestic high-risk facility at least once during the 5-year period following January 4, 2011, and each domestic non-high-risk facility at least once during the 7-year period following January 4, 2011. Once the initial cycle was completed, FSMA required FDA to inspect domestic high-risk facilities at least once every 3 years and domestic non-high-risk facilities at least once every 5 years. For the purposes of this report, we focus on FSMA's current mandated targets—inspecting each high-risk and non-high-risk domestic food facility at least once every 3 and 5 years, respectively.

[9]For example, in fiscal year 2023, FDA was required to inspect every domestic food facility with a cover-by date in this fiscal year. According to FDA data, this mandated target included a total of

22,414 high-risk and non-high-risk domestic facilities. Of these, FDA inspected 7,590 domestic facilities, attempted to inspect 3,481 facilities, and did not inspect 11,343 facilities, according to our analysis of FDA data.

[10]FSMA directed FDA to inspect at least 600 foreign facilities in the 1-year period beginning on January 4, 2011. For each of the 5 years following this 1-year period, FSMA directed FDA to inspect at least twice the number of facilities it had inspected during the previous year. In our January 2015 report, we describe two scenarios in which FDA responds to FSMA's requirements for conducting foreign inspections. The first scenario had FDA inspecting twice the actual number of foreign food facilities inspected the previous year, starting with the actual number of FDA inspections conducted in 2011. The second scenario had FDA inspecting 600 food facilities in 2011—the FSMA minimum—and then doubling that number in each of the 5 following years. For the purposes of this report, we use the second scenario since FDA has interpreted FSMA to impose an inspection target of 19,200 foreign facilities in 2016 and beyond. GAO, *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, GAO-15-183 (Washington, D.C.: Jan. 30, 2015).

[11]In January 2015, we found that FDA was not keeping pace with annual targets under FSMA for conducting foreign food safety inspections. Additionally, FDA had not conducted an analysis to determine the annual number of foreign food safety inspections that are sufficient to ensure the comparable safety of imported food. We recommended that FDA conduct an analysis and report the results to Congress, as appropriate. As of October 2024, this recommendation remained open. GAO-15-183.

[12]According to FDA data, FDA conducted food safety inspections of foreign facilities in more than 100 countries from fiscal year 2018 through fiscal year 2023. FDA data show that approximately one-third of these inspections were conducted at food facilities in China, Italy, India, Spain, and Japan.

[13]A full-time equivalent is a standard measure of labor that reflects the total number of regular straight-time hours (i.e., not including overtime or holiday hours) worked by employees divided by the number of compensable hours applicable to each fiscal year.

[14]FDA, *Strategic Workforce Plan: FYs 2023 to 2027* (Silver Spring, Md.). This plan defines a "mission critical occupation" as one deemed crucial to delivering FDA's mission commitments and priorities, based on the Office of Personnel Management's *Workforce Planning Guide*.

[15]In planning its reorganization, FDA considered findings and recommendations from a December 2022 report by the Reagan-Udall Foundation—an independent organization created by Congress to advance FDA's mission. Reagan-Udall Foundation, *Operational Evaluation of the FDA Human Foods Program* (December 6, 2022).

[16]The Office of Personnel Management's strategic human capital management regulation provides a framework for comprehensive workforce planning. 5 C.F.R. pt. 250, subpt. B. The regulation establishes the Human Capital Framework that is intended to improve human capital programs that enable an agency to accomplish its mission objectives. See 81 Fed. Reg. 89,357, 89,358 (Dec. 12, 2016). Under this framework, agencies are responsible for planning, implementing, evaluating, and improving human capital policies and programs, which must be based on comprehensive workforce planning and analysis and align with agency missions, goals, and strategic objectives. 5 C.F.R. § 250.204(a)(1)-(2).

[17]At the end of fiscal year 2024, there were approximately 12,400 foreign food facilities listed on an Import Alert Red List, according to FDA data.

[18]GAO-15-183.

[19]GAO, *Priority Open Recommendations: Department of Health and Human Services*, GAO-24-107257 (Washington, D.C.: May 28, 2024). Priority recommendations are those that GAO believes warrant priority attention from heads of key departments or agencies. They are highlighted because, upon implementation, they may significantly improve government operations, for example, by realizing large dollar savings; eliminating mismanagement, fraud, and abuse; or making progress toward addressing a high-risk or duplication issue.

[20]Department of Health and Human Services' Office of Inspector General, *Challenges Remain in FDA's Inspections of Domestic Food Facilities*, OEI-02-14-00420 (Washington, D.C.: September 2017).

[21]Since FDA's foreign inspections generally are announced—FDA notifies each foreign facility about an upcoming inspection—foreign inspections are less likely to result in attempted inspections than domestic facility inspections. For example, from fiscal year 2018 through fiscal year 2023, attempted inspections represented less than 2 percent of all foreign food safety inspections conducted, according to FDA officials.

[22]GAO, *Standards for Internal Control in the Federal Government,* GAO-14-704G (Washington, D.C.: September 2014).

[23]GAO, *Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts*, GAO-23-105460 (Washington, D.C.: July 12, 2023).