Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CHALLENGES REMAIN IN FDA'S INSPECTIONS OF DOMESTIC FOOD FACILITIES

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September 2017
OEI-02-14-00420

Report in Brief
September 2017
Report No. OEI 02-14-00420

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

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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 both food safety and compliance with regulations. Congress passed the Food Safety Modernization Act (FSMA), which enabled FDA to focus more on preventing food-safety problems rather than reacting to them after the fact. FSMA requires FDA to inspect domestic food facilities within certain timeframes.

How OIG Did This Review

We analyzed data from four sources: (1) information about facilities that FDA designated high risk and non-high risk pursuant to FSMA, and whether these facilities were inspected as required; (2) FDA's food facility inventory and inspection data from 2010 to 2015; (3) information about FDA's advisory and enforcement actions, such as warning letters and seizures, taken in response to significant inspection violations, as well as whether followup inspections were conducted for these violations; and (4) structured interviews with FDA officials.

What OIG Found

FDA is on track to meet the domestic food facility inspection timeframes for the initial cycles mandated by FSMA; however, challenges remain as FSMA requires FDA to conduct future inspections in timeframes that are 2 years shorter than the timeframes for the initial cycles. Also, inaccuracies in FDA's domestic food facility data result in FDA attempting to inspect numerous facilities that are either out of business or otherwise not in operation at the time of the visit.

Key Takeaway

FDA should do more to ensure that the food supply is safe by taking swift and effective action to ensure the prompt correction of problems identified at domestic food facilities.

Although FDA is on track to meet the FSMA inspection mandates during the initial cycles, the overall number of food facilities that FDA inspected since the passage of FSMA has decreased from a high of about 19,000 facilities in 2011 to just 16,000 facilities in 2015.

In addition, FDA did not always take action when it uncovered significant inspection violations—those found during inspections classified as "Official Action Indicated" (OAI). When it did take action, it commonly relied on facilities to voluntarily correct the violations. Also, it rarely took advantage of the new administrative tools provided by FSMA.

Moreover, FDA's actions were not always timely nor did they always result in the correction of these violations. FDA consistently failed to conduct timely followup inspections to ensure that facilities corrected significant inspection violations. For almost half of the significant inspection violations, FDA did not conduct a followup inspection within 1 year; for 17 percent of the significant inspection violations, FDA did not conduct a followup inspection of the facility at all.

What OIG Recommends

We recommend that FDA (1) improve how it handles attempted inspections to ensure better use of resources, (2) take appropriate action against all facilities with significant inspection violations, (3) improve the timeliness of its actions so that facilities do not continue to operate under harmful conditions, and (4) conduct timely followup inspections to ensure that significant inspection violations are corrected. FDA concurred with all four recommendations.

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OBJECTIVES

1. To assess whether FDA is on track to meet the inspection timeframes for domestic food facilities mandated by the FDA Food Safety Modernization Act.
2. To determine whether the inspection mandates increased the overall number of domestic food facilities FDA inspected.
3. To determine the extent to which FDA takes action in response to violations found during domestic food facility inspections.

BACKGROUND

Each year roughly 48 million people in the United States get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.[1] To help protect against foodborne illnesses, FDA inspects food facilities to ensure both food safety and compliance with regulations. In 2016, a flour processor initiated a recall after *E. coli* was found at one of its domestic facilities, infecting 63 people in 24 States.[2] This outbreak—as well as others resulting in large recalls of spinach, tomatoes, lettuce, and alfalfa sprouts—raises questions about FDA's inspections process and its ability to protect the Nation's food supply.

To strengthen the food safety system and better protect public health, Congress passed the FDA Food Safety Modernization Act (FSMA) and amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).[3] FSMA enabled FDA to focus more on preventing food safety problems rather than reacting to them after they occur.[4] To that end, FSMA required FDA to increase the frequency of its inspections of domestic food facilities.[5] FSMA also provided FDA with new enforcement authorities

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[1] Centers for Disease Control and Prevention, *CDC Estimates of Foodborne Illness in the United States*, February 2011. Accessed at https://www.cdc.gov/foodborneburden/estimates-overview.html on October 17, 2016.

[2] FDA, *FDA Investigated Multistate Outbreak of Shiga toxin-producing E. coli Infections Linked to Flour*. Accessed at http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm504192.htm on October 21, 2016.

[3] FDA Food Safety Modernization Act, P.L. No. 111-353 (enacted January 4, 2011).

[4] FDA, *Background on the FDA Food Safety Modernization Act (FSMA).* Accessed at http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm239907.htm on October 20, 2016.

[5] Section 201 of FSMA, amending and adding section 421 to the FD&C Act (21 U.S.C. § 350j).

designed to achieve higher rates of compliance and better respond to problems when they occur.[6]

This review builds on food safety work conducted by the Office of Inspector General (OIG) that identified weaknesses in FDA's food inspection program. In a 2010 review, OIG found that FDA inspected less than a quarter of domestic food facilities each year, and that many facilities had not been inspected in 5 years or more.[7] OIG also found that FDA did not always take action against facilities with significant inspection violations or take steps to ensure the violations were corrected. To date, FDA has not implemented two key recommendations from OIG's 2010 review: (1) take appropriate action against facilities with significant inspection violations and (2) ensure that those facilities correct the violations.

Domestic Food Facility Inspections

FDA is responsible for ensuring the safety of almost all food products sold in the United States, with the exception of meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture. As part of its efforts to ensure food safety, FDA inspects food facilities that manufacture, process, pack, and store food.[8] Investigators from FDA's 19 district offices conduct these inspections according to guidance from FDA headquarters.[9] In addition, FDA contracts with States to conduct inspections on behalf of FDA.

During the course of FDA inspections, investigators may identify potential violations of the FD&C Act as well as other applicable laws and regulations. Investigators document their findings and recommend a classification in an inspection report that is reviewed by a district office supervisor and in some cases by other FDA officials.[10]

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[6] FSMA provided FDA with new and expanded authorities to ensure compliance, including the authority to suspend a food facility's registration (FSMA § 102), issue a mandatory recall order (FSMA § 206), and administratively detain certain foods (FSMA § 207).

[7] OIG, *FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080), April 2010.

[8] Sections 702 and 704 of the FD&C Act (21 U.S.C. §§ 372 and 374).

[9] FDA's district offices work with FDA headquarters to develop priorities for inspection each fiscal year. Throughout the course of the year, however, FDA may change its priorities based on emerging issues such as outbreaks of foodborne illness. Of FDA's 20 district offices, 19 conduct food facility inspections.

[10] The inspection classification noted by an investigator is an initial determination, not a final decision; in more serious instances, the final decision is made by supervisors or other FDA officials.

When an investigator documents significant, objectionable conditions or practices at a facility, the investigator classifies the inspection as official action indicated (OAI), which signifies that a regulatory action—either an advisory or enforcement action—is warranted.[11] For the purposes of this report, we use "significant inspection violations" to reflect the conditions found during a food facility inspection that FDA classified as OAI.

When an investigator finds objectionable but less significant violations, an investigator classifies 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.[12]

Advisory and Enforcement Actions

When FDA finds significant inspection violations and classifies the inspection as OAI, an advisory action or an enforcement action is warranted.[13] FDA uses advisory actions to allow the facility to voluntarily correct the violations found during the inspection. Advisory actions include issuing a warning letter or untitled

Advisory actions rely on facilities to voluntarily correct violations, while enforcement actions require compliance.

[11] FDA, *Office of Regulatory Affairs (ORA): Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (rev. 01/28/14). Accessed at http://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM382035.pdf on October 17, 2016.

[12] In addition, inspections may be referred to the State when there is either no Federal jurisdiction over the violation in question or when it is determined that State action is the most efficient method of obtaining compliance. Inspections may also be referred to FDA headquarters when no clear policy has been established for the violations or significant technical issues exist that require a review and decision.

[13] FDA, *Regulatory Procedures Manual*, ch. 4, 5, 6, 9, and 10. Accessed at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ on October 17, 2016.

letter to the facility or holding a regulatory meeting with representatives of the facility.[14]

Conversely, FDA uses enforcement actions to require facilities to correct the violations, or to destroy adulterated or misbranded products. Enforcement actions include seizure, injunction, and even prosecution.[15] In some cases, FDA initiates an enforcement action after a facility's response to an advisory action is inadequate.

Followup Inspections

FDA is expected to conduct timely followup inspections of facilities with significant inspection violations. These followup inspections ensure that the facility is in compliance and corrects the violations found during the initial inspection.[16] Followup inspections are not advisory or enforcement actions.

Food Safety Modernization Act (FSMA)

FSMA aims to ensure that the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.[17] Signed into law January 4, 2011, FSMA mandated that FDA increase the frequency of its inspections of domestic food facilities based on risk.[18]

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[14] FDA, *Regulatory Procedures Manual*, ch. 4. Accessed at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ on October 17, 2016. FDA may issue a warning letter when it finds violations of Federal law that may lead to an enforcement action if the violations are not promptly and adequately corrected. FDA may issue an untitled letter when the violations are not significant enough to meet the criteria for the issuance of a warning letter. FDA may request a regulatory meeting with representatives of a facility to inform them that its products, practices, processes, or other activities are considered to be in violation of the law; FDA may hold these meetings when violations do not warrant a warning letter, or in combination with the issuance of a warning letter.

[15] FDA, *Regulatory Procedures Manual*, ch. 5 and 6. Accessed at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ on October 17, 2016.

[16] FDA, *Office of Regulatory Affairs (ORA): Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (rev. 01/28/14), section 6.7. Accessed at http://www.fda.gov/downloads/ICECI/Inspections/ Field ManagementDirectives/ UCM382035.pdf on October 17, 2016.

[17] FDA, *Background on the FDA Food Safety Modernization Act (FSMA).* Accessed at http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm239907.htm on October 20, 2016.

[18] Section 201 of FSMA amended and added section 421 to the FD&C Act (21 U.S.C. § 350j). FSMA provided FDA with new enforcement tools and eased the criteria for administratively detaining potentially unsafe food, provided FDA with authority to mandate the recall of certain foods, and allowed FDA to suspend the registration of a facility and prohibit that facility from distributing food.

Specifically, FSMA mandated that FDA inspect high-risk facilities at least once during the initial 5-year inspection cycle and then at least once every 3 years for subsequent cycles. FSMA requires that FDA also inspect non-high-risk facilities at least once during the 7-year initial inspection cycle and then at least once every 5 years for subsequent cycles. Prior to FSMA, there were generally no timeframes for food facility inspections.

In 2011, FDA created a list of all domestic food facilities and designated each one as high risk or non-high risk for the first inspection cycles. FDA determined whether a facility was 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.[19]

Related Work

OIG is currently conducting a review of FDA's monitoring of domestic and imported food recalls.[20] In an early alert memorandum released in June 2016, OIG raised concerns that FDA does not have adequate policies and procedures to ensure that facilities take prompt and effective action in initiating voluntary recalls.[21] OIG suggested that FDA update its policies and procedures to instruct its recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls. In response, FDA reported that it expedited changes to improve voluntary recall compliance and strengthen its enforcement strategies.

METHODOLOGY

Scope

This study focuses on domestic food facility inspections conducted by FDA or States under contract with FDA; it does not include inspections of

[19] To determine risk, FDA created a model that identifies high-risk facilities based on the known safety risks of foods at the industry-wide level and compliance history of the facility. See section 421(a)(1) of the FD&C Act (21 U.S.C. § 350(j)(a)(1)).

[20] OIG, *Monitoring of Domestic and Imported Food Recalls* (W-00-15-50004), forthcoming.

[21] OIG, Early Alert: *The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process* (A-01-15-01500).

foreign facilities[22] or inspections conducted under partnership agreements.[23] It primarily focuses on inspections of domestic food facilities conducted in the 5 years after FSMA was enacted. To provide context for the number of facilities that FDA inspected after the enactment of FSMA, we included data about the number of food facilities inspected from 2004 to 2010.

Data Sources

We based this study on data from four sources: (1) information about facilities that FDA designated high risk and non-high risk pursuant to FSMA, and whether these facilities were inspected as required; (2) FDA's food facility inventory and inspection data from 2010 to 2015; (3) information about FDA actions such as warning letters and seizures taken in response to significant inspection violations, as well as whether followup inspections were conducted for these violations; and (4) structured interviews with FDA officials.[24]

To assess whether FDA is on track to meet inspection timeframes mandated by FSMA, we analyzed data from FDA's food facility inventory and inspection data. We started with the lists of high-risk and non-high-risk facilities that FDA created for each inspection cycle. We then determined the extent to which FDA inspected—or attempted to inspect—these facilities. Attempted inspections occur when an investigator visits a facility but it is either out of business or otherwise not in operation. FDA counts facilities that it attempted to inspect toward meeting the inspection mandates.

Next, we determined the overall number of facilities that FDA actually inspected each year from 2004 to 2015. To do this, we requested from FDA data on all facilities known to be under FDA's jurisdiction and the number of these facilities that FDA inspected. This analysis includes facilities that were actually inspected and does not include facilities that FDA attempted to inspect.

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[22] The Government Accountability Office (GAO) analyzed inspections of foreign food facilities in 2015. Under FSMA, FDA is required to inspect at least 600 foreign food facilities in 2011 and, for each of the next 5 years, inspect at least twice the number of facilities inspected during the previous year. However, GAO found that FDA is not currently keeping pace with the FSMA mandate. See GAO, *Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food* (GAO-15-183), February 27, 2015. Accessed at http://gao.gov/products/GAO-15-183 on August 31, 2016.

[23] FDA also has partnership agreements with some States. These agreements allow States to share information with FDA about inspections they conduct, but these inspections are not conducted on behalf of FDA.

[24] When determining whether a facility received an OAI, we only considered final classifications. Investigators typically assign an initial classification, which FDA supervisors review and finalize.

Last, we reviewed inspections data to determine the extent to which FDA identified facilities with OAI classifications from 2011 to 2015. We analyzed the inspections data to determine the extent to which FDA took action—such as issuing a warning letter—and conducted followup inspections in response to these significant inspection violations. See Appendix A for a detailed description of the methodology.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

FDA is on track to meet the inspection timeframes mandated by FSMA; however, challenges remain

FSMA requires FDA to inspect domestic food facilities within certain timeframes, with high-risk facilities requiring more frequent inspection. To implement these requirements, FDA created a list of all domestic food facilities and designated each one as high risk or non-high risk. FDA then set out to inspect each facility within the specified timeframes. If FDA does not routinely inspect food facilities, it is unable to ensure that facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe. See the text box below for the timeframes required for each inspection cycle.

FDA is on track to meet the inspection timeframes for initial cycles

For the initial cycles, FDA identified 21,086 high-risk facilities requiring an inspection within 5 years from 2011 to 2015.[25] FDA also identified 61,010 non-high-risk food facilities requiring an inspection within 7 years from 2011 to 2017.[26]

FSMA requires FDA to inspect all high-risk facilities within 5 years for the initial inspection cycle, and every 3 years thereafter. FDA must inspect all non-high-risk facilities within 7 years for the initial inspection cycle, and every 5 years thereafter.

By the end of 2015, FDA inspected—or attempted to inspect—all but nine of the high-risk facilities that required inspection under FSMA as part of the first cycle. FDA counts facilities that it attempted to inspect toward meeting the inspection mandates. These facilities were either out of business or otherwise not in operation when the investigator visited the facility.

Additionally, with 2 years remaining in the initial 7-year cycle for non-high-risk facilities, FDA inspected—or attempted to inspect— about two-thirds (40,623) of these facilities. FDA officials maintain that the agency can inspect the remaining facilities by the end of 2017, and FDA appears to be on track to do so.

[25] All years presented in the report are fiscal years.

[26] The number of non-high-risk facilities includes 51,158 facilities that were identified in 2011 and an additional 9,852 facilities that were added to the list in 2014. Some of the facilities that were added to the 2014 non-high-risk list were initially on the 2011 high-risk list. FDA indicated that all of these facilities were to be inspected by the end of the first inspection cycle.

Shortened timeframes, inaccurate data, and lack of policy pose challenges for future cycles

Although FDA is on track to meet the inspection timeframes for the initial cycles, several factors pose challenges that could affect its ability to meet FSMA mandates in the future.

Shortened timeframes pose challenges for future non-high-risk cycles

As noted above, the timeframes that FDA is required to meet are shorter by 2 years in the second and subsequent cycles than they were for the initial cycles. FDA has demonstrated that it has the ability to meet the shorter timeframes for high-risk facilities. Although FDA had 5 years to meet the high-risk mandate for the initial cycle, FDA inspected—or attempted to inspect—almost all of those facilities within 3 years. FDA began a second inspection cycle for high-risk facilities in 2014, and it appears to be on track to inspect—or attempt to inspect—all high-risk facilities within the 3-year inspection cycle.

However, for non-high-risk facilities, the shorter timeframe poses a challenge for future cycles. FDA either inspected—or attempted to inspect—an average of 8,125 of these facilities per year from 2011 to 2015. If the number of non-high-risk facilities stays approximately the same, FDA would have to inspect at least 12,000 each year to inspect all non-high-risk facilities within a 5-year inspection cycle. Unless FDA increases its current pace of inspections of non-high-risk facilities, it will not be able to meet the mandates for future inspection cycles.

Inaccurate information consumes inspection resources

FDA's list of high-risk and non-high-risk facilities to be inspected contained inaccurate information about the operational status of some food facilities. As a result, FDA attempted to inspect numerous food facilities that were either out of business or otherwise not in operation at the time of the visit. FDA officials noted that the agency expended a considerable amount of resources on attempted inspections and that these resources might be better used on other activities.

Specifically, more than one-quarter of the high-risk and non-high-risk facilities that FDA counted toward meeting the inspection mandates for the initial cycles were out of business or not in operation at the time of the unannounced inspection. Moreover, the proportion of facilities on the list that FDA attempted to inspect increased each year. For example, the proportion of non-high-risk facilities FDA attempted to inspect increased

during the first cycle from 6 percent of the total number of facilities inspected in 2011 to 68 percent in 2015.[27]

Lack of policy allows some facilities to go without inspection

Certain food facilities that FDA attempted to inspect in this initial cycle still need to be inspected. For example, a facility that is a seasonal facility or temporarily closed on the day an inspection was attempted still requires inspection. FDA does not currently have a policy in place to reschedule—on a timely basis—attempted inspections of these facilities to ensure that they are eventually inspected.

Although FDA is on track to meet the FSMA inspection mandates, this did not result in a greater number of facilities being inspected

FDA did not inspect a greater number of facilities than it had in the years prior to implementation of FSMA. In fact, the number of food facilities FDA inspected—excluding the number of facilities that it attempted to inspect—decreased over time, from about 17,000 facilities in 2004 to just 16,000 facilities in 2015. Moreover, the number of facilities inspected each year since the implementation of FSMA has decreased from a high of about 19,000 facilities in 2011 to just 16,000 in 2015.

As noted earlier, when determining whether FDA meets these mandates, it counts attempted inspections as well as completed inspections. Excluding attempted inspections—as we did in this analysis—provides additional insight into FDA's overall coverage of the number of food facilities in the food supply that FDA inspects each year.

Further, as the number of facilities inspected has decreased, the number of facilities under FDA jurisdiction has increased. As a result, the proportion of food facilities inspected by FDA in a given year has decreased substantially over time—from 29 percent in 2004 to just 19 percent in 2015. Notably, the proportion of facilities inspected has decreased each year since the enactment of FSMA, with an overall drop by about a quarter from 2011 to 2015.[28] See Exhibit 1 and Appendix B for more information on inspections of food facilities over time.

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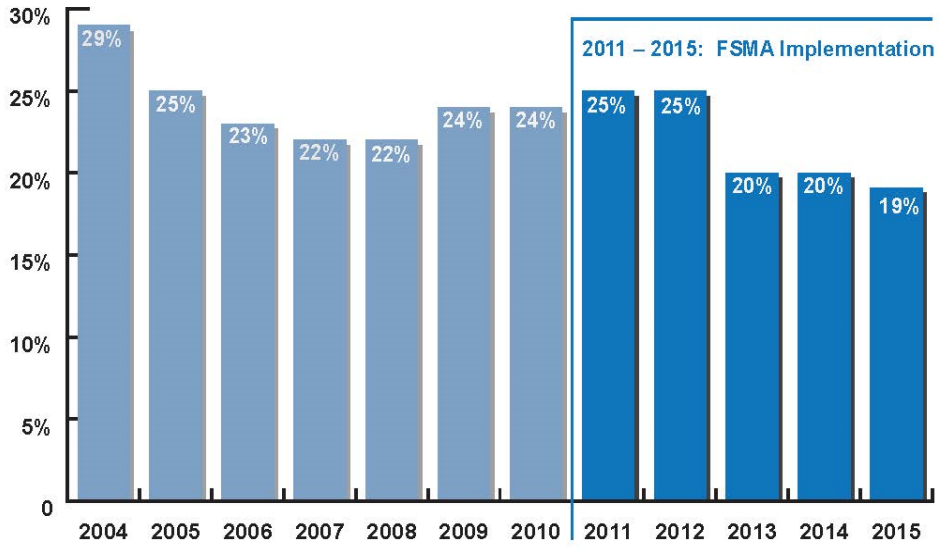
[27] The proportion of high-risk facilities FDA attempted to inspect also increased during the first cycle, from 4 percent of the total number of facilities inspected in 2011 to 39 percent in 2013.

[28] This analysis does not include facilities that FDA attempted to inspect.

Exhibit 1: Proportion of Food Facilities Inspected by FDA, 2004 to 2015



Source: OIG analysis of FDA data, 2016.

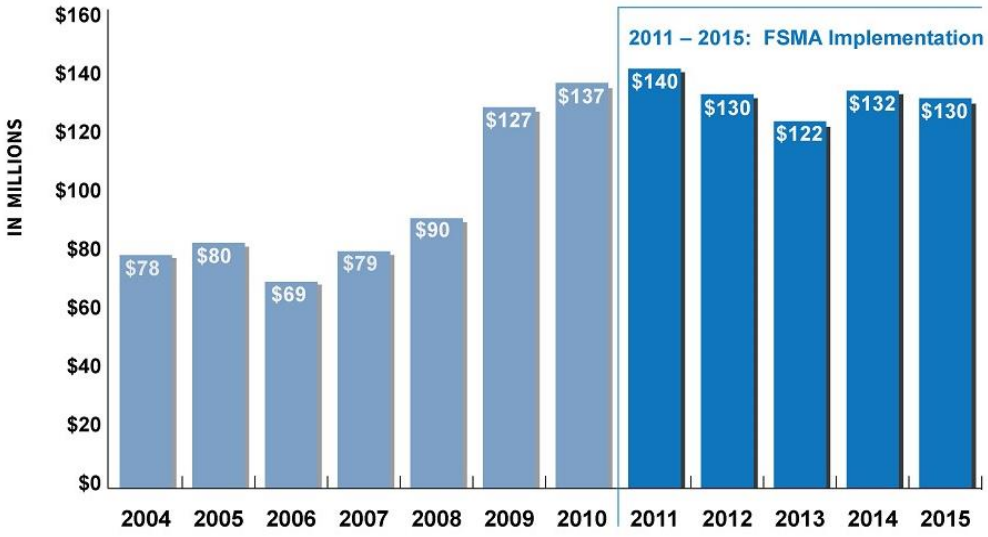
The proportion of facilities inspected decreased despite an increase in spending for FDA's domestic food facility inspections. Spending for FDA's domestic food facility inspections increased by 80 percent from about $78 million in 2004 to $140 million in 2011, the first year of FSMA implementation.[29] It then decreased to $130 million in 2015. See Exhibit 2 and Appendix C for more information on FDA spending.

FDA officials provided several reasons for why they were not able to inspect more facilities with the increase in resources. FDA officials explained that they are engaged in other activities to protect public health, such as responding to food recalls as well as collecting samples, records, and other evidence to identify the source of an outbreak. They also explained that they needed to expend resources to attempt to inspect facilities—sometimes to confirm that they were out of business—to meet the FSMA mandates.[30]

[29] Spending also increased in 2009 and 2010, 2 years prior to FSMA.

[30] Additionally, FDA officials explained that the same investigators conducted inspections of both foreign and domestic facilities, which may be another reason for not being able to inspect more domestic food facilities. According to FDA, foreign food facility inspections increased from 994 in 2011 to 1,363 in 2015.

Exhibit 2: FDA Spending for Domestic Food Facility Inspections, 2004 to 2015*



Source: OIG analysis of FDA data, 2016.
*Spending is in 2015 dollars.

FDA did not always take action to ensure that facilities corrected significant inspection violations

When FDA uncovers significant inspection violations and assigns an OAI classification, an advisory action or enforcement action is warranted. This ensures that the food handled by these facilities is safe and helps to prevent future outbreaks of foodborne illness.

FDA uncovered significant inspection violations in 1 to 2 percent of facilities inspected each year

FDA identified a total of 1,245 facilities that had significant inspection violations found during 1,535 OAI classified inspections from 2011 to 2015. FDA often classified inspections as OAI because investigators identified unsafe manufacturing and handling practices as well as unsanitary conditions.[31] See the text box for examples.

[31] This is based on a review of FDA's inspection reports from 2011, which was the most complete year of reports available.

Examples of Significant Inspection Violations

FDA found unsanitary conditions in a New Mexico facility that manufactures chili peppers and spices. FDA investigators took environmental samples at the facility, and 21 came back positive for *Salmonella.* The strain of *Salmonella* uncovered in this inspection was identical to the strain discovered in the plant during a previous inspection.

FDA found unsanitary conditions inside a tofu manufacturing facility in Washington. Among the agency's concerns were live birds and insects in production areas, mishandling of fresh tofu, and evidence of both live and dead rodents in the packaging room. In addition, FDA also uncovered a long list of labeling errors.

FDA found unsanitary conditions inside a cheese processing plant in Kentucky. FDA investigators found live and dead pests throughout the facility and an employee stirring cheese curds with bare hands. FDA investigators took environmental samples at the facility and 29 came back positive for *Listeria monocytogenes.*

FDA often took no action in response to significant inspection violations

FDA took no advisory or enforcement action in response to 22 percent of the significant inspection violations from 2011 to 2015.[32] If FDA takes no action in such cases, facilities may not correct the violations; this undermines FDA's efforts to ensure that the food supply is safe.

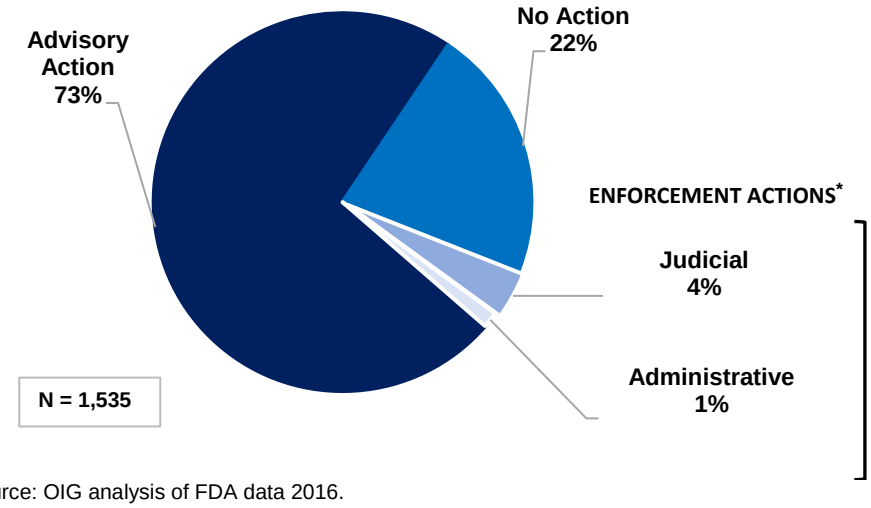
When FDA did take action, it most commonly relied on facilities to voluntarily correct significant inspection violations; these actions were not always timely nor did they always result in the correction of these violations

FDA most commonly initiated advisory actions in response to the significant inspection violations from 2011 to 2015. These actions included warning letters, untitled letters, or regulatory meetings. These

[32] A regulatory action—either an advisory action or an enforcement action—is warranted in response to significant inspection violations found during an inspection classified as OAI. FDA also expects to conduct a followup inspection in response to significant inspection violations, but these are not regulatory actions. See analysis on page 16.

actions communicate to the facility that FDA is aware of their violations and requests that the facility voluntarily correct them. See Exhibit 3.

Exhibit 3: Actions Taken by FDA in Response to Significant Inspection Violations, 2011 to 2015



Source: OIG analysis of FDA data 2016.
* In eight instances, FDA took an enforcement action in addition to an advisory action.

In contrast, FDA less frequently initiated enforcement actions in response to significant inspection violations. Enforcement actions require compliance and include judicial actions and administrative actions. Specifically, FDA initiated judicial actions such as seizures or injunctions in response to 4 percent of the significant inspection violations. FDA initiated administrative actions such as the detention of food products or suspension of a facility's registration in response to only 1 percent of the significant inspection violations.

Further, FDA rarely took advantage of the new actions provided by FSMA. As discussed above, FSMA provided FDA with several new administrative tools to allow the agency to take action by itself to correct violations. Most notably, FSMA eased the criteria for administratively detaining potentially unsafe food, provided FDA with authority to mandate the recall of certain foods, and allowed FDA to suspend the registration of a facility and prohibit that facility from distributing food.[33] However,

[33] Section 306 of the FSMA also amended section 807 of the FD&C Act (21 U.S.C. 384c(b)) and authorized FDA to refuse admission of food products into the United States if they are from a foreign facility that refuses to allow FDA investigators to enter.

FDA rarely used these tools in response to significant inspection violations.[34] From 2011 to 2015, FDA issued an administrative detention order in five instances and twice suspended facility registrations. Additionally, from 2011 to 2015 it had not initiated any mandatory recalls in response to significant inspection violations.[35]

FDA's actions were not always timely, allowing facilities to continue to operate under conditions that may threaten public health

In some cases, FDA took a long time to take an action in response to significant inspection violations found during an inspection classified as OAI. During this time, these facilities may have continued to operate under conditions that are harmful to public health.

Notably, FDA's goal is to issue all warning letters within 4 months of the end of the inspection or the return of a positive test sample.[36] However, from 2011 to 2015 FDA issued almost half of all warning letters after the expected timeframe. Even more concerning, it took FDA more than 6 months to issue 20 percent of all warning letters; 2 percent were issued more than a year after the inspection (see Exhibit 4). When warning letters are delayed, the facility may continue to manufacture food under potentially unsafe or unsanitary conditions—food that could then reach store shelves and restaurants.

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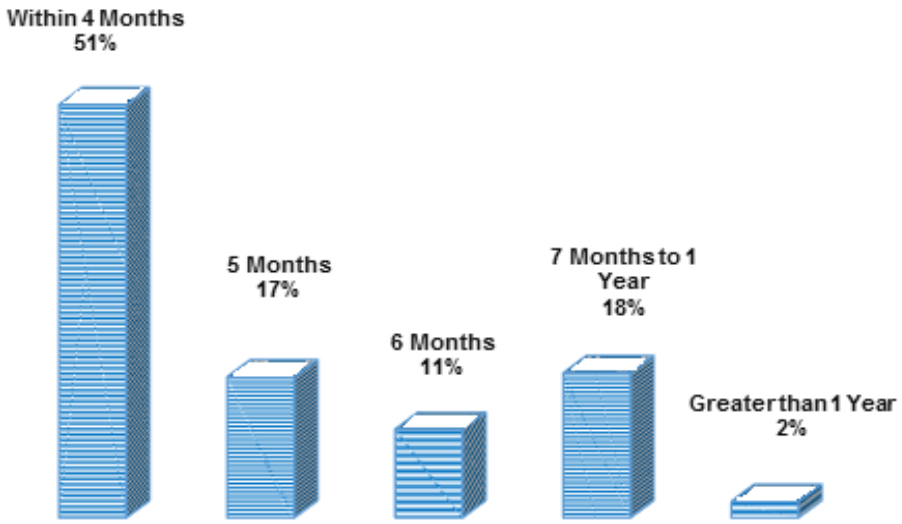
[34] There are statutorily established risk-level criteria associated with FDA's ability to suspend a facility registration (FD&C Act § 415(b)) and to issue an administrative detention order (FD&C Act § 304(h)(1)(A)).

[35] FDA has used mandatory recall twice in other circumstances unrelated to facility inspections. The first time was in February 2013 to contain pet food adulterated with *Salmonella*, and the second time was in November 2013 to address concerns about a dietary supplement containing a new ingredient.

[36] FDA, *Regulatory Procedures Manual*, ch. 4, § 4-1-1, Exhibit 4-1, "Procedures for Clearing FDA Warning Letters and Untitled Letters." Accessed at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf on October 17, 2016.

Exhibit 4: Time It Took FDA to Issue Warning Letters, 2011-2015



Source: OIG analysis of FDA data 2016.
Note: Percentages do not equal 100 percent due to rounding.

Facilities may also continue to operate under potentially unsafe conditions while FDA initiates other types of action. On average, FDA took 6.7 months to initiate a judicial action, 4.5 months to initiate an advisory action, and 2.8 months to initiate an administrative action.[37] In some cases, FDA took more than a year to take an action. In one example, FDA took 1.7 years to issue an untitled letter. In other examples, FDA took 1.1 years for a seizure and almost 2 years for an injunction.[38] Prompt action by FDA in response to significant inspection violations is an important safeguard of the food supply and is essential to preventing outbreaks of foodborne illness. See Appendix D for the length of time it took FDA to take action in response to significant inspection violations.

FDA's actions that relied on voluntary compliance did not always result in facilities correcting violations

When FDA relied on advisory actions—such as issuing warning letters—facilities did not always correct the problems. For example, FDA cited one facility for preparing its food under unsanitary conditions. FDA observed rainwater leaking through the roof, directly above where food was being prepared, as well as cracks and holes in the walls and floor that prohibited adequate cleaning. The inspection revealed the presence of

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[37] In seven instances, FDA initiated suspension of registration and administrative detention; it conducted these actions in a more timely manner. See Appendix D.
[38] We recognize that FDA's actions may be delayed, for example, by disputes over the lawfulness of a product.

Listeria monocytogenes in the facility, a dangerous pathogen that can cause life-threatening illness. Soon after the inspection, FDA issued a warning letter to the facility requesting prompt correction of the violations; however, these violations went uncorrected over the next 2 years. Three subsequent inspections documented that the facility did not correct the violations, and FDA continued to find unsanitary conditions and the presence of *Listeria monocytogenes*.

This facility was not unique. A number of facilities continued to be in violation after FDA took an advisory action. Of the 766 facilities that received advisory actions in which FDA conducted a followup inspection, about one in five facilities were cited as having significant inspection violations, resulting in a second OAI classification. In about three-quarters of these facilities, FDA investigators found violations identical to those in the previous inspection. If FDA does not take swift and effective action to ensure that all violations are corrected, it is unable to guarantee that the food handled by these facilities is safe and free of disease-causing organisms, chemicals, or other harmful substances.

FDA did not consistently conduct timely followup inspections to ensure that facilities had corrected significant inspection violations

FDA is expected to conduct followup inspections of facilities with significant inspection violations to verify that the facility has corrected the violations and to ensure that the facility does not have any new violations. Appropriate and timely followup inspections help to ensure prompt compliance and limit the threat of potentially harmful products entering the U.S. food supply.

Of the significant inspection violations:

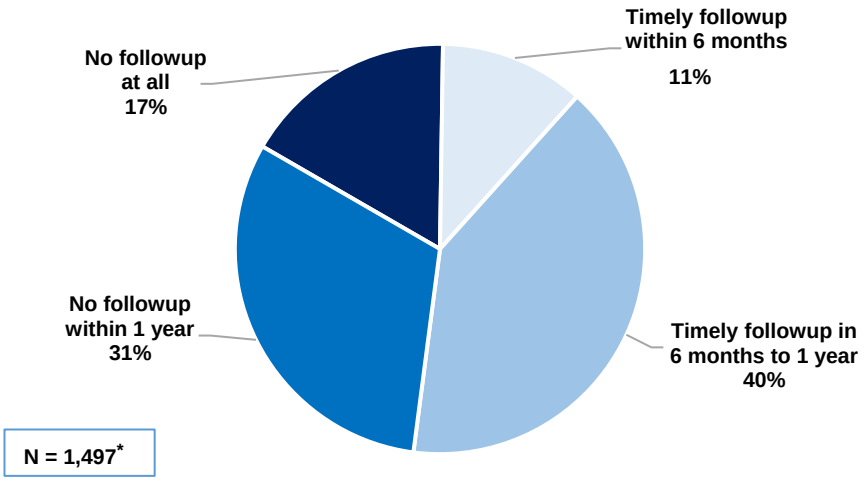
17% had no followup inspection at all

31% had no followup inspection within 1 year

For almost half of the significant inspection violations from 2011 to 2015, FDA did not conduct a timely followup inspection—an inspection within 1 year—to ensure that the facility had corrected the problem. For 17 percent of the significant inspection violations, FDA did not conduct a followup inspection of the facility at all. For another 31 percent of these significant inspection violations, FDA did not conduct a timely followup inspection of the facility. For 5 percent, FDA took multiple years to conduct a followup inspection. If FDA does not ensure that significant inspection violations are corrected in a timely manner, it is

unable to guarantee that these facilities are not producing and distributing food that is harmful to the public (see Exhibit 5).

Exhibit 5: Time It Took FDA to Conduct Followup Inspections of Significant Inspection Violations, 2011 to 2015



Source: OIG analysis of FDA data, 2016.

* We excluded 38 significant inspection violations because FDA did not have at least 1 year from the inspection date to conduct a followup inspection.

CONCLUSION AND RECOMMENDATIONS

The goal of FSMA is to prevent food safety problems rather than react to them. To that end, FSMA requires FDA to inspect domestic food facilities within certain timeframes, with high-risk facilities requiring more frequent inspection. It also provides FDA with new enforcement authorities designed to achieve higher rates of compliance and better respond to problems when they occur.

We found that FDA is on track to meet the inspection timeframes mandated by FSMA for the initial inspection cycles. Shortened timeframes in which to complete required inspections, inaccurate data that results in numerous attempted inspections, and the lack of a policy to reschedule attempted inspections could affect FDA's ability to meet FSMA mandates in the future.

Further, although FDA is on track to meet the FSMA inspection mandates, this did not result in a greater number of facilities being inspected. In fact, the overall number of food facilities FDA inspected—excluding the number of facilities that it attempted to inspect—decreased over time.

In addition, FDA did not always take action when it uncovered significant inspection violations that potentially threaten the safety of the food supply. When it did take action, it most commonly relied on facilities to voluntarily correct the violations. Also, it rarely took advantage of the new administrative actions provided by FSMA. Moreover, FDA's advisory and enforcement actions were not always timely nor did they always result in the correction of the violations. Further, FDA did not consistently conduct timely followup inspections to ensure that facilities corrected the violations.

Overall, the findings show that FDA did not always take swift and effective action to ensure that significant inspection violations were corrected; more needs to be done to protect our food supply. If FDA does not routinely inspect food facilities and ensure that violations are remedied, it is unable to ensure that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe.

We recommend that FDA take the following measures.

Improve how it handles attempted inspections to ensure better use of resources

FDA should take additional steps to improve the accuracy of its information about facilities requiring inspection. Specifically, it should identify facilities that do not need to be inspected because they are out of business and remove them from its list of facilities to inspect. It should also improve the details of these lists to indicate when temporarily closed facilities are open so that

future inspections can occur. This will allow FDA to decrease the number of attempted inspections each year and use its resources more efficiently.

FDA should also develop a policy that requires FDA to reschedule—on a timely basis—attempted inspections of facilities that are seasonal or temporarily inactive so that these facilities are inspected.

Take appropriate action against all facilities with significant inspection violations

In our previous report, we recommended that FDA take appropriate action against all facilities that have violations found during an OAI classified inspection. We continue to recommend that FDA take the most effective action to achieve compliance and to take administrative or judicial actions against facilities that do not voluntarily comply. FDA should also consider using more frequently the new administrative tools provided by FSMA.

Improve the timeliness of FDA's actions, including warning letters, so that facilities do not continue to operate under harmful conditions

FDA's advisory and enforcement actions were not always timely and allowed facilities to continue to operate under conditions that may threaten public health. FDA should initiate regulatory actions promptly in response to facilities with significant inspection violations found during an OAI classified inspection. This should include issuing warning letters in a timely manner.

Conduct timely followup inspections to ensure that significant inspection violations are corrected

In our previous report, we recommended that FDA ensure that all facilities correct significant inspection violations found during an OAI classified inspection. We continue to recommend that FDA do this, and that it conduct followup inspections in a timely manner to verify that facilities have remedied the violations.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA concurred with all four of our recommendations.

FDA concurred with our first recommendation to improve how it handles attempted inspections to ensure better use of resources. FDA noted that the number of attempted inspections was high during the initial inspection cycles but that these inspections help improve the accuracy of FDA's databases. FDA noted that as it continues to inspect facilities, the data will become more accurate and there will be fewer attempted inspections. FDA also stated that it is revising its procedures to address attempted inspections for seasonal or inactive facilities. Immediately after an attempted inspection of these facilities, FDA will establish a date to reschedule an inspection.

FDA concurred with our second recommendation to take appropriate action against all facilities with significant inspection violations. FDA stated that to monitor facilities that warrant followup, it developed a report that can display Official Action Indicated (OAI) inspection classifications and the resulting regulatory action(s) and activities that were taken or conducted. FDA noted that the relevant office can use the report to more efficiently track compliance activities resulting from OAI inspections for which it is responsible.

FDA concurred with our third recommendation to improve the timeliness of its actions, including warning letters. FDA indicated that it strives to take advisory and enforcement actions in a timely manner and that it is particularly focused on those scenarios that may involve immediate risk to public health. FDA also stated that it has taken steps to support timely advisory actions, including direct reference authority to district offices for certain violations. Direct reference is a business process whereby field offices may initiate regulatory actions without prior review by the Center or Office of Chief Counsel. FDA added that it will continue to examine its regulatory program for further activities to increase operational efficiencies.

FDA concurred with our fourth recommendation to conduct timely followup inspections to ensure that significant inspection violations are corrected. FDA stated that it is developing a system that will track activities or information relating to each specific inspection violation to ensure that all violations are corrected for all facilities that receive OAI classifications. It also developed a procedure to track OAI inspections and

followup inspections, and it created an oversight group for food-related cases that has enhanced the oversight of violative food facilities.

OIG appreciates FDA's commitment to its public health mission and its efforts to improve its performance of domestic food facility inspections. We value the steps FDA is taking to address the recommendations and look forward to FDA providing more information in its Final Management Decision. In particular, we appreciate FDA creating new procedures for establishing a reschedule date for facilities it attempted to inspect and a tracking system to monitor facilities that warrant further action. We look forward to FDA providing additional information about how these steps have reduced the number of attempted inspections in future cycles. We also look forward to FDA providing additional information about how these steps help it ensure that it takes appropriate action and conducts timely followup inspections of all significant inspection violations.

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

APPENDIX A: DETAILED METHODOLOGY

Analysis of Whether FDA Is On Track to Meet the Inspection Timeframes Mandated by FSMA

To assess whether FDA is on track to inspect domestic food facilities at the frequency mandated by FSMA, we requested the list of high-risk and non-high-risk facilities that FDA identified as requiring inspection during the initial inspection cycles.[39] In 2011, FDA created a list of all facilities subject to FDA inspection and designated each facility as high risk or non-high risk. FDA was required to inspect (1) all high-risk facilities within the 5-year period, from 2011 to 2015, and (2) all non-high-risk facilities within the 7-year period, from 2011 to 2017.[40]

We also requested from FDA data about inspections of food facilities from its Field Accomplishments and Compliance Tracking System (FACTS) for each year from 2009 to 2015. Using FACTS data, we calculated the number of all high-risk and non-high-risk facilities that FDA inspected from the high-risk list and from the non-high-risk list for the initial inspection cycles. We analyzed the number of unique facilities that FDA inspected—or attempted to inspect—to determine whether FDA was on track to meet the inspection mandates. Attempted inspections occur when an investigator visits a facility but it is either out of business or otherwise not in operation. FDA counts facilities that it attempted to inspect toward meeting the inspection mandates.

Changes in the Overall Number of Domestic Food Facilities Inspected by FDA and Spending

Next, we determined whether the FSMA inspection mandates changed the overall number of domestic food facilities that FDA inspected each year. To do this, we requested from FDA the total number of domestic food facilities known to be under FDA jurisdiction for each year from 2009 to 2015.[41] This information is from FDA's Official Establishment Inventory.

We used FACTS to determine the total number of domestic facilities that FDA inspected each year. This analysis includes only facilities that were actually inspected; it does not include facilities that FDA attempted to inspect. We then calculated the proportion of all domestic food facilities

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[39] The number of non-high-risk facilities includes 51,158 facilities that were identified in 2011 and an additional 9,852 facilities that were added to the list in 2014. FDA indicated that all of these facilities were to be inspected by the end of the first inspection cycle.

[40] All years presented in the report are fiscal years.

[41] We used data that we collected from FDA from 2004 to 2008 for our prior study. See OIG, *FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080), April 2010.

that FDA inspected each year since 2009 and noted any changes since 2011, when FSMA was implemented.

Additionally, we requested FDA's appropriations for each year from 2004 to 2015. We specifically asked for the total amount spent on domestic food facility inspections, including the amount for inspections conducted under State contracts on behalf of FDA. We adjusted all spending to 2015 dollars.[42]

There are several key differences between the analysis that determines whether FDA is likely to meet the inspection mandates and the analysis that determines the number of facilities under FDA's jurisdiction that were actually inspected each year. The analysis of whether FDA is on track to meet the inspection mandates is based on a list of facilities that are subject to the inspection timeframes mandated by FSMA.[43] This list does not include certain types of facilities, such as certain food brokers, that are not subject to the FSMA inspection mandates.[44] It also does not include facilities that came into the business after FDA created these lists.

Another reason these two analyses differ is that the number of facilities inspected are counted differently. For the analysis of the inspection mandates, we followed FDA's method for counting whether it met the mandates. Specifically, we counted the number of unique facilities that FDA inspected—or attempted to inspect—during the inspection cycle. In contrast, for the analysis that determines the number of facilities inspected each year, we included only facilities that FDA actually inspected, not attempted to inspect. This allowed us to understand the overall coverage of the number and proportion of facilities in the food supply that FDA inspects each year. Further,

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[42] To adjust spending to 2015 dollars, we used the U.S. Department of Commerce Bureau of Economic Analysis Implicit Price Deflator for Gross Domestic Product. Accessed at http://www.bea.gov on October 17, 2016.

[43] To compile this list FDA relied on information from its Official Establishment Inventory and incorporated supplemental information from the Bioterrorism Registry as of June 2011. Section 301 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directed FDA to create a registry of food facilities to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies. FSMA directed FDA to use the registry to identify food facilities subject to inspection. However, the registry included a number of facilities that were either not under FDA's jurisdiction or were not subject to the inspection mandates. We excluded from our calculations all facilities that FDA determined were not required to be inspected under FSMA.

[44] A food broker is an independent sales agent that negotiates sales for both food producers and food buyers, sometimes without taking possession of any products.

if a facility was inspected in multiple years, we counted the facility each year that it was inspected.[45]

Analysis of FDA Actions and Followup Inspections

We determined the extent to which FDA identified and took action in response to the significant inspection violations. For the purposes of this report, we use "significant inspection violations" to reflect the conditions found during a food facility inspection that FDA classified as OAI. First, we analyzed FACTS data from 2011 to 2015 to identify the domestic facilities that had an inspection that FDA classified as OAI. We determined that 1,245 facilities had significant inspection violations found during 1,535 OAI classified inspections. Additionally, to describe the nature and frequency of these conditions or practices, we reviewed the inspection reports for 2011, which was the most complete year of reports available at the time of our review.

We then requested information from FDA about any advisory or enforcement actions it took in response to these significant inspection violations found during the 1,535 OAI classified inspections, such as warning letters, regulatory meetings, or seizures.[46] We determined how often FDA initiated an advisory or enforcement action to respond to significant inspection violations.[47] We also determined how often FDA used administrative actions provided by FSMA, namely, administrative detention, suspension of facility registration, and mandatory food recalls.

Next, we calculated the average number of months for FDA to initiate an action in response to significant inspection violations.[48] We also calculated the average time it took FDA to initiate each type of action.[49] We determined the amount of time based on the number of days from the date the inspection ended to the date that FDA took the action.

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[45] We are not able to determine the number of facilities that still need to be inspected because we cannot distinguish between facilities that are seasonal (and therefore still require an inspection) and facilities that went out of business.

[46] FDA provided this information from its database, the Compliance Management System (CMS). This study focuses only on actions that FDA initiated; facilities may have initiated a voluntary recall, which is not included in this study.

[47] Our analysis includes the subsequent actions taken in response to each OAI classification. In 20 instances, FDA took more than 1 action following an OAI.

[48] In this analysis, the averages were generally similar to the medians.

[49] FDA sometimes initiated one action in response to multiple violations. In these cases, we calculated the time it took FDA to initiate the action in response to each of the violations.

Additionally, we determined the extent to which facilities corrected the violations in response to FDA's advisory actions. To do this, we started with the 1,245 facilities that had significant inspection violations from 2011 to 2015. We then identified the 766 facilities for which FDA took an advisory action and conducted a followup inspection so that it could determine whether the facility had corrected the problems. Next, we determined the number of these facilities that received a second, subsequent OAI classification after the advisory action. We reviewed the inspection report for both the first inspection and the subsequent inspection to determine the number of facilities that had the identical violations in both reports.[50]

Lastly, we determined the extent to which FDA conducted timely followup inspections. To do this, we reviewed FDA's FACTS data for significant inspection violations—violations found during inspections classified as OAI—and determined the length of time it took FDA to conduct a followup inspection.[51] We measured the number of days from the date the earlier inspection ended to the date the followup inspection ended. We then determined how often FDA conducted a followup inspection within 1 year from the date the earlier inspection ended.

Structured Interviews with FDA Officials

Throughout the course of the study, we conducted structured interviews with FDA officials to discuss the information FDA provided. These interviews focused on FDA's implementation of the FSMA inspection mandates, its designation of a facility as high risk, how it counts inspections toward the mandates, and any challenges it faces implementing FSMA inspection requirements.

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[50] Investigators identified the same violations or reported that the previous violation(s) was not corrected.

[51] We did not include 38 violations from this analysis because FDA did not have at least 1 year from the inspection date to conduct a followup inspection. However, we included additional data from FDA for 85 followup inspections that were conducted from October 2015 to May 2016.

APPENDIX B

Exhibit 1: Food Facilities Inspected by FDA, 2004 to 2015

Fiscal Year	Number of Food Facilities Subject to FDA Inspection	Number of Food Facilities Inspected	Percentage of Food Facilities Inspected
2004	59,305	17,032	29%
2005	61,930	15,773	25%
2006	62,929	14,547	23%
2007	65,520	14,339	22%
2008	67,819	14,966	22%
2009	66,196	15,920	24%
2010	73,930	17,609	24%
2011	75,990	19,369	25%
2012	77,672	19,176	25%
2013	82,401	16,846	20%
2014	82,280	16,287	20%
2015	86,032	16,135	19%

Source: OIG analysis of FDA data, 2016.

APPENDIX C

Exhibit 1: FDA Spending for Domestic Food Facility Inspections, 2004 to 2015[*]

Fiscal Year	Total Spending
2004	$77,620,360
2005	$80,204,679
2006	$68,846,750
2007	$78,820,744
2008	$89,963,823
2009	$126,716,576
2010	$137,487,328
2011	$139,702,725
2012	$129,555,357
2013	$121,581,171
2014	$131,992,388
2015	$129,824,038

Source: OIG analysis of FDA data for domestic food facility inspections, 2016.

[*] Spending is in 2015 dollars.

APPENDIX D

Exhibit 1: Time It Took for FDA to Take Regulatory Actions in Response to Significant Inspection Violations, 2011 to 2015

Advisory Actions	Total Number of Actions Taken	Average Number of Months
Warning Letter	903	4.4
Regulatory Meeting	136	4.4
Untitled Letter	74	6.1
Administrative Actions	**Total Number of Actions Taken**	**Average Number of Months**
Import Alert	12	3.2
Suspension of Food Facility Registration	2	0.8
Administrative Detention Order	5	0.2
Judicial Actions	**Total Number of Actions Taken**	**Average Number of Months**
Injunction	37	8.9
Seizure	21	3.1

Source: OIG analysis of FDA data, 2016.
Notes: FDA also initiated a reconditioning proposal, a post-inspection letter, and three emergency permit controls in response to significant inspection violations.
FDA sometimes initiated one action in response to multiple violations. In these cases, we calculated the time it took FDA to initiate the action in response to *each* of the violations.

APPENDIX E

Agency Comments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DATE: August 31, 2017

TO: Daniel R. Levinson
Inspector General

FROM: Lisa Rovin, JD
Deputy Associate Commissioner for Public Health Strategy and Analysis

SUBJECT: Food and Drug Administration's Response to Office of Inspector General Draft Report: *Challenges Remain in FDA's Inspections of Domestic Food Facilities*, OEI-01-13-00600

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, "Challenges Remain in FDA's Inspections of Domestic Food Facilities."

Lisa Rovin

Attachment

Food and Drug Administration's General Comments to
Office of Inspector General's Draft Report
"Challenges Remain in FDA's Inspections of Domestic Food Facilities OEI-01-13-00600"

FDA appreciates OIG's continued efforts to review and evaluate FDA's oversight of domestic food facilities. This report reviews FDA's oversight of domestic food facilities from 2011 to 2016, a time period that covers the enactment of the FDA Food Safety Modernization Act (FSMA). Signed into law in 2011, FSMA gave FDA new enforcement tools for both domestic and foreign facilities and included an inspection frequency mandate for high- and non-high-risk domestic facilities. FDA has been working diligently since 2011 to implement FSMA, including the systematic inspection of registered high risk and non-high risk facilities in the timeframes mandated in the statute.

FDA recognizes the importance of its oversight of domestic food facilities, the need to ensure that resources are utilized in the most efficient way, and the need to follow-up on public health concerns identified during inspections in a timely manner. OIG makes four recommendations in this Report: 1) improve how FDA handles attempted inspections to ensure better use of resources, 2) take appropriate action against all facilities with significant inspection violations, 3) improve the timeliness of FDA actions so that facilities do not continue to operate under harmful conditions, and 4) conduct timely follow-up inspections to ensure that significant inspection violations are corrected.

FDA agrees that there are challenges in its conduct of domestic inspections. FDA takes its public health mission very seriously and is committed to improvements in its performance of domestic inspections.

Response to OIG Recommendations

Recommendation 1: FDA should improve how it handles attempted inspections to ensure better use of resources.

FDA concurs with this recommendation. Under the FSMA inspection mandate and as you noted in the Report, we must attempt to inspect the facilities in our inventory of registered facilities. In recent years, the number of attempted inspections was high as FDA is finishing up the first non-high risk inspection cycle and, although they do not result in completed inspections and do use resources, they help improve the accuracy of FDA's databases. As we continue to inspect through the high- and non-high-risk cycles, the inventory data will become more and more accurate and there will be fewer attempted inspections, which the Agency agrees are not the best use of resources. The table below provides information on total activities supported by agency resources, including the number of attempted and completed inspections.

Fiscal Year	Number of Food Facilities Subject to FDA Inspection	Number of Food Facilities Inspected	Percentage of Food Facilities Inspected	Number of Firms receiving an Attempted Inspection	Number of Firms Receiving an Attempted Inspection and/or an Inspection	Percentage of Food Facilities Inspected/Attempted
2004	59,305	17,032	29%	7	17,039	29%
2005	61,930	15,773	25%	85	15,858	26%
2006	62,929	14,547	23%	472	15,019	24%
2007	65,520	14,339	22%	374	14,713	22%
2008	67,819	14,966	22%	389	15,355	23%
2009	66,196	15,920	24%	943	16,863	25%
2010	73,930	17,609	24%	943	18,552	25%
2011	75,990	19,369	25%	2,020	21,389	28%
2012	77,672	19,176	25%	6,180	25,356	33%
2013	82,401	16,846	20%	5,848	22,694	28%
2014	82,280	16,287	20%	4,249	20,536	25%
2015	86,032	16,135	19%	8,714	24,849	29%

FDA is currently revising its procedure to address attempted inspections for seasonal or inactive firms (e.g., small maple syrup facilities that are only open part of the year or firms that are temporarily closed for repairs, pre-production, installing new equipment, etc.) to help decrease the frequency of attempted inspections and make better use of resources. In the future, immediately after the attempted inspection for these firms, FDA will establish an inspection reschedule date based on when the firm has indicated it is, or will be, in production.

Recommendation 2: FDA should take appropriate action against all facilities with significant inspection violations.

FDA concurs with this recommendation. FDA's established regulatory procedures include using a variety of regulatory tools and promoting voluntary corrective actions by firms to ensure that firms are in compliance with regulatory requirements. These tools and activities work to ensure that compliance is achieved in the most efficient manner possible.

In addition, to monitor firms that warrant follow-up, FDA has recently developed the "Inspections Needing Work Activities" report that can display Official Action Indicated (OAI) inspection classifications and the resulting regulatory action(s) and activities that were taken or conducted. In addition to displaying details of the inspection such as the name of the inspected firm, the firm address, the inspection start and end dates, and the FDA field office/organization that accomplished the work, the report also displays links to other data systems where details for related activities such as the compliance case record or work activities can be viewed. Using the report, the relevant office can more efficiently track compliance activities resulting from OAI inspections for which it is responsible.

Recommendation 3: FDA should improve the timeliness of actions, including warning letters, so that facilities do not continue to operate under harmful conditions.

FDA concurs with this recommendation. FDA recognizes OIG's feedback about the importance of improving timeliness of regulatory actions. FDA strives to issue advisory actions (warning or untitled letters) and to take administrative enforcement (mandatory recall and/or suspension of food facility registration) and/or to initiate legal proceedings for enforcement actions through the Department of Justice, Federal magistrates or Federal courts (seizure, injunction, and prosecution) in a timely manner. FDA is particularly focused on those scenarios that may involve an immediate risk to public health. FDA agrees with OIG's finding that administrative enforcement action involving suspension of food facility registration occurred more rapidly than FDA's initiation and resolution of seizures or injunctions. The agency was able to accomplish this due to the enactment of the FDA Food Safety Modernization Act (FSMA) which provided FDA with this new administrative enforcement tool to address situations where a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals (hereafter, SAHCODHA) – the most serious risk to public health. FDA used this authority to respond effectively to scenarios of the most serious nature (i.e., Dixie Dew suspension Order in March 2017[1] and SM Fish suspension Order in September 2016[2]). FDA continues to seek injunctive restraint against facilities committing chronic serious violations that do not meet the threshold for presenting a reasonable probability of SAHCODHA and will continue to handle those regulatory actions as quickly as possible.

FDA agrees with OIG's finding that some warning letters were issued after FDA's target goal[3] to issue within four months after the end date of an OAI inspection or other most recent evidence of serious violation. FDA agrees that 80 percent of the warning letters were issued within six months and that FDA issued more than 50 percent within the target timing. FDA agrees with OIG that continued improvement should be pursued.

In response to OIG's draft report, FDA assessed the 20 percent of warning letters issued beyond six months from OAI inspections during the 2011-2015 timeframe. Of the warning letters issued beyond six months, over 65 percent involved dietary supplement facilities and all but a few issued after a year likewise involved dietary supplements. In December 2015, FDA announced the creation of the Office of Dietary Supplement Programs (ODSP), elevating the program from its previous status as a division under the Office of Nutrition Labeling and Dietary Supplements. In the 20 years since the establishment of the dietary supplement program, the industry has grown from about $4 billion to more than $40 billion in annual sales. FDA elevated the program's position to raise the profile of dietary supplements within the agency, and to enhance the effectiveness of dietary supplement regulation by allowing ODSP to better compete for government resources to regulate this rapidly expanding industry.

FDA also examined some of the letters in the 2 percent category which were issued a year after OAI inspections. Those warning letters included examples involving misbranded food and/or food or dietary supplements marketed with disease claims thus making those products unapproved drugs. FDA agrees with the fact that violation(s) may exist and may continue to exist while FDA pursues issuing the warnings; however, warning and untitled letters provide facilities an opportunity to voluntarily comply and are appropriate in certain circumstances. Some of those violations, while serious, represent less immediate public health risk compared with violations involving the safety of food production, bacterial contamination, or allergen declaration. FDA will continue its efforts to make regulatory actions timely.

[1] https://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm549734.htm
[2] https://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm520985.htm
[3] https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf

FDA has taken steps designed to support timely advisory actions. For instance, in FY 2017, CFSAN granted direct reference authority to District Offices (now Divisions under program alignment) for advisory actions for acidified food and juice Hazard Analysis Critical Control Point (HACCP) violations, subject to certain exceptions and limitations. This initiative built upon the success that CFSAN and ORA had in implementing the direct reference authority in 2011 for advisory actions involving seafood HACCP violations. Direct reference is a business process whereby field offices may initiate regulatory action without prior review of the cited violations and action by the Center or Office of Chief Counsel. FDA will continue to examine its regulatory program for further activities to increase operational efficiencies.

Recommendation 4: FDA should conduct timely follow-up inspections to ensure that significant inspection violations are corrected.

FDA concurs with this recommendation. FDA strives to conduct timely follow-up inspections to ensure that significant violations are corrected. FDA is currently developing a system that, once fully developed and implemented, will track activities or information relating to each specific inspection observation/violation to ensure that all violations are corrected for all facilities that receive OAI classifications. As noted in the response to Recommendation 2, the Agency recently developed a procedure to track OAI inspections and reconcile the need for follow-up inspections. In addition, the Agency created a multi-programmatic oversight group called the SCORE (Strategic Coordinated Oversight of Recall Execution) for foods-related cases. This group has enhanced the oversight of violative food firms to increase the timely response to violative inspections that warrant follow-up by the Agency.

ACKNOWLEDGMENTS

Vincent Greiber served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Marissa Baron, Jillian Husman, and Lauren Peterson. Office of Evaluation and Inspections staff who provided support include Althea Hosein and Melicia Seay.

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Nancy Harrison and Meridith Seife, Deputy Regional Inspectors General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

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The mission of the Office of Inspector General (OIG), as mandated by Public Law 95452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of individuals served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and individuals. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.