

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FDA INSPECTIONS OF DOMESTIC
FOOD FACILITIES**



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Inspector General

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E X E C U T I V E S U M M A R Y

OBJECTIVES

To determine the extent to which the Food and Drug Administration (FDA):

1. conducts inspections of domestic food facilities,
2. identifies violations in food facilities and takes action against those food facilities, and
3. ensures that violations are corrected.

BACKGROUND

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages. Recent high-profile outbreaks of foodborne illness have raised serious questions about FDA's inspections process and its ability to protect the Nation's food supply. The Senate Committee on Agriculture, Nutrition, and Forestry requested that the Office of Inspector General (OIG) review the extent to which FDA conducts food facility inspections and identifies violations.

FDA inspects food facilities to ensure food safety and compliance with regulations. During an inspection, FDA inspectors may identify potential violations of the Food, Drug, and Cosmetic Act as well as other applicable laws and regulations. Based on the outcome of the inspection, FDA assigns a facility one of three classifications: official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI). In addition, FDA may choose to change a facility's initial classification to another classification under certain circumstances.

According to FDA guidance, when inspectors uncover violations that are significant enough to warrant OAI classification, some type of regulatory action should be recommended. This regulatory action generally consists of either an advisory action or an enforcement action. Advisory actions usually allow an opportunity for the facility to voluntarily correct the violations found during the inspection, whereas enforcement actions are often initiated in court and the facility is generally required to correct the violations found during the inspection.

FDA relies on several approaches to determine whether a facility corrected the violations found by inspectors. FDA may review evidence provided by a food facility describing any completed corrective actions. FDA may also reinspect a facility to verify that corrections were made.

We based this study on three data sources: (1) FDA's food facility inspection data, (2) FDA documentation on facility violations and followup activities, and (3) structured interviews with FDA staff.

FINDINGS

On average, FDA inspects less than a quarter of food facilities each year, and the number of facilities inspected has declined over time.

Between fiscal years (FY) 2004 and 2008, FDA inspected annually an average of 24 percent of the food facilities subject to its inspection. Except for a few instances, there are no specific guidelines that govern the frequency with which inspections should occur. Further, the number of food facilities that FDA inspected declined between FYs 2004 and 2008, even as the number of food facilities increased. In addition, the number of inspections of facilities that have been designated by FDA as "high risk" has also declined. FDA officials noted that the overall decline in FDA inspections was largely due to a decline in staffing levels.

Fifty-six percent of food facilities have gone 5 or more years without an FDA inspection.

FDA identified 51,229 food facilities that were subject to inspection and were in business from the start of FY 2004 until the end of FY 2008. Of these, 56 percent were not inspected at all, 14 percent were inspected a single time, and the remaining 30 percent were inspected two or more times. If FDA does not routinely inspect food facilities, it is unable to guarantee that these facilities are complying with applicable laws and regulations.

The number of facilities that received OAI classifications has declined over time.

The number of inspected facilities that received OAI classifications decreased from 614 in FY 2004 to 283 in FY 2008. The percentage of facilities that received OAI classifications also dropped from nearly 4 percent to nearly 2 percent during this 5-year period. In addition, nearly three-quarters of the facilities that received OAI classifications in FY 2008 had a history of violations. Two percent of facilities that received OAI classifications refused to grant FDA officials access to their records.

FDA took regulatory action against 46 percent of the facilities with initial OAI classifications; for the remainder, FDA either lowered the classification or took no regulatory action.

In FY 2007, a total of 446 facilities initially received OAI classifications. FDA took regulatory action against 46 percent of these facilities. For the remainder, FDA

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lowered the OAI classification for 29 percent and took no regulatory action for 25 percent.

For 36 percent of the facilities with OAI classifications in FY 2007, FDA took no additional steps to ensure that the violations were corrected. In FY 2007, 280 facilities received OAI classifications that were not lowered by FDA. For 36 percent of these facilities, FDA did not reinspect them within a year of the inspection or review other evidence provided by facilities to ensure that the violations were corrected.

RECOMMENDATIONS

Our report found significant weaknesses in FDA's domestic inspections program. We found that there was a significant decline in the number of food facility inspections as well as a decline in the number of violations identified by FDA inspectors. Further, when violations were identified, FDA did not routinely take swift and effective action to ensure that these violations were remedied. Taken together, the findings demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary tools to prevent outbreaks of foodborne illness. Based on our findings, we recommend that FDA:

Increase the frequency of food facility inspections, with particular emphasis on high-risk facilities.

Provide additional guidance about when it is appropriate to lower OAI classifications.

Take appropriate actions against facilities with OAI classifications, particularly those that have histories of violations.

Ensure that violations are corrected for all facilities that receive OAI classifications.

Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.

Seek statutory authority to allow FDA access to facilities' records during the inspection process.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its response to the draft report, FDA noted that it was addressing many of the issues and recommendations noted in the report. Specifically, FDA stated that it supported our two recommendations to seek additional statutory authority from Congress. It noted that it is seeking more effective enforcement tools and that it supports proposed legislation to expand civil penalties for food violations and to provide additional access to facilities' records. FDA also agreed with our recommendation to provide additional guidance about when it is appropriate to lower OAI classifications and noted that it will revise its current guidance.

For the remaining three recommendations, FDA noted several actions it has taken, or plans to take, to address them. FDA stated that it received increased appropriations that have permitted it to increase the number of food facility inspections. It also stated that it has taken steps to implement our recommendations to ensure that appropriate actions are taken and that violations are corrected for all facilities that receive OAI classifications.

We support FDA's efforts and continue to emphasize the importance of FDA taking appropriate and swift action and ensuring that violations are corrected in all facilities with OAI classifications. We ask that, in its final management decision, FDA more clearly indicate whether it concurs with each of the recommendations listed in the report.

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BACKGROUND

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.¹ FDA is responsible for safeguarding the Nation's food supply by ensuring that all ingredients used in food are safe and that food is free of disease-causing organisms, chemicals, or other harmful substances. The recent salmonella outbreak caused by insanitary conditions at a peanut processing plant resulted in one of the largest food recalls in U.S. history.² This outbreak, as well as others resulting in large recalls of spinach, tomatoes, peppers, lettuce, and alfalfa sprouts, has raised serious questions about FDA's inspections process and its ability to protect the Nation's food supply.

The Senate Committee on Agriculture, Nutrition, and Forestry requested that the Office of Inspector General (OIG) review the extent to which FDA conducts food facility inspections and identifies violations. Among other things, the Committee was concerned about reports that the number of food facility inspections is declining, even as the number of food facilities regulated by FDA is increasing.

¹ Paul S. Mead et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases*, vol. 5, 1999, pp. 607–625. Available online at <http://www.cdc.gov/ncidod/eid/Vol5no5/mead.htm>. Accessed on December 14, 2009.

² FDA, *Update on the Salmonella Typhimurium Investigation, FDA/CDC Joint Media Teleconference*, January 28, 2009. Available online at <http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM169176.pdf>. Accessed on August 11, 2009.

Food Facility Inspections

FDA inspects food facilities to ensure food safety and compliance with regulations. Pursuant to the Federal Food, Drug, and Cosmetic Act, 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.

FDA inspects food facilities that manufacture, process, pack, and store food.³ Inspectors from FDA's 19 district offices conduct these inspections according to guidance from FDA headquarters. In addition, FDA contracts with States to conduct inspections on behalf of FDA.⁴ Except for a few instances, there are no specific guidelines that govern the frequency with which inspections should occur.⁵ Instead, FDA's district offices work with FDA headquarters to develop certain annual priorities for inspection. Throughout the course of the year, however, FDA may change its priorities based on emerging issues, such as outbreaks of foodborne illness.

FDA also designates certain facilities as high-risk facilities. Generally, these facilities handle types of food that have a greater potential to cause harm. FDA uses this high-risk designation to help prioritize facilities for inspection. This process allows FDA to target scarce resources based on relative vulnerability and risk.

In recent years, FDA has experienced significant decreases in staffing for its food program. Notably, in fiscal year (FY) 2003, FDA had 3,167 full-time equivalent employees (FTE) responsible for the oversight of food facilities; by FY 2005, the number of employees had dropped to 2,943; and by FY 2007, the number was down to 2,569.⁶ To address

³ 21 U.S.C. § 374; 21 U.S.C. § 372.

⁴ FDA also has partnership agreements with some States. These agreements allow States to share information with FDA about inspections they conduct.

⁵ FDA has specific guidelines for inspections of manufacturers of infant formula and manufacturers of acidified and low-acid canned foods. These guidelines contain recommendations on the frequency of inspections.

⁶ FTE data can be found in the *FDA FY 2007 Budget Summary* and the *FY 2010 Congressional Justification*. Available online at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2007FDABudgetSummary/ucm112799.htm> and <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153507.pdf>. Accessed on October 2, 2009.

concerns about staffing, in FY 2009, Congress increased funding for FDA's food program to a level that would support an estimated 3,019 FTEs.⁷

During the course of FDA inspections, inspectors from the district offices may identify potential violations of the Food, Drug, and Cosmetic Act as well as other applicable laws and regulations. Inspectors document their findings in a report, which is then reviewed by a supervisor and, in some cases, other district officials. Based on the outcome of the inspection, the district office assigns the facility one of three classifications: official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI).⁸

An OAI classification signifies that the inspector found objectionable conditions in the food facility and that these violations potentially "warrant regulatory action."⁹ This type of violation is the most significant identified by FDA inspectors. A VAI classification signifies that the inspector found violations that are serious enough to record but do not cross "the threshold for regulatory action."¹⁰ An NAI classification signifies that the inspector found either no violations of Federal law or violations that were so insignificant that no action is warranted.

Under certain circumstances, FDA may change a facility's inspection classification. For example, FDA may modify a classification from OAI to VAI if other FDA officials do not concur with the inspector's initial

⁷ FDA, *FY 2010 Congressional Justification*. Available online at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153507.pdf>. Accessed on October 2, 2009.

⁸ FDA, *Office of Regulatory Affairs (ORA): Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (rev. 06/07/07). Available online at <http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061430.htm>

Accessed on June 2, 2009. In addition, under certain circumstances, inspections may also 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 which require a review and decision.

⁹ FDA, *ORA Field Management Directive No. 86*. Available online at <http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061430.htm>. Accessed on June 2, 2009.

¹⁰ Ibid.

classification. In addition, the classification may be lowered if the facility takes, or promises to take, corrective action at some point after the inspection. FDA may also raise a classification, for example, if a facility promises during an inspection to make corrections and FDA subsequently determines that the facility did not make those corrections.

Actions Taken in Response to Violations

According to FDA guidance, when inspectors uncover violations that are significant enough to warrant OAI classifications, some type of regulatory action should be recommended.¹¹ This regulatory action generally consists of either an advisory action or an enforcement action.¹² Advisory actions usually allow an opportunity for the facility to voluntarily correct the violations found during the inspection, whereas enforcement actions are generally initiated in court. Enforcement actions generally require facilities to correct the noted violations or to destroy adulterated or misbranded products. In some cases, an enforcement action may be pursued after a facility's response to an advisory action is deemed to be inadequate.

Advisory actions. FDA may initiate advisory actions in situations involving violations of Federal law. These advisory actions include issuing a warning letter or an untitled letter, or holding a regulatory meeting.¹³ These actions allow facilities the opportunity to promptly correct the violations found during the inspection.

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.¹⁴ FDA asks that facilities respond to warning letters in writing within a specific timeframe (generally within 15 days) to indicate what actions they will take to correct the violations.¹⁵ FDA guidelines suggest that warning letters be issued within 4 months of the last day of the inspection; the date of sample

¹¹ Ibid.

¹² FDA, *Regulatory Procedures Manual*, chs. 4, 5, 6, and 10, March 2009.

¹³ FDA, *Regulatory Procedures Manual*, ch. 4 and ch. 10, § 10-3, March 2009. Note that all warning letters and untitled letters must be submitted to FDA headquarters for review for legal sufficiency and consistency with agency policy.

¹⁴ FDA, *Regulatory Procedures Manual*, ch. 4, § 4-1-1, March 2009.

¹⁵ FDA, *Regulatory Procedures Manual*, ch. 4, § 4-1-10, March 2009.

analysis; or the date of evidence collection.¹⁶ Warning letters are posted on FDA's Internet site.

FDA may issue an untitled letter when the violations are not significant enough to meet the criteria for the issuance of a warning letter.¹⁷

Untitled letters summarize the inspection's findings but do not include a warning statement that failure to make prompt correction may result in an enforcement action. They also request that the facility respond within "a reasonable amount of time," such as 30 days.¹⁸ Untitled letters are not posted on FDA's Internet site.

FDA may also request a regulatory meeting with representatives of a facility to inform them about how one or more products, practices, processes, or other activities are considered to be in violation of the law.¹⁹ FDA often holds these meetings when violations do not warrant the issuance of a warning letter or an untitled letter. However, in certain instances, FDA may hold regulatory meetings in conjunction with the issuance of a letter to emphasize the significance of the violations.

Enforcement actions. FDA may initiate enforcement actions in situations involving violations of Federal law that may not be resolved through voluntary compliance. These enforcement actions may include administrative detention,²⁰ seizure, injunction, and even prosecution.²¹

Depending on the nature of the violations identified, FDA may initiate a seizure or an injunction. A seizure often results in adulterated or misbranded food being seized and removed from the marketplace. An injunction often results in a facility receiving a court order prohibiting the production or distribution of a product or forcing the facility to

¹⁶ FDA, *Regulatory Procedures Manual*, ch. 4, Exhibit 4-1, § 6-1-1, March 2009.

¹⁷ FDA, *Regulatory Procedures Manual*, ch. 4, § 4-2-1, March 2009.

¹⁸ FDA, *Regulatory Procedures Manual*, ch. 4, § 4-1-10, March 2009.

¹⁹ FDA, *Regulatory Procedures Manual*, ch. 10, § 10-3, March 2009.

²⁰ Although FDA may initiate certain administrative actions, such as administrative detentions, such actions are not commonly imposed against food facilities.

²¹ FDA, *Regulatory Procedures Manual*, ch. 4, § 4-1-1, March 2009. FDA may also, under certain circumstances, initiate other types of enforcement actions including civil monetary penalties and mandatory recalls of infant formula (FDA, *Regulatory Procedures Manual*, ch. 5, § 5-8, and ch. 7, March 2009).

correct the conditions that caused the violation to occur.²² In general, FDA initiates these particular enforcement actions by working with the Department of Justice to file a complaint with the U.S. District Court where the facility holding the product is located. In addition, under certain circumstances, FDA may recommend criminal prosecution to the Department of Justice for a food facility or individual who is in violation of the law.²³

Approaches To Ensure That Violations Are Corrected

FDA relies on several approaches to determine whether a facility corrected the violations found by inspectors. FDA may review evidence provided by a food facility describing any completed corrective actions, including reports from private consultants detailing corrective actions that have been taken.

In addition, FDA may conduct followup inspections to ensure that facilities have corrected the violations. FDA guidelines state that, if necessary to ensure that corrections have been implemented, “follow-up inspections should be conducted promptly after the agreed upon date of completion of the promised corrections.”²⁴ FDA guidelines also suggest that facilities receiving OAI classifications be given a higher priority for followup inspections.²⁵

Related Reports

This report is a part of a larger body of work conducted by OIG on food safety. In a 2009 report on food traceability, OIG found that 35 of 40 selected products could not be traced through each stage of the food supply chain.²⁶ It also found that 59 percent of selected food facilities did not comply with FDA’s recordkeeping requirements and that these requirements were not sufficient to ensure the traceability of the food supply. OIG also issued a report which found that 5 percent of selected facilities failed to register with FDA, as required.²⁷ Additionally, that report found that 48 percent of the selected facilities

²² FDA, *Regulatory Procedures Manual*, ch. 6, §§ 6-1 (Seizures) and 6-2 (Injunctions), March 2009.

²³ FDA, *Regulatory Procedures Manual*, ch. 5, March 2009.

²⁴ FDA, *Regulatory Procedures Manual*, ch. 4, § 4-1-8, March 2009.

²⁵ FDA, *Compliance Program Guidance Manual*, ch. 3, pt. II, p. 2.

²⁶ OIG, *Traceability in the Food Supply Chain*, OEI-02-06-00210, March 2009.

²⁷ OIG, *FDA’s Food Facility Registry*, OEI-02-08-00060, December 2009.

either failed to provide accurate information when they first registered or after changes in the facilities' information, as required.

In another 2009 report, OIG found that FDA does not have statutory authority to require manufacturers to initiate pet food recalls and that FDA did not always follow its procedures in overseeing pet food recalls.²⁸ OIG recommended that FDA consider seeking statutory authority to mandate food recalls and to assess penalties for noncompliance with the terms of recalls. It also recommended that FDA amend its regulations or, if necessary, seek additional legislative changes to establish mandatory requirements for facilities to follow in conducting recalls.

METHODOLOGY

Scope

This study assesses the extent to which FDA conducted inspections and identified violations in domestic food facilities. It also assesses the extent to which FDA took action against food facilities with violations and ensured that these violations were corrected.

This study includes inspections of domestic food facilities conducted by FDA or by States under contract with FDA. We based this study on three sources of data: (1) FDA's food facility inspection data, (2) FDA documentation on facility violations and followup activities, and (3) structured interviews with FDA staff.

Analysis of FDA Food Inspection Data

To determine the extent to which FDA conducts inspections of domestic food facilities, we analyzed data from FDA's Field Accomplishments and Compliance Tracking System (FACTS). FACTS includes information about all FDA inspections as well as the classifications for each.

We requested FACTS data from FDA for all domestic food facility inspections for FYs 2004 through 2008. We also requested from FDA the number of food facilities within FDA's jurisdiction each year and those that were in business throughout this 5-year period. We analyzed these data to determine the percentage of facilities that FDA inspected

²⁸ OIG, *Review of the Food and Drug Administration's Monitoring of Pet Food Recalls*, A-01-07-01503, August 2009. Recalls are voluntary actions taken by facilities and are therefore not included in our analysis of regulatory actions taken by FDA.

each year and the percentage of facilities that FDA inspected during this 5-year period. We also determined the percentage of high-risk facilities that FDA inspected each year. We considered a facility to be high risk if it had a high-risk designation throughout the entire fiscal year.

In addition, we analyzed FACTS data to determine the extent to which FDA identified food facility violations. Specifically, we determined the number of facilities that received OAI, VAI, and NAI classifications each year. We also used these data to identify the most commonly reported violations found in facilities with OAI classifications and the extent to which these facilities had a history of violations.

Review of FDA Documentation

To determine the extent to which FDA took action against food facilities with violations and ensured that those violations were corrected, we requested from FDA all documentation related to OAI classifications received by facilities in FY 2007.²⁹ We chose FY 2007 because it was the most current timeframe that would also allow FDA sufficient time to initiate any actions and to complete any additional activities to ensure that the violations were corrected. We requested this documentation for all facilities that received OAI classifications, including those for which FDA eventually lowered the classification. In this report, we refer to these as facilities that received “initial OAI classifications” to distinguish them from facilities that received OAI classifications that were not lowered.

We specifically requested documentation of any advisory actions and enforcement actions that FDA initiated that were related to these OAI classifications. We also requested documentation of any additional inspections and any other activities that FDA conducted to ensure that the violations were corrected. FDA provided this documentation for actions taken as of April 2009.

We reviewed the documentation to determine the percentage of facilities for which FDA took advisory actions and enforcement actions. We also determined the percentage of facilities for which FDA lowered the OAI classification and the reasons for these decisions. Lastly, we reviewed

²⁹ Nineteen facilities had more than one inspection that resulted in an OAI classification in FY 2007. In these cases, we requested documentation related to the first inspection that occurred in the fiscal year.

the documentation to determine any additional steps that FDA took to ensure that violations were corrected. We conducted this analysis for facilities that received OAI classifications that were not lowered by FDA. We specifically looked at whether FDA reinspected the facility within 1 year of the initial inspection and whether FDA conducted any additional followup to ensure that the violations were corrected. As noted earlier, FDA guidelines do not specify a timeframe in which reinspections must occur; however, for the purposes of our analysis, we determined that a year is a reasonable amount of time for FDA to assess whether the facilities had promptly and adequately addressed the violations found during their inspections.

Structured Interviews With FDA Officials

We conducted structured telephone interviews with key staff at FDA headquarters and at 10 of the 19 district offices. We selected the 10 district offices that had the most food facilities within their jurisdictions and had conducted the most food facility inspections in FY 2007. Our interview questions focused on how the district offices classify food facility inspections and under what circumstances they choose to take advisory actions and enforcement actions. We conducted the interviews with the district offices between September and October 2008 and with headquarters staff throughout the course of the study.

Standards

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

FINDINGS

On average, FDA inspects less than a quarter of food facilities each year, and the number of facilities inspected has declined over time

Between FY 2004 and FY 2008, FDA inspected annually an average of 24 percent of the food facilities that were subject to FDA inspection.

Except for a few instances, there are currently no specific guidelines that govern the frequency with which inspections should occur. As shown in Table 1, the percentage of food facilities that FDA inspected annually ranged from 29 to 22 percent during this period.

In addition, the number of food facilities that FDA inspected declined, even as the number of food facilities increased. In FY 2004, FDA inspected over 17,000 facilities; in FY 2008, this number dropped to fewer than 15,000 facilities. During the same period, the number of food facilities subject to FDA inspection increased from about 59,000 facilities to almost 68,000 facilities. FDA officials noted that the decline in inspections was largely due to a significant decline in staffing levels that resulted from funding cuts. These officials noted that between 2003 and 2008, FDA lost almost a quarter of the staff that performs food facility inspections. They also noted that many of the losses came from the ranks of FDA's most experienced employees.

Table 1: Food Facilities Inspected by FDA, FYs 2004–2008

FY	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%

Source: OIG analysis of FDA data, 2009.

The number of high-risk facilities inspected by FDA has also declined over time

Each year, FDA designates certain facilities as high risk. This designation helps FDA determine which facilities should be given a higher priority for inspection. As shown in Table 2, the number of high-risk facilities that FDA inspected decreased from about 6,200 facilities in FY 2004 to 5,500 facilities in FY 2008. The

percentage of high-risk facilities that FDA inspected annually decreased from 77 percent to 63 percent.

Table 2: High-Risk Food Facilities Inspected by FDA, FYs 2004–2008

FY	Number of High-Risk Food Facilities	Number of High-Risk Food Facilities Inspected	Percentage of High-Risk Food Facilities Inspected
2004	8,102	6,241	77%
2005	8,330	5,547	67%
2006	8,347	5,664	68%
2007	8,568	5,535	65%
2008	8,667	5,460	63%

Source: OIG analysis of FDA data, 2009.

Further, FDA inspected a smaller percentage of facilities in industries that produce certain high-risk food products, such as cheese and seafood. For example, in FY 2004, FDA inspected 45 percent of facilities in the seafood industry, whereas in FY 2008, FDA inspected only 32 percent of such facilities. See Appendix A for more information on inspections by industry.

Fifty-six percent of food facilities have gone 5 or more years without an FDA inspection

FDA identified 51,229 food facilities that were subject to FDA inspection and were in business

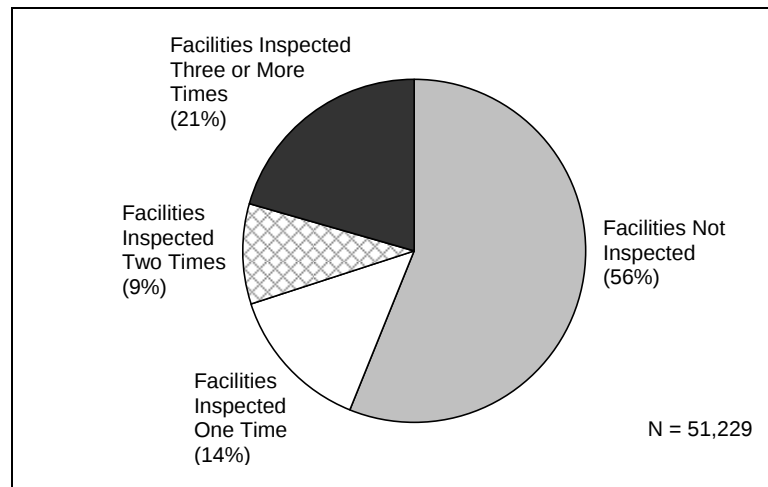
from the start of FY 2004 until the end of FY 2008.³⁰ FDA inspected only 44 percent (22,531) of these facilities during this 5-year period. As shown in Figure 1, 56 percent of these facilities were not inspected at all, 14 percent were inspected a single time, and the remaining 30 percent were inspected two or more times.

If FDA does not routinely inspect food facilities, it is unable to guarantee that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe and free of disease-causing organisms, chemicals, or other harmful substances.

³⁰ This excludes facilities within FDA's jurisdiction that began doing business at some point after October 1, 2004, as well as those that went out of business before September 30, 2008.

FINDINGS

**Figure 1:
Number of
Inspections
per Food
Facility
Between
FYs 2004 and
2008**



Source: OIG analysis of FDA data, 2009.

The number of facilities that received OAI classifications has declined over time

Facilities receive OAI classifications when inspectors determine that the violations

found are significant enough to potentially warrant regulatory action, such as an advisory action or an enforcement action. As shown in Table 3, the number of inspected facilities that received OAI classifications decreased from 614 facilities in FY 2004 to 283 facilities in FY 2008. The percentage of facilities that received OAI classifications also dropped from nearly 4 percent to nearly 2 percent during this 5-year period. See Appendix B for additional information on the percentage of facilities that received NAI and VAI classifications.

FINDINGS

Table 3: Food Facilities That Received OAI Classifications, FYs 2004–2008

FY	Number of Food Facilities Inspected	Number of Food Facilities That Received OAI Classifications	Percentage of Food Facilities Inspected That Received OAI Classifications
2004	17,032	614	3.6%
2005	15,773	511	3.2%
2006	14,547	432	3.0%
2007	14,339	304	2.1%
2008	14,966	283	1.9%

Note: For FY 2007, we did not include 17 facilities for which FDA officials had incorrectly entered OAI classifications in FACTS and 5 facilities that received an OAI classification for a nonfood-related inspection. We did not have information on data entry errors for the other years.

Source: OIG analysis of FDA data, 2009.

Facilities most commonly received OAI classifications for unsafe food manufacturing and handling practices and insanitary conditions in the facility

FDA identified unsafe food manufacturing and handling practices or insanitary conditions in 89 percent of the facilities that received OAI classifications in FY 2008.³¹ Specifically, FDA identified unsafe manufacturing and handling practices in 77 percent of these facilities and insanitary conditions in 44 percent of these facilities. These types of violations could lead to contaminated food products being sold to consumers.

Unsafe manufacturing and handling practices cited by inspectors commonly included failure to maintain refrigeration units at safe temperatures, inadequate design of manufacturing equipment, and improper handling of food products. For example, one inspector found that a facility improperly handled its food products by placing ice made from contaminated water in direct contact with the food manufactured at the facility. Insanitary conditions in the facility often included instances of mold or filth or evidence of insects, rodents, or other infestations. For example, one inspector observed that pigeons were

³¹ A facility may be cited for multiple types of violations during a single inspection. Other types of violations found by inspectors included labeling violations and failure to register the facility with FDA.

flying and roosting above open containers of food in a facility. The inspector noted that “bird droppings were observed on equipment” and that there were holes in the walls and roof of the facility.

Nearly three-quarters of the facilities that received OAI classifications in FY 2008 had a history of violations

Seventy-four percent of the facilities that received OAI classifications in FY 2008 had a history of violations found during prior inspections. Specifically, 63 percent of these facilities received at least one prior VAI classification, and 27 percent received at least one prior OAI classification.

In addition, 50 percent of the facilities that received OAI classifications in FY 2008 had been cited for the same violation in a prior inspection. For example, one facility had already received a warning letter for not adequately cleaning its manufacturing equipment, for insanitary conditions in the facility, and for labeling violations. The subsequent inspection revealed that the facility had failed to correct these violations. In another facility, FDA found the same unsafe manufacturing practices and insanitary conditions during the previous four inspections. After each inspection, the facility promised to make corrections but each subsequent inspection revealed that it had not.

Two percent of the facilities that received OAI classifications refused to grant FDA officials access to their records; most of these facilities had a history of violations

Five facilities—four of which had a history of violations—refused to provide FDA inspectors with certain requested records. This lack of access to records might impede FDA’s ability to determine the most appropriate action to take to ensure compliance with applicable laws and regulations. These records included descriptions of sanitation practices within the facility, lists of customers that received the facility’s products, or descriptions of consumer complaints. FDA does not have the statutory authority to require food facilities to provide access to these records.³²

³² FDA has access to certain records held by infant formula facilities as well as certain records needed to trace an article of food through the food supply chain. The limited circumstances under which FDA can access these records are described in 21 U.S.C. §§ 374 and 350.

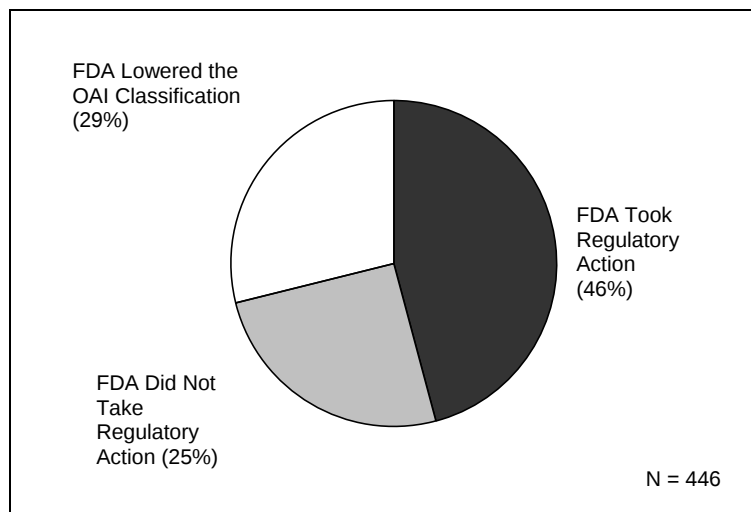
FDA took regulatory action against 46 percent of the facilities with initial OAI classifications; for the remainder, FDA either lowered the classification or took no regulatory action

According to FDA guidance, when inspectors uncover violations that are significant enough to warrant OAI classifications, some type of regulatory

action should be recommended. This regulatory action generally consists of either an advisory action or an enforcement action; however, under certain circumstances, FDA may also lower a classification.

In FY 2007, a total of 446 facilities initially received OAI classifications. FDA took regulatory action against 46 percent of these facilities. For the remainder, FDA lowered the OAI classification for 29 percent and took no regulatory action for 25 percent. See Figure 2.

**Figure 2:
Actions Taken
After Facilities
Received OAI
Classifications,
FY 2007**



Source: OIG analysis of FDA data, 2009.

Of the facilities that received initial OAI classifications, FDA took advisory actions against 44 percent and enforcement actions against 2 percent

Depending on the severity of the violations and any history of violations, FDA may choose to initiate an advisory action or an enforcement action. These actions can be taken independently or in combination with one another.

F I N D I N G S

Advisory actions. Of the 446 facilities that received initial OAI classifications in FY 2007, FDA took advisory actions against 44 percent.³³ Advisory actions allow an opportunity for a facility to voluntarily correct the violations found during the inspection. Advisory actions include warning letters, untitled letters, and regulatory meetings.

Specifically, FDA issued warning letters to 20 percent of the facilities with initial OAI classifications. In these letters, FDA requested that the facilities implement corrective action to remedy the violations. On average, FDA took 100 days after the last day of an inspection to issue a warning letter; however, for one-third of these facilities, FDA took longer than 4 months to issue the warning letters, potentially exceeding recommended guidelines. In addition, FDA asked that facilities respond in writing within 15 business days of receiving the warning letter; however, only 52 percent of these facilities responded within this timeframe, and another 26 percent did not respond to FDA at all.

FDA issued untitled letters to 13 percent of the facilities with initial OAI classifications. FDA issues such letters when the violations found during an inspection are not determined to be significant enough for the issuance of a warning letter.

In addition, FDA conducted regulatory meetings with 12 percent of the facilities with initial OAI classifications. FDA generally holds such meetings to encourage voluntary compliance when the violations do not warrant the issuance of a letter. For most of these facilities, this was the only action taken.

Enforcement actions. FDA brought enforcement actions against 2 percent of the facilities that received initial OAI classifications in FY 2007. FDA obtained injunctions against seven facilities and seized products at three facilities. FDA generally initiates enforcement actions in situations involving significant violations of Federal law. For example, FDA obtained an injunction after inspecting the same facility seven times in 6 years and consistently finding that the facility's seafood products were transported and refrigerated at inadequate

³³ Note that for 2 percent of facilities that received initial OAI classifications, FDA initiated multiple advisory actions, such as issuing a warning letter as well as holding a regulatory meeting.

temperatures. In another facility, FDA was able to prevent the sale of potentially adulterated food by seizing over 26,000 pounds of rice after an inspection revealed a widespread rodent infestation.

FDA lowered the classification of 29 percent of the food facilities that received initial OAI classifications

As noted earlier, under certain circumstances, FDA may choose to lower an inspection classification. FDA lowered the classifications of 29 percent of the facilities that received initial OAI classifications in FY 2007.³⁴ The most common reason that FDA district offices provided for lowering the classification was that other FDA district officials did not concur with an inspector's initial classification. The second most common reason for lowering the classification was that the facility either took or promised to take corrective actions to address violations identified during the inspection. In addition, a small number of these classifications were lowered because FDA headquarters officials did not approve the issuance of a warning letter.

FDA district offices appeared to be inconsistent in their approach to lowering classifications. For example, some district offices did not lower their OAI classifications after a facility promised to take corrective action, whereas other district offices did this more commonly. Similarly, some district offices lowered their OAI classifications when FDA headquarters did not approve the issuance of a warning letter, whereas other district offices retained the initial OAI classification. Finally, some district offices lowered the OAI classifications for which they had already taken regulatory action. In many of these cases, FDA reported lowering the classifications because the facilities' response to the action was deemed to be adequate.

FDA took no regulatory action against 25 percent of the food facilities that received initial OAI classifications

Of the facilities that received initial OAI classifications in FY 2007, FDA did not take regulatory action against 25 percent. This means that FDA did not take either an advisory action or an enforcement action against the facilities nor did it lower its initial classification. For over half of these facilities, FDA officials noted that they did not issue a warning letter due to their interpretation of FDA's technical guidance.

³⁴ In addition, FDA took regulatory action and then lowered the OAI classifications of 28 facilities.

Specifically, these officials reported that they did not issue a warning letter because the time it took the agency to prepare the letter exceeded the recommended 4-month timeframe for the issuance of warning letters, or because FDA had already issued a warning letter to the facility for a prior inspection. In other cases, FDA officials noted that they did not take regulatory action because they determined that the facilities had adequate plans in place to correct the violations. However, for 42 percent of the facilities with no regulatory action, FDA had no information about whether the facilities had corrected the violations.

For 36 percent of the facilities with OAI classifications in FY 2007, FDA took no additional steps to ensure that the violations were corrected

In FY 2007, 280 facilities received OAI classifications that were not lowered by FDA.³⁵ For 36 percent of

these facilities, FDA did not reinspect the facilities within a year of the inspection or review other evidence provided by facilities to ensure that the violations were corrected. If FDA does not ensure that violations are corrected in a timely manner, it is unable to guarantee that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe and free of disease-causing organisms, chemicals, or other harmful substances.

For the remaining facilities, FDA took additional steps to ensure that the violations had been corrected. Specifically, FDA reinspected 35 percent of the facilities within a year of the initial inspection. For an additional 30 percent of facilities, FDA reported that it reviewed some type of evidence from the facility that demonstrated that the facility had corrected violations. Examples of this evidence included photographs documenting corrections made in the facility, revised food labels documenting changes made to correct labeling violations, or a description of how employees were counseled as a means to improving food safety. It is important to note, however, that in the absence of another inspection, FDA may have been unable to verify whether the evidence provided was an accurate and truthful depiction of the corrections made by the facility.

³⁵ This excludes nine facilities that went out of business or ceased production. This number differs from the number presented in Table 3, possibly because our documentation review included classifications that had been lowered as of April 2009, whereas the FACTS data included classifications that had been lowered as of July 2008.

F I N D I N G S

In addition, for a large number of the facilities that were reinspected, FDA continued to find violations of FDA laws and regulations. Specifically, in 26 percent of facilities that were reinspected, FDA found violations that warranted OAI classifications. In another 47 percent of facilities that were reinspected, FDA found violations that warranted VAI classifications.



R E C O M M E N D A T I O N S

Our report found significant weaknesses in FDA's domestic inspections program. Notably, FDA inspects less than a quarter of food facilities each year and more than half of all food facilities have gone 5 or more years without an FDA inspection. If FDA does not routinely inspect food facilities, it is unable to guarantee that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe.

Our report also found that the number of violations identified in food facility inspections has declined over time and that food facilities most commonly received violations because FDA inspectors found insanitary conditions or unsafe food manufacturing and handling practices. In addition, nearly three-quarters of the facilities with OAI classifications had a history of significant violations, and some of those facilities refused to grant FDA officials access to their records. Because of the serious nature of these violations, FDA must take swift and effective action to ensure that the violations are remedied. However, we found that FDA took no regulatory action against a quarter of facilities with initial OAI classifications in FY 2007 and often did not take additional steps, such as reinspecting these facilities, to ensure that the violations were corrected.

Taken together, these findings demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary tools to prevent outbreaks of foodborne illness. Based on our findings, we recommend that FDA:

Increase the frequency of food facility inspections, with particular emphasis on high-risk facilities

FDA should attempt to inspect a higher proportion of food facilities within a 5-year period, as well as inspect a greater number of high-risk facilities. As part of this effort, FDA should consider developing guidelines for how frequently it should inspect food facilities, particularly those that are high risk.

R E C O M M E N D A T I O N S

Provide additional guidance about when it is appropriate to lower OAI classifications

FDA should develop more specific guidance describing when it is appropriate to lower OAI classifications. This guidance should encourage district offices to be consistent in their approach to lowering classifications. Greater consistency in FDA's approach will help to ensure that OAI classifications are adequately addressed and that the violations that led to the OAI classifications are remedied.

Take appropriate actions against facilities with OAI classifications, particularly those that have histories of violations

FDA should take appropriate regulatory action against facilities with OAI classifications that are not lowered. Facilities that receive OAI classifications have significant violations and FDA should take appropriate actions against these facilities.

In addition, FDA should take stronger actions against facilities that have a history of serious violations, particularly those that are cited for the same violations multiple times. FDA should also take stronger actions against facilities that do not voluntarily comply with requests to remedy violations. These actions could range from posting untitled letters on the FDA Internet site in situations where facilities fail to comply, to initiating a seizure or injunction.

Ensure that violations are corrected for all facilities that receive OAI classifications

FDA should take steps to ensure that violations are corrected within a reasonable amount of time from the initial inspection. Specifically, FDA should reinspect facilities that receive OAI classifications or conduct other followup activities to verify that the violations are remedied in a timely manner. In addition, FDA should develop more specific guidance about what steps it should take to ensure that violations are corrected.

Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements

Penalties should be levied against facilities that either fail to voluntarily correct violations or have a significant history of violations. Civil penalties could be an effective method of encouraging facilities to comply with statutory and regulatory requirements designed to safeguard the Nation's food supply.

R E C O M M E N D A T I O N S

Seek statutory authority to allow FDA access to facilities' records during the inspection process

This additional authority will help FDA to uncover additional violations that may otherwise go undetected and to determine the most appropriate actions to remedy those violations.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its response to the draft report, FDA noted that it was addressing many of the issues and recommendations noted in the report. FDA also noted that effective enforcement and compliance with FDA regulations will contribute to a stronger food safety system, and that improving the speed and predictability of followup to inspections is a top agency goal.

Specifically, FDA stated that it supported our two recommendations to seek additional statutory authority from Congress. It noted that it is seeking more effective enforcement tools and that it supports proposed legislation to expand civil penalties for food violations and to provide additional access to facilities' records. FDA also agreed with our recommendation that it provide additional guidance about when it is appropriate to lower OAI classifications and noted that it will revise its current guidance.

For the remaining three recommendations, FDA noted several actions it has taken, or plans to take, to address them. FDA stated that it received increased appropriations that have permitted it to increase the number of food facility inspections. In FY 2009, FDA increased the number of field staff for its food program and plans additional increases in FY 2010. It also stated that it has taken steps to implement our recommendations to ensure that appropriate actions are taken and that violations are corrected for all facilities that receive OAI classifications. Specifically, FDA noted that it had several new initiatives designed to ensure that enforcement actions it takes are swift, aggressive, and will have a positive impact on public health. Notably, FDA will make it a priority to follow up promptly and with the appropriate action for all facilities that receive warning letters.

FDA will also develop a new warning letter closeout process to ensure that all violations are addressed. Additionally, in cases in which FDA identifies significant health concerns or other egregious violations, it will no longer issue multiple warning letters to noncompliant facilities before taking enforcement actions.

R E C O M M E N D A T I O N S

We support FDA's efforts and continue to emphasize the importance of FDA taking appropriate and swift action and ensuring that violations are corrected in all facilities with OAI classifications. In addition, we ask that, in its final management decision, FDA more clearly indicate whether it concurs with each of the recommendations listed in the report.

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

A P P E N D I X A

Table A-1: Facilities Inspected by Industry, Fiscal Years 2004 and 2008

Top 10 Industries Inspected, FY 2008	Number of Facilities Inspected in FY 2004	Percentage of Facilities Inspected in FY 2004	Number of Facilities Inspected in FY 2008	Percentage of Facilities Inspected in FY 2008
Fishery/seafood products	3,803	45%	2,927	32%
Multiple food warehouses	1,575	12%	2,058	16%
Bakery products	2,230	41%	1,844	24%
Vegetables and vegetable products	1,491	23%	1,590	20%
Fruit and fruit products	1,321	25%	1,061	15%
Food services and conveyances	1,216	29%	855	22%
Multiple-food dinners	1,079	40%	816	22%
Soft drinks and water	755	29%	710	16%
Cheese and cheese products	786	60%	670	28%
Chocolate and cocoa products	427	32%	357	12%

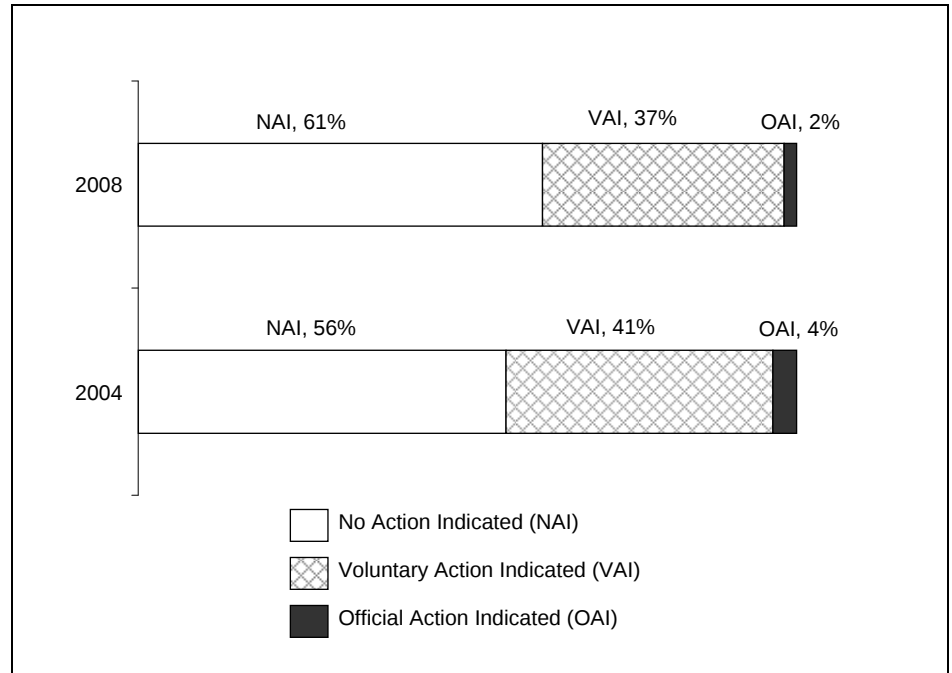
Note: The top 10 industries inspected were different for FYs 2004 and 2008.

Source: Office of Inspector General analysis of Food and Drug Administration data, 2009.



A P P E N D I X B

Figure B-1: Percentage of Inspected Food Facilities by Classification, Fiscal Years 2004 and 2008



Note: If a facility received more than one inspection classification in a year, we counted that facility as having received only the most significant classification.

Source: Office of Inspector General analysis of Food and Drug Administration data, 2009.

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: February 16, 2010
TO: Inspector General
FROM: Principal Deputy Commissioner of Food and Drugs
SUBJECT: FDA's General Comments to OIG's Draft Report entitled, *FDA Inspections of Domestic Food Facilities*, OEI-02-08-0080

FDA is providing the attached general comments to the Office of Inspector General's draft report entitled: *FDA Inspections of Domestic Food Facilities*, OEI-02-08-0080.

FDA appreciates the opportunity to review and comment on this draft report before it is published.

ISI

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of Food and Drugs

Attachment

FDA's General Comments to OIG's Draft Report entitled, *FDA Inspections of Domestic Food Facilities*, OEI-02-08-00080

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

FDA commends OIG's effort to take a comprehensive look at the US food safety system. This report, along with OIG's other recent work on food safety, is a useful snapshot in time of the food safety system as it has existed in recent years. OIG has identified areas of opportunity for enhancement in FDA's enforcement authorities. These reports also highlight the obligation and responsibility of industry for food safety and OIG has noted the need for better industry practices, such as improved traceability and accurate and timely registration. Effective enforcement and compliance with FDA regulations will contribute to a stronger food safety system that emphasizes prevention of harm to consumers; and is integrated with other food safety authorities for an effective approach to food safety inspections, which results in swift enforcement actions, sustained compliance, and quick identification and response to outbreaks of foodborne illness, as outlined by the President's Food Safety Working Group in July, 2009.

The recommendations in this report reflect FDA activities during the time period OIG studied (FY 2004 to FY 2007). FDA has already addressed many of the issues and recommendations noted in the report, and considerable progress is being made on the other recommendations. FDA appreciates OIG's support for FDA's continuing efforts to enhance food safety.

FDA also appreciates OIG's efforts to quantify several issues with respect to inspections from FY 2004 to FY 2007. FDA's internal analyses are not able to perfectly replicate these findings; however, FDA recognizes the importance of follow-up to make sure that public health is protected. Improving the speed and predictability of follow-up to inspections is a top agency goal.

Better targeting of FDA inspections to ensure the agency has the greatest public health impact through prevention of foodborne illness is also a central focus of future efforts to improve FDA's food safety program. This includes targeting sectors and facilities that pose the greatest risk and also focusing more of FDA's inspection activity on ensuring that within any facility, the firm is meeting its responsibility to prevent food safety problems. The agency believes there is significant opportunity to improve the public health productivity of FDA food inspections.

Additionally, FDA appreciates OIG's recognition of the gaps in the agency's authority with respect to inspections. FDA and the Administration support legislation to address these gaps.

New Authorities

- **OIG Recommendation:** Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.
- **OIG Recommendation:** Seek statutory authority to allow FDA access to facilities' records during the inspections process.

FDA is seeking more effective enforcement tools and supports OIG's legislative recommendations. Section 135 of the Food Safety Enhancement Act (FSEA) of 2009 (H.R. 2749) expands civil penalties for the Federal Food, Drug, and Cosmetic Act (FFDCA) violations related to food, and Section 106 gives FDA access to all records bearing on whether the food may be adulterated, misbranded, or otherwise in violation of the FFDCA. Routine records access is of particular importance to FDA because it will help to determine whether industry is both implementing proper preventive measures and complying with

recordkeeping requirements needed to respond to food safety problems or other public health emergencies. On July 29, 2009, a Statement of Administration Policy was issued in support of this bill.

Additionally, FDA and the Administration support several new legislative authorities that will allow the agency to prioritize prevention, strengthen surveillance and enforcement, and improve response and recovery. New food safety legislation, coupled with the necessary resources, will enable FDA to increase site inspections and to issue new, more modernized food safety regulations. Some necessary legislative authorities include:

- Enhanced ability to require preventive controls – By requiring companies to understand the hazards associated with foods under their control and then holding them accountable for implementing effective measures to prevent contamination, FDA will shift the emphasis of the agency's food safety system to the prevention of contamination, rather than mitigation of harm once contamination is discovered. Inspections can therefore focus on ensuring that preventive controls are in place rather than searching for sources of contamination.
- Flexible use of resources to target high risk food for maximum gain for public health – Flexibility is needed to tailor the mix of FDA inspections based on the best available data on risk. Additionally, FDA needs the ability to rely on inspections by other federal agencies as well as state, local, and foreign governments, and to establish a mechanism for some international inspections by certification of accredited third parties to perform inspections and determine compliance with FDA standards.
- Mandatory recall authority for foods – In cases where a food could cause adverse health consequences or death and a firm does not act promptly, it is important for FDA to have the authority to order a recall to remove the harmful product quickly from consumer channels to minimize illness or injury.

Increased Inspection Activities

- ***OIG Recommendation:*** Increase the frequency of food facility inspections with particular emphasis on high risk facilities

Since the timeframe for the OIG report, FY 2004-2007, the agency has received increased appropriations that have permitted the agency to increase the number of food facility inspections. For example, in fiscal year 2010, FDA will be able to increase field staff for the Foods Program to 2,505 from 2,166 in fiscal year 2009 and 1,806 in FY 2007. These field staff, once on board and trained, will allow the agency to increase the number of food facility inspections it performs annually.

In addition to FDA's efforts to increase the number of food inspections with these new resources, the Food Safety Enhancement Act (FSEA) of 2009 (H.R. 2749) and the Food Safety Modernization Act (FSMA) of 2009 (S. 510) both call for increased inspections. As the Commissioner pointed out, however, in recent testimony before the Senate Committee on Health, Education, Labor and Pensions, any food safety bill passed by Congress that calls for increased inspections must have a reliable, consistent funding source in order for FDA to fulfill its new inspections mandate and other responsibilities. Registration fees may provide a consistent source of funding, but the use of states for domestic inspections and third parties for foreign inspections may also provide the means to meet inspection targets. Improvements in the efficiency of how FDA uses its inspection resources to achieve public health goals will also contribute to meeting inspection targets. If these measures fall short of what is necessary to meet a target, Congress will have to consider the appropriate degree of flexibility for FDA to adjust the inspection frequencies.

In addition to increasing the number of inspections, FDA is applying information learned from the outbreak of *Salmonella* in peanut products to improve the inspection process and to identify potential food contamination issues. In 2008 and 2009, FDA began proactively approaching the prevention of foodborne illness by conducting intensive environmental sampling during certain FDA and state contract inspections that involved operations and food products more readily susceptible to pathogen contamination. Prior to this change, environmental sampling was initiated only when specific conditions observed during an inspection indicated that it was appropriate (so called, "for cause" sampling). Through this environmental sampling approach, unsuitable manufacturing conditions have been identified by FDA investigators which have resulted in corrective action at the processing facilities, as well as several product recalls to remove products from the market that were processed under unsuitable conditions.

The additional information gathered from environmental sampling provides FDA with broader situational awareness and will be considered in risk-based targeting and workplanning for field work. Also, since implementation, FDA has seen a number of firms adopt environmental sampling programs that assist in monitoring the in-plant conditions on a routine basis. Such an industry response is welcomed and encouraged since food safety is ultimately a shared responsibility between FDA, its regulatory partners, and industry.

Strong Enforcement Strategies

- ***OIG Recommendation:*** Take appropriate actions against facilities particularly those that have histories of violations.
- ***OIG Recommendation:*** Ensure that violations are corrected for all facilities that receive OAI classifications.

In August 2009, the Commissioner described enforcement as a core element in FDA's public health strategy to promote the health of the American public. Dr. Hamburg announced six initiatives to ensure that the enforcement actions the agency takes are swift, aggressive, and will have a positive impact on public health. The initiatives that address the OIG recommendations are as follows:

- ***Establishment of a Timeframe for Submission of Post-Inspection Responses*** establishes a timeframe for the inspected firm to submit post-inspection responses to FDA's findings (Form FDA-483) and thus facilitates the timely issuance of Warning Letters.
- ***Shift in Office of Chief Counsel's Review of Warning and Untitled Letters*** to limit review to certain areas and significant legal issues, thus streamlining the process.
- ***Development of Risk Control and Enforcement Strategies with our Regulatory Partners*** in situations when the public health is at risk and where local, state, and international officials may have the authority to take action more quickly than FDA.
- ***Warning Letter and Recall Follow-Up Inspections***; when a Warning Letter is issued or a recall with significant health implications occurs; FDA will make it a priority to follow-up promptly and with the appropriate action.
- ***Swift, Aggressive and Immediate Enforcement Action*** in cases where significant health concerns or egregious violations are identified. FDA will not issue multiple Warning Letters to noncompliant firms before taking enforcement action.

- *Warning Letter Close-Out Process:* if FDA determines that a firm has fully corrected the violations raised in a Warning Letter, FDA will provide the firm with a close-out letter, indicating that the issues in the Warning Letter have been successfully addressed.

OIG Recommendation: *Provide additional guidance about when it is appropriate to lower OAI classifications.*

FDA agrees with this recommendation and will revise the guidance in the ORA Field Management Directive #86: Establishment Inspection Report Conclusions and Decisions.



A C K N O W L E D G M E N T S

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

Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to the report include Lucia P. Fort, Vincent Greiber, and Bailey Gerstle Orshan; central office staff who contributed include Robert Gibbons and Sandy Khoury.

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