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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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DOMESTIC FOOD SAFETY

FDA Could Improve Inspection Program to Make Better Use of Resources

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GAO

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The Honorable John D. Dingell
Chairman, Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report responds to your request and later discussions with members of the Subcommittee staff regarding the Food and Drug Administration's (FDA's) use of resources for inspecting domestic food firms. The report presents the results of a briefing given to your staff and contains recommendations to the Secretary of Health and Human Services that will require the Commissioner of FDA to more efficiently and effectively use the agency's resources devoted to inspections of these firms.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the cognizant congressional committees and subcommittees, the Secretary of Health and Human Services, the Commissioner of FDA, the Director of the Office of Management and Budget, and other interested parties. We also will make copies available to others on request.

The major contributors to this report are listed in appendix III.

Sincerely yours,

Janet L. Shikles

Janet L. Shikles
Director, Health Financing
and Policy Issues

Executive Summary

Purpose

The Food and Drug Administration (FDA) is responsible for ensuring that the nation's food supply is safe, wholesome, and honestly labeled. To carry out its responsibilities, FDA is authorized to inspect the nation's food firms and to take action if problems are identified that may endanger the public health.

The Chairman of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to determine whether FDA was using its domestic food inspection resources efficiently. In response to the request, GAO examined whether FDA concentrated its resources on low-risk food firms—firms manufacturing what are considered low-risk health products—and whether FDA could make those resources available for higher priorities. GAO's review focused on (1) the criteria FDA used to select firms for inspection, (2) the frequency that FDA inspects low-risk and high-risk firms, and (3) the results of FDA's inspections.

Background

To carry out its domestic food safety responsibilities, FDA inspects firms that manufacture, process, pack, or hold food. To supplement its own inspection efforts, FDA also contracts with state agencies for inspections. In fiscal year 1987, FDA and its state contractors inspected about 11,500 domestic food firms. (Hereafter, unless otherwise noted, FDA and FDA-contractor inspections are referred to as FDA inspections.)

FDA performs food inspections for surveillance and compliance purposes. FDA does routine surveillance inspections at firms with no known history of serious problems to evaluate how well the industry as a whole is complying with FDA standards. When FDA knows of or suspects a problem at a firm it performs a compliance inspection to determine whether the firm has corrected the problem or to discover the extent of any suspected problems.

Results in Brief

GAO found that FDA spends over 50 percent of its food inspection resources on establishments that (1) pose low health risks, (2) are inspected regularly by state agencies apart from FDA-contracted inspections, and (3) have no history of serious violations. Except for food canners and infant formula manufacturers, which FDA considers to be producers of potentially high-risk food products, FDA has no criteria on how often domestic food firms should be inspected. FDA does require that canners having a good inspection history be inspected at least every 3 years and infant formula manufacturers be inspected annually.

In October 1986, FDA instructed its food safety staff to place more effort on inspecting firms having problems in previous inspections. This became known as FDA's "for cause" inspection strategy. This strategy was adopted to increase the efficiency and effectiveness of FDA's resources. However, FDA data for fiscal year 1987 showed that the agency continued to focus most of its inspections on low-risk firms (warehouses, bakeries, and bottlers) and did not inspect most of the firms with histories of violations. Although FDA has made some effort to reduce the number of low-risk firms it inspects, it could take additional actions to further reduce the number of these inspections. This would free up more of FDA's resources to inspect firms posing a greater health risk.

Principal Findings

Low-Risk Firms Receive Heavy Inspection Coverage

In fiscal year 1987, FDA instructed its field staff to concentrate their inspection resources on food firms with a history of violations. However, FDA did not specify how frequently these firms should be inspected. (See pp. 14-15.)

GAO's review of FDA food inspection data disclosed that many FDA districts continue to use a large amount of resources to make frequent inspections of low-risk firms. For example, in fiscal year 1987, FDA spent over half of its food sanitation inspection resources inspecting firms, such as warehouses, bakeries, and bottlers, which FDA considers low-risk firms. In contrast, FDA inspected fewer than half of the firms with histories of violations. In addition, FDA did not include firms with prior violations identified by FDA state contractors in its inspection schedule. (See pp. 15-20.)

FDA usually inspected these low-risk firms for routine surveillance purposes, and the inspections generally did not identify serious violations. Moreover, the resources FDA devoted to inspecting such firms resulted in many of them being inspected as frequently as drug and medical device firms that manufacture high-risk products and are required by law to be inspected at least once every 2 years. During the 4 fiscal years 1984-87, FDA inspected 37 percent of the warehouses, bakeries, and bottlers in the agency's food establishment inventory at least every 2 years, and it inspected some every year. (See pp. 19-20.)

FDA Duplicates Routine State Agency Inspections

In scheduling inspections, FDA does not consider the extensive level of state agency inspections other than those contracted for with state agencies. Each state has its own statutes, regulations, and agencies that regulate the quality and safety of food products. State agencies independently inspect the same firms as FDA, some as often as four times annually. In view of the significant state role in regulating food safety, GAO believes FDA should rely more on them for inspections, especially inspections of low-risk food firms. (See pp. 16-18.)

FDA Should Use Statistical Sampling to Help Select Firms Without Prior Violation Histories for Inspection

To assess the industry's overall compliance with its regulations, FDA believes that it needs to maintain the current level of routine surveillance inspections. About 90 percent of the inspections FDA performed in fiscal year 1987 were for this purpose. Alternatively, GAO believes that inspecting a statistically valid sample of these firms would allow FDA to make decisions about the nature of the food establishments in its inventory while requiring fewer resources than are now used to inspect every establishment in the inventory. (See pp. 18-22.)

Recommendations

GAO recommends that the Secretary of Health and Human Services direct the Commissioner of FDA to

- reduce its inspection of firms that the states routinely inspect under their own programs;
- develop a policy on the frequency of food inspections that incorporates the use of statistical sampling to monitor low-risk and nonproblem firms; and
- instruct FDA's district offices to target all firms with histories of violations, including those identified by state contract inspections, in its plans for future inspections. (see p. 23).

Agency Comments

Although FDA said that it disagreed with the premise for GAO's findings, FDA concurred with GAO's recommendation to reduce the inspection of firms that state agencies routinely inspect. FDA also agreed with GAO's recommendation to develop a policy on the frequency of inspections, but it stated the agency does not have the resources to develop an appropriate statistical sampling scheme. GAO believes that FDA may have misinterpreted the intent of its recommendation to include state contract inspection results in its future inspection plans. GAO has clarified this recommendation. GAO is emphasizing that in planning future inspections FDA should target not only the firms it has found to be in violation of

federal standards but also firms that the states have found to be in violation. (See pp. 23-26.)

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Abbreviations

FDA	Food and Drug Administration
GAO	General Accounting Office
HHS	Department of Health and Human Services
OEI	official establishment inventory
ORA	Office of Regulatory Affairs
PODS	program oriented data system

Introduction

The Commissioner of the Food and Drug Administration (FDA) testified during congressional hearings that in 1988, the food industry represented an estimated $450 billion business in the United States.[1] The prime responsibility for ensuring the safety of food products rests with the industry. However, the Federal Food, Drug and Cosmetic Act gives FDA the authority to regulate food and to inspect firms in which food is manufactured, processed, packed, or held,[2] and to take action if problems are identified that may endanger the public's health.

Concerned with whether FDA was using its food inspection resources effectively and whether FDA could improve how it uses these resources, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to review FDA's use of resources for inspecting domestic food establishments. Specifically, the Chairman wanted to know whether FDA concentrated its resources on low-risk food firms—firms manufacturing what are considered to be low-risk health products—(see p. 10) and whether these resources could be made available for higher priorities.

Background

FDA, an agency of the Department of Health and Human Services (HHS), is responsible for regulating foods, cosmetics, human drugs and biologics, medical devices and radiological products, and animal drugs and feeds. To carry out its regulatory mission in fiscal year 1988, FDA had a budget of $477.5 million; $126 million of this was allocated to its food regulatory program. The objective of FDA's food regulatory program is to assure that the nation's food supply is safe, wholesome, sanitary, and honestly labeled.

FDA has authority to take action when it finds foods to be adulterated or misbranded. Food is adulterated if, among other things, it (1) contains any poisonous or deleterious substances that may injure health (e.g., pathogenic bacteria or their toxins); (2) consists of any filthy, putrid, or decomposed substance or is otherwise unfit for use as food; or (3) has been prepared, packed, or held under insanitary conditions making it injurious to health.

Food is misbranded if, among other things, (1) its labeling is false or misleading or (2) it is offered for sale under the name of another food.

[1] House Hearings, Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies Appropriations for 1989, Part 8, p. 431.

[2] Meat, poultry, and eggs, however, are regulated by the Department of Agriculture.

FDA regulatory activities range from letters requesting firms to correct problems that have potential for causing product adulteration, to court ordered seizures of adulterated or misbranded products and injunctions forbidding an establishment to continue its operations until it corrects the deficiencies.

FDA's monitoring of the food industry is part of its foodborne biological hazards program, which, in fiscal year 1988, had a budget of $48.1 million. This represents 38 percent of FDA's $126 million budget for food regulation activities and 10 percent of its total budget. This program focuses on reducing the incidence of microbial contamination, filth, decomposition, and other adulteration of the nation's food supply. Regulation of domestic food safety is a major part of the program.

FDA's Organization and Approach to Monitoring the Food Industry

FDA carries out its food regulatory responsibilities through two organizational components: the headquarters based Center for Food Safety and Applied Nutrition (Center for Foods) and its field operations, directed by the headquarters Office of Regulatory Affairs (ORA). The Center for Foods is one of five product-oriented centers.[3] In conjunction with ORA, it establishes the basic policies FDA uses in implementing its food monitoring activities. ORA, FDA's investigative arm, exercises direct-line authority over the agency's field operations and is the central point to which headquarters officials can turn to for field support services.

FDA's field workforce performs inspections, makes and analyzes sample collections, and initiates regulatory actions for all of FDA's major product areas, including foods. The field operation, which comprised about 40 percent of FDA's fiscal year 1988 staffing level of about 7,100, includes 21 district offices and 130 resident posts located in the 50 states, the District of Columbia, and Puerto Rico.

For the domestic food safety program, ORA distributes inspection resources to the field based on each district's respective workload. ORA allocates 20 percent of available resources based on the proportion of time districts spent inspecting problem firms in the prior 3 years. ORA distributes the remaining 80 percent of resources based on the number and types of food firms in each district's inventory. In fiscal year 1988, FDA allocated its district offices a total of 150 staff years for domestic

[3]The other four are: the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, The Center for Devices and Radiological Health, and the Center for Veterinary Medicine.

food safety program activities. FDA supplements its field inspections of domestic food establishments through contracts with states to conduct inspections within their boundaries. In fiscal year 1988, FDA had contracts with 35 states and Puerto Rico valued at about $2.4 million.

In fiscal year 1987, FDA, together with its state contractors, inspected 11,468 firms. Hereafter in this report, unless otherwise noted, we refer to FDA and FDA-contractor inspections as FDA inspections.

High- and Low-Risk Food Firms

FDA's inventory of food establishments that are subject to inspection consists of firms handling food products considered to pose a potentially high health risk or little or no health risk to the public. A firm is considered potentially high-risk if its product is susceptible to microbial contamination if the firm does not follow good manufacturing practices in processing the product.[1] Such products include seafoods; eggs; products containing eggs, such as macaroni and noodles; and low-acid canned foods. Canned foods (particularly those with a low-acid content), if improperly processed, can provide an environment for the growth of a microorganism whose toxin causes the potentially fatal food poisoning known as botulism. The foods most commonly recognized as being low-acid canned foods are canned vegetables and soups.

Low-risk food firms include warehouses, bottlers, and most bakeries (primarily those that produce bread and bread products, which make up the majority of bakeries in FDA's inventory). FDA considers warehoused products as low-risk because they are not changed by manufacturing or processing procedures. FDA considers bakeries and bottlers to be low-risk firms because their products are not as susceptible to microbial contamination during the manufacturing process.

Objectives, Scope, and Methodology

We reviewed FDA's inspections of domestic food firms and concentrated on those firms considered to pose a low risk to the public health. We focused our review on the following three issues:

- the criteria FDA uses to select firms for inspections,
- the frequency that FDA inspects low-risk firms, and
- the results of these inspections.

[1]Good manufacturing practices provide criteria for food establishments to follow to assure that food is safe and has been prepared, packed, and held under sanitary conditions.

Our review work was performed at FDA headquarters in Washington, D.C., and Rockville, Maryland. We also performed work at FDA's Atlanta, Baltimore, Detroit, Minneapolis, and San Francisco district offices. Focusing on these districts gave us broad geographic coverage of FDA food establishment inspection efforts. These districts cover all or part of 14 states, 11 of which made food safety inspections under contracts with FDA.

To determine the number and annual percentage of domestic food firms inspected nationwide, we analyzed two FDA automated information system data files—the Program Oriented Data System (PODS) and the official establishment inventory (OEI). We also used the PODS data file information and FDA-created PODS tables to identify the outcomes (serious or not serious conditions) of inspections.

To provide establishment-specific information on inspections, we reviewed inspection reports on 320 randomly selected warehouse, bakery, and bottler firms and inspection reports on 11 food canners located in the five districts we visited. The reports covered inspections made in fiscal years 1984 through 1987.

During our visits to FDA headquarters and district offices we reviewed FDA policies, procedures, and practices concerning the agency's

- food monitoring strategy and associated allocation of resources,
- coordination with state food monitoring agencies to minimize duplication of effort and maximize regulatory effectiveness,
- oversight efforts to assure the completeness and uniformity of its automated information system data files, and
- internal evaluations of food monitoring programs.

Our work at state agencies included visits to one state agency (Michigan) and telephone contacts with agency representatives in 12 other states (California, Georgia, Illinois, Maryland, Massachusetts, Minnesota, New Jersey, New York, Pennsylvania, South Carolina, Texas, and Virginia). We conducted interviews with officials and program representatives of these state agencies and reviewed available state agency annual reports. The objective was to (1) determine the extent to which state agencies inspect food establishments independent of FDA and (2) obtain state officials' opinions on efforts and successes in coordinating food firm inspections with FDA.

We performed our work between April 1988 and April 1989 in accordance with generally accepted government auditing standards.

FDA's Field Inspection Resources Are Not Effectively Utilized

In October 1986, FDA's Center for Foods instructed FDA's field staff to concentrate inspections on firms with a history of violations. The objective was to increase the efficiency and effectiveness of FDA's resources. Despite these instructions, in fiscal year 1987, FDA and its state contractors spent over 53,100 hours or about 57 staff years[1] inspecting low-risk food firms—warehouses, bakeries, and bottlers. This represented over half of the FDA resources spent on domestic food inspections that year. Many of these inspections duplicated state inspections of the same firms. Further, over 90 percent of FDA's inspections of warehouses, bakeries, and bottlers were of firms with no recent history of violations. FDA inspected many of these firms repetitively even though it found no problems. In addition, FDA inspected fewer than half of the firms with prior violations in 1987.

Faced with budget cuts and competing demands, FDA has reduced by over 40 percent the number of inspections of warehouses, bakeries, and bottlers (see app. I) from fiscal years 1984 to 1987. However, FDA continues to inspect a substantial percentage of these types of establishments each year.

Criteria Concerning Food Inspection Monitoring

FDA monitors the safety of domestic food primarily through inspections of warehouses, manufacturers, packers/repackers, and other types of food establishments. FDA inspects for adherence to sanitary conditions and the food manufacturing process. The sanitation phase of the inspection focuses on such things as rodent and insect infestation and other conditions that could contaminate food products. Inspection of the manufacturing process concerns the quality controls that are in place to assure compliance with good manufacturing practices.

FDA carries out two types of food inspections—surveillance and compliance. Surveillance inspections are routinely done on firms with no known serious problems at the time of the inspections to gauge overall industry compliance with good manufacturing practices. Compliance inspections are generally done when FDA knows or suspects problems exist at a firm. Most compliance inspections also involve follow-up visits to assess whether the firms have corrected serious problems identified during previous inspections.

[1]Based on a conversion factor of 930 hours per staff year, which FDA uses for preparing its annual work plan for inspection personnel.

FDA requires that canners of low-acid food with a good inspection history be inspected at least every 3 years and infant formula manufacturers be inspected annually. Except for these requirements, FDA has not established a policy on how often inspections of nonproblem food firms should be performed. Although FDA instructed its field staff to concentrate their resources on firms with a history of violations, it has not specified how frequently these firms should be inspected.

In March 1987, the Commissioner of FDA testified during congressional appropriations hearings that in view of budget constraints FDA had moved to reduce its many routine surveillance inspections.[2] In October 1986, FDA directed its field inspectors to focus on an inspection strategy that targeted firms with violative inspection histories. The Commissioner also said firms with nonviolative histories would be inspected less frequently. This became known as FDA's "for cause" inspection strategy.

The "for cause" strategy was adopted after a study by FDA's Office of Planning and Evaluation that examined inspection records for FDA food inspections done during fiscal years 1978 through 1985. The study showed that establishments with violations during the prior 6 years were more than three times as likely to be violative during the next inspection than those with no prior violations. In fiscal year 1987, FDA amended its instructions to include, as an additional inspection priority, establishments with histories of sanitation violations.

Low-Risk Firms Receive Heavy Inspection Coverage

FDA's district offices determine the number, type, and specific firms to be inspected with a minimum of guidance from FDA headquarters. District offices maintain an official establishment inventory (OEI), which is a detailed inventory of food establishments subject to FDA inspection. The OEI provides the principal basis on which FDA allocates inspection resources to its field offices.

[2]House Hearings, Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies Appropriations for 1988, Part 5, pp. 511-772.

At the end of fiscal year 1987, the OEI contained about 48,400 food firms,[3] about half of which were warehouses. The rest were manufacturers, packers/repackers, and other firms dealing in foods that FDA groups into over 30 different product categories.[4]

Warehouses, bakeries, and bottlers account for a large part of FDA's food firm inventory and FDA uses a large amount of its resources to inspect them. As shown in table 2.1, about 61 percent of all food establishments in FDA's inventory were warehouses, bakeries, or bottlers.

Table 2.1: FDA Inventory of Food Firms at the End of Fiscal Year 1987

Type of firm	Number of firms	Percent of all food firms
Warehouse	24,388	50.4
Bakery	3,199	6.6
Bottler	1,833	3.8
Subtotal	**29,420**	**60.8**
Other food firms	18,978	39.2[a]
Total	**48,398**	**100.0**

[a]These are the manufacturers, packers/repackers, and miscellaneous firms dealing in the FDA food categories cited in footnote 4 of this chapter, exclusive of bakeries and bottlers. Some of these firms, such as processors of beans, peas, or corn in sauce, (low-acid canned foods) are high-risk firms.

We found that, notwithstanding the low-risk nature of warehouses, bakeries, and bottlers, they were the subject of a high number of FDA's food firm inspections performed in fiscal years 1984 through 1987. As shown in table 2.2, in each of these fiscal years, over 62 percent of the food firms inspected involved these three types of firms. Appendix I shows by district the numbers of warehouses, bakeries, and bottlers inspected by FDA in fiscal years 1984 through 1987.

[3]This represents the number of firms under single ownership at one location. It does not include the number of establishments (manufacturer, packer, repacker, etc.) associated with each firm.

[4]These include bakery foods, macaroni and noodles, cereal and breakfast foods, snack foods, dairy, fishery/seafood, fruits and fruit products, vegetable and vegetable products, soft drinks and waters, coffee and tea, candies and chocolates, soups, and baby foods.

Table 2.2: Comparison of Warehouse, Bakery, and Bottler Firms Inspected With Total Food Firms Inspected (Fiscal Years 1984-87)

	Number of firms inspected					
Fiscal year	Warehouse	Bakery	Bottler	Three group total	All food firms	Three groups as a percentage of all firms inspected
1987	5,371	1,132	665	7,168	11,468	62.5
1986	7,215	1,422	938	9,575	15,053	63.6
1985	9,380	1,683	1,059	12,122	18,170	66.7
1984	10,648	1,951	1,240	13,839	20,124	68.8

Our analysis of FDA's fiscal year 1987 inspection data also showed that the same three types of firms accounted for over half of FDA's inspection time. Specifically, in fiscal year 1987, FDA spent about 51 percent (53,100 of 103,200 staff hours) of the food sanitation inspection time on warehouse, bakery, and bottler inspections.

FDA Food Firm Inspections Duplicate Inspections Routinely Made by States

In addition to the high frequency of FDA inspections of warehouses, bakeries, and bottlers, many state agencies also routinely inspect these same firms as a part of their own food safety program. Each state has its own statutes, regulations, and agencies that regulate the quality and safety of food products. States also have the authority to inspect all food establishments within their boundaries. FDA told us that although the extent of inspection coverage varies among the states, the states have great capability, interest, and authority in the food sanitation area.

Regarding the quality of state inspection programs, ORA officials told us that generally state inspectors have the same qualifications as FDA inspectors and FDA provides training and technical assistance for food establishment inspections to states. In addition, FDA makes independent reinspections to evaluate state inspections done under FDA contracts. ORA officials told us that in such reinspections FDA generally finds no deficient performance by states.

As shown in table 2.3, an ORA Division of Federal-State Relations survey found state agencies inspected on average each bakery, warehouse, and bottler in its inventory at least once per year. As shown in appendix II, FDA also conducts many inspections of these firms. Because of the frequency of the state inspections, we believe that FDA's inspection of these firms could be further reduced.

Table 2.3: Annual State Agency Inspections of Warehouses, Bakeries, and Bottlers (State Fiscal Year 1987[a])

Type of firm	Number of states reporting	Number of inventory firms[b]	Number of inspections	Annual average number of inspections
Warehouse	38	15,693	17,699	1.1
Bakery	40	18,384	22,271	1.2
Bottler	36	2,448	2,889	1.2

[a]Not all states had complete fiscal year 1987 data. Those that did not provided fiscal year 1986 data.

[b]There is not a one-to-one correspondence between FDA's OEI and state inventories. For example, the FDA OEI excludes retail bakeries doing no wholesale business and bakeries selling 75 percent or more of their products to retail consumers on premises and doing less than $500,000 annual sales volume.

Some states made more frequent inspections than others. For example, one state agency reported an inventory of 391 bakeries and 431 warehouses that received 1,591 and 1,692 state inspections, respectively; an average of about 4 inspections annually. State agency officials informed us that their state agencies routinely inspect food firms four times annually. Officials from two other states told us that they routinely inspect the same food establishments that FDA inspects.

In an earlier report,[5] we recommended that FDA take into account the level of state inspection efforts and determine which firms also subject to FDA inspection should be removed from its inventory.[6] However, our analysis of FDA's 1987 inspections and its current resource allocation process showed that FDA has not integrated independent state inspection efforts into its planning and scheduling of food inspections. FDA does not take independent state agency food firm inspections into consideration because it does not routinely receive state inspection reports.

If FDA does not have state inspection reports, it could review its inventory and categorize firms into several classes of inspectional priorities using available summary data on state coverage. For example, if certain states are inspecting all bakeries or warehouses in their jurisdictions annually or more often, FDA could significantly reduce its inspections of such firms.

[5]Food Inspections: FDA Should Rely More on State Agencies (GAO/HRD 86-2, Feb. 18, 1986).

[6]There is precedent for reliance on independent state agency efforts. Although FDA has the authority to monitor the retail segments of the industry (food stores, restaurants, and vending locations) it has traditionally relied on state and local government agencies to inspect retail food establishments. HHS, in commenting on our 1986 report, stated that FDA continues to coordinate its inspection efforts with state agencies to reach a level of surveillance that would optimize food safety while best using limited resources.

Implementation of the "For Cause" Strategy Not Working

Most inspections of warehouse, bakery, and bottler firms continue to be for surveillance purposes and FDA does not inspect all firms with a violation history. FDA fiscal year 1987 inspection data showed that about 90 percent of the food sanitation inspections were for surveillance purposes. Moreover, an FDA Office of Planning and Evaluation review of how FDA was implementing its "for cause" strategy noted that FDA inspected fewer than half of the firms with prior violations in 1987. This review showed that there were 1,745 "for cause" firms at the start of fiscal year 1987. Of these (which included both low- and high-risk firms), 819, or fewer than half, were inspected during the year. This did, however, represent an increase of 325 more "for cause" inspections in 1987 over the previous year.

An additional problem with FDA's implementation of this strategy is that FDA did not identify for inspection all of the violative firms. Our comparison of listings of firms with prior violations (which were available in four district offices we visited) with randomly selected warehouse, bakery, and bottler firms selected from a list of such firms inspected in fiscal year 1987, showed that FDA had identified fewer than half of the firms that had violative conditions in fiscal years 1984 through 1987.[7] This happened because FDA did not screen its inspection information to select violative firms identified by FDA contracted inspections.

Inspections of more firms with prior violations did not occur because FDA did not place a high enough priority on such inspections. Specifically, food safety program guidance instructed district offices to consider several priorities when deciding how program resources should be expended. When we discussed the possibility of more clearly mandated directions with ORA officials, they told us that field managers are in the best position to determine how inspection resources should be utilized and that it was not possible for ORA to closely direct the field workforce.

FDA Inspections Identify Few Problems

Many warehouses, bakeries, and bottlers are receiving repetitive FDA inspections that identify few problems. During the 4 fiscal years 1984 through 1987, FDA inspected 37 percent of these firms at least every 2 years. These repetitive inspections are generally not based on problems discovered in prior inspections and usually do not uncover new problems. For example, we found one warehouse that FDA inspected five

[7]Specifically, of the 223 firms inspected by FDA and its contractors whose records we looked at, 45 had been found violative. Only 18 of these firms were on the "for cause" lists. The remaining 27 firms were not on the list because they were found to be violative through FDA contracted inspections.

times between February 1984 and November 1987, none of which identified any problems. During the same time, the state inspected the same warehouse twice and also found no problems.

To determine how frequently FDA made repetitive inspections, we identified how many warehouse, bakery, and bottler firms in each district's 1987 inventory FDA inspected in multiple years during the 4 fiscal year period 1984 through 1987. This analysis showed that nationally FDA inspected over 33 percent of the warehouses, about 54 percent of the bakeries, and about 63 percent of the bottlers in at least 2 of the 4 years.

Although we did not evaluate inspections of high-risk firms, inspection data on all firms showed that the frequency with which FDA inspected these firms was similar to FDA's inspections of warehouses, bakeries, and bottlers. FDA conducted these repetitive inspections of low-risk firms as often or more often than it inspected many drug and medical device firms that manufacture high-risk products and have a statutory biennial inspection requirement.

The repetitiveness varied greatly by district (see app. II). For example, FDA inspected all of the bottlers in the New Orleans and Nashville districts' inventories during at least 2 of the 4 years we reviewed and FDA inspected about 85 percent of them during 3 of the 4 years. In contrast, FDA inspected only about 8 percent of the Buffalo district bottlers in at least 2 of the 4 years. Table 2.4 summarizes, for the five districts we reviewed, the number of warehouses, bakeries, and bottlers that received FDA inspections in 2, 3, and 4 of the 4 fiscal years.

Table 2.4: Five District Comparison of Warehouses, Bakeries, and Bottlers Inspected in Multiple Years With District OEIs of Such Firms (Fiscal Years 1984-87)

			Firms inspected (FDA and FDA contracted) in multiple years as a percentage of OEI							
			2 of the 4 years		3 of the 4 years		4 of the 4 years		2, 3, or 4 of the 4 years	
Type of firm	Districts[a]	1987 OEI	Number of firms	Percent of OEI	Number of firms	Percent of OEI	Number of firms	Percent of OEI	Number of firms	Percent of OEI[b]
Warehouse										
	MIN	843	307	36.4	288	34.2	97	11.5	692	82.1
	SFO	1,179	245	20.8	19	1.6	1	.1	265	22.5
	ATL	1,642	330	20.1	130	7.9	6	.4	466	28.4
	BAL	1,001	248	24.8	302	30.2	114	11.4	664	66.3
	DET	1,057	366	34.6	87	8.2	18	1.7	471	44.6
	Combined	5,722	1,496	26.1	826	14.4	236	4.1	2,558	44.7
Bakery										
	MIN	143	80	55.9	47	32.9	22	15.4	149	104.2
	SFO	182	47	25.8	4	2.2	0	0.0	51	28.0
	ATL	169	47	27.8	10	5.9	20	11.8	77	45.6
	BAL	96	33	34.4	27	28.1	15	15.6	75	78.1
	DET	268	97	36.2	46	17.2	9	3.4	152	56.7
	Combined	858	304	35.4	134	15.6	66	7.7	504	58.7
Bottler										
	MIN	81	27	33.3	38	46.9	10	12.3	75	92.6
	SFO	100	20	20.0	2	2.0	0	0.0	22	22.0
	ATL	179	61	34.1	19	10.6	17	9.5	97	54.2
	BAL	102	25	24.5	37	36.3	25	24.5	87	85.3
	DET	100	40	40.0	22	22.0	7	7.0	69	69.0
	Combined	562	173	30.8	118	21.0	59	10.5	350	62.3

[a]These are the districts visited during our review: Minneapolis (MIN), San Francisco (SFO), Atlanta (ATL), Baltimore (BAL), and Detroit (DET)). Similar repetitive patterns were found for the other 16 districts (see app. III).

[b]Our computed multiple year inspection percentages may be slightly overstated or understated due to inventory decreases or increases between fiscal years 1984 and 1987. For example, the Minneapolis district bakery count as of the end of fiscal year 1986 was 155, 12 more than 1987. Because some of these additional bakeries received inspections, our computed percentage is greater than 100 percent. In contrast, the bakery count in two districts increased between 1986 and 1987.

We also reviewed fiscal year 1984 through 1987 FDA inspection records for randomly selected warehouses, bakeries, and bottlers to determine whether there were any specific reasons or special compliance problems that justified a high number of repetitive inspections for such firms. We found that FDA inspected these firms primarily for surveillance purposes

and that it discovered few serious problems. For example, in the Minneapolis district, FDA inspected 25 randomly selected warehouses a total of 78 times in the 4 years and in the San Francisco district, it inspected 24 randomly selected bakeries a total of 50 times in the 4 years. The records showed these inspections did not identify serious problems at about 92 percent (45 of 49) of the firms.

Nationally, most FDA food inspections are for surveillance purposes based on summary data obtained from FDA. For fiscal years 1984 through 1987, of the warehouses, bakeries, and bottlers FDA inspected, over 95 percent were for surveillance purposes. National statistics also showed that inspections of warehouses, bakeries, and bottlers generally identify few serious problems.

Each FDA inspection results in a report summarizing the conditions found and what action the FDA district will take based on the inspection results. We grouped FDA findings into two categories: (1) serious and (2) not serious. Serious problems involved inspections that found insanitary conditions, such as filth, rodent infestation, or poor quality controls, that had caused product adulteration or that, if not corrected, could lead to adulterated food. Not-serious problems involved inspections that found no insanitary conditions or minor conditions not likely to cause product adulteration. As shown in table 2.5, in fiscal years 1984 through 1987, an average of about 8 percent of the warehouses, bakeries, and bottlers inspected had serious problems.

Table 2.5: Incidence of Serious Problems at Warehouses, Bakeries, and Bottlers Receiving Inspections
(Fiscal Years 1984-87)

Fiscal year	Number of firms inspected	Number with serious problems	Percent of firms with serious problems
1987	7,168	663	9.2
1986	9,575	770	8.0
1985	12,122	970	8.0
1984	13,839	1,061	7.7
1984-87	42,704	3,464	8.1

As discussed earlier, the states also inspect annually the approximately 43,000 warehouses, bakeries, and bottlers FDA inspects. Since the states are routinely inspecting these firms, we do not see a need for FDA to use its inspection resources to also routinely inspect these same firms.

When we discussed the repetitive inspections of low-risk firms with FDA officials they told us that they believed this amount of coverage was justified. ORA officials said that a reduced amount of coverage would result

in a drop in food industry compliance and that the threat of an FDA inspection fosters compliance. One official said that inspections that found no problems were valuable in that they helped FDA define the compliance level of the food industry. The ORA officials also said that food firm inspections are used as vehicles for training inspection staff. The Center for Foods official who manages the foodborne biological hazards program said that monitoring sanitation remains a priority within FDA, and the number of problems identified justifies the resources expended.

As an alternative to inspecting every firm, FDA could stratify its inventory of firms into risk categories and tailor its inspection approach to include random sampling to identify low-risk firms for inspection. For example, under the medicated feed mill monitoring program, FDA's Center for Veterinary Medicine has divided the inventory of firms into two groups, high- and low-risk mills. The high-risk mills are inspected biennially. The low-risk mills are monitored by inspecting about 6 percent of them (identified by random sampling) annually. FDA's domestic food firm inspection strategy could be improved by adopting a similar approach.

Conclusions, Recommendations, and Agency Comments and Our Evaluation

Conclusions

Our analysis of 4 years of food sanitation inspection data, including the first year of implementation of FDA's "for cause" inspection strategy, showed that FDA inspected and continues to inspect a large number of nonproblem food firms. It used almost 57 staff years inspecting many firms (1) that the states inspect (2) whose products posed low health risks, and (3) with few prior problems.

FDA could significantly reduce its workload by further reducing inspections of firms that states routinely inspect and those with no history of serious problems. On the other hand, FDA should expand its inspections of firms with histories of prior violations. Presently, FDA targets for inspection only problem firms identified by its inspection staff. FDA should also target firms identified by state contract inspections as having violations for inspection.

FDA continues to direct over half of its domestic food inspections on low-risk, nonproblem firms. While FDA may need to assess the level of compliance by such firms with sanitation and manufacturing standards, it could reduce the number of inspections by developing a statistical sampling approach to inspecting these firms.

Recommendations to the Secretary of HHS

To more efficiently and effectively use the resources FDA devotes to domestic food sanitation inspections, we recommend that the Secretary of HHS direct the Commissioner of FDA to

- review FDA's current inventory of food firms and reduce its inspection of firms that the states routinely inspect as part of their own programs;
- develop a policy on the frequency of food inspections that incorporates the use of statistical sampling to monitor low-risk, nonproblem firms; and
- instruct FDA's district offices to target all firms with histories of violations, including those identified by state contract inspections, in its plans for future inspections.

Agency Comments and Our Evaluation

In commenting on a draft of this report, FDA disagreed with the report's premise. FDA said the report takes a simplistic view of a very complex FDA responsibility by concentrating on the relatively small resource savings that might be realized should FDA significantly further reduce inspection coverage of warehouses, bakeries, and bottlers.

FDA does not believe the report considers certain important, although intangible, aspects of FDA's inspection strategy that the agency must consider. These, according to FDA, include consumer expectations that FDA can and will assure that food is safe, wholesome, and honestly marketed; congressional expectations; the deterrent effect of an active inspection program; and FDA's commitment to uphold the law. FDA also indicated that duplicative inspections of certain low-risk firms contracted to state agencies may be justified in some circumstances, such as a follow-up to an outbreak of food poisoning or a consumer complaint. We agree with FDA that under such circumstances inspection overlap may be justified.

While FDA acknowledged that most warehouses, bakeries, and bottlers may be "low-health-risk" firms, it said that unless these firms follow good manufacturing and storage practices, the opportunity exists for violations of the law that could result in problems. Referring to table 2.5 in our report, FDA noted that the percentage of firms found to have serious problems increased from 7.7 in fiscal year 1984 to 9.2 in fiscal year 1987. FDA believes that a 9.2-percent rate of serious violations and the potential for problems justifies a significant level of inspection coverage as a deterrent to wrongdoing.

We recognize that FDA has major responsibilities to assure the safety of domestic food products and our recommendations are designed to further improve FDA's program. While FDA has taken steps to focus more of its inspection resources on firms that are most likely to be in violation of federal laws, it continues to spend more than half of its food sanitation resources inspecting the same low-risk firms that states are inspecting. On the other hand, FDA is not inspecting many firms with a history of violations that it should inspect under its policy.

We believe FDA needs to take additional steps to assure that it targets its resources to firms identified as being in violation of federal food sanitation laws. We also believe that if FDA follows our recommendations to further target its resources to firms with a history of food safety violations, the percentage of firms found to be in violation will, in all likelihood, further increase as it did during the first year of implementation of its "for cause" strategy and it will have made better use of its resources.

Although FDA disagreed with the premise for our findings, it concurred with our recommendation to reduce the inspection of firms that the states routinely inspect. FDA also agreed with our recommendation to

develop a policy on frequency of inspections, but it stated the agency does not have the resources to develop an appropriate statistical sampling scheme. FDA's response to our recommendation that it should include state inspection results in planning furture inspections did not specifically address the recommendation. FDA comments on each of our recommendations are presented in more detail below.

Reduce Inspections of Firms Routinely Inspected by State Agencies

FDA said that the 40-percent decrease in the number of inspections of warehouses, bakeries, and bottlers between fiscal years 1984 and 1987, as noted in our report, was due, in part, to recommendations made in a previous GAO report.[1]

To further this process, FDA said it will examine data for fiscal years 1988 and 1989 relating to both FDA and state contract inspections in the food sanitation area to refine its inspection targeting criteria. In addition, FDA will solicit the appropriate committees of the Association of Food and Drug Officials[2] to propose standard formalized agreements, which, when adopted by FDA and the various state agencies, would lead to a more closely integrated work planning process between the FDA districts and their state counterparts. FDA cautioned, however, that it must closely monitor the consequences of further reducing inspection coverage to guard against deterioration of the industries.

Policy on Frequency of Inspections Based on Statistical Sampling

FDA agreed that it needs to refine and clarify its guidance on the frequency of inspections. As a first step, FDA will review data from fiscal years 1988 and 1989 to determine if there is a continuation of repetitive nonviolative inspections. FDA said it will closely monitor its inspection activities in fiscal year 1990, to ensure that its criteria for inspection priorities are being followed. FDA said it had used statistical techniques in developing its "for cause" inspection strategy. Through the use of such techniques FDA found that firms with a previous history of violations have a higher probability of repeating violative actions than do those whose previous inspections did not detect any problems. Therefore, FDA targeted problem firms under the "for cause" strategy for inspection. If, according to FDA, it had the resources to provide appropriate statistical quality control expertise, FDA believes it could create a better scheme of inspection coverage. FDA said that any such program

[1]Food Inspections: FDA Should Rely More on State Agencies (GAO/HRD-86-2, Feb. 18, 1986).

[2]A national organization of federal, state, and local food and drug regulatory agency officials.

using statistical techniques would have to continue to be responsive to consumer complaints and to maintain a regulatory presence throughout the food industry, no matter what the level of risk assigned to a given process or product.

Need to Include State Inspection Results in Future Planning

FDA said that our finding that FDA inspected fewer than half of the firms with histories of violations does not appear to consider the corrective actions taken by management either during the inspection or subsequently. FDA further said that it did not believe any greater public health protection is achieved by FDA conducting follow-up inspections on violations identified by the states under contract. However, FDA may have misinterpreted the intent of our recommendation, which we have clarified.

We are not questioning FDA's procedures or practices relating to its attempts to achieve corrective action of violations found during inspections. We also are not recommending that FDA conduct follow-up inspections on violations identifed by the states. The state enforcement efforts appear to be effective in assuring that violations are corrected. However, in planning for future inspections, we believe FDA should target not only the firms it found to be in violation of federal standards in its inspections, but also firms that the states found to be in violation.

FDA Warehouse, Bakery, and Bottler Inspections by District (Fiscal Years 1984-87)

The following tables show the percent of warehouses, bakeries, and bottlers that were inspected by FDA and its contractors during fiscal years 1984-87.

Table I.1: Warehouses—Percent of FDA and Contractor Inspections by FDA District (Fiscal Years 1984-87)

District	OEI warehouse 1987	Firms inspected, 1987		Firms inspected, 1986		Firms inspected, 1985[a]		Firms inspected, 1984[a]	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
Los Angeles	1,062	201	18.9	272	25.1	334	30.8	381	35.1
Minneapolis	843	368	43.7	491	54.9	598	66.8	746	83.4
New Orleans	1,044	324	31.0	484	45.4	560	52.6	574	53.9
Brooklyn	943	182	19.3	111	13.3	105	12.6	199	23.8
Philadelphia	1,012	316	31.2	274	25.9	752	71.2	657	62.2
San Francisco	1,179	343	29.1	263	20.8	450	35.7	478	37.9
Seattle	1,309	434	33.2	664	50.1	915	69.0	805	60.7
Nashville	924	249	26.9	270	30.5	409	46.2	403	45.5
Orlando	771	195	25.3	328	40.6	386	47.8	280	34.7
San Juan	586	119	20.3	66	11.1	78	13.1	99	16.6
Newark	1,162	34	2.9	176	20.4	276	31.9	283	32.8
Kansas City	2,009	252	12.5	225	10.0	417	18.5	510	22.7
Atlanta	1,642	288	17.5	355	22.1	416	25.9	942	58.7
Baltimore	1,001	386	38.6	496	49.0	588	58.0	668	65.9
Boston	925	164	17.7	287	30.9	243	26.1	461	49.6
Buffalo	1,050	100	9.5	156	15.8	234	23.7	319	32.3
Chicago	1,229	348	28.3	466	38.1	368	30.1	339	27.7
Cincinnati	963	181	18.8	237	25.5	317	34.2	230	24.8
Dallas	1,998	439	22.0	950	45.2	1,194	56.8	1,384	65.9
Denver	1,679	198	11.8	281	15.9	302	17.0	343	19.4
Detroit	1,057	250	23.7	363	32.9	438	39.7	547	49.5
Nationwide	**24,388**	**5,371**	22.0	**7,215**	29.3	**9,380**	38.1	**10,648**	43.3

[a]Percent of firms inspected computed using fiscal year 1986 OEI data because 1985 and 1984 data were not available. A comparison of an earlier OEI file (1982) with the fiscal year 1986 and 1987 files showed that the absolute count of firms remained relatively the same.

Table I.2: Bakeries—Percent of FDA and Contractor Inspections by FDA District (Fiscal Years 1984-87)

District	OEI bakeries 1987	Firms inspected, 1987		Firms inspected, 1986		Firms inspected, 1985[a]		Firms inspected, 1984[a]	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
Los Angeles	157	38	24.2	63	39.1	83	51.6	104	64.6
Minneapolis	143	77	53.8	108	69.7	123	79.4	143	92.3
New Orleans	71	22	31.0	52	71.2	48	65.8	51	69.9
Brooklyn	127	34	26.8	34	25.6	44	33.1	21	15.8
Philadelphia	143	60	42.0	56	37.6	90	60.4	130	87.2
San Francisco	182	59	32.4	35	18.4	71	37.4	82	43.2
Seattle	121	62	51.2	72	61.0	85	72.0	99	83.9
Nashville	83	42	50.6	51	58.6	63	72.4	63	72.4
Orlando	117	61	52.1	89	71.8	106	85.5	157	126.6
San Juan	274	54	19.7	63	23.4	66	24.5	93	34.6
Newark	286	51	17.8	84	36.4	106	45.9	166	71.9
Kansas City	120	46	38.3	31	24.6	57	45.2	57	45.2
Atlanta	169	63	37.3	69	42.6	68	42.0	87	53.7
Baltimore	96	48	50.0	61	67.0	65	71.4	68	74.7
Boston	120	30	25.0	49	40.2	49	40.2	69	56.6
Buffalo	83	24	28.9	34	33.0	37	35.9	16	15.5
Chicago	206	95	46.1	111	61.3	99	54.7	92	50.8
Cincinnati	116	60	51.7	18	14.9	74	61.2	86	71.1
Dallas	254	88	34.6	169	63.3	196	73.4	194	72.7
Denver	63	26	41.3	28	39.4	30	42.3	19	26.8
Detroit	268	92	34.3	145	53.3	123	45.2	154	56.6
Nationwide	**3,199**	**1,132**	35.4	**1,422**	44.4	**1,683**	52.5	**1,951**	60.9

[a]Percent of firms inspected computed using fiscal year 1986 OEI data because 1985 and 1984 data were not available. A comparison of an earlier OEI file (1982) with the fiscal year 1986 and 1987 files showed that the absolute count of firms remained relatively the same.

Table I.3: Bottlers—Percent of FDA and Contractor Inspections by FDA District (Fiscal Years 1984-87)

District	OEI bottlers 1987	Firms inspected, 1987		Firms inspected, 1986		Firms inspected, 1985[a]		Firms inspected, 1984[a]	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
Los Angeles	112	21	18.8	38	34.9	48	44.0	54	49.5
Minneapolis	81	47	58.0	55	67.9	69	85.2	78	96.3
New Orleans	83	39	47.0	97	105.4	106	115.2	118	128.3
Brooklyn	31	11	35.5	6	19.4	2	6.5	5	16.1
Philadelphia	106	31	29.2	42	38.9	46	42.6	68	63.0
San Francisco	100	30	30.0	20	20.4	17	17.3	33	33.7
Seattle	72	27	37.5	37	50.7	36	49.3	56	76.7
Nashville	91	60	65.9	88	89.8	91	92.9	110	112.2
Orlando	54	21	38.9	29	48.3	42	70.0	37	61.7
San Juan	24	10	41.7	10	37.0	13	48.1	16	59.3
Newark	38	11	28.9	25	54.3	23	50.0	17	37.0
Kansas City	117	31	26.5	22	17.3	37	29.1	33	26.0
Atlanta	179	62	34.6	67	36.0	76	40.9	133	71.5
Baltimore	102	65	63.7	79	73.1	68	63.0	85	78.7
Boston	121	31	25.6	41	33.9	40	33.1	62	51.2
Buffalo	66	7	10.6	9	12.3	19	26.0	19	26.0
Chicago	65	36	55.4	43	64.2	40	59.7	33	49.3
Cincinnati	64	12	18.8	39	58.2	52	77.6	38	56.7
Dallas	159	61	38.4	114	68.3	143	85.6	157	94.0
Denver	68	15	22.1	27	29.0	31	33.3	27	29.0
Detroit	100	37	37.0	50	43.5	60	52.2	61	53.0
Nationwide	**1,833**	**665**	36.3	**938**	48.2	**1,059**	54.4	**1,240**	63.7

[a]Percent of firms inspected computed using fiscal year 1986 OEI data because 1985 and 1984 data were not available. A comparison of an earlier OEI file (1982) with the fiscal year 1986 and 1987 files showed that the absolute count of firms remained relatively the same

Comparison by District of 1987 OEI Warehouses, Bakeries, and Bottlers Inspected in Multiple Years (Fiscal Years 1984-87)

Many warehouse, bakery, and bottler firms in each district's OEI were inspected in 2, 3, or 4 of 4 fiscal years (1984 through 1987). The tables below provide data on these multiple inspections by district as well as nationwide. Firms inspected by both FDA and by state agencies under contract are accounted for in this analysis. Of particular note, these tables present the degree that districts varied in making the multiple inspections. Some districts inspected some types of firms frequently and other districts inspected the same types of firms infrequently.

Table II.1: Comparison by District of Warehouses Inspected in Multiple Years

		Number of years in which firms were inspected							
		2 of 4		3 of 4		4 of 4		2, 3, or 4	
	OEI warehouse	Firms inspected		Firms inspected		Firms inspected		Firms inspected	
District	1987	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Los Angeles	1,062	170	16.0	54	5.1	17	1.6	241	22.7
Minneapolis	843	307	36.4	288	34.2	97	11.5	692	82.1
New Orleans	1,044	163	15.6	178	17.0	140	13.4	481	46.1
Brooklyn	943	82	8.7	6	0.6	0	0.0	88	9.3
Philadelphia	1,012	409	40.4	98	9.7	13	1.3	520	51.4
San Francisco	1,179	245	20.8	19	1.6	1	0.1	265	22.5
Seattle	1,309	559	42.7	277	21.2	37	2.8	873	66.7
Nashville	924	192	20.8	90	9.7	29	3.1	311	33.7
Orlando	771	97	12.6	135	17.5	60	7.8	292	37.9
San Juan	586	47	8.0	7	1.2	2	0.3	56	9.6
Newark	1,162	120	10.3	25	2.2	2	0.2	147	12.7
Kansas City	2,009	186	9.3	36	1.8	14	0.7	236	11.7
Atlanta	1,642	330	20.1	130	7.9	6	0.4	466	28.4
Baltimore	1,001	248	24.8	302	30.2	114	11.4	664	66.3
Boston	925	244	26.4	29	3.1	10	1.1	283	30.6
Buffalo	1,050	75	7.1	8	0.8	3	0.3	86	8.2
Chicago	1,229	289	23.5	114	9.3	17	1.4	420	34.2
Cincinnati	963	194	20.1	68	7.1	11	1.1	273	28.3
Dallas	1,998	536	26.8	402	20.1	79	4.0	1,017	50.9
Denver	1,679	195	11.6	21	1.3	6	0.4	222	13.2
Detroit	1,057	366	34.6	87	8.2	18	1.7	471	44.6
Nationwide	**24,388**	**5,054**	20.7	**2,374**	9.7	**676**	2.8	**8,104**	33.2

Table II.2: Comparison by District of Bakeries Inspected in Multiple Years

		Number of years in which firms were inspected							
		2 of 4		3 of 4		4 of 4		2, 3, or 4	
	OEI bakeries	Firms inspected		Firms inspected		Firms inspected		Firms inspected	
District	1987	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Los Angeles	157	50	31.8	18	11.5	5	3.2	73	46.5
Minneapolis	143	80	55.9	47	32.9	22	15.4	149	104.2
New Orleans	71	21	29.6	15	21.1	13	18.3	49	69.0
Brooklyn	127	25	19.7	0	0.0	0	0.0	25	19.7
Philadelphia	143	65	45.5	26	18.2	2	1.4	93	65.0
San Francisco	182	47	25.8	4	2.2	0	0.0	51	28.0
Seattle	121	36	29.8	42	34.7	17	14.0	95	78.5
Nashville	83	21	25.3	23	27.7	18	21.7	62	74.7
Orlando	117	34	29.1	43	36.8	36	30.8	113	96.6
San Juan	274	41	15.0	3	1.1	1	0.4	45	16.4
Newark	286	79	27.6	38	13.3	0	0.0	117	40.9
Kansas City	120	36	30.0	19	15.8	2	1.7	57	47.5
Atlanta	169	47	27.8	10	5.9	20	11.8	77	45.6
Baltimore	96	33	34.4	27	28.1	15	15.6	75	78.1
Boston	120	36	30.0	27	22.5	0	0.0	63	52.5
Buffalo	83	17	20.5	4	4.8	0	0.0	21	25.3
Chicago	206	74	35.9	44	21.4	11	5.3	129	62.6
Cincinnati	116	46	39.7	26	22.4	2	1.7	74	63.8
Dallas	254	78	30.7	81	31.9	17	6.7	176	69.3
Denver	63	21	33.3	6	9.5	2	3.2	29	46.0
Detroit	268	97	36.2	46	17.2	9	3.4	152	56.7
Nationwide	**3,199**	**984**	30.8	**549**	17.2	**192**	6.0	**1,725**	53.9

Table II.3: Comparison by District of Bottlers Inspected in Multiple Years

		Number of years in which firms were inspected							
		2 of 4		3 of 4		4 of 4		2, 3, or 4	
	OEI bottlers	Firms inspected		Firms inspected		Firms inspected		Firms inspected	
District	1987	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Los Angeles	112	31	27.7	12	10.7	2	1.8	45	40.2
Minneapolis	81	27	33.3	38	46.9	10	12.3	75	92.6
New Orleans	83	38	45.8	49	59.0	21	25.3	108	130.1
Brooklyn	31	7	22.6	0	0.0	0	0.0	7	22.6
Philadelphia	106	41	38.7	12	11.3	2	1.9	55	51.9
San Francisco	100	20	20.0	2	2.0	0	0.0	22	22.0
Seattle	72	34	47.2	17	23.6	3	4.2	54	75.0
Nashville	91	21	23.1	45	49.5	37	40.7	103	113.2
Orlando	54	14	25.9	11	20.4	10	18.5	35	64.8
San Juan	24	11	45.8	4	16.7	0	0.0	15	62.5
Newark	38	9	23.7	5	13.2	1	2.6	15	39.5
Kansas City	117	21	17.9	8	6.8	2	1.7	31	26.5
Atlanta	179	61	34.1	19	10.6	17	9.5	97	54.2
Baltimore	102	25	24.5	37	36.3	25	24.5	87	85.3
Boston	121	38	31.4	14	11.6	2	1.7	54	44.6
Buffalo	66	4	6.1	1	1.5	0	0.0	5	7.6
Chicago	65	24	36.9	20	30.8	5	7.7	49	75.4
Cincinnati	64	30	46.9	18	28.1	0	0.0	48	75.0
Dallas	159	60	37.7	62	39.0	22	13.8	144	90.6
Denver	68	22	32.4	6	8.8	1	1.5	29	42.6
Detroit	100	40	40.0	22	22.0	7	7.0	69	69.0
Nationwide	**1,833**	**578**	31.5	**402**	21.9	**167**	9.1	**1,147**	62.6

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