

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

FDA FOOD SAFETY INSPECTION



**Richard P. Kusserow
INSPECTOR GENERAL**

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AUGUST 1991

EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection was to examine the authorities for and the breadth of domestic food safety inspections of low-risk food firms conducted by the Food and Drug Administration (FDA) and the States.

BACKGROUND

The FDA is responsible for assuring the safety of the nation's foods, drugs, medical devices, radiological products and cosmetics. Under the Food, Drug and Cosmetic Act, FDA's primary role in food sanitation is to monitor through inspections the conditions under which food is manufactured, processed, packed and stored.

In response to a September 1989 General Accounting Office recommendation that FDA reduce their inspections of low-risk food firms, FDA pointed out that problems with low-risk firms are of serious concern to the American consumer, and represent violations of the law. These firms, FDA stated, handle food products that are particularly susceptible to contamination. Large volumes of food improperly stored, bottled beverages contaminated by mold, and the use of contaminated raw baking ingredients represent a potential for problems, like outbreaks of food poisoning, that justify the use of a high level of inspection coverage.

METHODOLOGY

We contacted the 21 FDA district offices, and inspection agencies in all States, the District of Columbia, and Puerto Rico. We obtained descriptions of how the workplanning, priority setting, and enforcement processes actually work and how they might be improved. Respondents also gave their perceptions of whether low-risk food safety inspections act as a deterrent to insanitary food processing and storage conditions.

FINDINGS

- ▶ *Although FDA believes that the potential exists for serious problems with low-risk foods, FDA assigns a low priority to these inspections. States give a higher priority to these low-risk food safety inspections than does FDA.*
- ▶ *Not all food firms are known to FDA or the States. Respondents believe there are possible public health risks associated with unidentified firms, since they are not inspected.*

- ▶ *Food safety inspectors do not have all the enforcement tools they need to do an effective job.*
- ▶ *Despite efforts by Federal and State agencies and industry groups to promote uniformity, no national requirements exist for the inspection of low-risk food firms. Consequently, the public receives different levels of food safety, depending on their geographic location.*

RECOMMENDATIONS

The FDA, working with the States, should develop and seek legislative authority for a system to inspect low-risk food firms based on the following principles:

- ▶ there is a need for a complete and uniform system for inspecting low-risk food firms;
- ▶ the FDA's role should be in oversight, developing standards, and providing technical assistance to the States; and
- ▶ the States should have the responsibility for inspecting low-risk food firms.

At a minimum, the system should include the following recommendations.

- ▶ *The FDA should design a uniform system that ensures both a systematic identification of all food firms and collection of inspection results.*
- ▶ *The FDA should develop requirements for low-risk food safety inspections, and certify which States meet these requirements.*
- ▶ *Certified States should conduct inspections of low-risk food firms.*
- ▶ *The FDA should seek legislation to provide inspectors with the inspection tools necessary.*
- ▶ *The FDA should collect an inspection user fee from all food firms. This user fee will fund low-risk food safety inspection activities of both FDA and the States that meet FDA's certification requirements.*

AGENCY COMMENTS TO THE DRAFT REPORT

We received comments from the Public Health Service (PHS), FDA's parent agency, the Assistant Secretary for Planning and Evaluation (ASPE), and the Assistant Secretary for Management and Budget (ASMB). All respondents concurred in principle with the recommendations. The PHS asked for refinement of several recommendations, and suggested that the States' initial receptivity to a linkage of State certification with the user fee be measured.

OFFICE OF INSPECTOR GENERAL RESPONSE TO AGENCY COMMENTS

Responding to PHS' suggestion, the Office of Inspector General recontacted 10 States to gauge States' initial reaction to the recommendations. The States were unanimous in supporting the need for consistency in inspections. Eight of the 10 States supported the user fee concept to fund inspection activities as outlined in our recommendations.

We did not provide more exact details regarding the recommendations, as PHS suggested. Our view is that PHS, in concert with States, professional organizations, and industry, should determine the exact requirements and their planned implementation.

In response to concerns of ASPE and ASMB, the report was changed to indicate that we had no estimate of the eventual cost of the program suggested. The amount of the user fee in the report is shown as an example.

Technical revisions to the body of the report were also made as suggested by PHS.

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INTRODUCTION

PURPOSE

The purpose of this inspection was to examine the authorities for and the breadth of domestic food safety inspections of low-risk food firms conducted by the Food and Drug Administration (FDA) and the States.

BACKGROUND

The FDA is responsible for assuring the safety of the nation's foods, drugs, medical devices, radiological products and cosmetics. Under the Food, Drug and Cosmetic (FD&C) Act, FDA's primary role in food sanitation is to monitor through inspections the conditions under which food is manufactured, processed, packed and stored. Food firms' compliance with the FD&C Act is secured through inspections of facilities and products, analysis of samples, educational activities, and legal proceedings.

Food firms engaging in interstate commerce are regulated by FDA. State and local jurisdictions have authority over food firms within their boundaries, whether or not interstate commerce is involved.

The FDA inspects high-risk food firms that manufacture products that are highly susceptible to microbial contamination, like mayonnaise or low-acid canned foods. These foods, if improperly processed, can cause problems considered to be high-risk, like staphylococcal enterotoxin and histamines.

The FDA inspects low-risk food firms, which they define as bakeries, bottlers and food warehouses. The types of foods found in low-risk food firms vary widely. In bakeries, one would encounter raw foodstuffs such as flour, sugar and eggs, as well as finished products like bread and pastries. Soda pop, mineral water, and fruit juices are bottled or canned at bottling firms. Food warehouses store any raw materials or finished foodstuffs, from sacks of coffee beans to cartons of breakfast cereals.

Many FDA findings of insanitary conditions or practices are resolved through voluntary compliance from the firms rather than interdicting the suspect foodstuffs by a Federal court warrant, a lengthy and labor-intensive process. While all States have embargo authority, or immediate seizure power over domestic food products, FDA lacks this immediate seizure authority. This often makes it necessary for FDA to rely on States to detain adulterated food products. However, States' definitions of "adulterated" may differ from FDA's and, as a result, they may not be able to comply with every FDA embargo request.

Many factors impact on the level and frequency of inspection coverage of low-risk food firms. The FDA relies on its headquarters to provide national guidance through its Compliance Program Guidance Manual and on its 21 district offices to set priorities for low-risk food safety inspections. These district offices consider the full range of their other FDA inspection responsibilities, such as high-risk food firms, pharmaceutical firms and blood banks, in determining how many low-risk food safety inspections they will undertake. Staffing levels also affect this planning.

The FDA's strategy is to target violative firms for inspection. The FDA district offices consider food firms for inspection based on a combination of the following priorities:

- ▶ knowledge of the existence of potential problems;
- ▶ firms that produce a food product with a history of causing potential health problems;
- ▶ firms inspected during the past 6 years with violations serious enough to warrant product seizure, prosecution and/or injunction;
- ▶ firms that have never been inspected; and
- ▶ firms that have a violative history on a national level.

The FDA currently supplements its inspections by contracting with 36 States¹ to conduct food inspections. The FDA district offices perform audit inspections on a percentage of the firms inspected by States under contract.

The General Accounting Office (GAO) issued a report in September 1989 entitled "FDA Could Improve Inspection Program to Make Better Use of Resources." The GAO recommended, in part, that FDA reduce its inspections of low-risk food firms in States that routinely inspect these firms.

In response, FDA pointed out that problems with low-risk firms are of serious concern to the American consumer, and represent violations of the law. These firms, FDA stated, handle food products that are particularly susceptible to contamination. Large volumes of food improperly stored, bottled beverages contaminated by mold, and the use of contaminated raw baking ingredients represent a potential for problems, like outbreaks of food poisoning, that justify the use of a high level of inspection coverage.

¹Throughout this report, any reference to "the States" includes both Puerto Rico and the District of Columbia.

METHODOLOGY

Our inspection focused on FDA and States low-risk food safety inspection activities of domestic bakeries, bottlers and food warehouses. We considered these activities in light of the full range of responsibilities for these agencies.

This inspection was primarily a system review. No evidence gathered indicates an increase in food contamination. Rather, we addressed the potential for problems and methods to avoid them. We did not examine the methods used to inspect firms, nor perform any qualitative review of the inspections being performed.

Through open-ended discussions with the 21 FDA district office directors, we elicited information concerning their workplanning processes, use of resources, enforcement techniques, and the setting of priorities for low-risk food safety inspections. We personally visited FDA district offices in: Buffalo, New York; Baltimore, Maryland; Chicago, Illinois; San Francisco and Los Angeles, California; Orlando, Florida; Nashville, Tennessee; Kansas City, Missouri; Denver, Colorado; and the Indianapolis, Indiana resident post of the Detroit, Michigan district office. The other district directors were interviewed by telephone.

We also contacted all States to obtain similar information from State agency directors with responsibility for conducting low-risk food safety inspections. On-site contacts were made with State agency heads from New York, Rhode Island, Indiana, Florida, Tennessee, California, Kansas and Wyoming.

During our on-site visits at FDA district offices and the State agencies, we held discussions with food safety inspectors² to obtain descriptions of how the workplanning, priority setting, and enforcement processes actually work, how they might be improved, and their perception of low-risk food safety inspections as a deterrent to insanitary food processing and storage conditions.

The FDA and all States, with the exception of Georgia and Ohio who did not respond to our data request, provided quantitative data reporting the extent of low-risk food safety inspections being conducted by their agency. Some States and FDA were unable to respond completely because the information requested was not collected by them, or was not accessible in the detail we had requested.

²Discussions were with those who perform low-risk food safety inspections. At FDA, these were either inspectors or investigators. At the States, their job titles varied. In each case, these inspectors were responsible for a range of inspections, and not limited solely to low-risk food safety inspections.

FINDINGS

FINDING 1: Although FDA believes that the potential exists for serious problems with low-risk foods, FDA assigns a low priority to these inspections. States give a higher priority to these low-risk food safety inspections than does FDA.

The FDA, and their State counterparts, strongly contend that low-risk food safety inspections encourage good sanitary practices on the part of food firms. However, FDA district offices, and a few State inspection agencies, often treat these inspections as less important than their other responsibilities.

Most respondents believe that low-risk food safety inspections act as deterrents against insanitary practices in the food industry, and feel that more low-risk food safety inspections should be conducted.

Nineteen FDA district directors and 49 State inspection agency directors agree that low-risk food safety inspections serve to prevent insanitary conditions from becoming widespread. A commonly advanced notion is that firms become lax in food sanitation practices if they know that there is little likelihood of being inspected. Many feel their inspection presence compares to that of "a cop on the beat."

The problems inspectors encounter when they conduct low-risk food safety inspections include: (1) rodent and insect defilement; (2) failure to comply with standards of identity (these define what a given food product is, its name and the ingredients which must be used, or may be used, and which ones must be declared on the label); (3) use of unapproved food and color additives; (4) product substitution; (5) short weight; and, (6) insanitary storage and processing conditions.

Because of these problems, and the deterrent value of low-risk food safety inspections, 14 of the FDA district directors, and 30 State directors feel they would like to see more low-risk food safety inspections performed. No FDA district director, and only one State director think there should be a decrease in the inspections being performed.

Respondents indicate that public health safety is enhanced by performing low-risk food safety inspections.

Some respondents express concern that although these firms are categorized as low-risk, there are public health risks associated with the food products handled by low-risk firms. Most typical was the notion that "low-risk does not mean no risk." Respondents point out that the understanding of the potential hazards associated with food and food processing is constantly changing, and requires a constant re-evaluation of the risk identified with a particular food. For example, until 1990, fresh tomatoes were not known to carry any strains of salmonella contamination.

Most problems caused by ingesting adulterated low-risk food are admittedly unlike the more serious problems connected with high-risk foods. Contaminated high-risk foods, we were told "can kill you;" ... but (eating an adulterated low-risk food) "just makes you wish you were dead."

Low-risk food safety inspections are considered a low priority by FDA district offices.

Overwhelmingly, FDA district offices do not feel that low-risk food safety inspections are a high priority. Twenty of the FDA district directors describe low-risk food safety inspections as being a low priority, with the other director characterizing it as of medium importance. Most FDA district directors feel that given current resources and other responsibilities, this treatment of low-risk food safety inspections is appropriate. Because of its large workload and limited resources, FDA must establish priorities for its inspections. In doing this, low-risk food safety inspections may not necessarily have the same importance as some other inspections.

We do not suggest that FDA's priorities are misplaced. Low-risk food safety inspections should not be placed above the vital need to inspect high-risk food firms, blood collection facilities, drug manufacturers, or makers of medical devices.

The FDA district offices are given considerable latitude in determining how their inspection resources are expended. This discretion is offset by the need to respond to new FDA headquarters' priorities, or to react at once to public health emergencies. Each FDA district office must react to the district's immediate needs as well as to national crises.

Typically, low-risk food safety inspections are postponed or cancelled when crises arise, or if new demands are made on the FDA district offices. All FDA district offices report having to cancel low-risk food safety inspections to react to potentially dangerous public health hazards, like the 1990 incident involving cocaine in the imported beverage, "Malta," or in 1989, when canned and pickled mushrooms from China caused several food poisoning outbreaks. Secretarial initiatives, like the current focus on proper labelling of products, will also impact on FDA district office inspections.

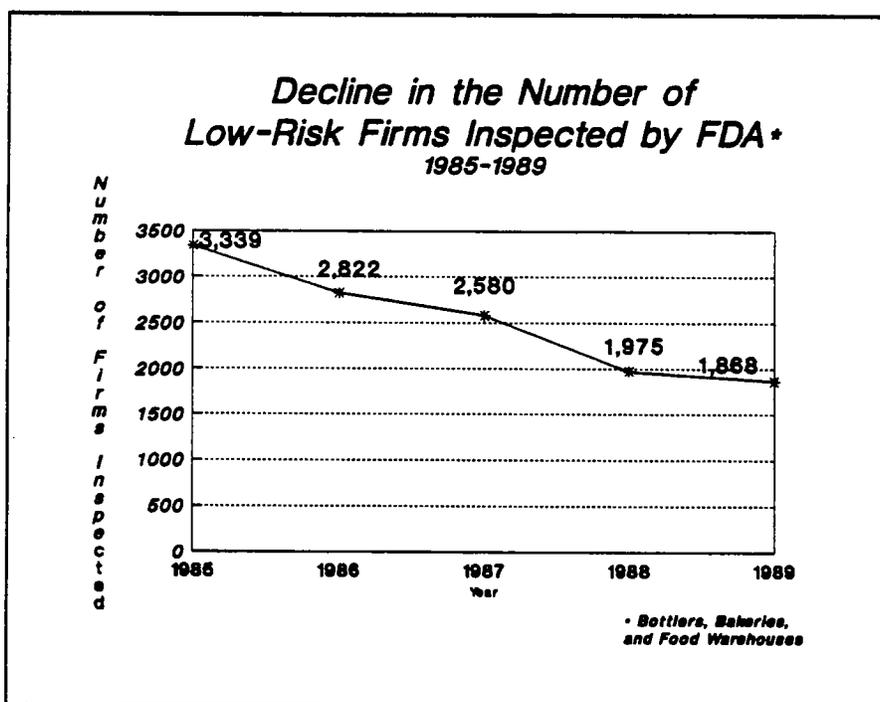
In some instances, FDA may not be able to reschedule low-risk food safety inspections. For example, in 1989 FDA planned to conduct 14,145 food inspections themselves (not exclusively low-risk inspections). By year's end, FDA conducted only 54 percent of their planned food inspection work.

The FDA has considerably reduced the number of low-risk food firms inspected.

The number of bottlers, bakeries, and food warehouses inspected by FDA has decreased by 44 percent since 1985. In 1985, FDA inspected 3,339 different bottling, baking, and food warehouse establishments. In 1989, only 1,868 such establishments were inspected by FDA. Some firms are inspected more than once in a year in order to verify that a violative condition is corrected. These figures do not account for all of the low-risk food safety inspections that FDA conducted, since some firms receive more than one inspection during a year. These follow-up inspections are not included in FDA's inspection count.

During this time period, a combination of factors caused FDA to devote less resources to low-risk food safety inspections. Two major factors were the declining number of inspectors each year, and those inspectors available being frequently used for other priorities.

The following chart illustrates the decline in the number of low-risk food firms inspected by FDA. No inspections performed by States under contract are included.



Other FDA inspections of food firms, which includes high-risk firms, dropped 39 percent from 1985 to 1989. In contrast, the number of firms inspected in the non-food FDA program areas has remained fairly stable since 1985. Inspection of firms in these centers declined only 6 percent during this period.

Respondents expect that 1990 inspection data will show an increase in the

number of low-risk food firms inspected by FDA, due to staff increases. This expected increase is not surprising since FDA district offices frequently use low-risk food safety inspections to train new staff in inspection procedures and documentation.

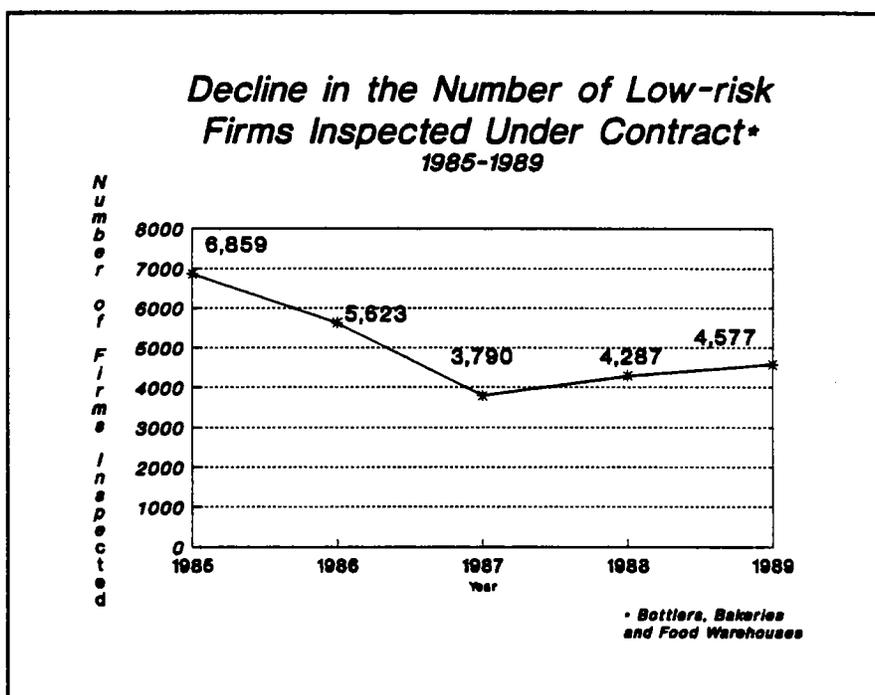
The FDA has also reduced the number of low-risk food firms States inspect under FDA contract.

The FDA relies heavily on State contracts to ensure low-risk food firms' compliance with the FD&C Act. In 1989, contract inspections comprised 75 percent of the bakery inspections conducted, 74 percent of the bottler inspections conducted, and 70 percent of the warehouse inspections conducted for FDA.

Despite FDA's dependence on State contracts, the number of low-risk establishments inspected by States under FDA contract, has decreased by 33 percent since 1985, from 6,859 firms to 4,577 firms. The following chart reflects this decline in the number of low-risk firms inspected under FDA contract.

Several reasons explain this decline. Reduced funding for contracting restricted the number of inspections the States could perform. Also, in some cases the FDA district offices chose to assume more of this workload, and in others, States opted not to do as many contract inspections as before.

The number of firms inspected under contract began to rise in 1988 and 1989 as FDA responded to GAO recommendations to do so.



State inspection agencies give a higher priority to low-risk food safety inspections than does FDA.

Unlike FDA district offices, most State directors do not consider low-risk food safety inspections to be of low priority. Twelve State directors consider low-risk food safety inspections to be a high priority for their agency, while only 10 States feel it is of low import. The other State directors either characterize these inspections as of medium priority, or make distinctions in priority for different types of firms.

The States' responses to the priority of low-risk food safety inspections often are colored by their agency's varied inspection activities. Frequently, States would describe one type of low-risk firm as being of high priority, while downgrading the importance of other types. Connecticut, for example, considers bakeries to be a high inspection priority, bottlers a medium priority, and warehouses a low priority. In contrast, Hawaii considers warehouses and bottlers high priorities, with bakeries a medium priority. Choosing which type of firm is more likely to be in violation or considered a potential health hazard, varies by State and often reflects current problems a State is encountering with a particular firm or product.

Like FDA district offices, State inspection agencies often have responsibility for many types of inspections, and must respond to emergencies. Postponing or cancelling inspections to react to these exigencies is commonplace. Characteristically, one State agency director said that "...the inspections of) foods are the first to get sacrificed."

No reliable estimate of the total number of low-risk food firms being inspected by States is available, due to the dissimilarities of State reporting data.

The number of different firms receiving low-risk food safety inspections under State law, and not under FDA contract, is unknown. While exact figures are not available, we do know that States conducted at least 37,000 inspections of low-risk food firms in 1989.

The level of inspection coverage for a particular firm depends on the State requirements and priorities. Some firms receive more than one annual inspection, because of States' mandated multiple inspections, or due to reinspection to ensure that insanitary conditions found previously are corrected.

Although most State directors feel the number of low-risk food safety inspections has remained constant in recent years, this impression is not universal. Fourteen said that over the last 3 years their agencies were doing fewer low-risk food safety inspections; 11 said they were performing more inspections during this period. Trending data describing the number of low-risk food safety inspections conducted by the States was requested, but generally was not available.

FINDING 2: Not all food firms are known to FDA or the States. Respondents believe there are possible public health risks associated with unidentified firms, since they are not inspected.

There is no national registry of food firms, either mandated or voluntary. The current techniques that identify firms who process and store food products do not guarantee that all will be identified. If a low-risk food firm is not identified, it will continue to manufacture, process, store and ship food that is not inspected. Thus, firms operating in insanitary conditions will continue to do so unchecked, placing the public's health at risk.

The FDA does have an inventory of food firms, but admits it is not complete or up to date.

The FDA tracks food firms through the Official Establishment Inventory (OEI). The OEI is a computerized data base containing information on establishments whose activities fall within FDA's jurisdiction. As of August 1990, there were 28,700 bakeries, bottlers and food warehouses on the OEI.³ The OEI is updated by FDA district offices. Although the FDA district offices feel that most firms are identified in the OEI, 17 of the 21 FDA district offices believe that the identification of food firms could be improved. The FDA district offices currently use a variety of methods to identify these firms.

The FDA relies on its inspectors to identify food firms to update the OEI. Since there is no systematic procedure to identify new food firms, inspectors do so by reviewing newspapers, magazines, phone books, industry publications, trade periodicals, surveillance reports, and consumer complaints. Inspectors may also walk through stores looking for new products.

To a degree, all FDA district offices count on notification and referrals from the States to identify food firms and update the OEI. A memorandum of understanding between the State of New York and the Brooklyn and Buffalo district offices formalizes the exchange of inventories between these agencies. In most instances however, informal networks provide this exchange of information. Twenty States routinely share their firm inventory lists with FDA. Most of the States commented that they would furnish FDA with a copy of their inventory lists if FDA requested it. Twenty-nine States said that FDA routinely shares its OEI with them.

The lack of timeliness in adding firms to the OEI presents problems for inspecting agencies. Firms could be operating for some time without FDA (or the State) being aware of it. During this period, these firms would not be subject to food safety inspections, nor be required to correct any violations. Insanitary conditions could be rife, or adulterated raw materials could be used during processing, or finished products could be stored improperly.

Shifting priorities and decreasing resources within FDA has affected the contents of the OEI. As a result of these factors, an auxiliary OEI file was established in fiscal year 1981. Firms are removed from the active OEI and transferred to the auxiliary file if: (1) they are out of business; (2) their products or activities no longer fall under FDA's jurisdiction; (3) their annual sales are less than \$500,000 and they sell 75 percent or more to retail customers on the premises; or, (4) the FDA determines that the firm cannot be covered within currently available resources. Establishing the auxiliary OEI freed FDA staff to concentrate on larger firms.

³ *The actual count of firms could be smaller, since an establishment could be counted in more than one category.*

However, updates to the auxiliary OEI are infrequent. Firms in this inactive inventory could easily change the nature of their business, or grow larger, without FDA's knowledge. Whether they would ever be transferred to the active OEI, and subject to FDA inspection, is problematic. Like firms who are never identified by inspecting agencies, these auxiliary OEI firms may be operating with food safety violations, and if so, represent potential public health risks.

Most States maintain inventories of food firms, but admit not all food firms are identified.

Forty-two States license, register, or issue operating permits to food firms. Most States rely heavily on self-identification by food firms to comply with their requirements. Some States require an annual license, while others merely demand a one-time registration. Sometimes it is the local government, rather than the State, that licenses food firms.

Like FDA inspectors, State inspectors take an active role in identifying food firms. Using techniques similar to FDA inspectors, State inspectors act as "eyes and ears" to identify new firms. Often, these inspectors have an assigned geographic territory and through the years come to know most of the firms operating in their jurisdiction.

However, even with mandated licensure or registration and the best efforts of inspectors to identify food firms, most States believe they are not identifying all the food firms operating in their State. In New York City, a respondent estimates that one-fourth of the operating food firms are unknown to the State, despite mandatory licensing. States also report problems tracking seasonal operations.

There are possible public health risks associated with firms not being identified by inspection agencies.

Food firms operating without the knowledge of inspection agencies can produce, manufacture, pack, and store food that is adulterated and/or mislabelled. Unless problems arise, like an outbreak of food poisoning, that identify these firms, they may never be inspected. Routinely conducting low-risk food safety inspections not only serves to act as a deterrent against insanitary food products, but also educates firms and their employees about safe food handling.

FINDING 3: Food safety inspectors do not have all the enforcement tools they need to do an effective job.

The food industry is becoming increasingly complex. New products, equipment, and packaging are constantly being developed, and each change poses new potential risks to consumers. Without comprehensive regulatory and enforcement powers, inspectors are at a disadvantage in protecting the public's health and enforcing the food safety laws.

The FDA inspectors cannot immediately seize, or embargo, food products found that appear contaminated. All States have immediate embargo authority.

The FDA lacks the power to immediately embargo suspected adulterated foodstuffs found while conducting an inspection. The FDA process to seize adulterated foodstuffs entails a Federal court action, whether the product is considered high or low-risk. While this legal process is underway, potentially dangerous foodstuffs can be shipped, and subsequently, sold to the public. The FDA seizure process can take several weeks. One FDA district manager related that when it does effectuate a seizure order, "it's rare the entire lot is there when we return."

In some cases, the FDA turns to the States to effect an embargo to prevent potentially hazardous foods from being marketed. Because of the potential health risks associated with contaminated food, the States treat FDA embargo requests as high priority. However, the possibility exists that the food in question will be transported before the State can act.

Seventeen FDA district directors feel that not being able to immediately embargo violative foodstuffs hinders them, and could present a public health risk. An FDA district director said he finds it frustrating not having this authority, since he sees immediate embargo as an essential element of consumer protection.

Twenty of 21 FDA district directors believe FDA should have immediate embargo power. Although FDA gives States considerable credit for responding to their requests, States cannot always immediately embargo on FDA's behalf. For example, the State may not have an inspector available either due to a State holiday or the logistics of travel to the inspection site.

All States have the power to immediately embargo suspected adulterated food. In some States, the embargo continues indefinitely, while in others the embargo must be lifted if no legal action has been initiated in a specified time period. In the latter instance, agreeing to assist FDA with an embargo could present a problem, if Federal court action on the case is not accomplished timely. One State embargoed a product called "Oil of Primrose," at FDA's request. The FDA seizure took several months to accomplish. During this time, the State was continually pressured by the firm to release the embargoed product.

An FDA embargo request can pose other difficulties for States. Some States require their own inspection to confirm FDA's findings prior to embargoing. If the problem is not present when the State inspection takes place, the State cannot embargo. One State could not embargo at FDA's request when their inspectors could not find the product infestation that the FDA inspector had. This suggests that either the infested product was shipped or destroyed before the State could inspect, or that the inspection conducted by the State was different than that conducted by FDA.

Joint FDA-State inspections are sometimes conducted when problems are known to exist, or are anticipated. But the geographic spread of low-risk food firms, and the relatively few numbers of inspectors mitigate against joint inspections, or even same-day State inspections in many cases.

States cannot always comply with FDA embargo requests, although this is rare. Violations found by an FDA inspector must also be violations under State law, and under the jurisdiction of the inspecting agency before the State can embargo the product. In some instances, violations of the FD&C Act are not violations of State law and no embargo can be enacted.

The FDA inspectors lack the inspection authorities used by most States.

The FDA inspectors do not have the authority to access low-risk food firms' shipping, billing, quality control, formulation and complaint records. Almost all FDA district offices consider the absence of these record review authorities a hinderance in their inspection of these firms. While FDA can obtain records via a Federal court warrant, this is often a lengthy and involved process. Four FDA district offices commented that they have asked States to obtain records on their behalf.

Shipping and billing records readily prove the interstate nature of a firm's business, required for FDA jurisdiction. Presently, FDA spends considerable inspection resources proving that a firm ships or receives goods from other States. These shipping and billing records are also vital in expediting the recall of adulterated products from the marketplace.

Quality control and complaint records are important for pinpointing problem areas that deserve special inspection attention. Access to formulation records would help ensure that product labelling is correct.

In contrast, most States have access to all records in question. Many State inspection agencies have the authority to review any record needed to conduct their inspection. Not all States give express statutory authority for individual types of records, but inspectors may request the records they feel are necessary.

Forty-one States have the authority to access billing and quality control records. Forty-three States have access to shipping records. Thirty-six States can inspect formulation records. At least 30 States can review consumer complaint records, while another 8 States are unsure if this is specifically authorized in their State statutes.

The FDA lacks explicit authority to take photographs during inspections.

Although FDA has the right to take photographs under normal inspection procedures, that right has been questioned because the statute is not explicit on this point. All FDA district offices think that photographs are invaluable in documenting violations. A graphic depiction of a violation is especially valuable in the event of prosecution, or can obviate the need to litigate. Twenty of the FDA district offices state that they routinely take photographs of suspected violations.

Thirty-nine States report photographing conditions in a firm while conducting inspections.

FINDING 4: Despite efforts by Federal and State agencies and industry groups to promote uniformity, no national requirements exist for the inspection of low-risk food firms. Consequently, the public receives different levels of food safety, depending on their geographic location.

The FDA and State low-risk food safety inspections often differ, both in the focus as well as the breadth of the inspection. While many States have laws patterned after the FD&C Act, there are considerable variations. Some States do not have the authority to inspect all types of low-risk food firms.

Not all low-risk food safety inspections are alike.

The FDA district directors feel that the inspections States perform under contract are generally well-done. However, two-thirds of the FDA district directors believe that the inspections States perform, not under FDA contract, are not equivalent to those performed by FDA.

No national requirements for conducting low-risk food safety inspections exist because no means of obtaining consistency from State to State has been fully successful. Because of the different standards and requirements of FDA and State laws, low-risk food firms are often held to different inspection requirements. An inspection of a low-risk firm, uncovering no violations, could take either 30 minutes or 3 days depending on who performs the inspection. Also, firms that operate in different States may have to meet differing State inspection requirements for the same product. This can cause confusion for these firms in deciding what should be stressed to guarantee a minimum level of food safety.

Most State directors believe that the quality of their low-risk food safety inspections is equal to those done by FDA inspectors. However, many States concede that the degree of inspection documentation demanded by FDA exceeds that usually collected by their inspectors. This difference, as well as FDA's emphasis in laboratory sampling of suspected foodstuffs, ensues from the FDA posture that each violation may result in legal action.

Where there are State mandated inspections of firms, there are considerable demands on State inspectors to inspect these firms timely. However, perforce, only the obvious violations may be uncovered. One State director said that they look for "the 3 B's - birds, bats, and bugs." One State inspector said that he performs "flashlight inspections," implying that he scans the flashlight beam around the facility to find violations.

The FDA has no mandated inspection frequency for low-risk food firms.

Based on workload demands and current priorities, each FDA district office decides which low-risk firms in their district will be inspected and how often.

State inspection frequency for low-risk firms vary widely.

In contrast to FDA, 30 States are mandated by law or policy, to periodically inspect all low-risk firms, or certain types of low-risk firms. Of these 30 States, 14 report that they try to inspect establishments annually. Others have statutes mandating inspections as often as six times annually.

However, adherence to these inspection frequency requirements is problematic. The State inspection agencies frequently have responsibility for a wide range of inspection activities. Like FDA, States must deal with resource shortages, other organizational priorities, and the need to respond to emergencies.

When scheduling low-risk food safety inspections, States also consider whether local entities, such as city or county health departments, do their own inspections of low-risk food establishments. States must coordinate with local inspecting agencies to avoid duplication of efforts, and to spread inspection coverage to more firms.

Unlike FDA, not all States perform low-risk food safety inspections of bakeries, bottlers and warehouses. For example, Mississippi has no authority to inspect food warehouses under State law. In Idaho, local authorities have complete responsibility for food safety inspections; the State neither conducts food safety inspections nor exercises any control over these agencies. Montana acts mostly in an advisory role to the local county health departments, usually getting involved if an enforcement action is necessary.

There is little data shared on completed inspections.

Information sharing by States on completed low-risk food safety inspections is meager. The information shared is usually problem-based, not routine. Less than half of the States share any inspection information with FDA. Sixteen States share their inspection findings only if a problem or violation is involved; and three States supply FDA with their inspection results only if an interstate problem occurs. Only six States routinely share all their inspection results with FDA.

The FDA does not always share inspection data with all of the States either. Only 14 States report that FDA routinely provides them all FDA inspection findings. Seventeen State directors said that FDA will send them information on any firms found to be violative. Ten more States report that they occasionally receive FDA inspection results. The remaining States report receiving no FDA inspection results.

There are some efforts to promote uniformity in food safety inspections.

The FDA, the States, and the food processing industry have taken some steps to foster consistent requirements for food processors and consistent food safety inspection criteria. These steps include training both for industry and inspection agencies, the contracting of FDA inspections, and the development of common standards that help ensure that food manufacturing, processing, packing and storing is done under strict sanitary conditions.

The FDA promotes uniformity in low-risk food safety inspections through regulation, training, and contracting.

The FDA has issued seven Good Manufacturing Practice Regulations (GMPs) for food processing since 1969.⁴ The GMPs describe the minimal conditions and controls that food firms must use to produce food products that meet the standards of the FD&C Act. The purpose of these GMPs is to prevent violative products from being produced and marketed. The FDA uses these GMPs to evaluate sanitary conditions and practices in the food industry.

The FDA State Training Branch offers training to State and local regulatory agencies on a wide range of topics. Short-term courses are offered tuition free, and are presented on location at the requesting agency. The courses are designed to meet the specific training needs of the sponsoring agency. The Training Branch solicits recommendations from States concerning their training needs and States bid yearly for the courses they want. The FDA trains and certifies many State inspectors to conduct different types of inspections.

By providing training and technical assistance to inspection agencies, FDA helps promote a consistent approach to defining, identifying, and correcting the potential health hazards found at food manufacturers, processors, packers and warehouses. Even though individual State requirements for these firms differ, FDA can present an inspection training course that applies the precepts of the FD&C Act tailored to their laws. Enrollment is open to other agencies and industry applicants if training slots are available.

⁴The GMPs cover: (1) current good manufacturing practice in manufacturing, processing, packing or holding human food; (2) thermally processed low-acid foods packaged in hermetically sealed containers; (3) acidified foods; (4) cacao products and confectionery; (5) smoked and smoke-flavored fish; (6) frozen raw breaded fish; and, (7) processing and bottling of bottled drinking water. The GMP's for cacao products and smoked fish are not currently in effect.

Many State agencies praised FDA's training efforts, citing both the expert level of the trainers and the content of the courses. But many lament that budgetary restraints prevent their staff from attending, or that they cannot afford to attend more than once every 1 or 2 years.

Another form of FDA training that promotes not only uniformity of approach, but also better information sharing, is the joint inspection. In these instances, an FDA and State inspector form a team to conduct an inspection. In recent years, due to staff shortages, there have been relatively few joint inspections conducted.

The FDA contracts with States to conduct low-risk food safety inspections require a common approach and reporting of the findings. The FDA demands that States performing inspections under contract use FDA methods, requirements, and forms. Aside from the uniformity demanded by FDA in conducting inspections under contract, States set their own guidelines for inspecting low-risk food safety firms.

The inspections done under contract usually require more inspection time, product sampling, and documentation than those normally performed by States. A spin-off effect of contracting is that States sometimes adopt FDA techniques or use FDA forms to perform their own inspections.

Hazard Analysis Critical Control Point Programs focus on quality control standards.

The FDA, food processing industry, and professional organizations embrace the concept of Hazard Analysis Critical Control Point Programs (HACCP). The HACCP is a quality control approach that identifies the processing steps where food contamination is most likely to occur. At these points, the product is tested for microbiological, chemical and physical hazards.

Although the HACCP concept is one that can be applied universally throughout the food industry, the critical control points will vary for each type of firm. In food warehouses, for example, a critical control point might occur during their efforts to eliminate rodents. However, a bottler of spring water may not typically have rodent infestation, but would face problems to guarantee the purity of their water. Establishing critical control points where the water purity is monitored would reflect the risk point where inspection needs to take place. This HACCP specificity for each type of food firm helps assure the quality of the product.

The food processing industry has taken the lead in promoting HACCPs. In conjunction with FDA in many cases, they develop HACCPs for specific types of food processors, and offer training on their application. Compliance with HACCPs is voluntary.

RECOMMENDATIONS

The FDA is responsible for the safety of most of the nation's food supply. To accomplish this formidable task, and still have the resources to tackle their other duties, we believe that the inspection of low-risk food firms should be restructured.

This restructuring is necessary because of the vital ongoing need to inspect low-risk food firms coupled with FDA's need to devote more resources to their higher priorities.

At present, the frequency and the quality of these inspections varies greatly. Little information is shared on completed inspections, and consequently some firms are inspected by both FDA and States, while other firms are not inspected at all. Any duplication of inspection effort takes away scarce resources from FDA's other activities.

The FDA, working with the States, should develop and seek legislative authority for a system to inspect low-risk food firms based on the following principles:

- ▶ there is a need for a complete and uniform system for inspecting low-risk food firms;
- ▶ the FDA's role should be in oversight, developing standards, and providing technical assistance to the States; and
- ▶ the States should have the responsibility for inspecting low-risk food firms.

At a minimum, the system should include the elements described in the recommendations below.

RECOMMENDATION 1: The FDA should design a uniform system that ensures both a systematic identification of all food firms and collection of inspection results.

The FDA should ensure that all food firms, high-risk and low-risk, are registered. This registry will help ensure that all food firms are identified, and therefore subject to inspection. To guarantee that all food firms are subject to inspection, registration by firms should be mandatory.

Options include FDA developing and maintaining a single national registry, or having each State keep its own registry. In either case, data should be shared between FDA and States. Options for enforcing registration include requiring either a Federal food permit, a State license for food firms, or another form of user fees as discussed in Recommendation 5.

RECOMMENDATION 3: Certified States should conduct inspections of low-risk food firms.

States certified by FDA should conduct all low-risk food safety inspections in their State. The FDA would monitor States' compliance with the inspection requirements, perform quality control reviews, and provide ongoing training to the States. The FDA would recertify States periodically.

If a State does not meet the inspection requirements, FDA should arrange for the inspection of low-risk food safety inspections. The FDA could perform these inspections, or contract with a certified State, or other entity they deem qualified.

We do not anticipate that all States will be able to meet all of the proposed FDA requirements immediately. Some States may choose not to meet the requirements. In these cases, the food firms in these States should be held to the same inspection requirements as food firms in certified States.

RECOMMENDATION 4: The FDA should seek legislation to provide inspectors with the inspection tools necessary.

The FDA should obtain authority for inspectors to immediately embargo suspected adulterated products, review all necessary records, and clarify the right to photograph suspected violative practices. These inspection authorities should apply equally to all FDA-regulated products.

Currently, the FDA's lack of immediate embargo authority can allow adulterated foods to get into the marketplace. Many low-risk firms receive and ship foodstuffs daily. Even an expedited Federal seizure process cannot prevent the shipment of all foods suspected of being adulterated.

The FDA should not have to rely on State officials, or the vagaries of State statutes to prevent adulterated food from being sold to the public. Likewise, using both FDA and State inspectors to inspect the same materials in order to justify a State embargo for FDA, is a redundant use of resources.

An additional issue to consider is how Federal authority could be delegated or otherwise used by certified States when conducting low-risk food safety inspections.

All food firms should be presumed to deal in interstate commerce, as is the case with medical device manufacturers. This presumption could be rebutted by the food firm, but the burden of proof would fall to them. Eliminating the requirement that FDA prove their jurisdiction allows them to make better use of scarce resources.

The registry should also receive, and share information on inspections of food firms, whether conducted by FDA, States, or local entities. The registry should furnish information to these agencies on inspections conducted by others. Information on firms operating in more than one State can be provided to all States involved.

Inspection results, positive or negative, are vital to agencies trying to plan their inspections. Problem areas found during another agency's earlier inspections can be stressed when a new inspection is conducted. Additionally, the sharing of this data will eliminate some of the duplicative inspections of firms by different agencies, since an agency will know when the firm was last inspected.

RECOMMENDATION 2: The FDA should develop requirements for low-risk food safety inspections, and certify which States meet these requirements.

These requirements should be based on FDA's long experience in inspecting low-risk food firms, and their extensive knowledge of risk analysis factors associated with the different types of low-risk food firms. The FDA should also solicit input from States, the food industry, and professional groups in developing these requirements.

The requirements might vary by food, the size of the facility, and all of the considerations FDA currently uses to decide when to inspect a low-risk food firm. The requirements should include minimum inspection frequency requirements.

Also to be considered is a firm's adoption of HACCP or their use of GMPs in food processing or storage. Firms that follow these principles, and provide access to inspectors that allow monitoring of these requirements, should not require inspection as frequently as other firms.

The FDA should certify which States meet all requirements for conducting low-risk food safety inspections. The FDA currently provides specialized training for States in many inspection areas. The FDA should continue to provide training for States, with special emphasis for those States working toward FDA certification, as discussed in Recommendation 5. The new focus on training would emphasize preparing States to meet the proposed inspection requirements.

RECOMMENDATION 5: The FDA should collect an inspection user fee from all food firms. This user fee will partially fund food safety inspection activities of both FDA and the States that meet FDA's certification requirements.

A July 1990 OIG report, "Implementing User Fees in the Food and Drug Administration," indicates that applying the collected user fees to inspection activities would be consistent with the way some Federal agencies fund their inspection activities. The total user fees collected should not exceed the FDA and States' costs for these activities.

The additional funds made available from the user fees would encourage many States to strive to meet these inspection requirements. The public, as well as many food firms, would also want their States to meet food safety inspection requirements and become FDA certified.

Food firms benefit from an inspection program that provides uniform requirements, which also helps to assure the public of the quality of the product. So, firms that adopt HACCP or follow GMPs might qualify for a discount in the user fee.

Collection of these fees could be accomplished in several ways. The FDA could devote additional resources to compile a registry of all food firms, with concomitant staff to collect fees and enforce non-collection. Or, States could collect the user fee through the licensure process.

Another option would employ the Internal Revenue Service (IRS) to collect the user fees. The IRS could add a reporting line on tax returns for businesses involved in the food industry to compute their user fee. The IRS could receive a flat percentage of the collections to compensate them for their expenses.

The FDA should end the current contracting of low-risk food safety inspections with State inspection agencies. This would represent annual savings of more than \$2.5 million. States would be supplemented for the loss of contracted inspections with a share of the user fees, if they adhere to the inspection requirements designed by FDA and become certified.

The FDA would not share any of the inspection user fees collected with States not certified. These funds would be used for FDA resources necessary to conduct the low-risk food safety inspections, or arrange for their performance in those States.

Although we have not estimated the costs of restructuring the food safety inspection program as described, initial costs are likely to be high. User fees should be used to fund all food inspection activities. These user fees will fund FDA high-risk and low-risk food safety inspections, with certified States receiving a portion to fund their low-risk food safety inspections. The FDA will retain the balance of the user fees to fund the registry of firms, the development of standards, the certification and re-certification processes, and training. Other uses of the user fees could include additional inspection staff, expansion of laboratory operations, or contracting for the maintaining the registry.

As an example, a user fee of one-tenth of one percent on the gross sale of all food and kindred products would generate \$513 million annually on sales of \$513 billion. In contrast, FDA funding for all food safety activities in 1989 was \$132 million. Collection of the proposed user fees would allow current operating funds to be redirected to other non-food inspections.

The share to States who meet the inspection requirements should equal half of all user fees collected in their State. Half of these collections, up to \$256 million in our example, would be earmarked for States meeting the proposed FDA requirements. This potential funding dwarfs the \$2.5 million currently expended for State contracts by FDA. In fact, in 1986, 48 States reported food inspection expenditures totalling approximately \$121 million. With the user fees, certified States could conceivably expand their low-risk food safety inspection coverage, while reducing the State outlays for food inspections.

Again, the user fees collected should not exceed the FDA and States' costs for these activities.

DEPARTMENTAL COMMENTS

We received comments from the Public Health Service (PHS), FDA's parent agency, the Assistant Secretary for Planning and Evaluation (ASPE), and the Assistant Secretary for Management and Budget (ASMB). All concurred in principle with the recommendations. Both ASMB and ASPE questioned the need to collect \$513 million annually in user fees. The PHS proposed contacting States to determine their receptivity to the recommendations and further refinement of the user fee concept, as well as making several technical revisions to the report.

On the basis of the reviewers' suggestions, we made several technical corrections to the report. We have clarified that collection of \$513 million in user fees represents one illustration of possible revenues that could be collected through the fees, rather than an estimate of how much revenue will need to be generated.

We recontacted the food safety inspection agency in 10 States to discuss the recommendations. Eight of the ten States supported the user fee concept to fund inspection activities and the proposed linkages to FDA certification, as outlined in the report. The comments of the States are presented in more detail in Appendix B.

Although we appreciate the need to further refine the user fee concept, this should properly be addressed in the development of an implementation plan by PHS. As PHS indicated in its response, such an implementation plan will need to be consistent with FDA's comprehensive user fee strategy.

APPENDIX A

AGENCY COMMENTS ON THE DRAFT REPORT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
JUN 14 1991

Assistant Secretary for Health

Office of Inspector General Draft Report "FDA Food Safety
Inspection," OIG-05-90-01070

Inspector General, OS

Attached are the Public Health Service (PHS) comments on the subject draft report. We concur with each of recommendations. However, we note that implementation of these recommendations would require significant changes in legislative authorities, State/Federal relationships, and funding of FDA operations. Most of these changes, regardless of their merit, cannot be implemented by PHS alone.

/s/ James O. Mason
James O. Mason, M.D., Dr.P.H.

Attachment

cc:

ES/PHS

OM #3353

ASH

OM, Rm. 17-25, Parklawn

ORM, Rm. 17A-13, Parklawn

DFM, Rm. 17A-13, Parklawn

CAMB:DFM:BGillen,scr,06/04/91

File: OM3353B

COMMENTS OF THE PUBLIC HEALTH SERVICE (PHS) ON THE OFFICE
OF INSPECTOR GENERAL (OIG) DRAFT REPORT "FDA FOOD SAFETY
INSPECTION," OEI-05-90-01070

OIG RECOMMENDATION

1. FDA should design a uniform system that ensures both a systematic identification of all food firms and collection of inspection results.

PHS COMMENT

We concur in principle. A national system for the uniform collection of state and Federal inspectional results would be desirable. However, unless Congress legislates increased authorities for FDA and unless States participated in a federally supervised food inspection system, its value would be questionable. The registry system described in this report would be very resource intensive in terms of costs and time to both develop and maintain.

OIG RECOMMENDATION

2. FDA should develop requirements for low-risk food safety inspections, and certify which States meet these requirements.
3. Certified States should conduct inspections of low-risk food firms.

PHS COMMENT

We concur in part. Standard requirements for low-risk food safety inspections performed by FDA and the States would be a good idea. Currently, States, under contract with FDA, do perform inspections of low-risk food firms using FDA methods, requirements, and forms.

However, FDA does not have the authority to require States to participate in a certification program. States are separate entities, historically retaining the right to do things their own way, on their own schedule, and under their own laws unless specifically preempted. A certification program for low-risk food safety inspections would require that Federal Sanitation and Good Manufacturing Practices (GMP) regulations preempt state regulations.

If in fact a certification program were developed and a State chose not to participate or was unable to meet the requirements, FDA, itself, would have to do the inspection. Additionally, in the past, when preempted, many State legislatures have eliminated

funding State programs in favor of other State priorities such as schools, roads, and prisons.

OIG RECOMMENDATION

4. FDA should seek legislation to provide inspectors with the inspection tools necessary.

PHS COMMENT

We concur. Once a violation is uncovered, embargo or seizure may be the most important regulatory tool. However, to uncover violations, FDA needs access to records, subpoena powers, and other inspection authorities. In 1990, FDA proposed a comprehensive package of enhanced enforcement legislation that subsequently was approved by the Department. The DHHS General Counsel has formulated the proposals into legislative language that is being considered by OMB for submission to Congress as part of the Administration's requested legislation for fiscal year 1992. If submitted and acted favorably upon by Congress, this legislation would provide the tools recommended in the OIG report.

OIG RECOMMENDATION

5. FDA should collect an inspection user fee from all food firms. This user fee will partially fund food safety inspection activities of both FDA and States that meet FDA's certification requirements.

PHS COMMENT

We believe the feasibility of implementing this recommendation depends on a number of considerations. The most obvious factor would be the receptivity of the States to the proposed financial and certification linkages to FDA. Initial reactions from a sampling of state officials regarding their views on the merits of this proposal would be a very practical addition to the final report.

A second, but less obvious, factor that deserves closer attention in the report is parity between the fee burden on domestic and imported food. As the proposal stands, it is silent on how sales-based fees would be applied to imported foods. It would strengthen the recommendation to examine how this sales-based fee approach could be extended to imported food while conforming to various international trade and tariff constraints.

A third factor that would increase the receptivity to this proposal is a more developed rationale for the uniform fee rate on all levels of the food industry. As it stands, wholesalers

will pay most of these fees, since the value of food at the wholesale level is greater than at the manufacturer level, yet FDA and state inspection efforts spend more time on manufacturers and processors. In addition, profit margins are typically much thinner at the wholesale level, so the relative impact of a constant rate fee will be disproportionately burdensome on wholesalers.

A two-level fee structure would certainly be possible, but the rationale would need to be sufficiently crisp to prevent drift toward a complicated multi-tiered fee system that would be too cumbersome to administer. Conceptually, this recommendation presents a novel approach to managing federal and state food inspection resources. Its viability will depend considerably on how well the final report refines the idea and explores its feasibility.

Finally, any attempt to implement user fees for food inspections needs to be considered in the context of the comprehensive user fee strategy. The Office of the Secretary has asked FDA to develop "a blueprint for how best to develop a rational mechanism for achieving Congressional, industry, agency, and public consensus on the establishment of user fees." The information on food inspections developed in the final version of this OIG report will be considered by FDA in its preparation of the blueprint for user fees.

TECHNICAL COMMENTS

1. Page 1, paragraph 4, last sentence: Mayonnaise and many other high risk foods do not present a botulism hazard. Rather there are several other problems they may cause, such as staphylococcal enterotoxin and histamines, which are considered to be high risk.
2. Page 2, sentence 2: Should read, "The FDA relies on its headquarters to provide national guidance through its Compliance Program Guidance Manual and on its 21 district offices to set their own local priorities."
3. Page 4, line 6: Because of its large workload and limited resources, FDA must establish priorities for its inspections, in doing this, low-risk food safety inspections may not necessarily have the same importance as some other inspections.
4. Page 13, paragraph 3, sentence 1: This sentence should read, "Although FDA has the right to take photographs under normal inspection procedures, that right has been questioned because the statute is not explicit on this point."

5. Page 13, last paragraph, sentence 1: No national requirements exist, because no means of obtaining consistency from State to State has been fully successful.
6. Page 15, footnote: The seven GMP's cited are not all still in effect. The one on cacao products and the one on smoked fish are not in effect. A new GMP on smoked fish is presently under consideration and changes in the GMP's for bottled water are being considered.
7. Page 20, paragraph 3: The word "foodstuffs" should be replaced with the word "products". To read, "Recommended inspection authorities should apply equally to all FDA-regulated products."
8. Page 22, paragraph 3, sentence 4: To run such an expanded laboratory operation devoted to low-risk foods, FDA would need additional FTEs and money from Congress.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Washington, D.C. 20201

MAY 1 1991

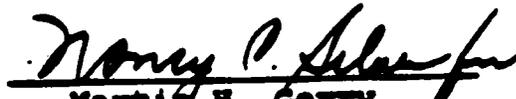
TO: Richard P. Kusserow
Inspector General

FROM: Assistant Secretary for
Planning and Evaluation

SUBJECT: OIG Draft Report: "FDA Food Safety Inspection,"
OEI-05-90-01070

I have reviewed the OIG Draft Report, "FDA Food Safety Inspection," and I concur with the first four recommendations of the report. The diminishing priority FDA has placed on inspection of low risk food firms coupled with their limited authority to access firm records has resulted in an inefficient system of food safety inspection that requires FDA to supplement its efforts by contracting with 36 states to conduct the inspections. The recommendations for a uniform system monitored by FDA with certification of states to conduct inspections would eliminate current inefficiencies and result in more frequent inspections of all firms.

With regard to the fifth recommendation, the collection of user fees, the proposal to collect \$513 million annually in user fees to fund the creation of a uniform system as well as inspection activities is unjustified and may be excessive. In 1989 total FDA funding for all food safety activities was only \$132 million. It is unclear why program enhancements would raise the cost of the current program (\$132 million) almost four-fold (\$513 million). I cannot concur with recommendation five without explanation and justification for the user fee expenditures.


Martin H. Gerry



APR 16 1991

MEMORANDUM TO : Richard P. Kusserow
 Inspector General

FROM : *[Signature]*
 Kevin E. Moley
 Assistant Secretary for Management and Budget

SUBJECT : OIG Draft Report Entitled "FDA Food
 Inspection"

While we concur with the Report as written, we would like to point out that the amount of user fees (\$513 million per year) which the report recommends FDA collect is far larger than the level of resources currently devoted to food safety. The \$513 million figure is 160% larger than FDA's planned FY 1992 user fee collections from all regulated industries, 304% larger than the FY 1992 amount budgeted for the field operations of the Center for Food Safety and Applied Nutrition, and 67% of FDA's entire FY 1992 budget. Since the Report does not present information that there are major safety problems in the food industry, we think that the idea of collecting so much more from the food industry than is currently being spent on food safety will be difficult to justify. It might be advantageous to present the \$513 million figure as an illustration of the amount of user fees which could be raised from user fees based on sales. Alternatively, the \$513 million could represent several years of fee collections.

With respect to the other recommendations, we agree that registration of food firms should be mandatory (recommendation 1) and that states should begin to take over responsibility for inspecting low risk food firms within their borders (recommendation 3). We also agree that FDA should seek legislation to provide its investigators with additional authority (recommendation 4) and note that such legislation is presently under review at OMB. While we certainly do not oppose the idea of FDA developing specific standards for low risk food inspections (recommendation 2) we are concerned that the cost of developing such standards might not be justified by the historically low risk posed by these industries.

APPENDIX B

OFFICE OF INSPECTOR GENERAL RESPONSE TO AGENCY COMMENTS

OIG RESPONSE TO PHS COMMENTS

We welcome the support for the recommendations in our draft report and at the same time appreciate the concerns raised in the Public Health Service's (PHS) response to the draft report, especially in emphasizing that they cannot act unilaterally on any of the recommendations. As the report points out, none of these recommendations can be implemented without congressional action. And considerable FDA-State cooperation and coordination is vital to the acceptance and success of the changes suggested.

We recontacted a random sample of 10 States to determine their initial receptivity to the user fee concept, and to the other recommendations that would affect State inspection activities. The States were unanimous in supporting the need for consistency in inspections. Eight of the 10 States supported the user fee concept to fund inspection activities.

Some State concerns about the recommendations included the effect on State funding and State user fees, the proposed division of the user fees, and the preemption of State and local statutes by Federal standards.

Our view is that the user fee suggested could replace much of the State funding for low-risk food safety inspections, and may reduce some of the current State budgetary concerns as it regards food safety inspections. The user fees should allow full funding of low-risk food safety inspections for certified States.

We expect that the initial costs of starting a national program that encompasses a national registry, collection and dissemination of inspection results, a certification of State inspection agencies, the performance of all low-risk food safety inspections in non-certified States, the expansion of training and technical assistance to States, and increased laboratory testing will be costly at first. However, as the program matures, a different sharing of the user fees might be in order.

We feel that the proposed requirements should allow for State or local requirements to require stricter controls on food where they feel the need exists. However, the standardized inspection requirements should be not reduced as a result of lesser State or local requirements.

The PHS also mentioned extending the user fee to imported foods. However, this inspection was limited in scope to low-risk domestic food products. We cannot speculate on ways to include imported food products under these rubrics.

In addition, PHS suggested a two-level user fee schedule. The recommendation we made was not intended to be restrictive. Instead, as with suggesting a reduction for firms adhering to HACCPs, or suggesting that IRS might serve as the collecting agent for the user fee, we feel there are many possible ways to approach these concepts.

Technical revisions to the body of the report were made as suggested by PHS.

OIG RESPONSE TO ASPE COMMENTS

We welcome the support for the recommendations. The ASPE did question the need for the amount of the proposed user fees in the draft report since it would generate nearly four times the current expenditures for FDA food safety inspections. The report was changed to indicate that we had no estimate of the eventual cost of the program suggested. The amount of the user fee in the report is shown as an example.

Although we have not estimated the costs of restructuring the food safety inspection program as described, initial costs are likely to be high. User fees should be used to fund all food inspection activities. These user fees will fund FDA high-risk and low-risk food safety inspections, with certified States receiving a portion to fund their low-risk food safety inspections. The FDA will retain the balance of the user fees to fund the registry of firms, the development of standards, the certification and re-certification processes, and training. Likewise, State expenditures would likely increase to meet the demands of certification.

Additionally, we expect that the level of inspections conducted by States would be raised, and the frequency of inspections increased in many instances.