

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FDA Oversight of State
Food Firm Inspections**

A Call for Greater Accountability



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EXECUTIVE SUMMARY

PURPOSE

To assess the Food and Drug Administration's oversight of food firm inspections conducted by States through contracts and partnership agreements.

BACKGROUND

Inspections as a Key to Food Safety

The World Health Organization recently estimated that up to 30 percent of people living in industrialized countries may suffer from foodborne illnesses each year. In the United States, the Centers for Disease Control and Prevention recently estimated that foodborne diseases cause about 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year. The annual cost of foodborne illness in the United States is estimated to be between \$7.7 and \$23 billion.

The Food and Drug Administration (FDA) plays a key role in overseeing the nation's food supply. It is responsible for the oversight of most foods involved in interstate commerce, with the major exceptions of meat and poultry. Under the Federal Food, Drug, and Cosmetic Act, the FDA's primary role in food safety is to inspect the conditions under which food is manufactured, processed, packed, and stored. The States also play a critical role in overseeing the nation's food supply. State and local governments conduct the majority of inspections in the U.S., including food retailers, manufacturers, processors and distributors within their State boundaries in accordance with their own laws and authorities.

Over the past 25 years, FDA has extended its inspection coverage by utilizing the resources and expertise in the States to fulfill its responsibility. For many years, FDA relied on contract arrangements, through which FDA paid the States to conduct inspections in accord with Federal regulations. In recent years, FDA has initiated partnership agreements with a number of States. Under these arrangements, the States agree to conduct inspections under their own authorities, without Federal funding, and to share the results with FDA. An effective food safety system depends on the collective efforts and coordination among Federal, State and local levels of government.

FDA Oversight as a Key to Accountability

In recent years, groups including the National Academy of Sciences, the Association of Food and Drug Officials, industry trade associations, consumer groups, and the States

themselves have recognized the importance of strong Federal oversight of State food firm inspections. Such oversight is essential to assure consumers that necessary food safety protections are in place, and to assure domestic industries and international trading partners that the FDA is committed to the quality and uniformity of food safety regulation.

This Inquiry

In this report, we begin by reviewing three fundamental factors that underscore the importance of FDA oversight of State inspections conducted through contracts and partnership agreements. We then turn, in more depth, to assess the adequacy of that oversight system. We draw on a variety of sources in this inquiry, including analysis of FDA inspection data, national surveys, site visits, observations of FDA audits, reviews of the State contracts and partnership agreements, reviews of year-end evaluations, and interviews with industry, consumer groups, and food policy experts.

IMPORTANCE OF OVERSIGHT

FDA Relies Heavily on State Food Firm Inspections.

We found that in the past 3 years, States conducted through contracts and partnership agreements, on average each year, 61 percent of food firm inspections recorded in FDA's national database. Although traditionally States have focused heavily on low-risk food firms, increasingly, these State inspections are focused on high-risk food firms. Partnership agreements, which rely primarily on State authorities and resources, are becoming a significant source of food firm inspections. State inspections offer FDA an important source of industry coverage, as well as expertise.

States Vary Significantly in their Capacities to Conduct Inspections.

We identified five significant ways in which State inspections and food programs vary: inspection classifications, enforcement authorities, inspection authorities and regulations, inspector education and training, and time spent on inspections. These variations raise concern about the quality and uniformity with which FDA's food program is carried out.

Variation in State Regulatory Programs can Inhibit Commerce.

The variation in State laws and inspection practices adds complications, costs, and frustrations for food firms engaged in multi-State commerce. For our international trading partners, variation in State laws and inspection practices can undermine confidence in the uniformity of U.S. food safety standards and enforcement efforts.

FINDINGS

FDA's Oversight of State Food Firm Inspections is Limited.

Under contracts, FDA obtains minimal information to assess the quality of State food firm inspections.

FDA's on-site audits have declined. Over the past 5 years, the number of audits dropped 59 percent, from 253 in 1993 to 104 in 1998. In 1998, FDA district offices did not conduct a single audit in 21 of the 38 States holding contracts.

FDA's on-site audits provide a limited basis for assessing State performance. FDA relies primarily on independent audits, which focus on the accuracy of inspection findings but give little attention to how State inspectors drew conclusions. FDA's lack of documentation of State performance further limits the effectiveness of audits.

FDA's reviews of State contract inspection reports lack much rigor. FDA conducts minimal assessment of the quality of inspection reports submitted by States. In response to our survey, 14 of 17 FDA district offices overseeing contracts reported that they use no formal criteria to evaluate the quality of the reports.

FDA rarely seeks input from external sources to evaluate State performance. FDA takes little advantage of its public meetings, food safety hotlines, or food safety websites to solicit input from food firms, trade associations, or consumers about the quality of State inspections.

Under partnership agreements, FDA obtains even less information to assess the quality of State food firm inspections.

FDA does not audit State performance, but participates in some joint inspections with States. FDA and State officials regard joint inspections as a mechanism to provide on-site training for both Federal and State inspectors rather than as a tool to evaluate State performance.

FDA's reviews of State partnership inspection reports are even more limited than its reviews of contract inspection reports. States submit differing levels of information about partnership inspections, depending on the States' inspection resources, policies, and procedures. We found that FDA district offices often lacked enough information to assess the quality of inspections.

FDA provides limited feedback to States on the quality of their inspections.

The majority of FDA’s ongoing feedback to States relies on informal communication and individual district office initiatives. FDA does not routinely provide States with written feedback on either its on-site audits or reviews of State inspection reports.

FDA’s performance evaluations provide States with little feedback about the quality of State inspections. The majority of contract and partnership evaluations contain cursory and general comments with little meaningful assessment of States’ performance. Furthermore, FDA rarely provides the evaluations to States.

FDA’s feedback places little emphasis on improving the quality of State inspections. FDA’s feedback is geared toward identifying deficiencies in food firm inspections rather than enhancing State performance. FDA does little to identify best practices among States and disseminate this information.

FDA provides limited feedback to the public regarding its oversight of contracts and partnership agreements.

FDA does not make information available about its reliance on State inspections or about State performance. Despite its extensive reliance on State inspections, it shares little information about the extent and nature of its reliance. Such information would provide an important source of FDA accountability to consumer, industry, and other groups.

FDA Faces Significant Barriers in Overseeing States

FDA’s ability to conduct quality oversight depends largely on its own internal capacities. A number of barriers inhibit FDA’s capacity to conduct effective oversight:

Low priority of food safety inspections. Without a statutory requirement to inspect a minimum number of food firms, FDA’s resources to conduct food firm inspections has diminished. Within the food inspection program, FDA’s resources to oversee State food firm inspections competes with its own resources to inspect food firms.

Limited leverage to oversee partnership agreements. The majority of FDA and State officials we spoke with underscored the fact that States are doing FDA a favor by helping the FDA to extend its inspection coverage at a very low cost. FDA’s heavy reliance on States compromises its ability to be truly critical of these inspections.

Reduced training and agency expertise. Maintaining agency expertise is vital to effectively overseeing States. In the past decade, however, formal training has declined and FDA has lost field experience in States that inspect the bulk of the food firms.

Limited accountability of FDA district offices. FDA does little to assess the effectiveness of district offices in overseeing State inspections.

Lack of important enforcement authorities. FDA must rely on State enforcement authorities that it lacks, including the ability to revoke a firm's license, to immediately embargo food suspected of being adulterated, and to access all of a food firm's records without a Federal warrant. Several FDA and State officials have raised concerns that this reliance compromises FDA's ability to be critical of State inspections.

RECOMMENDATIONS

State governments play a critical role in ensuring the safety of the nation's food supply, both under their own authorities and in concert with FDA through contracts and partnership agreements. They provide valuable resources and expertise that serve as a complement to FDA's own inspection efforts. Our recommendations recognize and build on the importance of this State role.

For State inspections carried out under FDA auspices, it is essential that FDA provide effective oversight to ensure both the quality and uniformity of inspections. FDA brings important strengths to this oversight role through a tradition that emphasizes science-based research and a public health perspective. We offer seven recommendations, based on the following template, on how FDA can provide leadership to address the shortcomings we identified in its current system of oversight. FDA has already undertaken some recent initiatives in the direction we call for.

Template For Effective FDA Oversight of State Food Firm Inspections

- ✓ **Equivalency:** Equivalency among Federal and State food safety standards, inspection programs, and enforcement practices.
- ✓ **On-site Audits:** An effective on-site mechanism for evaluating State inspection performance.
- ✓ **Inspection Information:** Routine submission of standardized inspection information.
- ✓ **External Sources:** Information from varied external sources on State inspection performance.
- ✓ **Feedback to States:** Substantive and timely FDA feedback to States on inspection performance.
- ✓ **Internal Capacities:** Enhanced FDA capacities to conduct effective oversight.
- ✓ **Public Information:** Proactive public disclosure of FDA's reliance upon and oversight of State inspections.

We present our specific recommendations below. But first we offer a caution.

An Initial Caution: FDA Should Reevaluate Its Reliance on the Partnership Agreements as a Mechanism for Conducting Inspections.

Partnership inspections have grown to account for 43 percent of the State food firm inspections conducted in association with FDA. While many of the State inspections may well be of high quality, FDA is not in a position to adequately attest to the quality or uniformity of these inspections.

We believe that a two-tier system of FDA oversight, under which there is less oversight of partnerships than contracts, is inappropriate. As follows, we offer our recommendations as actions that FDA can take to oversee State inspections conducted through both the partnership agreements and contracts. FDA must be able to assure consumers, industry, and international trading partners that its commitment to quality and uniformity is independent of the mechanism through which inspections are conducted.

Recommendation 1. FDA Should Work with States to Achieve Basic Equivalency in Food Safety Standards and Laws, and in Inspection Programs and Practices.

- ▶ Pilot test a system audit as a mechanism to foster equivalency and evaluate State capacity and performance.

Recommendation 2. FDA Should Devote High Priority to Improving its On-Site Audit Mechanism for Evaluating the Effectiveness of State Inspections.

- ▶ Stress joint audits rather than independent audits.
- ▶ Develop guidance for effective on-site audits.
- ▶ Determine the appropriate minimum frequency for on-site audits.

Recommendation 3. FDA Should Require that States Routinely Provide FDA with Standardized Information on the Inspections They Conduct.

- ▶ Define a core set of information to collect from States about food inspections.
- ▶ Provide guidance on the extent and nature of inspection report reviews.

Recommendation 4. FDA Should Draw on Multiple External Sources of Information in Assessing State Inspection Performance.

- ▶ Solicit feedback from industry, consumer, and other groups on the adequacy of State inspections.

Recommendation 5. FDA Should Provide Substantive and Timely Feedback to States on Their Inspection Performance.

- ▶ Provide States with ongoing and written feedback from on-site audits.
- ▶ Provide States with periodic evaluations assessing overall performance.
- ▶ Promote information exchange on promising approaches of State programs.

Recommendation 6. FDA Should Enhance Its Internal Capacities to Conduct Effective Oversight.

- ▶ Ensure inspector competence in both inspection and audit functions.
- ▶ Hold district offices more accountable for conducting effective oversight.
- ▶ Ensure the systematic identification of all food firms in interstate commerce.
- ▶ Seek broader FDA enforcement authorities.

Recommendation 7. FDA Should Increase Public Disclosure of Its Oversight of State Food Firm Inspections.

- ▶ Make more explicit information available about FDA's reliance upon States and its oversight of State inspections.

COMMENTS ON THE DRAFT REPORT

We received written comments on the draft report from the Food and Drug Administration, the Association of Food and Drug Officials, the National Food Processors Association, the National Fisheries Institute, and the Center for Science in the Public Interest. In general, the report received wide support among each of the groups. In the body of the report, we summarize the major comments and offer our responses. We incorporated several changes recommended by these groups in the text of the final report. The full text of each set of comments is included in appendix M.

The Food and Drug Administration

The FDA welcomes our report as a tool to strengthen Federal oversight of State food safety inspections. The FDA agrees with the majority of our recommendations and points to a number of recent initiatives underway that move in the direction we call for. The FDA does not agree with our recommendation to solicit external information sources in assessing State performance. The agency believes that its own audit process is the best way to assess State performance. The agency also does not address our specific recommendations about increasing public disclosure of information regarding FDA oversight and State performance. Regarding oversight of the partnership agreements, the FDA agrees that it must “fundamentally modify the nature of these agreements.”

We recognize that FDA is dealing constructively with many of the shortcomings we identify in our report. We encourage the agency to continue to do so. We also urge the agency to reconsider the value of external sources of information in assessing State performance. We continue to believe that such information can serve as an important complement to FDA's own audit information. On the matter of publicly disclosing information, we urge FDA to take immediate action to post the performance information we recommend. Such information could include identification of the States with which FDA holds a contract or partnership, the number and types of inspections under each arrangement, the ratio of FDA-to-State inspections in particular States, and the FDA's assessments of State performance through audits or periodic performance evaluations.

External Organizations' Comments

The external parties express support for the major thrust of our findings and recommendations. Each group also raises several concerns. The Association of Food and Drug Officials (AFDO) emphasizes the expertise of many State programs and questions whether all FDA district offices are currently in a position to adequately judge the quality and uniformity of State inspections. The AFDO also underscores the work of the Roles and Responsibilities work group within the National Food Safety System (NFSS) project as an important reference point that FDA may want to consider in redesigning its oversight of State food firm inspections.

The two industry groups, the National Food Processors Association (NFPA), and the National Fisheries Institute (NFI), express particular support for our recommendation to incorporate feedback from external parties in the evaluation of State programs. The NFPA urges that our recommendations go further by also including feedback from external parties on the performance of Federal inspections. Neither group agrees with our recommendation to provide FDA with additional enforcement authorities. The groups believe that the current system of relying on State authorities for enforcement has worked well. The Center for Science in the Public Interest (CSPI) strongly supports our report, but does not feel that we went far enough with our recommendations. The CSPI's comments point out vulnerabilities and potential weaknesses in State inspection programs, such as the potential influence of State politics and economics on regulatory oversight. The group suggests that FDA should restrict reliance on States to low-risk inspections.

We are pleased with the broad support from each of the external parties for the major thrust of the findings and recommendations in our report. On the matter of State and Federal expertise, we believe that AFDO raises an important point regarding the variation in food safety expertise and inspection and audit practices among FDA district offices. We recommend that FDA ensure inspector competence in both inspection and audit functions. Such expertise is critical to the credibility of the oversight process. We also recognize the current work underway through the NFSS project and we have modified the text of our report to more fully reflect this work. Regarding concerns with our recommendation to provide FDA with additional enforcement authorities, we continue to believe that these authorities are a vital component of effective oversight. We, along with other groups, raise concern that FDA's reliance on States to take enforcement actions may compromise FDA's ability to be critical of States' performance. On the issue of Federal reliance on State inspections, we do not seek to determine what would be an appropriate balance of inspection duties among Federal and State governments. However, we do emphasize that FDA should assure consumers that its commitment to food safety is no less under partnerships than it is under contracts.

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INTRODUCTION

PURPOSE

To assess the Food and Drug Administration's oversight of food firm inspections conducted by States through contracts and partnership agreements.

BACKGROUND

Importance of Food Safety

The World Health Organization recently estimated that up to 30 percent of people in industrialized countries may suffer from foodborne illness each year, and the problem is likely to be greater in developing countries.¹ In the United States each year, the Centers for Disease Control and Prevention estimated that foodborne diseases cause about 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths.² Even these figures may be low due to the number of foodborne illnesses that go unreported each year. The symptoms of foodborne illness range from mild stomachaches and intestinal upset to life-threatening nerve, liver, and kidney problems. The annual cost of foodborne illness in the United States each year is estimated to be between \$7.7 and \$23 billion.³ Some experts project that the reported incidence of foodborne illness will increase by 10 to 15 percent in the next decade.⁴

In 1997, in response to increasing challenges in maintaining the safety of the nation's food supply, the President launched the Food Safety Initiative to improve food safety and reduce the incidence of foodborne illness. At the request of Congress, the National Academy of Sciences assessed the effectiveness of the current food safety system. The Academy's report, entitled, *Ensuring Safe Food from Production to Consumption*, raised concerns about the fragmentation of the current system.⁵ In 1998, the President established a Council on Food Safety to coordinate food safety policy and resources. Each of these groups has recognized the roles for Federal, State and Local agencies and the importance of Federal oversight in ensuring the safety of our national food supply.

Inspections as a Key to Food Safety

Inspections of food firms, carried out by State and Federal agencies, are an essential component of the national food safety system intended to prevent foodborne illnesses. The 1997 report to the President entitled, *Food Safety from Farm to Table: A National Food Safety Initiative*, cited food inspections as one of six key components of a national food safety system.⁶

The Food and Drug Administration (FDA) plays a key role in overseeing the nation's food supply. It is responsible for the oversight of most foods involved in interstate commerce, with the major exceptions of meat and poultry. Under the Federal Food, Drug, and Cosmetic Act, the FDA's primary role in food safety is to inspect the conditions under which food is manufactured, processed, packed, and stored. FDA's 20 district offices carry out the food inspections under guidance from FDA headquarters.

The States also play a critical role in overseeing the nation's food supply. State and local governments conduct the majority of inspections in the U.S., including food retailers, manufacturers, processors and distributors within their State boundaries in accordance with their own laws and authorities. Many of the food firms inspected by States may also fall under Federal jurisdiction if they are involved in interstate commerce. States are generally in the field more frequently than FDA and offer an important source of front-line experience and expertise.

FDA Contracts and Partnership Agreements with States

Over the past 25 years, FDA has extended its inspection coverage by utilizing the resources and expertise in the States to fulfill its responsibility. Until recently, this assistance was limited to contract arrangements, through which FDA paid the States to conduct inspections in accordance with Federal regulations. In 1998, FDA held 40 food contracts with 38 States (see appendix A).⁷ These contracts covered 4,155 food firm inspections, ranging from 10 to 353 per contract. In States where FDA did not enter into a contract, FDA conducted the food firm inspections itself. In 1998, FDA spent \$2.04 million on the State food contracts.

Since 1994, FDA has further extended its inspection coverage through partnership agreements with States. Many, though not all of these States, also hold contracts with FDA. Under partnership agreements, States agree to conduct inspections under their own authorities, without Federal funding, and to share the results with FDA. In 1998, FDA held 37 such partnership agreements with 29 States (see appendix B). These agreements covered 3,165 food firm inspections, ranging from as few as 5 to as many as 635 food firm inspections per partnership agreement. In 1998, FDA contributed \$319,000 to the partnership agreements in the form of training, technical assistance, and equipment.

The 20 FDA district offices negotiate with the States for the types of food firm inspections to be conducted under the contracts and partnership agreements. These inspections may be of high- or low-risk food firms. Currently, the FDA has no standardized, agency-wide criteria for measuring the risk of a food firm.⁸ In general, high-risk food firms involve food products or manufacturing and processing technologies that have higher potential for contamination. Seafood firms and low-acid canned food firms are two major categories of high-risk food risk food firms inspected by States through contracts and partnership agreements. Food firms typically considered to be low-risk include warehouses, bottlers, and bakeries.

FDA has set forth specific mechanisms for its 20 district offices to oversee the State contracts and partnership agreements.⁹ In 1998, 17 of these offices were responsible for overseeing State food inspection contracts; and 17 offices were responsible for overseeing State partnership agreements related to food inspections (see appendix C). The oversight mechanisms and the basics of the two arrangements are more fully described in the primer on page 12.

FDA Oversight as a Key to Accountability

Oversight of State food firm inspections conducted in association with FDA is essential to assure consumers that necessary food safety protections are in place, and to assure domestic industries and international trading partners that FDA is committed to achieving quality and uniformity in food safety regulation. In recent years, a number of other groups have recognized the importance of strong Federal oversight including the President's Council on Food Safety, the National Academy of Sciences, industry trade associations, consumer groups, and the States. For example, in January 2000, the Association of Food and Drug Officials issued a statement to FDA underlining, from a general State perspective, the importance of Federal oversight "to assure to U.S. consumers and our foreign trading partners that the inspections conducted by States are indeed equivalent to those conducted by the federal government."

Two Recent Initiatives in Food Safety

The Hazard Analysis Critical Control Point (HACCP) Approach to Inspections. The HACCP system, which introduces a science-based system of control and prevention, has fundamentally altered the way in which government oversees and inspects the nation's food supply. A HACCP inspection focuses on a science-based assessment of a food firm's hazard and prevention control processes. This is a dramatic shift from the traditional approach of assessing food safety through basic observations of sanitation.¹⁰ In 1997, FDA implemented final regulations requiring the seafood industry to implement HACCP programs and is currently sponsoring pilot HACCP programs in other products and industries.

In 1999, FDA set forth a goal of inspecting 100 percent of the seafood industry for compliance with the seafood HACCP requirements. Many FDA district offices have been struggling to fulfill this requirement given their rising workloads. Increasingly, they are relying on States to meet the seafood HACCP inspection requirements. Oversight takes on an increasing significance given the potential risks involved with seafood and the complexity of these inspections.

The Emergence of a Nationally Integrated Food Safety System. Concerns about our fragmented system of food oversight have led a number of groups, including the President's Council on Food Safety, the Association for Food and Drug Officials, and the National Academy of Sciences, to promote a nationally integrated food safety system that

maximizes and coordinates food safety resources. Such a system would integrate food safety activities at the local, State, and Federal levels of government. While different models are being discussed, many envision a system in which the Federal government would provide leadership through standard setting, technical support, risk assessment, training, and program oversight and evaluation. While the Federal agencies would not turn over the entire inspection process, the States and local governments would be responsible for conducting the great majority of food inspections. Such an integrated regulatory system holds much promise.

In an effort known as the National Food Safety System (NFSS) project, Federal, State and local officials have initiated six work groups to address issues pertaining to the goal of a seamless federal-state-local food safety system.¹¹ In particular, these work groups are addressing issues relevant to Federal oversight of State inspections. Federal and State officials have called for a framework that includes “equivalent minimum regulatory standards; adequate training of inspectors; information exchange on inspection results; verification of performance; and enforcement.”¹²

This Inquiry and Report

This study focuses on FDA oversight of State inspections conducted under State food contracts and partnerships agreements.¹³ These inspections focus on food manufacturing and processing firms. Throughout the report, we refer to these inspections as food firm inspections.¹⁴ We do not address State contracts related to medicated feed, tissue residue, and feed contaminants. We also exclude from our analysis other food inspection programs, such as Cooperative Programs pertaining to Milk, Shellfish, and Retail Foods.¹⁵ In this study, we did not assess inspections that States are conducting independently of FDA, nor did we seek to assess the quality of State inspections.

Our inquiry draws on a variety of sources. These include: an analysis of FDA’s national inspection data; an analysis of FDA’s audit data; a review of all 40 State food contracts and a review of 19 of the 37 partnership agreements involving food inspections; a review of the year-end performance evaluations of States; a review of FDA’s oversight guidance documents; a survey of the 20 FDA district offices, for which we had a 100 percent response rate; a survey of the 40 State food inspection agencies holding contracts, for which we had a 92 percent response rate; in-depth site visits to 3 FDA district offices and 3 States; observations of FDA joint and independent audits; and interviews with industry, consumer groups, and food policy experts. See appendix D for a fuller description of the methodology.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President’s Council on Integrity and Efficiency.

FDA Oversight of State Food Firm Inspections: A Primer

1. Three Types of Food Firm Inspections: FDA and State food firm inspections fall into one of three categories. This report focuses on inspections in the middle category.

State Inspections	State Inspections in Association with FDA	FDA Inspections
<p>The States oversee all food firms operating within their State boundaries, regardless of whether the firms are also subject to FDA oversight. The States conduct these inspections under their own authorities and procedures.</p>	<p>There are two types of arrangements through which States may conduct inspections in association with FDA:</p> <p>Contracts: FDA pays the States to conduct these inspections. They are conducted by the States under the auspices of Federal food inspection laws and procedures.</p> <p>Partnership Agreements: FDA does <u>not</u> pay the States to conduct these inspections, although it may provide training and equipment to the States. These are essentially State inspections, for which the States share information with FDA. The States conduct these inspections under their own authorities and procedures.</p>	<p>FDA oversees all food firms involved in interstate commerce. FDA district offices conduct these inspections in accord with Federal inspection laws and procedures. The great majority of the food firms in this category are also inspected by States, under State authorities.</p>

2. FDA Oversight of the Contracts:

Audits: FDA conducts audits of State inspections. These can take the form of independent audits that occur within 30 days of a State inspection, or joint audits that are conducted concurrently with the State. FDA audit standards call for district offices to conduct a level of audits proportionate to the number of inspections under each contract.

Contract Inspection Reports: FDA reviews contract inspection reports. States submit these reports to FDA within 15 days of completion of an inspection. They are standardized forms, designed in accordance with Federal food inspection laws.

Semi-Annual Evaluations: FDA evaluates State performance twice a year. These evaluations are designed to summarize audits conducted, deficiencies found in food firms, and provide an assessment of State performance.

3. FDA Oversight of the Partnership Agreements:

Joint Inspections: FDA conducts inspections jointly with the States. Standards for the number of joint inspections vary with each partnership agreement.

State Inspection Reports: FDA reviews State inspection reports. These reports vary according to a State's laws and procedures. Standards for report submission vary with each partnership agreement.

Annual Evaluations: FDA conducts an annual assessment jointly with the States. These evaluations are designed as an overall evaluation of the work accomplished.

THE IMPORTANCE OF OVERSIGHT

An effective food safety system depends upon the collective effort among Federal and State government agencies. States offer an important source of industry coverage, as well as front-line inspection expertise. Federal oversight of State food firm inspections plays a key role to ensure the quality and uniformity among both Federal and State inspections. Below we identify and describe three fundamental factors that underscore the importance of FDA oversight of State food firm inspections.

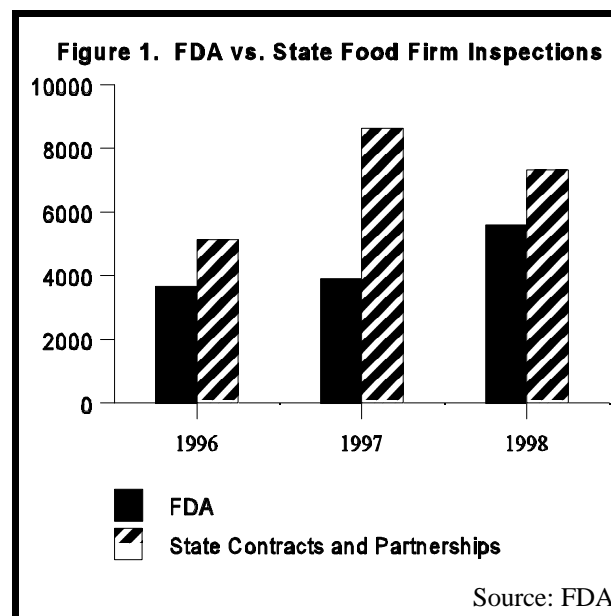
FDA relies heavily on State food firm inspections.

States, through contracts and partnership agreements, inspect a greater number of food firms than FDA.

In the past 3 years, the States conducted through contracts and partnership agreements, on average each year, 61 percent of food firm inspections recorded in FDA's national database. We found that the States inspected an average of 7,032 food firms per year, while FDA inspected an average of 4,391 (see figure 1). FDA's reliance on State food firm inspections has remained consistent over the past 10 years (see appendix E).

We found several cases in which FDA relies on States to inspect a significantly higher proportion of food firms. In Texas, for example, the State inspected 5 times as many food firms as FDA did in 1998.¹⁶ In Alaska, which accounts for over half of seafood processed in the United States, FDA relies on the State to inspect all fishing vessels (about half of the seafood industry in Alaska) and all food firms in remote areas.

In general, FDA's reliance on State inspections plays an important role in reducing regulatory duplication among Federal and State food safety efforts, and in extending FDA's inspection coverage of industries within States.



State inspections are increasingly focused on high-risk food firms.

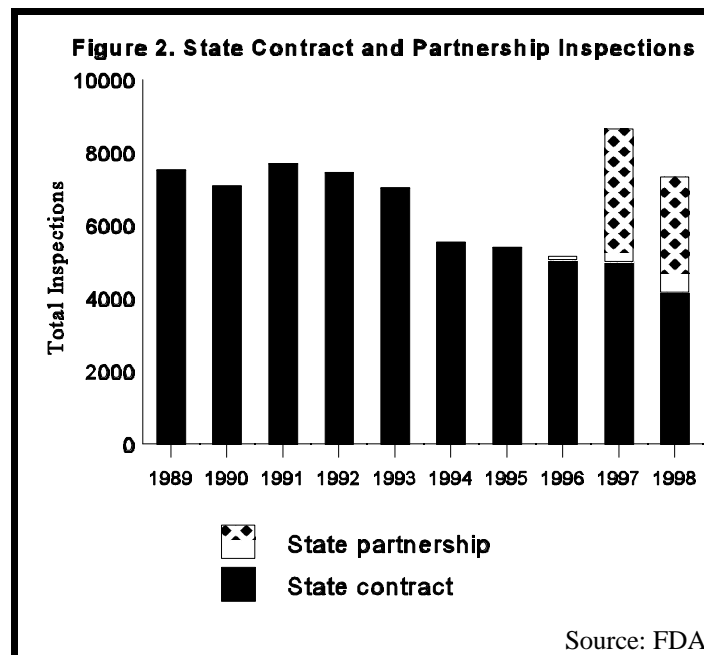
In response to our survey, 10 of the 17 FDA district offices overseeing contracts reported that, over the past 5 years, an increasing proportion of contracted food firm inspections have focused on high-risk food firms.¹⁷ Inspections of warehouses, which have been traditionally considered a low-risk type of food firm, have been almost completely eliminated from the State food contracts. For fiscal years 1999 and 2000, FDA guidance calls for assignments to the States to emphasize high risk areas. These include seafood, low-acid canned food, and microbiological health hazards.

Under partnership agreements, an even greater number of inspections focus on high-risk food firms. In response to our survey, 11 of 17 FDA district offices overseeing partnership agreements reported that more than half of the food firm inspections carried out by States under partnership agreements focused on high-risk food firms. In a number of cases, inspections of high-risk food firms, such as those involving seafood and low-acid canned food, have shifted from contracts into partnership agreements.¹⁸

FDA officials consistently reported that demands on inspection resources have necessitated increasing reliance on States to inspect high-risk food firms. Indeed, States may have expertise and resources beyond that of FDA. We were unable to obtain exact data on the risk-level of food firm inspections assigned to States because FDA lacks a systematic mechanism for assigning risk.

State partnership agreements, which rely primarily on State authorities and resources, are becoming a significant source of food firm inspections.

In 1998, about 43 percent of the State food firm inspections conducted in association with FDA were conducted through partnership agreements. Over the past 10 years, the number of contract inspections has dropped by 45 percent.¹⁹ FDA has relied heavily on partnership agreements to meet its inspection priorities and to maintain industry coverage. In 1998, States conducted nearly as many domestic food safety inspections under partnerships as FDA did.²⁰



Partnership agreements, in large part, have arisen as a practical adaptation to resource constraints. Over the past 10 years, funds to support the State food contracts have remained constant while the complexity and cost of food firm inspections has increased. We found that, with the addition of partnership inspections, States are conducting about the same proportion of inspections, relative to FDA, as they did a decade ago (see figure 2).

States vary significantly in their inspection capacities.

Based on data from our survey and from FDA's national database, we identified variation among State inspection programs along five key dimensions: inspection classifications, enforcement authorities, inspection authorities and regulations, inspector education and training requirements, and hours per inspection.²¹

The variations among State inspection programs raise concerns about the quality and uniformity with which FDA's food inspections are carried out. Under partnership agreements, which have become a significant source of State inspections, FDA relies fully on the States' inspection authorities and resources. The shift to a nationally integrated food regulatory system, under which States would take primary responsibility to inspect food firms, will make concerns about the consistency of State programs even more pressing in the coming decade.

Variation in State inspection classifications.

Based on our analysis of national inspection data, we found variation in State inspection classifications for contracted inspections. Between 1996 and 1998, over half of the States failed to classify even one inspection as *Official Action Indicated*, which would indicate that serious violations were found during the inspection.²² During this same time period, two States classified almost one-fourth of their inspections as *Official Action Indicated*. We present the State-by-State variations in appendix F.

Several factors may contribute to the variation in State inspection classifications for contracted inspections. First, not all States conduct inspections of high-risk food firms. The States that conduct inspections of low-risk food firms could be less likely to find violations warranting severe classifications. Because FDA does not have a mechanism to classify the risk of a food firm, there is no way to evaluate the impact of inspection risk on State inspection classifications. Second, FDA district offices vary in their guidance to States in cases where the State has taken an enforcement action under its own authority. Some district offices may guide States to classify an inspection as *No Action Indicated*, while others may guide the State to use an inspection classification congruent with the State's enforcement action. These factors raise questions about the reliability of FDA's data on inspection classifications and enforcement actions taken by States on inspections conducted for Federal purposes.

Variation in State enforcement authorities.

We identified wide variations in State enforcement authorities based on our State survey responses. Eight of 36 States responding to our survey reported that they lack the authority to revoke a food firm's permit or license; 13 States lack access to all firm records; and 2 States lack immediate embargo authority. See appendix G for a distribution of State enforcement authorities.

FDA itself lacks many of these important authorities. It does not have the authority to revoke a State-issued food firm license; it cannot immediately embargo food suspected of being adulterated while conducting an inspection; and in most cases, it cannot review all of a food firm's records without a Federal warrant. In cases where such actions are warranted, FDA must rely on States. It is a significant problem, however, when a food firm's license needs to be revoked or a food product embargoed, and neither FDA nor the State have the authority to do so.

Several Federal officials and consumer groups raised concerns about States' willingness to take enforcement actions in the face of industry and economic pressures. Their concerns were heightened for States that are economically dependent on food processing and manufacturing firms. Some State officials we spoke with indicated that they prefer to let FDA take action in these sensitive situations.

Variation in State inspection authorities and regulations.

In our survey of State officials, 5 of 37 States reported that their laws and regulations are not equivalent to the Federal Food, Drug and Cosmetic Act; another 4 States reported that they have not adopted Good Manufacturing Practice laws equivalent to Federal standards. The majority of other States operate under statutes containing language similar to Federal statutes.

The lack of uniform regulations among States, and between FDA and the States, is of concern because it means that food firms are held to different inspection standards. We identified, for example, a case in which FDA and a State differ in their implementation and interpretation of the Seafood HACCP inspection requirements with regard to what constitutes a hazard. FDA requires that food firms identify the presence of undeclared allergens or have critical control points to ensure that their labels correctly declare such substances. In evaluating a firm's HACCP plan, FDA will ensure that the food firm has identified the hazard and has the appropriate controls in place. By contrast, the State may check the food product's label to ensure that all ingredients are listed but does not require the firm to identify allergens as a hazard in its HACCP plan or to have controls in place at a critical control point.

Under contracts, States are required to conduct inspections in accordance with FDA laws and procedures. Under partnership agreements, however, FDA has no authority to mandate that States use similar inspection criteria or that they rely on standard critical

control points. As one FDA official put it, when discrepancies are raised at regional meetings, the best FDA can do is simply “agree to disagree” with the States.

Variation in State inspector education and training requirements.

As food manufacturing and processing has become more complex and technical, inspector expertise and training is more pressing. Twenty-three of 35 States responding to our survey require a college degree including science courses, which is equivalent to FDA’s own standard.²³ Eleven States have less stringent requirements. These range from a high school diploma to a college degree without a science background. The States responding to our survey also reported wide variation in the level of training provided to inspectors, ranging from fewer than 5 days per year to over 15 days. See appendix H for a distribution of State inspector education and training requirements.

FDA provides limited training for the States in the areas of manufacturing and processing inspections. Such training must come out of the district offices’ own budgets. In an era of diminishing resources, many district offices are hardpressed to find the resources to conduct such training. Even when training is available, States are expected to fund their own travel costs. Several States reported that limited funding and travel restrictions had routinely prevented them from attending FDA training.

With the exception of the Seafood HACCP certification program, there is no national program to certify the competency of food inspectors. A number of State and Federal officials pointed out that educational and training requirements are important, but that they do not guarantee an inspector’s level of knowledge or his ability to incorporate inspection theory into practice. FDA has begun to move in the direction of voluntary certification in its seafood HACCP program. This certification program, which involves a written exam and an on-site performance review, has been well received by Federal and State inspectors. Many view the Seafood HACCP certification program as an important step toward promoting uniformity and consistency in inspections.

Variation in State inspection times.

Based on our analysis of national inspection data, we found that between 1996 and 1998 the average length of State contract inspections ranged from 2.8 to 9.5 hours among States. The average time overall for States was 5.7 hours per contract inspection with a standard deviation of 1.5 hours. The variation in State inspection times may be even greater under partnership agreements than under food contracts. Under partnership agreements, the States follow their own procedures and use their own forms. A number of State officials told us that they generally conduct shorter inspections than FDA, but at a higher frequency. We present State-by-State variation in appendix F.

A number of factors may influence the amount of time a State spends inspecting a food firm. These include the complexity of the inspection, the firm’s size, the risk of the processing and manufacturing operations, and the inspector’s familiarity with the food

firm. However, given the other evidence we present on variation among States, we raise concerns that the variations among inspection times may well indicate differences in the quality and thoroughness of inspections.

Variation in State regulatory programs can inhibit commerce.

The variation in State laws and inspection practices adds complications, costs, and frustrations for food firms engaged in multi-State commerce. These firms are already subject to significant variation in inspection regulations and practices among the Federal food inspection agencies. Industry representatives have expressed concern that an even heavier reliance on State inspections, such as under a nationally integrated regulatory system, could magnify the existing complications and costs. They are calling for uniform laws and inspection standards across the nation and for strong Federal oversight as a means of fostering and maintaining consistency among State inspections.

To our international trading partners, variation in State laws and inspection practices can undermine confidence in the uniformity of U.S. food standards and enforcement efforts. Some countries have raised concerns about discrepancies in U.S. food laws. For example, FDA prohibits the sale of raw milk and unpasteurized cheese in interstate commerce; yet, at least one State allows the commercial sale of such products within its State borders. This discrepancy has resulted in tension between the U.S. and foreign trading partners wishing to import unpasteurized cheese. Our foreign trading partners have also raised concerns about the lack of uniformity for inspections of imported products. This problem may be exacerbated if imported products are inspected under the partnership agreement mechanism.²⁴ Others have raised concerns that variation in State inspection practices and laws may lead some trading partners to concentrate imports in more lenient States.

FINDINGS

FDA's oversight of State food firm inspections is limited.

Under contracts, FDA obtains minimal information to assess the quality of State food firm inspections.

FDA's on-site audits have declined.

On-site audit inspections are a key component of FDA's validation of State performance. Yet, over the past 5 years, FDA on-site audits dropped by 59 percent, from 253 in 1993 to 104 in 1998 (see appendix I).²⁵

FDA's audit standards call for its district offices to conduct a level of audits proportionate to the number of inspections under each contract.²⁶ Yet, the majority of district offices failed to meet these standards. In 1998, 7 of the 17 district offices overseeing State food contracts did not conduct a single audit.²⁷ Many of district office officials we spoke with did not view on-site audits as a priority. In fact, many stressed that on-site audits were unnecessarily "duplicative of State efforts."

The distribution of audits is widely disproportionate among States with contracts. In 1998, FDA conducted over half of its audits in only 5 of the 38 States. Those 5 States conducted just 13 percent of the total inspections conducted under contracts. By contrast, FDA did not conduct a single audit in 21 of the 38 States holding contracts. These States conducted over 50 percent of the contract inspections. This pattern of disproportionate coverage has remained consistent over the last 3 years.

FDA's on-site audits provide a limited basis for assessing State performance.

FDA relies on independent and joint audits to assess the quality of State inspections. Independent audits, FDA's primary audit approach, are conducted up to 30 days after the State's inspection.²⁸ The purpose of these audits is to validate whether the State's inspection findings match FDA's. During the 30 days, however, conditions in the food firm may have changed, introducing a margin of error in the audit findings. Furthermore, these audits focus on the accuracy of inspection findings and give little attention to how the State inspector drew conclusions. Finally, FDA's approach to independent audits focuses on conditions in the food firm as a proxy for the performance of the State; the independent audit does not assess State performance directly.

Despite FDA's reliance on the independent audits, district offices consistently reported that the joint audits were more useful to assess the quality of State inspections. In contrast to the after-the-fact approach of the independent audits, the joint audits allow for FDA to directly observe State inspections and provide immediate feedback. State officials

also emphasized the benefits of joint audits in improving the quality of their inspections. Nevertheless, FDA provides limited guidance on how to conduct the joint audits. Several FDA officials raised concern that FDA auditors, while trained to conduct inspections, lack important training and guidance on how to evaluate State performance.

The lack of documentation further limits the effectiveness of audits as an assessment tool. At most, FDA auditors fill out a separate inspection report. However, the auditor does not document an assessment of State performance. As a result, FDA has a limited ability to review previous audit findings or to assure consumers, food firms, or international trading partners of its oversight.

Finally, FDA may not be appropriately selecting its audits. According to FDA guidance, audits should represent the types of inspections under contract. Based on our site visits, however, we found that FDA selected food firms to audit largely based on a firm's location and the auditor's schedule. Several FDA staff questioned whether the audits represent State inspections of the most complex and risky food firms.

FDA's reviews of State contract inspection reports lack much rigor.

During contract inspections, State inspectors complete a standardized inspection report documenting violations found during the inspection. This information is essential for FDA to understand what took place during the inspection and the enforcement actions that are necessary. FDA requires States to submit the contract inspection reports within 15 days of the completed inspection.

In response to our survey, 14 of the 17 district offices overseeing contracts reported that they do not use *any* formal criteria to review the quality of State contract inspection reports. Based on our site visits, we found wide variation among district offices in assessing these reports. In one district office, the FDA reviewer skimmed every tenth report, focusing primarily on completeness of the forms. Other reviewers conducted more detailed reviews of each report. These reviews included, for example, assessing the inspectors' ability to identify and clearly report violations found.

FDA maintains national inspection data in its Program Operations Data System. In the district offices we visited, only one reviewer made use of this database to analyze aggregate State inspection data. While we recognize that this database contains limited information, it can be used to track basic trends in State work. FDA is in the process of implementing a new Field Activity and Compliance Tracking System that will provide more specific information on State inspection results.

FDA rarely seeks input from external sources to evaluate State performance.

An important source of State evaluation can come from external sources, such as food firms, trade associations, or even consumer groups. Such sources can provide information and perspectives that FDA inspectors would be hardpressed to match through audits and review of inspection reports alone.

The FDA does not proactively solicit information from external sources. For example, it does not take advantage of its public meetings, food safety hotline, and food safety websites as avenues for obtaining information about the quality of State inspections. None of the district office officials we spoke with had ever contacted the trade associations or consumer groups in their area to learn about the quality of State inspections. Instead, FDA district office staff told us that they typically rely on informal communications with industry officials at food-related conferences as their only source of external feedback.

Industry surveys can be an important source of information about the performance of State inspectors. Overall, however, the district offices have initiated little outreach of this type. In recent years, at least one district office tried to survey food firms regarding the performance of its own inspectors. It appears, however, that the Paperwork Reduction Act and the Federal Advisory Commission Act are factors inhibiting such efforts.²⁹

By contrast, each of the three States we visited routinely surveyed industry for feedback on the quality of their own inspections. Below, we present several examples of questions posed in their surveys.

State-Initiated Industry Surveys

- ➔ Was the inspector prepared and knowledgeable about your type of operation?
- ➔ Were the inspection findings adequately explained including the public health significance and the relationship to the law and regulations?
- ➔ Generally, Food Safety Program representatives offer options or provide assistance in correcting violations or problems: (Strongly Disagree-Strongly Agree)
- ➔ Inspection reports left by the Food Safety Program Representative are useful in correcting violations and problems: (Strongly Disagree-Strongly Agree)
- ➔ How do we rate on job knowledge? (Scale of 1-5, Poor to Excellent)

Source: Texas Dept. of Health; Washington State Dept. of Agriculture; Maine Dept. of Agriculture

Under partnership agreements, FDA obtains even less information to assess the quality of State food firm inspections.

Since their inception in 1994, partnership agreements have become a significant source of State inspections. In 1998, these inspections accounted for 43 percent of the total State food firm inspections that FDA records in its national database.³⁰ Under partnership agreements, States conduct their own inspections, which FDA accepts as equivalent to its own. In many cases the partnership agreements involve inspections of higher-risk food firms than under contracts.

FDA does not audit State performance, but participates in some joint partnership inspections with States.

In contrast to the contracts, partnership agreements do not call for an on-site audit of State performance. Instead, the partnership agreements call for FDA and State inspectors to conduct joint inspections. There is no formal guidance on the purpose of these joint inspections.³¹ FDA and State officials we interviewed regarded joint inspections as a mechanism to provide on-site training and share inspection expertise among Federal and State inspectors. They repeatedly emphasized to us that an FDA audit role was inappropriate for inspections accomplished through partnership agreements.

The partnership agreements contain a wide range of expectations about the number of joint inspections to be conducted. Among the five low-acid canned food partnership agreements we analyzed, the expectations ranged from “one joint inspection per year with each inspector” to joint inspections based on “availability of personnel and agency priorities” (see appendix J). FDA only has uniform standards under its Seafood HACCP partnership agreements, where it calls for a minimum of 5 percent joint inspections.

Based on our site visits, FDA district offices conducted fewer joint inspections than called for by the partnership agreements. For example, in one district office, the States holding partnership agreements conducted over 500 Seafood HACCP inspections. Yet, the district office conducted less than 5 joint inspections total. This is less than one-fifth of the joint inspections called for by the Seafood HACCP partnership guidance document.

FDA’s reviews of State partnership inspection information are even more limited than its reviews of contract inspection information.

The States submit widely varied levels of information about their partnership inspections. In contrast to the contracts, where FDA requires States to submit standardized inspection reports within 15 days of completion of an inspection, FDA district offices and States negotiate different levels of information sharing in each partnership agreement. Our analysis of five low-acid canned food partnership agreements revealed expectations ranging from “periodic inspection summary reports” to the “prompt exchange of full inspection reports” (see appendix J). Even in cases where FDA obtained full State inspection reports, the reports were based on the States’ own inspection procedures and

codes. In several cases these reports lacked elements required in FDA's inspection reports. One State, for example, based its inspection report on a checklist that lacked elements to record observations of a firm's processing methods and a narrative section to describe violations found during inspections.

During our site visits, we identified a number of partnership agreements where FDA did not obtain enough information to assess the quality of State inspections. In several seafood HACCP partnership agreements, for example, FDA did not obtain a narrative description of violations found. Without a narrative portion, FDA reviewers were unable to assess the significance of violations or the thoroughness of the inspection. Under the Oklahoma Food Safety Partnership Agreement, which is significant because the State has agreed to inspect 100 percent of the food firms within the State, FDA obtains extremely limited information to assess the quality of State inspections (see box).³² While this may represent an extreme case, nevertheless it raises concern about the level of information FDA receives through the partnership mechanism.

The Oklahoma Pilot

In 1994, FDA entered into a 5-year pilot partnership agreement with the State of Oklahoma, under which the State conducts *all* of the food firm inspections within the State, including products subject to interstate commerce. FDA does not conduct any inspections in the State.

On a quarterly basis, Oklahoma submits a spreadsheet of inspection data. The spreadsheet provides only information on inspection results, and lacks information to assess the quality of inspections.

Outside of this spreadsheet, the partnership calls for an annual performance evaluation. Since 1995, however, FDA has conducted only one performance evaluation of Oklahoma's food manufacturing and processing inspections. A second audit is planned for fiscal year 2000. In preparation for this audit, the FDA has offered several training courses to State inspectors.

FDA has less accountability for the enforcement actions that States take under partnership agreements than it does for enforcement actions that States take under contracts. Under contracts, FDA reserves the right to approve a State's inspection classifications and enforcement actions, and to take action itself when necessary. Under partnership agreements, however, FDA simply accepts the State's inspection classifications and enforcement actions. FDA does not outline clear expectations to share information about enforcement actions taken under partnership agreements (see appendix J).³³ By contrast, FDA requires States to regularly submit full documentation of all enforcement actions taken under contract.

FDA provides limited feedback to States on the quality of their inspections.

Two-way communication is an essential component of an effective oversight system. The information that FDA obtains can provide an important source of evaluation for State programs. Feedback is especially important to help States identify weaknesses and to improve the quality of inspections. Feedback can also facilitate the exchange of expertise or resolve discrepancies between FDA and State policies.

The majority of FDA's ongoing feedback to States relies on informal communication and individual district office initiatives.

FDA does not routinely provide States with feedback concerning its on-site audits or reviews of inspection reports. While feedback may occur informally over the telephone or in person, many of the State officials we spoke with told us that they would like to receive written feedback from FDA regarding the narrative portions of their inspection reports and the results of FDA's audits. As we stated earlier in this report, FDA's assessment of the information it obtains through audits and inspection reports is limited. As such, the FDA has limited basis to provide States with useful feedback.

Where FDA does provide feedback, it depends on initiatives of individual district offices. In one district office we visited, FDA provided States with a periodic assessment of problems found in their inspections reports. The State officials reported that this feedback has helped to improve the quality of their inspections.

FDA's performance evaluations provide States with little feedback about the quality of State inspections.

The only formal mechanisms through which FDA documents its evaluation of State performance are a semi-annual State contract evaluation and an annual partnership evaluation.³⁴ Based on our review, however, these evaluations provided limited assessment of the quality of State inspections.

We found that 13 of the 34 semi-annual contract evaluations we analyzed for 1998 did not provide any assessment of State performance. Fourteen of the 34 evaluations provided only minimal assessment of State performance, offering cursory and general comments such as 'overall history of performance has been good' or 'no deficiencies reported.' Only seven of the evaluations provided more details in their assessment of State performance, such as problems found with inspection reports, or changes in State personnel that affected performance (see appendix K).

FDA's annual partnership evaluations were equally limited in their assessment of State performance. Ten of the 17 partnership evaluations we analyzed for 1998 contained broad summary statements of activities and little evaluation of the States' performance. For example, statements included "Communication and coordination efforts between parties were improved. Resources were better utilized to meet goals of the partnership. The

goals of the partnership were met.” Seven of the annual evaluations provided more detail in their assessment of inspections accomplished. These evaluations included comments that addressed in more depth, for example, the quality and consistency of inspections, the extent and nature of communication between the partners, and recommendations to improve work in the future. Most of the district offices we interviewed seemed to regard the partnership evaluations as a means to communicate a summary of activities to headquarters, as opposed to a tool to evaluate State performance (see appendix L).

The majority of States never received copies of the 1998 evaluations, further limiting their usefulness as tools for feedback. In their survey responses, over two-thirds of the States holding contracts reported that they did not receive a copy of the semi-annual contract evaluations. Over half of the States holding partnership agreements reported that they did not receive a copy of the annual partnership evaluations.

FDA’s feedback places little emphasis on improving the quality of State inspections.

FDA’s feedback is geared toward identifying deficiencies rather than toward enhancing State performance. Generally, the States only hear from FDA regarding their performance if there is a significant problem. Several State officials emphasized that FDA’s assessments should include evaluation of both strengths and weaknesses.

FDA is in a strategic position to observe best practices among the States and to disseminate this information widely. Where FDA district offices have shown initiative in this direction, the results have been positive. For example, one district office promotes information sharing through annual meetings and a monthly conference call. Both the district office and the States report that these initiatives have facilitated communication and raised awareness of innovative practices. FDA, however, does not generally take advantage of its position to facilitate this type of information sharing.

FDA provides limited feedback to the public regarding its oversight of contracts and partnership agreements.

Providing information to the public is an important mechanism through which government agencies can hold themselves and the bodies they oversee accountable. With advances in information technology, it has become increasingly easy to provide the public with information. FDA has several websites, a telephone hotline, and a facsimile information service through which it can make information available to the public.³⁵

FDA does not make information available to the public about its reliance on State inspections or about State performance.

Despite FDA's extensive reliance on States to inspect food firms, it shares little with the public about the extent and nature of its reliance. The FDA website does not identify the States with which it holds contracts or the number and type of inspections that States conduct under contract. The website provides slightly more information about partnership agreements, but lacks specific information such as the number and types of inspections conducted under each partnership agreement. We called the FDA hotline to learn about State inspections conducted on FDA's behalf and were told that the only way to obtain such information was to contact the States directly or to submit a Freedom of Information Request.

FDA provides no information to the public about its oversight or assessment of State performance. For example, FDA does not provide information about the mechanisms it uses to oversee States nor the extent to which it carries out these responsibilities. FDA does not make available any assessment of State performance and does not provide information about the results of State inspections conducted on its behalf. By contrast, a few States are posting performance measures on their own State websites (see box.)

The State of Alaska makes the following types of information available on its website:

- Percentage of domestic seafood production originating from Alaska and an overview of food facilities within the State.
- Number of high-risk inspections accomplished vs. number of inspections conducted based on a risk model.
- Trends in violations and compliance actions.
- Number of State and nation-wide deaths and illnesses associated with food products.

Source: www.state.ak.us:80/dec/deh/safefood.htm, 12/6/99

Consumer advocates and industry representatives repeatedly told us that they would like more information about FDA's reliance on States and the mechanisms through which FDA oversees these inspections. Such information would provide an important source of FDA accountability to the public.

FDA faces significant barriers in overseeing State food firm inspections

Low priority of food safety inspections.

No statutory requirement exists for FDA to inspect a minimum number of food firms, as there is in other programs within FDA's purview, such as inspection of mammography facilities. In developing its work priorities, FDA must allocate resources to the mandatory inspection areas first. The resources that remain go to the non-mandatory programs, such as food firm inspections. Over the past decade, FDA's regulatory responsibilities have increased, while FDA's resources have not kept pace. Without mandatory requirements to conduct food inspections, resources to conduct these inspections have diminished. For example, the number of operational full time equivalents in the district offices have declined in almost all food areas, excluding fish and fishery products.³⁶

Within the food inspection program, resources to conduct oversight of the State food firm inspections compete with FDA's own inspection resources. At present, FDA manages to inspect only a small fraction of the food firms under its own purview.³⁷ In developing its annual work plans, FDA does not set aside resources to conduct oversight. In response to the limited resources available for oversight, a number of district offices have spread oversight responsibilities, previously held by one supervisor, to several FDA inspectors. Many of these inspectors carry full inspection loads, leaving little time for oversight.

Limited leverage to oversee partnership agreements.

The majority of State and Federal officials we spoke with were uncomfortable with the concept of FDA overseeing the partnership agreements. Many of them underscored the fact that States agreeing to conduct inspections under partnership agreements are doing FDA a favor by helping the agency to extend its inspection coverage at a low cost. Several officials also pointed out that the basic principle of partnerships, whereby each partner accepts the other's work as equal, contradicts the need for Federal oversight.

Because FDA is not paying its partner States to conduct inspections, it has limited ability to require States to submit information, to provide critical feedback on inspections conducted, or to facilitate change in the State's inspection habits.³⁸ This concern is heightened under Seafood HACCP inspections, where States may not be adequately shifting from inspections focusing on basic observations of sanitation to a science-based assessment of a food firm's hazard prevention and control processes.

FDA's oversight of partnership agreements is further weakened by its lack of incentives to terminate partnership agreements. Because FDA cannot afford to conduct these inspections itself, there is little incentive to terminate the partnership agreements. Furthermore, in contrast to the contracts, there are few financial consequences for States that do an inadequate job of inspecting food firms.

Reductions in training and agency expertise.

In the past decade, formal classroom training for FDA inspectors declined significantly. We found that training hours received by FDA personnel decreased by 41 percent between 1992 and 1998. In 1992, FDA personnel received 23,749 hours of training; in 1998, FDA personnel received 13,992 hours. Where training has been provided, it focused on Seafood HACCP, as opposed to manufacturing and processing inspections.

In a number of States, the FDA is conducting only a minimal number of inspections.³⁹ FDA district office officials consistently raised concerns about whether they were retaining enough workload to ensure program area competence. FDA has not set forth a minimum level of Federal inspections to be conducted in each State.⁴⁰ Several officials within FDA were concerned that agency expertise is unevenly distributed throughout the country. FDA's diminishing inspection expertise raises concern about its effectiveness in overseeing the States.

Limited accountability of FDA district offices.

FDA has set forth general guidelines for its oversight of State food firm inspections, but has few mechanisms to ensure the uniformity and effectiveness of the oversight carried out by district offices. FDA does not provide audit training for FDA inspectors nor does it have mechanisms to ensure that audits are carried out appropriately. Annually, FDA headquarters compiles a summary of audits conducted by the district offices. In the past few years, however, many district offices have not submitted this information to headquarters. Furthermore, FDA lacks a system for district offices to track time they spend on oversight activities. As a result, FDA headquarters is unable to hold district offices accountable for how effectively they deploy their limited resources.

Lack of important enforcement authorities.

FDA lacks the authority to revoke a food firm's license, to immediately embargo food suspected of being adulterated, and to access all of a food firm's records without a Federal warrant. Most States have access to these authorities. FDA consistently relies on States to take such actions, because they are subject to fewer legal and administrative loopholes, and because States can often take action more quickly.

Several FDA and State officials have raised concerns that FDA's reliance on State enforcement authorities compromises its ability to be critical of State inspections. On the one hand, FDA needs to ensure the adequacy of State inspections. On the other, it needs to maintain a good relationship with the States. In our 1991 report on food safety inspections, we raised concerns about the adequacy of FDA's enforcement tools and the negative ramifications of FDA's reliance on States.⁴¹ In 1999, the Canadian Food Inspection Agency also raised concerns about FDA's limited powers and its reliance on State enforcement authorities.⁴²

RECOMMENDATIONS

Key Role of State Government

State governments play a critical role in ensuring the safety of the nation's food supply, both under their own authorities and in concert with FDA through contracts and partnership agreements. They provide valuable resources and expertise that serve as a complement to FDA's own inspection efforts. Our recommendations recognize and build on the importance of this State role.

Template for Reform

For State inspections carried out under FDA auspices, it is essential that FDA provide effective oversight to ensure both the quality and uniformity of inspections. FDA brings important strengths to this oversight role through a tradition that emphasizes science-based research and a public health perspective. Moreover, on the front-lines FDA oversight is carried out by many knowledgeable and dedicated staff. We met many of them and were impressed by their commitment to food safety.

But our review has revealed major shortcomings in FDA's current system for overseeing State food firm inspections. In this section, we recommend actions FDA can take to address these shortcomings and to develop a system of oversight that holds the States more fully accountable for the inspections they conduct in association with FDA. Our recommendations are based on a template of effective oversight that includes the following seven key elements.

Template For Effective FDA Oversight of State Food Firm Inspections

- ✓ **Equivalency:** Equivalency in Federal and State safety standards, inspection programs, and enforcement practices.
- ✓ **On-site Audits:** An effective on-site mechanism for evaluating State inspection performance.
- ✓ **Inspection Information:** Routine submission of standardized information on State inspections.
- ✓ **External Sources:** Information from varied external sources on State inspection performance.
- ✓ **Feedback to States:** Substantive and timely FDA feedback to States on inspection performance.
- ✓ **Internal Capacities:** Enhanced FDA capacities to conduct effective oversight.
- ✓ **Public Information:** Proactive public disclosure of inspection and oversight information.

The specific recommendations that flow from this template are in accord with the National Academy of Science's call for a Federal food safety system with "well defined accountability" and "responsibility for each partner in the system."⁴³ The Academy calls for FDA to devote more attention to building and carrying out an effective oversight system. FDA itself, through the Center for Food Safety and Applied Nutrition, has made the evaluation of State inspection programs a top agency priority for the year 2000.⁴⁴ We recognize that in an environment of limited resources and competing priorities, such attention is not easily or readily provided. However, we feel that oversight is a critical area that FDA should not neglect. These recommendations should be viewed as a blueprint for action that can be carried out over a period of time.

In the following pages, we elaborate on the seven elements in the template. We begin, however, by offering a caution concerning FDA's reliance on partnership inspections. The partnership agreements, as we have indicated earlier, have grown to account for 43 percent of the State food firm inspections conducted in association with FDA.

An Initial Caution: FDA should reevaluate its dependence on partnerships as a mechanism for conducting inspections.

FDA's increased reliance on partnership inspections is understandable. In an environment of limited resources, it is a practical way of extending inspection coverage at little cost. FDA provides the States with certain benefits, mainly in the form of training or technical assistance, and the States agree to conduct inspections at their own cost.

But the operational reality is disturbing. The inspections that States carry out under partnership agreements are primarily inspections that they already conduct under their own State requirements. In most cases, State officials felt that they were doing FDA a favor by including inspections under the partnership agreements, a feeling which FDA district office officials were well aware of. Thus, FDA is not in a position to exert much leverage in overseeing the inspections. In fact, both FDA and State officials tend to see FDA oversight of partnership inspections as an anomaly in what they regard as a partnership of equals.

We suggest that current conditions are counter to effective FDA oversight of partnership inspections. FDA uses partnership agreements as vehicles to accept State inspections as equivalent to its own. While many of the State inspections may well be of high quality, FDA is not in a position to adequately assess their quality or equivalency. For its oversight to be credible, it must be able to offer such attestation. If FDA moves in the directions we call for below, then the time will come when partnership agreements can serve more reliably as a mechanism for FDA-State collaboration.

In the recommendations that follow, we take the position that a two-tier FDA system of oversight is inappropriate. Oversight geared to partnership inspections must be just as effective as that geared to contract inspections. While there can be some differences in approaches, FDA must be able to assure consumers that its commitment to safety is no

less under one mechanism than the other. And, similarly, it must assure industry officials and international trading partners that its commitment to quality and uniformity is independent of the vehicle through which inspections are conducted. Thus, we offer our recommendations as actions FDA can take to hold States more accountable for food firm inspections conducted under both contracts and partnership agreements.

Recently, FDA assigned the Office of Regulatory Affairs Federal-State Field Advisory Committee the task of developing acceptable language for the oversight of partnership inspections for inclusion in the partnership guidance document. We encourage this committee to address the concerns and recommendations highlighted in this report.

Recommendation 1. FDA should work with the States to achieve basic equivalency in food safety standards and laws, and in inspection programs and practices.

In many respects, a common set of standards for industry to comply with and for State and Federal inspectors to apply in their inspections provides an essential foundation for effective oversight. FDA oversight of State inspections has only limited value without a common frame of reference.

Standards for State inspection programs already exist in several areas of our nation's food safety system. The Department of Agriculture has program standards for States participating in its meat and poultry inspection program. The Conference for Food Protection recently established voluntary standards for retail food inspection programs. These standards are now being tested in six States.

The National Uniform Criteria work group within the National Food Safety System (NFSS) project is exploring national standards that would achieve uniformity among food safety programs. We recognize that FDA and the States face a number of barriers in moving toward greater consistency and uniformity in food safety inspection and regulation. We encourage FDA to continue to take leadership in working with the States and the NFSS project national work groups to accelerate progress in this direction.

1a. Pilot test a system audit as a mechanism to foster equivalency and evaluate State capacity and performance.

A system audit is a comprehensive review that focuses on a State's capacity to conduct food safety inspections and effectively oversee its own program. It can also add depth to FDA's oversight and allow for somewhat less emphasis on audits of individual State inspections. The Food Safety Inspection Service of the Department of Agriculture has moved in this direction with its oversight of meat and poultry programs.

For a system audit to work as an FDA tool of oversight, however, a State must have, or be ready to develop, standards, regulations, and inspection approaches substantially equivalent to those of FDA. The Role and Responsibilities work group within the NFSS

project has made considerable progress in developing a model for a system approach to oversight. The work group has prepared a document, "Evaluation of Regulatory Food Safety Systems as Part of a Nationally Integrated Food Safety System," which has been forwarded to the Federal agencies involved and the President's Food Safety Initiative. We applaud this work as an important reference point in developing an appropriate oversight model and encourage further work in this direction.

If FDA were to find two or more States willing to test the system audit approach, the parties could work to advance equivalency and improve oversight. One possibility would be for FDA to work with one State that has laws and approaches that are similar to FDA and another State that lacks equivalency but is willing to work toward it. The results of the test could provide a laboratory for how best, over time, to integrate a system audit into FDA's oversight.

Recommendation 2. FDA should devote high priority to improving its on-site audit mechanism for evaluating the effectiveness of State inspections.

This is a matter of considerable importance warranting immediate attention. The on-site audit of State inspections serves as the core of FDA's oversight and evaluation efforts and is likely to do so for some time to come. That core is deficient.

Given the importance of the on-site audit, FDA may wish to contract for some outside assistance in carrying out this function. But over time, and in the interest of developing a nationally integrated food safety system with State agencies playing key roles, it is clearly desirable to strengthen FDA's in-house capabilities to assess how well States conduct inspections. Below we address policy changes FDA should take governing the nature and frequency of on-site audits. In each case, FDA has recently undertaken some initiatives that move in the direction we call for. In the following three sections, we briefly elaborate on these initiatives.

2a. Stress joint audits rather than independent audits as the primary mechanism to conduct on-site reviews of State inspection performance.

Our analysis leads us to recommend that FDA rely on the joint audit as its major approach to on-site reviews. The joint audit allows an FDA inspector to assess first-hand the performance of the State inspector and to offer immediate feedback. This approach has considerable support among both FDA district offices and State officials.

This emphasis on joint audits, we should note, need not preclude some use of independent audits. FDA should still conduct periodic independent audits on both a for-cause as well as a random basis. They can serve as a valuable, albeit secondary, component of a strengthened oversight system.

In a February 18, 2000 memo to the field, the Associate Commissioner for Regulatory

Affairs called for a focus on joint audits for fiscal year 2000. While this action is not yet part of FDA's audit policy, it represents a significant shift away from FDA's current emphasis on independent audits. We encourage FDA to evaluate the implementation of this new approach to develop an appropriate audit strategy.

2b. Develop guidance that provides clear and firm direction on the essentials of FDA on-site audits.

Given the shift we recommend toward a focus on joint audits and the limited training that has been offered to FDA inspectors in audit and evaluation methodologies, we recommend that FDA develop a guidance document on the essentials of on-site audits. Such guidance can serve as a basis for training and as a reference point for FDA in evaluating State performance. It will be essential to establishing uniformity among district office audits and to reaching uniformity across States.

This guidance document should clarify and specify the auditing role that FDA inspectors play and the performance criteria that FDA inspectors should use to evaluate State inspections. In contrast to the current standards, which focus narrowly on the accuracy of State inspection findings, FDA should develop criteria that provide a comprehensive review of State performance. FDA guidance should also clarify how its inspectors can document their assessment of State performance and the manner, nature, and timing of the feedback that FDA provides to States about the on-site audits. In developing this guidance, FDA could consider similar guidance manuals that it uses for other programs, such as those currently used in the Mammography Quality Standards Act program. For example, FDA may want to create a checklist that Federal auditors can use in evaluating the quality and performance of State inspections.

FDA should seek input from its State counterparts in developing guidance about the on-site audits. State input is vital to developing sound performance criteria. As States and the Federal government move toward greater uniformity in their standards and practices, the on-site audit mechanism can spur consistency among food inspections.

In at least one State, the FDA is currently developing a pilot field audit program that will require Federal auditors to utilize an audit evaluation form when conducting a joint audit. We encourage FDA to evaluate the effectiveness of this audit guidance and form and, if effective, to consider employing it more broadly in its oversight of State inspections.

2c. Determine the appropriate minimum frequency for on-site audits.

For the on-site audits to serve as an effective tool of oversight, FDA must conduct them often enough and regularly enough for the States to take notice of FDA's presence and for FDA to obtain sufficient information to assess the adequacy of the States' inspections. We documented the reduced frequency of FDA's on-site audits for contract inspections and their uneven distribution across States. We also identified the infrequency and variation in joint inspections undertaken through partnership agreements.

We recognize that, in large measure, the frequency of on-site audits is a function of available resources. The same resources that the district offices draw upon to conduct these audits must also be used for many other activities, including FDA's own food firm inspections and inspections in other program areas, such as medical devices and blood banks. We urge that FDA, in assessing its various priorities, provide clearer direction in defining an appropriate minimum number of on-site audits, for both contract and partnership inspections, and then hold the district offices accountable for meeting the minimum. Given that FDA relies on States for the majority of its food firm inspections, oversight deserves considerable attention. Without regular on-site audits, FDA's oversight will lose credibility and its capacity to attest to the quality and uniformity of State inspections will erode.

In its recent memo to the field, the FDA also called for joint audits for 5 percent of the inspections assigned to States under contract for fiscal year 2000. Further, the memo further called for all State inspectors to have at least one joint inspection over the next three years. We encourage these efforts and urge FDA, over the coming years, to evaluate the implementation of these strategies for the most effective use of resources.⁴⁵

Recommendation 3. FDA should require that States routinely provide FDA with standardized information on the inspections they conduct.

Beyond on-site audits, a second key source of information is FDA's on-going review of inspection reports. In collecting such information, FDA must seek to minimize the reporting burden on the States, but at the same time ensure that it has a core of information to provide effective oversight. Our recommendations may require contractual changes, but most certainly will require changes in the partnership agreements.

3a. Define a minimum set of information to collect from the States on inspections conducted under both contracts and partnership agreements.

The information that FDA obtains about partnership inspections is highly variable and depends on the States' own policies and practices. In contrast, FDA obtains standardized information about contract inspections. This information includes contract inspection reports with narrative portions, information to assess a firm's compliance with FDA regulations, and a detailed description of a food firm's manufacturing processes.⁴⁶

We recommend that FDA define the core set of information it regards as essential for oversight of State food firm inspections and then require that States provide it under both contract and partnership agreements. We urge that State enforcement actions be part of that essential core. At present, FDA lacks information about enforcement actions that States take under their own authority for contract inspections. FDA almost always lacks such information with respect to partnership inspections since enforcement actions under that arrangement are typically taken under State authority. For FDA to assess how and how well States are performing, it must be fully and accurately informed on the extent and

type of enforcement actions the States take. We urge FDA to use information that will be available through the Field Activity and Compliance Tracking System to analyze and track enforcement actions taken by States for inspections conducted in association with FDA.

3b. Provide guidance to district offices addressing the extent and nature of their reviews of State inspection reports.

In its guidance, FDA should provide a framework for how the district offices can best review inspection reports submitted by States. The guidance could address how and how often the offices might review individual inspection reports. FDA should establish uniform criteria by which all district offices should evaluate the quality of State inspection reports. As with the criteria to assess State performance during audits, the criteria to review these reports should provide a level of accountability and a mechanism for providing the States with feedback. Again, we encourage FDA to seek input from States regarding review criteria that would be most useful to improve their programs.

We also urge FDA to provide guidance to the district offices on how best to use existing data sources to complement their ongoing reviews of State inspections reports. The data that is collected and stored in the Program Operations Data System (PODS) can help district offices and States identify trends in State inspection practices and opportunities for improvement. We recognize that the current PODS database is somewhat limited, and thus we encourage FDA's shift to a new system called the Field Activity and Compliance Tracking System (FACTS) database. This system will provide considerably more information that will enable FDA, for instance, to track the types of violations found and the types of enforcement actions taken. We are aware that the FACTS system is designed to accommodate enforcement actions that are characteristic of FDA's regulatory process. To the extent that State enforcement processes are different from FDA's, some redesigning of FACTS could be necessary. We urge FDA to consider how it can use the FACTS system to maximize efficiency in its oversight efforts.

Recommendation 4. FDA should draw on multiple external sources of information in assessing State inspection performance.

In its recent report on improving food safety, the National Academy of Sciences called for FDA to ally with non-federal partners, including the food industry and consumer groups.⁴⁷ The perspectives of external sources can be a valuable complement to the information that FDA obtains from its on-site audits and review of inspection reports.

4a. Solicit feedback from industry, consumer, and other groups on the adequacy of State inspections.

FDA could transform many of its existing outreach mechanisms into avenues for public feedback on the quality of State inspections. For example, FDA's food safety website is

an ideal forum through which to solicit external perspectives. FDA could create a separate section on its website for feedback on State inspections. Another avenue for obtaining feedback would be through public meetings. FDA could explicitly ask for comment on State performance or it could arrange to hold regular focus groups with industry and consumer groups.

In addition, FDA may want to consider developing a national feedback survey for food firms involved in interstate commerce. It could require State inspectors to leave these feedback forms at the firms that they inspect in association with FDA. Many States are already employing such surveys under their own auspices. An option FDA may want to consider is requiring that States conducting their own industry surveys share results with FDA.

Recommendation 5. FDA should provide substantive and timely feedback to States on their inspection performance.

The prior three recommendations addressed the information sources upon which FDA should rely. But getting the information is insufficient if FDA fails to foster improvements and take corrective actions where necessary. It is particularly important in this regard for FDA to provide the States with regular, substantive feedback on what it has learned about their performance. In carrying out this recommendation, FDA will need to make changes in the language of the contracts and partnership agreements.⁴⁸ These documents should establish clearer and more uniform guidelines for providing regular and substantive feedback to the States.

In a February 18, 2000 memo to the field, the Associate Commissioner for Regulatory Affairs called for district offices to provide the results of the document reviews and joint audits to the States in writing at the completion of reviews or at least quarterly. While this clearly demonstrates a concerted step to improve feedback, we urge FDA to further its efforts in accord with recommendations below.

5a. Provide the States with ongoing and written feedback on the on-site audits it conducts.

At present, FDA's formal feedback from audits is geared toward identifying deficiencies rather than enhancing State performance. To the maximum extent possible, the audits should be redirected to serve as a vehicle to help States improve and maintain good performance. When FDA inspectors conduct these audits, whether on a joint or independent basis, they should in each case prepare a summary assessment to give to the State. That assessment should assist in fostering continuous improvement in State inspection efforts. The report should reflect, as we discussed previously, standard performance criteria that provide States a useful basis to assess and improve their own performance.

5b. Provide States with periodic evaluations that assess the States' overall performance.

As we have noted, the annual and semi-annual evaluation reports that FDA district offices now prepare are more of an accounting of activities than a mechanism for accountability or improvement. We suggest that the time and resources spent on these evaluations could well be redirected. FDA should reevaluate the purpose of these reports and consider either enhancing their substance or eliminating them all together. In any case, the emphasis should turn to more flexible, ongoing evaluations.

As FDA develops and improves its database of information on State inspection activities, it should draw on that, its on-site audit reports, and external sources of information to engage in continuing assessments of State inspection performance. These assessments should not just concern individual inspections but should also provide a comprehensive evaluation of State performance. FDA can help the States by providing them with summary data, thereby enabling them to assess not only their own performance but also how they compare with other States. FDA should determine appropriate cycles in which to provide this aggregate feedback.

5c. Promote information exchange on promising approaches of State programs.

FDA has exposure to food safety inspections conducted throughout the nation, and, as such, is in prime position to disseminate information about promising approaches. At present, there are limited means for States to communicate among themselves and learn from best practices and experiences of other States. FDA could play a pivotal role in facilitating communication among States. For example, FDA could foster communication by using its website, organizing an electronic communication forum among State agencies, or initiating telephone conference calls in various regions. The promotion of voluntary best practices is in line with the actions items called for by the President's Council on Food Safety in the Draft Preliminary Food Safety Strategic Plan.⁴⁹

Recommendation 6. FDA should enhance its internal capacities to conduct effective oversight.

We have called for a demanding and complex oversight agenda for FDA. To carry it out, FDA must remain attentive to the distinctive characteristics of individual State governments, keep abreast of changing technologies in food processing and manufacturing, stay informed on the international and other forces stressing equivalency in food safety systems, and maintain respect for an enduring national ethic that calls for the minimum necessary regulation.

Thus, we call upon FDA to appropriately equip itself. We urge that FDA consider the ways in which it needs to bolster its own capacities. Below, we outline four actions that FDA can take toward that end.

6a. Ensure inspector competence in both inspection and audit functions.

The credibility of the oversight process rests in large measure on the knowledge and skills of the FDA inspectors in the district offices. But with diminished training time for FDA inspectors and with increased regulatory responsibilities in an array of programs, FDA inspectors are increasingly challenged to maintain their expertise in food science technology and in techniques of assessing a food firm's processes and products. We recommend that FDA respond to these pressures by seeking to buttress the valuable base of in-house expertise it has in food safety.

As important as the latter is, there is another training area that may well warrant even more attention: evaluation and auditing. Expertise in conducting food safety inspections is essential to performing the on-site audit role for which we have called. But alone it is insufficient. To conduct oversight, FDA inspectors must develop an evaluation mind-set and learn how to go about evaluating performance. Traditionally, FDA inspectors have not received training of this kind.⁵⁰

One element that FDA might wish to consider as it upgrades its training is a certification program for FDA inspectors who audit State performance. This would be a way of adding some rigor and substance to the oversight role. Furthermore, this type of certification program is in line with the action items called for by the President's Council on Food Safety in the Draft Preliminary Food Safety Strategic Plan.⁵¹

6b. Hold district offices more accountable for their performance in overseeing State food firm inspections.

Just as FDA must play a leading role in holding States accountable for meeting standards, so too must FDA hold its own district offices accountable. The move toward quality and uniformity must be apparent across district offices as well as across States.

FDA should address key questions about the effectiveness of district office oversight: How effective are the district offices in conducting on-site audits? How effective are the district offices in reviewing State inspection reports? Do the district offices provide useful feedback to the States? FDA should work with the district offices to determine the best possible ways of answering such questions.

In holding the district offices more accountable for their performance, FDA headquarters is in a strategic position to foster continuous improvement among the district offices. For example, FDA headquarters could share trend data with the 20 district offices about State performance and about issues and problems that the district offices have detected. FDA headquarters could also facilitate information sharing about innovative practices among the district offices.

6c. Ensure the systematic identification of all food firms in interstate commerce.

Without access to information in a national registry, FDA must rely on a patchwork of

State information to identify the food firms it should oversee. This heightens FDA's dependence on the States and impedes both its oversight and its own inspection efforts. In our 1991 report we recommended that FDA develop or maintain a single national registry or require that each State maintain its own registry and share information with FDA.⁵² We reiterate the need for FDA to have a more reliable mechanism for identifying the food firms under its purview.

6d. Seek broader FDA enforcement authorities.

Many States have enforcement authorities that FDA lacks. This imbalance inhibits further progress toward national uniformity and hinders Federal oversight because it contributes to FDA's dependence on the States. Among the enforcement authorities that would seem to be important are those that would allow inspectors to immediately embargo suspected adulterated products, to review all necessary records without a Federal warrant, and to photograph suspected violations. In our 1991 report on food safety, we also called for FDA to obtain these authorities.⁵³

Recommendation 7. FDA should increase public disclosure of its oversight of State food firm inspections.

An important mechanism of accountability is public disclosure of information. Through greater disclosure, FDA can reinforce that States are accountable for the quality of food safety inspections that they conduct for national purposes.

We urge FDA to proactively make information available about its reliance on State inspections and its mechanisms for overseeing State inspections. While this information is accessible through a Freedom of Information Act request, consumers would have a difficult time even knowing what to ask for. We recommend that the FDA make the following information available on its food safety website, its telephone hotline, or its fax information service:

- **The extent and nature of FDA's reliance on State inspections through contracts and partnership agreements:** FDA could identify States with which it holds partnership agreements and contracts. It could provide information regarding the number and type of inspections and the risk of food firms being inspected by States under these arrangements. FDA could also provide information on the ratio of food firms inspected by FDA versus the States.
- **The extent and nature of FDA's oversight of State inspections:** FDA could be more explicit about its mechanisms to oversee State inspections and the extent to which it has carried out these responsibilities.
- **State performance:** FDA could make available its assessments of State performance. This could include both assessments made during audits as well as reviews of the States' inspection reports. FDA could also make available its

annual assessments of State performance. It could consider developing a list of State programs that meet certain performance standards.⁵⁴

- **Inspection results:** FDA could make available aggregate information of State inspection results. This could include a summary of inspection classifications and trends in critical violations and compliance actions taken. FDA could take similar steps to make the results of its own inspections available.

COMMENTS ON THE DRAFT REPORT

We received written comments on the draft report from the Food and Drug Administration (FDA), the Association of Food and Drug Officials (AFDO), the National Food Processors Association (NFPA), the National Fisheries Institute (NFI), and the Center for Science in the Public Interest (CSPI).

In general, the report was well received by each of the groups. Below, we summarize the major comments and, in italics, offer our responses. We incorporated several changes in the final report, most of which were technical in nature. The full text of each set of comments is included in appendix M.

The Food and Drug Administration

The FDA welcomes our report as a tool to strengthen Federal oversight of State food firm inspections. The agency stresses that States can effectively augment Federal inspection capacity and that States provide a valuable source of inspection coverage and expertise.

In general, FDA agrees with our recommendations and points to a number of recent initiatives underway that move in the direction we call for. We refer to many of these initiatives in our text. In response to the concerns we raise regarding oversight of the partnership agreements, the FDA agrees that it must “fundamentally modify the nature of these agreements.”

In two areas of our recommendations, the FDA does not agree with the activities we suggest. First, FDA does not agree that it should draw on external sources of information to assess State inspection performance. The agency believes that its own audit process is the best way to assess State performance. Second, the agency does not directly address some of the specific and near-term actions we call for to increase public disclosure of its reliance on, and oversight of, State inspections. Instead, the agency references a future performance assessment of State programs and public disclosure of those performance assessments via the Internet.

We recognize that FDA is dealing constructively with many of the shortcomings we identify in our report. We encourage the agency to continue to do so and to prioritize resources to meet its oversight goals. We also urge the agency to reconsider the value of external sources of information to assess State performance. We continue to believe that such information can serve as an important complement to FDA’s own audit information. On the matter of publicly disclosing information, we urge FDA to take immediate action to post State inspection performance information. Such information could include identification of the States with which FDA holds a contract or partnership, the number and types of inspections under each arrangement, the ratio of FDA-to-State inspections in particular States, and the FDA’s assessments of State performance through audits or periodic performance evaluations.

The Association of Food and Drug Officials

The AFDO strongly supports Federal oversight of State food firm inspections. It agrees with the major thrust of our recommendations and feels that our report is generally on target. The AFDO underscores the importance of the Federal-State alliance and the role that States can and should play in developing an oversight system. However, the AFDO also raises a number of issues related to FDA's oversight. Among the issues raised, three areas are particularly prominent.

On the issue of State inspection capacities, the AFDO emphasizes that the expertise of many State programs exceeds the expertise in the FDA district offices. The AFDO raises concern about FDA's loss of "institutional memory" and questions whether *all* FDA district offices are currently in a position to adequately judge the quality and uniformity of State inspections. The AFDO also points out that, although documentation may be sparse, FDA district office staff are often in contact and familiar with the abilities of various State programs. Furthermore, many of the State officers are commissioned by FDA and therefore conduct Federal inspections, not merely State contract inspections.

On the issue of resources, the AFDO points out that our recommendations will require considerable resources on the part of State programs. The oversight expectations we call for will require incentives that reward States for maintaining and improving their programs. In particular, AFDO warns that under partnership agreements, whereby FDA extends its inspection coverage for "next to nothing," States may choose not to participate rather than accept additional reporting requirements.

Finally, the AFDO underscores the work of the Roles and Responsibilities work group within the National Food Safety System project as an important reference point that FDA may want to consider in redesigning its oversight of State food firm inspections. The AFDO underscores the importance of programmatic oversight as more effective than oversight based on audit inspections alone. The AFDO also raises concern that our recommendations do not adequately address how oversight can go beyond identifying problems to providing a mechanism to improve performance.

We are pleased that the AFDO agrees with the major thrust of our recommendations. On the issue of State food safety expertise, we recognize that the lack of FDA oversight does not necessarily indicate the lack of a strong State program. Our report underscores the importance of a strong system of Federal oversight in order to assure consumers, industry, and foreign trade partners about the quality and uniformity of food safety regulation across the nation. A system based on informal communication among Federal and State agencies does not carry adequate assurance that such a safety system exists. In regards to the concern raised about the expertise of all FDA district offices to assess State performance, we recommend that the FDA ensure inspector competence in both inspection and audit functions. We recognize that such expertise is critical to the credibility of the oversight process.

On the matter of resources, we recognize that States are performing inspections under partnership agreements for little cost to FDA. In our report, we urge FDA to reevaluate its reliance on the partnership agreements as an appropriate mechanism to accept State inspections. We continue to believe that, regardless of the mechanism through which FDA accepts State inspections, the oversight of partnership inspections must be just as effective as that of contract inspections.

Finally, we recognize the important work currently underway in the Roles and Responsibilities work group within the National Food Safety System (NFSS) project. We have modified the text of our report to more fully reflect the work of NFSS work groups as potential reference points in developing an appropriate oversight system. We also recognize the value of a systems approach to oversight of States' capacities, laws, regulations, and abilities. To start, we recommend that FDA pilot a system audit with States willing to develop standards, regulations and inspection approaches substantially equivalent to FDA's own. In response to the contention that our recommendations focus on oversight mechanisms that merely identify problems with State performance, we believe we place considerable emphasis on feedback mechanisms that would improve State performance.

National Food Processors Association

The NFPA recognizes the extensive role that States play in food safety and the importance of strong Federal oversight as a means to achieve uniformity and quality in the regulatory landscape. The NFPA, however, views the need for oversight even more broadly than we define it in the report. It points to the wide variation in food safety expertise and auditing styles among the FDA district offices and suggests that a review function be established within the FDA to provide greater oversight of its own inspectors and audits.

In general, NFPA agrees with most of our recommendations and shares our concerns regarding accountability in the food inspection system. The only recommendation that NFPA disagrees with is our recommendation to provide FDA with additional legal authorities. It believes that the agency's current authorities are sufficient to assure a continuous safe food supply. The NFPA supports our recommendation that FDA draw on external sources of information in assessing State performance. In fact, it urges the recommendations to go even further, by requiring that both State and Federal inspections be subject to feedback from external parties.

We continue to believe that additional FDA enforcement authorities are a vital component of effective oversight. We, along with other groups, raise concern that FDA's reliance on States' enforcement actions may compromise FDA's ability to be critical of States' performance. We believe that NFPA raises an important issue concerning variation in food safety expertise, and inspection and audit practices among FDA district offices. We agree that the credibility of an effective oversight system rests in large measure on the knowledge and skills of the FDA inspectors in the district offices. We recommend that FDA develop a training course for its own inspectors in both inspection and audit functions. Finally, we are pleased that the NFPA agrees with our

recommendation to include external sources of information as a key component of an effective oversight system. We encourage the FDA to develop as transparent an oversight system as possible.

National Fisheries Institute

The NFI agrees with the major portions of our findings and recommendations. In particular, the NFI emphasizes the importance of external perspectives on the oversight process, which can augment the limited number of FDA on-site audits. The groups also strongly supports the shift from independent to joint audits as a more effective and less burdensome oversight tool for both the State and Federal inspectors, as well as for manufacturers. Finally, the group reiterates the importance of Federal and State food safety expertise, and encourages that the current voluntary Seafood HACCP certification program become mandatory in the future.

The NFI agrees with most of our recommendations except for two areas. First, the NFI does not support the need for additional FDA enforcement authorities. The group believes that the FDA generally receives adequate enforcement support from States when necessary. Second, the NFI supports limited disclosure of State inspection information, but is concerned about the possible misinterpretation of detailed inspection results.

We are pleased with the broad support from NFI regarding the importance of an effective oversight system and the role of many of our recommendations. On the issue of FDA enforcement authorities, we continue to believe that these authorities are a critical component of an effective oversight system. We do not believe that FDA should rely on a patchwork of State authorities to accomplish actions that it deems necessary. On the issue of public disclosure of State inspection and performance information, we do not recommend that FDA make the results of specific inspections publicly available. Instead, we recommend that FDA, at a minimum, publish aggregate information, such as a summary of inspection classifications and trends in critical violations.

The Center for Science in the Public Interest

The CSPI strongly supports our report, but does not feel that we went far enough with our recommendations. The group expresses concern with FDA's reliance on State partnership inspections and with the reallocation of duties from the Federal to State governments. The CSPI's comments point out vulnerabilities and potential weaknesses in State inspection programs, such as the potential influence of State politics and economics on regulatory oversight. The group suggests that FDA should restrict reliance on States to low-risk inspections.

The scope of our study was to assess the extent and nature of FDA's oversight of State food firm inspections. We did not set out to determine the appropriate balance of inspection duties among the Federal and State governments, nor to define the appropriate balance between contracts and partnerships. However, we do emphasize that FDA should assure consumers that its commitment to food safety is no less under

partnership agreements than under contracts. In our report, we document variation among States in order to emphasize the importance of Federal oversight in supporting uniformity and quality in its program. We recognize that States have important expertise and resources in food safety; in some cases, State capacities may exceed those of FDA's. We support collective efforts among Federal and State agencies for an effective food safety system that maximizes resources.

**Overview of States Holding
Contracts and Partnership Agreements
Fiscal Year 1998**

State	Number of Contracts	Number of Partnership Agreements
Alabama	1	-
Alaska	1	1
Arizona	-	1
Arkansas	1	-
California	-	3
Colorado	1	1
Connecticut	1	-
Delaware	-	-
Florida	1	1
Georgia	1	1
Hawaii	-	-
Idaho	1	-
Illinois	1	1
Indiana	-	1
Iowa	1	-
Kansas	1	-
Kentucky	1	-
Louisiana	1	1
Maine	1	1
Maryland	1	1
Massachusetts	1	1
Michigan	1	2
Minnesota	1	1
Mississippi	1	2
Missouri	1	-
Montana	1	-
Nebraska	1	-
Nevada	-	-
New Hampshire	-	-
New Jersey	1	1
New Mexico	-	1
New York	1	1
North Carolina	1	1

APPENDIX A

State	Number of Contracts	Number of Partnership Agreements
North Dakota	1	-
Ohio	1	-
Oklahoma	-	1
Oregon	1	1
Pennsylvania	-	2
Rhode Island	1	1
South Carolina	2*	-
South Dakota	-	-
Tennessee	1	2
Texas	1	2
Utah	-	-
Vermont	-	-
Virginia	1	1
Washington	1	1
West Virginia	2*	1
Wisconsin	1	2
Wyoming	1	-
Puerto Rico**	1	-
Total = 51	40 contracts (38 States)	37 partnerships (29 States)

* The Department of Health holds one contract, the Department of Agriculture holds the other.

** One territory holds a food inspection contract.

Types of Partnership Agreements, Fiscal Year 1998

Seafood HACCP Partnerships:

1. Alaska
2. California
3. Colorado
4. Georgia
5. Louisiana
6. Maine
7. Maryland
8. Minnesota
9. Mississippi
10. New Jersey
11. New Mexico
12. New York
13. North Carolina
14. Oregon
15. Pennsylvania
16. Tennessee
17. Texas
18. Virginia
19. Washington
20. Wisconsin

Low-Acid Canned Food and Acidified Food Partnerships:

21. Illinois
22. Pennsylvania
23. Tennessee
24. Texas
25. West Virginia

Cheese and Dairy:

26. Michigan
27. Wisconsin

Other:

28. Arizona - Raw agricultural products
29. California - Raw agricultural products
30. California - Exotic Game Facilities
31. Florida - Blue Crab Partnership
32. Indiana - Food Safety
33. Massachusetts - Inspection/samples
34. Michigan - Pilot Cider HACCP
35. Mississippi - Sandwich
36. Oklahoma - Food Safety
37. Rhode Island - Inspection/samples

**FDA District Offices Overseeing
Contracts and Partnership Agreements
Fiscal Year 1998**

FDA District Office	Number of Contracts	Number of Partnership Agreements
Atlanta District	4	2
Baltimore District	4	3
Chicago District	1	1
Cincinnati District	2	---
Dallas District	2	3
Denver District	2	2
Detroit District	1	3
Florida District	1	1
Kansas City District	4	---
Los Angeles District	---	4
Minneapolis District	3	3
Nashville District	2	2
New England District	4	3
New Jersey District	1	1
New Orleans District	2	3
New York District	1	1
Philadelphia District	---	2
San Francisco District	---	*
San Juan District	1	---
Seattle District	5	3
Total = 20 FDA district offices	40 contracts (17 FDA district offices)	37 partnerships (17 FDA district offices)

Methodology

We collected information presented in this report from the following sources:

FDA

Program Operation Data System (PODS). We analyzed national food firm inspection data over a 10-year period spanning 1989 to 1998. We reviewed the number and types of FDA inspections and the number and types of State contract and partnership agreement inspections. We analyzed State contract inspection classifications and time spent on contract inspections. We also reviewed the hours of training received by FDA inspectors between 1989 and 1998.

FDA Audit Summary Data. We reviewed summary audit data between 1993 and 1998. We analyzed the number of joint and independent audits conducted by FDA district offices in each of the States holding contracts. We compared the numbers of audits conducted to the standards in FDA's Field Management Directive No. 76.

Food Contracts and Partnership Agreements. We requested from FDA headquarters copies of all of the food contract and partnership agreements active in 1998. We received 40 of the 40 State food contracts, and 23 of the 37 partnership agreements pertaining to food firm inspections (FDA district offices reported in our survey that they held this number of active partnership agreements during 1998). We reviewed the contracts and partnership agreements for expectations regarding oversight, submission of State inspection and enforcement information, and FDA feedback to the States.

FDA Evaluations of State Contracts and Partnership Agreements. We requested and reviewed semi-annual contract evaluations and annual partnership evaluations for 1998. We received 34 of 40 contract evaluations and 17 of 37 partnership evaluations for 1998. We assessed these documents for the depth of comments pertaining to State performance.

FDA Oversight Directives and Guidance Documents. We reviewed FDA's Field Management Directive No. 76 audit guidance for evaluation of State contract inspectional performance. We reviewed the Model Partnership Agreement Guidance Document (ORA-21) and the Model Seafood HACCP Partnership Agreement, FDA's guidance document for the development and oversight of partnership agreements.

OIG Mail Surveys

FDA District Offices. We surveyed all 20 district offices. We received 100 percent response rate. The survey addressed the following areas: oversight of the State food

contracts, oversight of the State food partnership agreements, challenges facing FDA in overseeing State contracts and partnerships, and recommendations for improving oversight.

States. We surveyed all 40 State agencies holding food contracts. We received 37 responses, a 92 percent response rate. The survey addressed the following areas: background information on the State food firm inspection programs, FDA oversight of the food contracts and partnership agreements, challenges facing State food inspection programs, and recommendations to improve FDA oversight.

OIG Field Work

Site Visits to FDA District Offices. We conducted site visits to three geographically diverse FDA district offices. Each of the district offices held both contracts and partnership agreements with States. The emphasis of the visits was on understanding the extent and nature of FDA's oversight and the barriers that FDA faces in carrying out that oversight.

Site Visits to States. We conducted site visits to three geographically diverse States. Each State was affiliated with one of the FDA district offices we visited and held at least one contract and one partnership agreement. The emphasis of the visits was on understanding the States' experiences with FDA oversight, their internal oversight mechanisms, and their recommendations for improving FDA oversight.

Audit Observations. During our site visits to the FDA district offices, we observed three FDA audits of State performance. We observed an independent audit of a seafood firm, a joint audit of a low-acid canned food firm, and a joint audit of a pasta firm. Our purpose was not to evaluate the FDA's audit of State performance, but rather to observe the way in which FDA inspectors conducted audits.

Stakeholder Interviews

We interviewed representatives of organizations we considered to be stakeholders in food safety oversight. These stakeholders included food safety experts, consumer groups, and industry groups.

Other Documents

In addition to the documents referenced above, we reviewed statutes and regulations, FDA work plans and priority-setting agendas, reports by external agencies, and relevant literature.

**FDA and State Inspections
in Foodborne Biological Hazards (Project 03)
Fiscal Years 1989-1998**

Fiscal Years	FDA Food Firm Inspections (number and percent of total) ¹		State Food Firm Inspections under Contract (number and percent of total)		State Food Firm Inspections under Partnership Agreement (number and percent of total)		Total Food Firm Inspections	
	Regular	Seafood HACCP	Regular	Seafood HACCP	Regular	Seafood HACCP	Regular	Seafood HACCP
1989	4524 (38 %)		7507 (62 %)		--		12,031	
1990	3896 (36 %)		7071 (64 %)		--		10,967	
1991	6618 (46 %)		7697 (54 %)		--		14,315	
1992	4332 (37 %)		7441 (63 %)		--		11,773	
1993	3884 (36 %)		7017 (64 %)		--		10,901	
1994	3555 (39 %)		5530 (61 %)		--		9,085	
1995	3517 (39 %)		5392 (61 %)		--		8,909	
1996	3669 (42 %)		5047 (57 %)		95 (1 %)		8,811	
1997	3901 (31 %)		4991 (40 %)		3643 (29 %)		12,535	
1998	5603 (43 %)		4155 (32 %)		3165 (25 %)		12,923	
	2186 Regular	3417 Seafood HACCP	3881 Regular	274 Seafood HACCP	2247 Regular	918 Seafood HACCP	8314 Regular	4609 Seafood HACCP

Source: FDA Program Operations Data System

¹ For FDA Inspections from 1989-1992, we adjusted the number to compensate for the cooperative program inspections that moved out of the 03 project category and into their own project category in 1992. In sum, we subtracted the 03026 (A-E) PACS from the FDA food firm inspections in the years 1989-1992.

**State Contract Inspection Data
in the Foodborne Biological Hazards (Project 03)
Fiscal Years 1996-1998**

State	Total Number of Inspections	Average Number of Hours per Inspection	Inspections resulting in No Action Indicated (NAI)	Inspections resulting in Voluntary Action Indicated (VAI)	Inspections resulting in Official Action Indicated (OAI)
Alabama	274	7.16	47.1%	52.2%	0.7%
Alaska	155	3.71	73.5%	25.8%	0.7%
Arkansas	467	2.85	59.5%	39.2%	1.3%
Colorado	248	9.50	19.77%	76.6%	3.6%
Connecticut	109	5.47	53.2%	46.8%	0.0%
Florida	626	3.36	19.7%	70.6%	9.7%
Georgia	173	5.73	25.4%	73.4%	1.2%
Idaho	199	7.70	76.9%	23.1%	0.0%
Illinois	700	6.61	83.0%	16.9%	0.1%
Iowa	150	6.14	13.3%	86.0%	0.7%
Kansas	83	5.78	31.3%	67.5%	1.2 %
Kentucky	220	7.15	68.2%	31.4%	0.4%
Louisiana	567	6.18	42.0%	58.0%	0.0%
Maine	151	6.09	78.8%	21.2%	0.0%
Maryland	431	4.43	94.2%	5.3%	0.5%
Massachusetts	378	3.81	18.8%	80.2%	1.0%
Michigan	512	6.15	45.3%	48.6%	6.1%
Minnesota	455	5.23	56.0%	41.3%	2.6%
Mississippi	72	4.27	13.9%	86.1%	0.0%
Missouri	161	6.53	19.9%	73.9%	6.2%
Montana	187	4.11	73.8%	26.2%	0.0%

APPENDIX F

State	Total Number of Inspections	Average Number of Hours per Inspection	Inspections resulting in No Action Indicated (NAI)	Inspections resulting in Voluntary Action Indicated 2 (VAI 2)	Inspections resulting in Official Action Indicated (OAI)
Nebraska	170	4.53	72.3%	27.7%	0.0%
New Jersey	1009	7.19	17.2%	82.8%	0.0%
New York	641	4.83	5.6%	70.8%	23.6%
North Carolina	437	7.38	39.1%	58.6%	2.3%
North Dakota	115	4.11	9.6%	90.4%	0.0%
Ohio	712	4.72	29.2%	70.7%	0.1%
Oregon	461	7.35	39.3%	60.1%	0.6%
Puerto Rico	165	4.94	3.03%	95.2%	1.8%
South Carolina	193	8.64	10.9%	89.1%	0.0%
Tennessee	347	4.71	87.0%	12.1%	0.9%
Texas	917	7.92	29.0%	46.0%	25.0%
Virginia	510	6.24	86.1%	10.0%	3.9%
Washington	693	5.70	65.5%	33.6%	0.9%
West Virginia	284	4.67	31.7%	75.0%	6.3%
Wisconsin	859	6.80	70.8%	29.0%	0.2%
Wyoming	40	4.68	90.0%	10.0%	0.0%

Source: FDA Program Operations Data System

Note: We excluded Rhode Island from our analysis because the State did not hold a contract for the duration of fiscal years 1996-1998.

Definitions: FDA uses three primary classifications for inspections: *Official Action Indicated*, which signifies serious violations found during an inspection leading to a recommendation for regulatory or administrative sanctions; *Voluntary Action Indicated*, which signifies some deficiencies found during an inspection, but not significant enough to warrant regulatory or administrative sanctions (any corrective action is left to the firm to take voluntarily). Note: This category represents our analysis of 'VAI2' classifications; and *No Action Indicated*, which signifies that minor or no deficiencies were found during an inspection and that a routine reinspection is recommended.

FDA and State Enforcement Authorities for Overseeing Food Firms

Authority	Percentage of States with Authority (N=36)	FDA Authority
License/ permit revocation	28 (77.7%)	No
Civil monetary penalties	26 (72.2%)	No
Immediate Embargo	34 (94.4%)	No
Recall	16 (44.4%)	Voluntary
Seizure	28 (77.7%)	Yes
Injunction	31 (86.1%)	Yes
Prosecution	31 (86.1%)	Yes
Access to all firm records in question	22 (61.1%)	No
Use of photographic equipment during inspection	23 (63.8%)	No

Source: Office of Inspector General Mail Survey, August 1999.

States with Multiple Enforcement Authorities

Number of Authorities*	Number of States holding these authorities (N=36)
1	1 (2.7%)
2	--
3	2 (5.5%)
4	2 (5.5%)
5	4 (11.1%)
6	5 (13.8%)
7	7 (19.4%)
8	7 (19.4%)
9	8 (22.2%)

Source: Office of Inspector General Mail Survey, August 1999.

* These include license revocation, civil monetary penalties, immediate embargo, recall, seizure, injunction, prosecution, access to all firm records in question, and the use of photographic equipment during inspection.

Educational and Training Requirements for State Food Inspectors

Minimum Educational Requirements	States (N=35)
High school diploma	4 (10.8%)
High school diploma with college-level science courses	2 (5.4%)
College Diploma	5 (13.5%)
College Diploma with science courses	23 (62.2%)
Other	1 (2.7%)

Source: Office of Inspector General Mail Survey, August 1999.

Number of Days of Formal Training	States (N=36)
5 days or less	8 (21.6%)
6-10 days	18 (48.6%)
11-15 days	5 (13.5%)
More than 15 days	5 (13.5%)

Source: Office of Inspector General Mail Survey, August 1999.

FDA Audits of State Food Contracts

	Number of FDA Audits	Number of Contract Inspections	Number of States receiving at least one audit
FY 93	253	7354	34/39 (87%)
FY 94	139	5801	26/40 (65%)
FY 95	135	5661	24/40 (60%)
FY 96	140	5312	25/38 (66%)
FY 97	120	5231	17/38 (45%)
FY 98	104	4252	17/38 (45%)

Source: FDA

Partnership Agreement Expectations: Comparison of Five Low-Acid Canned Food Partnership Agreements

We analyzed five low-acid canned food partnership agreements for their expectations in five key areas: inspection reports, joint inspections, enforcement actions, training, and assessment mechanisms. These partnerships were active at some point during fiscal years 1996-1998. Low-acid canned food firm operations are generally considered high-risk and complex, heightening the importance of effective FDA oversight.

State	Submission of Inspection Reports	Submission of Information about Enforcement Actions	FDA-State Training
California	<ul style="list-style-type: none"> • Summary inspection reports only; full inspection reports upon request. • No report elements specified. • “Periodic” exchange. 	<ul style="list-style-type: none"> • Enforcement actions, “if requested.” 	<ul style="list-style-type: none"> • Not addressed.
New Jersey	<ul style="list-style-type: none"> • Inspection reports. • No report elements specified. • No time frame specified. 	<ul style="list-style-type: none"> • Not addressed. 	<ul style="list-style-type: none"> • Training “as needed.”
Illinois	<ul style="list-style-type: none"> • Inspection reports. • No report elements specified. • No time frame specified. 	<ul style="list-style-type: none"> • Not addressed. 	<ul style="list-style-type: none"> • Training “as needed.”
Pennsylvania	<ul style="list-style-type: none"> • Inspection reports. • No report elements specified. • “Prompt” exchange. 	<ul style="list-style-type: none"> • Enforcement actions. • “Prompt” exchange. 	<ul style="list-style-type: none"> • Training “will depend on availability of personnel and resources.”
Texas	<ul style="list-style-type: none"> • Inspection reports. • No report elements specified. • No time frame specified. 	<ul style="list-style-type: none"> • Enforcement actions. • Summary reports may also be prepared. • No time frame specified. 	<ul style="list-style-type: none"> • Training “will depend on availability of personnel and resources.”

**Partnership Agreement Expectations:
Comparison of Five Low-Acid Canned Food
Partnership Agreements
(Continued)**

State	Number of Joint Inspections	FDA-State Assessment Mechanisms	
		Interim Evaluation	Final Evaluation
California	<ul style="list-style-type: none"> • Not addressed. 	<ul style="list-style-type: none"> • Not addressed. 	<ul style="list-style-type: none"> • Final evaluation criteria not specified.
New Jersey	<ul style="list-style-type: none"> • Joint inspections “as needed.” 	<ul style="list-style-type: none"> • Interim evaluation should track number of inspections, cost, and classifications. 	<ul style="list-style-type: none"> • Final evaluation should analyze inspection findings and regulatory actions.
Illinois	<ul style="list-style-type: none"> • Joint inspections “sufficient to train two inspectors.” • “Subsequently, at least one joint inspection per year with each inspector.” 	<ul style="list-style-type: none"> • Interim evaluation should track number of inspections, classifications, and training; establish database of adverse findings; and calculate cost per inspection. 	<ul style="list-style-type: none"> • Final evaluation criteria not specified.
Pennsylvania	<ul style="list-style-type: none"> • Joint inspections “as necessary.” 	<ul style="list-style-type: none"> • Not addressed. 	<ul style="list-style-type: none"> • Not addressed.
Texas	<ul style="list-style-type: none"> • Joint inspections “upon request,” based upon “availability of personnel and agency priorities.” 	<ul style="list-style-type: none"> • “This agreement does not require in-process measurements.” 	<ul style="list-style-type: none"> • Final evaluation criteria not specified.

Contract Semi-Annual Report

The FDA evaluates State inspection performance under contract twice a year in its semi-annual reports. The semi-annual report contains three primary sections. Section A includes the number of joint and independent audit inspections accomplished during the reporting period and the number of deficiencies uncovered in those audits. Section B includes details of deficient performance, assessment of the cause of the problem, and solutions planned or accomplished. Section C provides space for FDA district offices to comment on overall contract performance, to highlight significant State accomplishments or actions, and to raise questions and concerns.

For our review, we asked the Division of Federal-State Relations to provide us with all State contract semi-annual reports for fiscal year 1998. We received reports for 34 of the 40 contracts. These 34 contracts covered 3351 food sanitation inspections in fiscal year 1998. We analyzed the semi-annual reports along the following dimensions: the number of audits conducted, the number of deficiencies found, and the extent of comments on State performance. We categorized comments about State performance in one of three ways, as defined below:

Definitions:

- a. No Assessment:* The semi-annual report contains no comment regarding State performance or the quality of inspections.
- b. Minimal Assessment:* The semi-annual report contains vague, broad statements of State performance with few details that describe the quality of State inspections or other information relevant to State performance.
- c. Some Assessment:* The semi-annual report includes examples on which to base FDA's assessment of State performance. This may include analysis of violations identified and inspection classifications or enforcement actions taken. The report may also include information on training conducted or changes in the State's personnel that affect the State's performance.

Analysis of Contract Semi-Annual Reports (FY 1998)

State	Number of Joint Audits	Number of Independent Audits	Number of Deficiencies	Comments on State Performance		
				No Assessment	Minimal Assessment	Some Assessment
AK	1	0	0		X	
AL	0	5*	0		X	
AR	0	1	1		X	
CO	0	0	0	X		
CT	0	2	2			X
FL	0	0	0			X
GA	0	0	0	X		
ID	4	7	0		X	
KS	0	0	0	X		
KY	8	4	0		X	
LA	0	4*	0		X	
ME	0	0	0			X
MI	0	3	0	X		
MN	0	0	0	X		
MO	3	0	0			X
MS	0	0	0		X	
MT	2	0	0		X	
ND	0	0	0	X		
NE	0	0	0	X		
NJ	0	9	0		X	
NY	0	0	0	X		
OH	0	5	0		X	

**Analysis of Contract Semi-Annual Reports (FY 1998)
(Continued)**

State	Number of Joint Audits	Number of Independent Audits	Number of Deficiencies	Comments on State Performance		
				No Assessment	Minimal Assessment	Some Assessment
OR	3	0	0			X
PR	0	0	0		X	
SC - Dept. Of Agriculture	8	0	0	X		
SC - Dept. of Health	0	0	0	X		
TN	0	4*	0		X	
TX	0	0	0	X		
VA	0	10	0			X
WA	6	0	0			X
WI	0	0	0	X		
WV - Dept of Agriculture	2	3	0		X	
WV - Dept of Health	4	8	0		X	
WY	0	0	0	X		
TOTALS (N = 34)	41	65	3	13	14	7

Note: We received no information from FDA regarding State food sanitation contracts with the States of Illinois, Iowa, Maryland, Massachusetts, North Carolina, and Rhode Island.

* It is unclear from the semi-annual reports whether the audits conducted were joint or independent. We listed them as independent audits, because according to the FMD-76, that is the primary evaluation mechanism for the food sanitation contract.

Annual Partnership Evaluation

The Partnership Agreement Guidance Document (ORA -21) calls for annual evaluation of partnership agreement activities. These annual evaluations are conducted jointly by FDA district offices and States. The FDA district offices submit copies of these evaluations to headquarters.

The annual partnership evaluation form (attachment C of the ORA-21) contains 10 elements. Four of these elements are particularly relevant to evaluating the quality and effectiveness of work performed under partnership agreements. These include Outputs (*e.g.* number of inspections, number of people trained), Outcomes (*e.g.*, what was the result, benefit to partners), Evaluation of Partnership Agreement (*e.g.* strengths and weaknesses, positives and negatives), and Recommendations.

For our review, we asked the Division of Federal-State Relations to provide us with copies of all of the fiscal year 1998 partnership agreement evaluations pertaining to food firm inspections. We received 17 evaluations of 37 partnership agreements reported by district offices as active during fiscal year 1998. We analyzed these evaluation documents according to the following dimensions: the extent of comments on State performance, whether there were comments on FDA performance, and whether there were critical comments regarding the partnership activities. We provide definitions of these categories below.

Definitions:

Comments on State Performance:

a. Minimal Assessment: Contains vague, broad statements of State performance with few details that describe the quality of State inspections or other information relevant to State performance.

b. Some Assessment: Includes examples on which to base FDA's assessment of State performance. This may include analysis of violations identified and inspection classifications or enforcement actions taken. The report may also include information on training conducted or changes in the State's personnel that affect the State's performance.

Comments on FDA performance: Contains information on the quality of FDA inspections conducted.

Critical Comments: Contains critical comments including comments about problems encountered, solutions identified, and recommendations to improve performance.

Analysis of Partnership Evaluations (FY 1998)

State	Comments on State Performance		Comments on FDA Performance	Critical Comments
	Minimal Assessment	Some Assessment		
CA		X	no	no
GA	X		no	no
IL	X		no	no
LA		X	no	yes
ME	X		no	no
MI		X	no	yes
MS (sandwich)	X		no	no
MS (seafood)		X	no	yes
NY	X		no	no
NC	X		no	no
OK		X	no	no
PA		X	no	yes
TN	X		no	no
TX (seafood)		X	no	yes
TX (low-acid canned food)	X		no	no
WI (seafood)	X		no	no
WI (cheese)	X		no	yes
Totals (N = 17)	10	7	Yes = 0 No = 17	Yes = 6 No = 11

Full Text of Comments on the Draft Report

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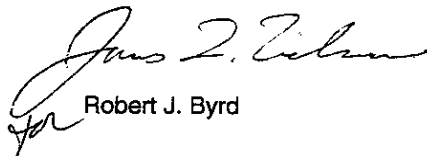
DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Food and Drug Administration

Date: APR 28 2000
From: Deputy Commissioner for Management and Systems, FDA
Subject: Office of Inspector General (OIG) Draft Inspection Report: *FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability*
To: June Gibbs Brown
Inspector General

Thank you for the opportunity to review and comment on the OIG draft report, *FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability*. The Agency prepared General and Technical Comments for your consideration.


Robert J. Byrd

**AGENCY COMMENTS TO THE OFFICE OF INSPECTOR GENERAL DRAFT
REPORT, FDA OVERSIGHT OF STATE FOOD FIRM INSPECTIONS: A CALL
FOR GREATER ACCOUNTABILITY**

General Comments:

1. FDA welcomes the OIG report as a tool to strengthen Federal oversight of State food safety inspections. FDA believes it is critical that American consumers receive the same level of protection regardless of whether food establishment inspections are conducted by Federal, State or Local officials.
2. New management in FDA's food safety program requested the OIG to conduct this study. The study was designed to provide a benchmark of FDA's oversight activities at the time and a recommended template of what these oversight activities ought to be in order to faithfully fulfill the vision of an integrated national food safety system.
3. FDA believes States can effectively augment Federal inspectional capacity. For example, in the first year of seafood HACCP inspections, FDA inspected approximately 70% of domestic seafood processors, with the remaining 30% conducted by the States.
4. FDA convened a 50-State meeting in 1998 in order to improve consumer protection through an enhanced national food safety system (NFSS). FDA stated clearly at that meeting that an essential component of any such system is adequate Federal oversight of State inspection programs. OIG staff attended this meeting as observers.
5. Even in advance of this report, FDA established "Evaluation of State Programs" as an "A List" item in CFSAN's 2000 Program Priorities. The goal states, "In conjunction with ORA, enhance system for FDA evaluation of State inspection programs."
6. FDA is committed to achieving this goal, and has listed concrete objectives to audit 5% of State inspections under contract in FY 2000, increasing to 7% in FY 2001 and increasing again to 10% in FY 2002, as resources permit. In addition, FDA has directed that every State inspector be audited at least once every three years.
7. FDA will increase training of FDA auditors, with a new training course to be offered in September 2000. The course will train FDA Field investigators who audit State programs on the process and techniques for auditing State contracts or partnerships.

8. FDA will pilot its enhanced auditors program with a focused review of one State's seafood HACCP inspections and of a second State, which performs primarily other types of food inspections.
9. FDA will ensure that State inspections conducted under partnership agreements are of comparable quality to those conducted under State contracts. FDA is mindful that the OIG was highly critical of State partnership agreements. FDA will fundamentally modify the nature of these agreements.
10. The States agree that Federal oversight is essential and needs to be enhanced, and that such oversight must be comparable for all State food inspections, whether they are conducted under State contracts or partnership agreements. FDA believes the State food regulatory officials, through the Association of Food and Drug Officials (AFDO) and the NFSS project, are to be commended for working with FDA to improve the quality of the food inspection program in this way.
11. FDA and the States are working together to develop a standard template for a State manufacturing/food processing inspection program. This template is to include: (a) Regulatory Foundation; (b) Trained Regulatory Staff; (c) Inspection Program based on HACCP Principles; (d) Uniform Inspection Program; (e) Foodborne Illness Investigation and Response; (f) Compliance and Enforcement; (g) Industry Recognition; (h) Program Support and Resources; and (i) Program Assessment.
12. FDA will seek from Congress the necessary resources to carry out this oversight function. The President's proposed FY 2001 budget now before Congress includes funds to increase FDA's audits of State food safety inspections.

Page 31, Recommendation #1: FDA should work with States to achieve basic equivalency in food safety standards and laws, and in inspection programs and practices.

We agree with this recommendation. FDA's experience with the seafood Hazard Analysis Critical Control Point (HACCP) approach to inspections has fundamentally altered the way in which the government oversees and inspects the food supply. Seafood HACCP has a certification program to certify the competence of food inspectors. This certification program has been received well by both Federal and State inspectors and is an important step toward promoting uniformity and consistency in inspections. The agency is also developing other certification programs in the foods area that will be extended to the State/Local programs over the long term.

As part of a NFSS project, FDA will pilot a systems audit of a State's seafood HACCP program. The audit would use a uniform set of minimum standards and

criteria for assessing a State's capacity and performance. Results of the pilot audit would advance equivalency and improve oversight.

Page 32, Recommendation #2: FDA should devote high priority to improving its on-site audit mechanism for evaluating the effectiveness of State inspections.

We agree with this recommendation and several activities are underway. Released in January, CFSAN's 2000 Program Priorities document has an "A List" activity "Evaluation of State Programs" that is a top agency priority to be implemented jointly by ORA and CFSAN.

Shortly thereafter, the Associate Commissioner for Regulatory Affairs (ACRA) issued a memo on February 18, 2000 to the field that called for a focus on joint audits for FY 2000. FDA has called for joint audits for 5% of the inspections assigned to States under contract for FY 2000. The Division of Federal-State Relations (DFSR) is working with FDA's Southwest Region to field test a new audit form that will accompany each joint audit. In FY 2001, the percentage will increase to 7%; in FY 2002 to 10%, as resources permit. A memo to the Field from DFSR called for all State inspectors to have at least one joint inspection over the next three years. ORA is developing a training course for FDA investigators on the process and techniques for auditing State contracts and partnerships. The course is planned to be offered in September 2000.

Also in FY 2000, FDA plans to pilot an audit of food inspection work being done by the State of Oklahoma under a partnership agreement. Under the partnership agreement, several training events have been conducted with State inspectors responsible for the inspection of food manufacturers and processors. FDA auditors will observe the conduct of State inspections and complete a two-page form indicating the establishments' status in various areas normally observed during an inspection. The form also contains questions regarding the quality of the inspection conducted by the State inspector. The FDA auditor will not issue a 482, Notice of Inspection, since this is not an official FDA inspection, but rather an evaluation of the State inspection. At the conclusion of the inspection and after the State inspector has completed all the required paperwork, the FDA auditor will lead a discussion of the inspection with the State inspector. All forms from the audit will be forwarded to the FDA partnership coordinator for this project for review and evaluation.

FDA also plans to develop an audit document for FDA investigators to use in auditing State contract inspections that will be based on work done during the Oklahoma pilot.

Page 34, Recommendation #3: FDA should require that States routinely provide FDA with standardized information on the inspections that they conduct.

We agree with this recommendation. The ORA Federal-State Field Advisory Committee has been assigned the responsibility of developing acceptable language for the oversight of partnership inspections for inclusion in a partnership guidance document. The Committee will consult with and review a draft federal oversight model document and a draft model partnership agreement prepared by the National Food Safety System (NFSS) project Roles and Responsibilities Workgroup. The draft partnership agreement contains a requirement that State inspectors must use appropriate FDA forms. As part of the audit of food inspection work being done by the State of Oklahoma under a partnership agreement, State inspectors will be asked to complete a one-page form developed by FDA for each jointly inspected facility to capture inspection information in a standardized format that will be useful in comparing data. The results of this pilot will be evaluated and will assist FDA in developing forms for States to use in order to provide standardized information on the inspections they conduct. The outcome of the pilot and development of the audit documents will be assessed by the Federal-State Field Advisory Committee and ORA's Field Food Committee.

Page 35, Recommendation #4: FDA should draw on multiple external sources of information in assessing State inspection performance.

We do not agree with this recommendation. While FDA frequently solicits feedback from industry and consumers on various issues, we believe that the Federal audit process itself is the best mechanism to provide information on the performance of State inspectors.

Page 36, Recommendation #5: FDA should provide substantive and timely feedback to States on their inspection performance.

We agree with this recommendation. As noted above, ORA is developing a training course for FDA investigators on the process and techniques for auditing State contracts and partnerships. The course is planned to be offered in September 2000. The training will propose formal criteria to review the quality of State inspection reports and include a requirement that timely feedback be provided to States on their inspection performance. FDA agrees that timely feedback on state inspection performance is needed because it would allow States to more effectively manage or procure needed resources, establish risk-based priorities and be able to perform more effective self-evaluations of their own programs.

FDA addressed this issue in the February 18, 2000 memo to the Field from the Associate Commissioner for Regulatory Affairs (ACRA) referenced above. The

ACRA called for a focus on joint audits for fiscal year 2000. FDA has called for joint audits for 5% of the inspections assigned to States under contract for FY 2000. The Division of Federal-State Relations (DFSR) is working with FDA's Southwest Region to field test a new audit form that will accompany each joint audit. In FY 2001, the percentage will increase to 7%; in FY 2002 to 10%, as resources permit. A memo to the Field from DFSR called for all State inspectors to have at least one joint inspection over the next three years.

As part of the pilot audit of food inspection work being done by the State of Oklahoma under partnership agreement, FDA auditors will observe the conduct of State inspections and after the State inspector has completed all the required paperwork, the FDA auditor will lead a discussion of the inspection with the State inspector. The results of this pilot will help FDA design an effective audit/evaluation program to ensure timely information and feedback is provided to States on their inspection performance.

Page 37, Recommendation #6: FDA should enhance its internal capacities to conduct effective oversight.

We agree with this recommendation. A well-designed and operated oversight and evaluation system is a key element of a nationally integrated food safety system. One way that FDA will enhance its internal capacities to conduct effective oversight will be through the training course ORA is developing for FDA investigators, referenced above, on the process and techniques for auditing state contracts and partnerships. The course is planned to be offered in September 2000. The goal of this activity is to enhance the system for FDA evaluations of State inspection programs. The integration of all the concepts discussed in this document will help us implement an effective comprehensive oversight program that will have the support of the State/Local agencies.

Page 39, Recommendation #7: FDA Should Increase Public Disclosure of Its Oversight of State Food Firm Inspections.

FDA has been working with the States for several years to develop a set of standard criteria for administering a regulatory program. The result is the "Voluntary National Retail Food Regulatory Standards". This best practices document has been pilot tested by several State and Local agencies and currently is being cooperatively reviewed by the FDA, Conference for Food Protection and the NFSS project National Uniform Criteria workgroup. Using the retail standards document as a template, the Agency has asked the NFSS workgroup to work with the FDA to develop by the end of FY 2000, a template for a State manufacturing/processing inspection program. The template includes nine standards of best practices for a regulatory program: (a) Regulatory Foundation; (b) Trained Regulatory Staff; (c) Inspection Program based on HACCP Principles; (d) Uniform Inspection Program; (e) Foodborne illness

Investigation and Response; (f) Compliance and Enforcement; (g) Industry Recognition; (h) Program Support and Resources; and (i) Program Assessment.

Using this model, the FDA will be able to audit a State's program not only to insure consistency of the inspections, but of the entire structure and performance of the State regulatory program. While it may take 24 –30 months to design, validate, test and implement the program, the long-term results will benefit the State and Federal programs as well as enhance the oversight of the States programs. Eventually, we will list the State programs in some sort of Internet list that will show the public and other states the status of the regulatory programs implementing the regulatory standards. The types and methods of the listing will have to be determined during development of the standards.

CONCLUSION

The States offer a valuable source of inspection coverage and expertise. An effective food safety system depends on the collective efforts and coordination among Federal, State and Local levels of government. An effective food safety system also requires strong Federal oversight and leadership. FDA has initiated a number of activities and plans more action in FY 2000 to address the concerns identified in this report on FDA's oversight of State food firm inspections.

Technical Comments:

We suggest the following statement in the draft be changed:

Page 2 – “FDA Relies Heavily on State Food Firm Inspections.”

“...States conducted through contracts and partnership agreements... 61% of food firm inspections recorded in FDA's national database. Increasingly, these State inspections are focused on high-risk food firms such as seafood firms.”

We suggest the following: ... 61% of food firm inspections recorded in FDA's national database. **Although traditionally States have focused heavily on lower risk areas**, increasingly, these State inspections are focused on high-risk food firms such as seafood firms. **In the first year of seafood HACCP inspections, FDA conducted 70 % of these inspections and the States conducted 30%.**

We suggest the following statement in the draft be changed:

Page 3 – “FDA's reviews State Contract inspection reports lack much rigor.”

Suggest “...reports need formal criteria.

We suggest the following statement in the draft be changed:

Page 3 – “Under partnership agreements, FDA obtains even less information to assess the quality of State food firm inspections.”

Suggest “...FDA needs more information...”

We suggest the following statement in the draft be changed:

Page 3 – “FDA provides limited feedback to States on the quality of their inspections.”

Suggest “FDA should provide more feedback...”



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April 26, 2000

Ms. June Gibbs Brown
 United States Inspector General
 330 Independence Avenue, S.W., Room 5246
 Washington, D.C. 20201

Re: OEI-01-98-00400

Dear Inspector General Brown:

The Association of Food and Drug Officials Board of Directors, hereinafter referred to as AFDO, is pleased to offer comments on the Draft Report on "FDA Oversight of State Food Firm Inspections" (OEI-01-98-00400) recently requested by you and your staff from the Office of Evaluation and Inspections.

AFDO is the 104 year old principal organization which represents federal, state, and local government regulatory officials and industry associates with food safety responsibilities throughout the U.S. AFDO's motto is "Uniformity Through Cooperation and Communication," which we have been fulfilling these many years through the development of model laws, regulations, and guidelines, and by conducting training and education. AFDO strongly supports an adequate oversight role for federal agencies to ensure that State program capacities produce inspections which are equivalent to federal inspections conducted throughout the U.S.

AFDO realizes that the U.S. Food and Drug Administration (FDA), due to a lack of capacity (current staff are needed to complete their own field assignments), has not been in a position to implement an adequate oversight program to provide assurance to those outside the agency that State inspections are indeed equivalent. Although many States do quality inspections in a much more efficient manner than FDA, this has not been adequately documented. In this respect, AFDO believes that for the most part the Draft Document prepared by the Office of Inspector General's Office of Evaluation and Inspections is on target.

AFDO agrees that adequate training in auditing and evaluations is necessary for both FDA staff engaged in this activity, as well as State program personnel who must assure both FDA and their own legislatures that inspections are of good quality and equivalent to those conducted by their federal counterparts. AFDO agrees that FDA, the States, and those outside the agencies need such assurances. FDA auditors must

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be able to demonstrate good audit technique (good judgement and excellent diplomatic skills), as well as program knowledge to be able to perform a fair and accurate evaluation, communicate it well, and convey a sense of confidence in a State's ability to make any recommended improvements to its food safety system.

AFDO also agrees that any audit inspections conducted by FDA should be joint audits rather than the independent audits that are typically used to "catch" mistakes rather than correcting deficiencies. Joint inspections have worked well in the past, both between FDA and the States, and the States and locals, especially for training purposes. This helps to ensure uniformity. The States welcome any opportunities to document that our inspections are equivalent, as well as opportunities to improve. We wholeheartedly agree that "...State input into developing the guidance document for on-site audits...." should necessarily be a part of the overall plan.

AFDO believes that the OIG should utilize the draft documents prepared by the National Food Safety System (NFSS) Roles and Responsibilities Work Group on "oversight" and "uniform standards" as a template for federal oversight of State programs. These documents have been forwarded to the federal agencies involved in the NFSS activities under the President's Food Safety Initiative.

Although AFDO supports the OIG's intentions and the overall goals presented in the document, we have a number of concerns.

First, we believe that FDA has not issued contracts and partnerships with States who do not provide quality inspections which are equivalent to those conducted by FDA investigators. Although documentation and oversight may appear sparse, FDA District staff are quite familiar with the personnel and the abilities of the various State programs with which they have contracts and partnerships. Further, many of these same state program personnel are *commissioned* by FDA and therefore conduct *federal inspections* - not merely state contract inspections. Consequently, the problem may involve a lack of *documentation* that the inspections are equivalent, rather than equivalency itself.

Under the current system, FDA receives a large capacity for inspections at a very cheap price by federal standards. For an oversight system to have any significant leverage with the States, there will have to be significant incentives for States to do all of the things the OIG recommends in the Draft Report. Building and maintaining adequate training systems, continuously providing key inspection and performance data, performing and reporting inspections in a standardized way, and making program improvements recommended by FDA as a result of audits may be essential elements for evaluating the adequacy and equivalence of a State program, but these



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requirements will be neither easy nor cheap for the States. For such an oversight system to be feasible and palatable for the States, the FDA will have to invest in a system that assists States in building a standardized system and rewards them for maintaining and improving their programs within boundaries negotiated with FDA. FDA pays for contracts, but most of the leveraging involves partnerships, which FDA receives for next to nothing. Without incentives the States may chose not to participate rather than accept additional reporting requirements.

AFDO also does not believe that the OIG can adequately compare State and federal inspections based upon the number of hours per inspection, the classification of inspections, or the number of days spent in training. Although a two hour inspection of a large food processor might be suspect, one might also question the necessity of spending 30 or more hours to conduct the same inspection as does FDA. The efficiency with which many States conduct inspections is unparalleled. Most utilize laptop computers during the inspection, thereby printing the FD-483 form along with other forms (detention, destruction, etc.) before the closing conference with management. The body of the report is often completed at the end of the inspection rather than over several days back in the office from notes taken during the inspection. Copies of labels are scanned and submitted electronically to the office, and the reports are often submitted electronically.

Further, some States require investigators to have the previous inspection report on disk so that the previous inspection report can be updated, rather than duplicating the collection of information that has not changed from one inspection to the next. Therefore, in AFDO's opinion most State inspections are more than adequate and time should not automatically reflect negatively on the quality of the inspection.

AFDO is also aware that FDA's reliance on the States to conduct many food inspections has often been due to the fact that, as OIG points out, FDA has for many years utilized its own field staff to conduct drug, device, and biologics inspections. Most FDA personnel hired during the last 15 years are able to chose which area of regulation they wish to specialize in. In some cases this has created a situation where there are few FDAers in some Districts who have expertise in foods. There have always been some FDAers in the Districts who have continued to work in the area of foods, but the numbers have dwindled. AFDO suspects that in certain areas at least some of FDA's *institutional memory* (longtime expertise) may have been lost. We mention this because it is important to note that in some instances the States have **more** expertise in foods than does the FDA District which would be engaged in oversight and audits. Therefore, depending upon who the FDA auditor is, the joint audits may point out that the federal investigator has less expertise than the State investigator. In order for an oversight mechanism to work, FDA must improve its

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own capacity for quality food inspections, and this requires dollars from Congress and time for training.

Many State programs pride themselves on not only the quality of their inspections, but also on the breadth of the knowledge of their investigators. As an example, a number of States have ensured throughout the years that their field investigators have an excellent working knowledge of food labeling, including the application of the Nutrition Labeling and Education Act and Dietary Supplement Health and Education Act requirements; whereas, FDA does not expect their own field investigators to have a good working knowledge of these regulations, depending instead on the compliance staff in the Districts to analyze food labels. In fact, FDA investigators are discouraged from listing food labeling violations on the FD-483 unless the investigator is certain of his judgement. Many States would reject inspection reports which did not include labeling review/violations as deficient or incomplete.

Based upon these and other comments from AFDO Board members, we question whether all FDA *Districts are currently* in a position to adequately judge the quality and uniformity of State inspections and the capacities of State programs. This is not to say that State programs would not benefit from better FDA oversight. We firmly believe in oversight and the need for such oversight to document for all, including Congress and consumer advocates, that contract and partnership dollars are being well spent. Therefore, this begs the question, "What should such an oversight mechanism look like, and where do we begin?"

AFDO has previously mentioned the need for OIG to utilize the oversight document prepared by the NFSS Roles and Responsibilities Work Group. This is not to say that OIG's comments do not have merit. Both FDA and State program personnel should have additional training in auditing and program evaluation. Both agencies should conduct more joint inspections, which many years ago used to be the rule, not the exception. At the same time, AFDO cautions that only extremely well trained individuals, who know all of the ins and outs of a particular type of inspection (acidified foods, low acid canned foods, etc.), should attempt to engage in a joint audit inspection where the sole purpose is to "improve" the State program only. We are also not convinced that a single audit inspection of a State investigator every three years will provide much in the way of significant information on the *State inspection program*. We strongly believe that *programmatic* oversight is much more important than audit inspections. In other words, OIG's outline of an adequate audit mechanism should *begin* with a look at a State's capacities, laws, regulations, and abilities, rather than the inspections. Further, *investigator certification* should be a requirement for both FDA and State personnel.



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AFDO is also concerned with OIG's comments on contracts and partnerships with respect to the benefits they provide to both FDA and the States. OIG appears to view these merely as inspections that the States would otherwise conduct under their own laws and regulations. In a vacuum this is true. Nearly all of the States would indeed continue to conduct inspections irrespective of contracts and partnerships. However, the Federal Managers Financial Integrity Act (FMFIA) requires the States to *subtract* any fees for licenses or permits they collect for their state inspections *before* determining the costs FDA is to pay for the inspections. In many cases these fees the states collect do not pay the actual costs of the inspections. In fact, some states either have no license fees or the fees are minimal (\$25.00 in some cases). Therefore, many States rely on the contracts as a mechanism to recover their full costs of conducting the inspections. Many states do not have enough resources to inspect their entire inventories and therefore rely on the contracts to supplement their travel funds, or purchase computers or equipment related to inspections. Funding of these essentials is quite limited in a number of States.

Further, partnerships are not limited only to inspections. They also include sampling (which in some States would not occur if it were not for the partnership funds from FDA), recalls, recall effectiveness checks, and so forth. The OIG Draft Report also does not address the huge successes of a number of the "other than inspection" partnerships. For example, the recalls conducted by the New York Department of Agriculture and Markets amounted to over 84 percent of all of the food recalls classified by FDA in the New York District (69 of 82 recalls).

The OIG Draft Report also does not mention that two types of FDA contracts/partnerships already have built-in inspection performance standards. These include low acid canned foods/acidified foods and seafood processors. Again, some States conduct these inspections using the FDA commissioning process whereby the inspections are literally FDA inspections and not State inspections. In these instances the State is utilizing federal laws and regulations and federal authority to conduct the inspections, rather than relying on state laws and regulations.

Also, FDA already requires that all inspection data needed to capture the results of State inspections (contracts and partnerships) into the FACTS system is included in the State inspection reports or in summaries. Further, entry of the information into FACTS takes an additional 0.5 to 2.0 hours per inspection. This is time taken away from State and FDA personnel who would otherwise be conducting additional inspections. Consequently, the additional cost of data entry must now be built into the contracts. Although this was a part of the OIG Draft Report (data entry into FACTS), the FACTS system has been utilized for this purpose for less than a year, even by FDA. FACTS was previously utilized only for sample data entry. Also, access to the FACTS system requires security clearance and the purchase of many

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additional rights to the software, which thus far FDA has not been able to fund. Therefore, data entry often requires both the FDA investigator and the State investigator to sit down side-by-side at the computer in order to get the information entered into the system. To reduce or eliminate this problem, FDA needs funding to create a system which promotes uniformity in inspection reports and which can be utilized by both FDA and the States to directly input the data electronically, rather than having to expunge the data FDA needs from the State reports. Again, financial and other incentives must be forthcoming to the States to encourage them to take advantage of such a system.

Although OIG is correct in its assessment of the lack of documented oversight of contracts and partnerships with the States, and the need for such oversight, contracts and partnerships are the only current mechanisms (besides "work sharing") FDA has to capture the inspectional and sampling data from the States. Today's funding of both federal and State inspection programs dictates that we must leverage our resources in order to ensure that high and medium risk establishments receive adequate inspectional coverage. AFDO has long advocated the use of contracts, partnerships, memoranda of understanding, and work share agreements to assist FDA in the completion of their annual work plans, and to ensure that gaps and duplication in the system are eliminated. With the exception of the addition of adequate oversight of these programs, AFDO does not see a rationale for changing the basic system. The States need resources such as funding for travel, laboratories to analyze samples, training, and equipment; while FDA needs the States to complete inspections and collect samples. No proposed system should require duplication of these activities.

The Draft Report states that variations in State laws and regulations and inspection practices add complications, costs, and frustrations for food firms engaged in multi-state commerce. Although AFDO agrees to a point that some non-uniformity exists, most of the non-uniformity exists among local regulatory jurisdictions and not among State jurisdictions. Contract and partnership inspections have long been one way of ensuring a certain amount of uniformity in both practice and regulation. FDA does not accept inspections that are not conducted utilizing state regulations alone that are not in conformance with the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder. For example, States which conduct seafood HACCP inspections and which have not adopted FDA regulations as State regulations are required to conduct these inspections utilizing their federal commissions rather than under "partnerships" using any non-uniform state regulations. AFDO fully supports uniformity of laws and regulations and has consistently advocated this for many years, including in our official comments to the President's Council on Food Safety Draft Strategic Plan.

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Also with respect to the *uniformity* issue, AFDO is concerned that the OIG's Draft Report does not adequately address the issue of *how the FDA and the States can use the results of the oversight and audit mechanism to improve uniformity*. It is not enough to merely identify problems and non-uniformity, but there must be mechanisms and incentives to directly address and correct the problems. A program must be developed to accomplish this *in conjunction* with the development and implementation of the oversight and audit process. Considerable thought by both FDA and the States is needed in advance.

AFDO is also concerned with the OIG's recommendation that consumer groups be one of the judges of the successes and failures of the inspections conducted by States. During the past several years at least one consumer advocate has repeatedly represented that many inspections conducted by the States are "inadequate" and "subject to local politics," which are generalizations that do not fit all situations. The same group also repeats the fact that FDA inspects firms only once every ten years on average, without acknowledging that the States may be inspecting these facilities twice every year. On the other hand, AFDO believes that consumer advocates should be consulted regarding what elements they consider to be essential to an adequate oversight program that would satisfy their concerns. Further, they should have access to the results of the inspections. We cannot operate in a vacuum and expect consumers to trust in our inspectional results.

AFDO also does not agree with the comment that "...Industry representatives have expressed concern that an even greater reliance on State inspections such as under a nationally integrated regulatory system could magnify the existing complications and costs." Both the National Food Processors Association and the Grocery Manufacturers of America are on record as supporting AFDO's vision of a *fully integrated food safety system*. That system, as visualized by AFDO, includes adequate oversight by FDA. At the same time, industry is also on record in support of contracts and partnerships because these agreements eliminate the need for multiple inspections of their facilities. AFDO believes that an oversight system that includes clear, scientifically sound, practical, and fair expectations regarding performance of the States, coupled with performance incentives, should allay any fears industry may have expressed to OIG! AFDO also encourages industry input into what such a system should entail.

In conclusion, AFDO believes that many of the proposals found in the OIG Draft Report have merit, especially where FDA oversight of both contracts and partnerships is concerned. At the same time such mechanisms should not be overly burdensome to either party. An oversight mechanism should be flexible enough to ensure equivalence of federal and State programs and inspections without diverting too many resources away from essential activities. OIG should advocate for more



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human resources for FDA so that FDA is indeed in a position to fill any void that might exist if/when a state falls short and cannot meet the equivalency criteria. FDA will also need additional resources to provide the training necessary to keep FDA and State/local investigators at the cutting edge of new technology and regulation. Incentives must be provided to the States to encourage continued participation.

Oversight should be a *shared* responsibility between FDA and the States. Before any oversight plan is initiated, the States should be consulted and the plan mutually agreed upon. The plan must include mechanisms which allow for flexibility to ensure that the oversight is the least burdensome possible for both agencies when quality inspections, equivalency of programs and inspections, and uniformity can be easily documented. The plan must also recognize that in some cases the quality of State inspections may exceed the quality of FDA inspections, and that audit inspections should address both sides of the issue. Both FDA and State investigators should be certified to conduct the various types of inspections. The oversight tool should also establish procedures that both FDA and State training and auditing personnel should follow. The OIG and FDA should utilize the documents produced by the NFSS Work Groups as a template. Further, we firmly believe that AFDO is the appropriate national organization with which FDA should consult to obtain State input into the development of a proposed oversight and auditing document.

Finally, it is AFDO's hope that in the near future Congress will supply FDA with ample long-term funding for leveraging with the States. Building State capacities in a more permanent fashion can only improve food safety in the U.S. and will go a long way towards facilitating the oversight process recommended by OIG.

AFDO wishes to thank the Office of the Inspector General for the opportunity to comment on the Draft Report and offer potential solutions from the point of view of the States.

Respectfully submitted,

R. D. (Dan) Sowards
President
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cc: AFDO Board of Directors
AFDO Office
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May 2, 2000

June Gibbs Brown
Inspector General
Department of Health & Human Services
Office of Inspector General
Washington, DC 20201

Dear Ms. Brown:

The National Food Processors Association (NFPA) appreciates the opportunity to comment on the Inspector General's Report, "FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability."

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

NFPA shares the Department of Health and Human Services' concerns regarding accountability in the food inspection system. NFPA notes that the United States continues to enjoy a food safety record that is unparalleled. This continuing record is due not only to inspection and oversight but also to a substantial voluntary effort by the food industry. As the Department moves forward with many of the recommendations in the Report, it should be kept in mind that industry must be a partner in these efforts. Despite a continuing record of achievements in producing safe food, current FDA budgetary priorities and the resources available for performing inspections warrant a thorough review.

NFPA notes that while it is a common perception, even among those in industry, to view food safety and food inspections as mostly a federal government activity, most inspections continue to be conducted by state and local health officials. This is due to the wide diversity of the food industry and the fact that the majority of food firms do not conduct business via interstate commerce, but rather are intrastate only. This fact leads us to

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conclude that FDA must continue to work with states and must continue to provide leadership, training and certain resources in order to promote a uniform system of food inspection.

NFPA has reviewed the recommendations contained in your report and we are in agreement with many of these recommendations. We do not, however, agree that FDA needs additional legal authorities, as the current authorities appear to have served well in assuring a continued safe food supply.

Regarding the specific recommendations in your Report, we agree that oversight to assure uniformity is of paramount importance. However, we view the need for oversight even more broadly than is addressed in your Report. We agree that FDA should provide auditing of state programs and audits conducted by state inspectors in a coordinated fashion through the FDA District offices to promote uniformity. It has been our experience however that there is a continuing issue regarding uniformity between FDA districts, which may be perpetuated by leaving the audit function strictly within-district. We view the audit function not only as helping to assure uniformity between states and the federal government, but between units of the federal government as well. Thus, we suggest that a review function be established within the Food and Drug Administration to provide for greater oversight of its own inspectors and audits. This will help assure uniformity on a national basis, while at the same time implementing "standards" for inspections that are being developed through the National Food Safety System to assure uniformity between state and federal inspections.

As a closely related matter to inspection uniformity, we also agree with the need for the development of uniform standards, not only for conducting inspections and audits of food firms, but standards for other functions to be conducted by regulatory agencies. We applaud the FDA's leadership in initiating efforts to develop such standards through efforts of those involved in developing the "National Food Safety System." These standards should cover such items as agency record keeping criteria, information reporting, laboratory sample handling and analysis and other areas in addition to inspections. If these functions achieve some standardization and are supported by uniform auditing, many of the problems referred to in your Report regarding data handling, reporting etc. can be minimized. Current problems related to reporting by states and lack of feedback from FDA may be linked to the lack of uniformity in reporting format. Such non-uniformity requires much more time to analyze information to develop feedback. NFPA feels this situation could be alleviated to a certain degree by instituting a uniform system of reporting.

We also agree with the recommendation contained in your report regarding uniform training and for providing oversight and evaluation. FDA should play a leadership role in this regard and should also evaluate its own level of training through the establishment of standard criteria and certifications. The Agency should also avail itself of the many courses and training methods developed by industry. As we have learned through our experiences with HACCP for seafood, there appears to be great benefit in training government inspectors and industry together.

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Finally, we agree that FDA should draw on external sources of information in assessing inspection performance. While the recommendation in your report is specific to state inspection performance, as we noted earlier, we consider uniformity to be a more globally important matter. Thus, we respectfully suggest that feedback from industry, consumer groups and others should address not only state inspections, but federal inspections as well. NFPA believes this process of developing auditing standards and standards for federal and state regulatory agencies should be an open and transparent process involving feedback from interested constituent groups. To date, the effort to develop a "National Food Safety System" has been closed to all but government representatives. NFPA looks forward to the time when this system can be more open such that all stakeholders can participate in development of these concepts.

Regards,





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May 9, 2000

Ms. June Gibbs Brown
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Dear Ms. Brown:

I have been asked by Richard Gutting, President of the National Fisheries Institute (NFI), to review your draft report entitled, "FDA Oversight of State Food Firm Inspections." On behalf of Mr. Gutting and the NFI organization I wish to thank you for the opportunity to comment on the draft.

For your information, the NFI is the largest, non-profit trade association representing the U.S. fish and seafood industry. NFI's mission is to ensure an ample, sustainable, and safe supply of seafood for consumers and our members include fishing and aquaculture companies, processors, importers/exporters, wholesalers/ distributors/retailers, brokers, restaurant/foodservice operators and members of allied support industries.

Most of our member firms are defined as either "fish processors" or "fish importers" under 21 CFR Part 123 Fish and Fishery Products (FDA HACCP Inspection Program). Therefore, a large number of these companies are subject to inspection by state agencies under contract or partnership arrangements with FDA. It is with this perspective that we submit the following comments and observations about the report.

The stated purpose of the report is to assess the Food and Drug Administration's oversight of food firm inspections conducted by states through contracts and partnership agreements. The report correctly identifies these contractual and partnership agreements as critical to the successful implementation of FDA inspection obligations. NFI members confirm that, in some localities, they are more likely to be inspected by State food and health agencies than FDA.

The report finds that FDA's heavy reliance on State inspections is a concern under the current practices and policy and may undermine consumer and trading partner confidence in the uniformity of U.S. food standards and enforcement

efforts. The report notes that under contracts and partnerships FDA obtains minimal information to assess the quality of State food firm inspections, provides limited feedback to States on the quality of their inspections and provides limited feedback to the public regarding its oversight of contracts and partnership agreements. In addition, the report notes that FDA faces significant barriers in overseeing States.

NFI is impressed with the report's comprehensiveness and the quality of analysis. NFI agrees with many of the observations concerning FDA's oversight of State contract and partnership inspections and agrees with many but not all of the recommendations in the report. The following comments regarding the findings and recommendations in the report are organized and presented by section beginning with "The Importance of Oversight."

The Importance of Oversight

This section discusses the growing reliance of FDA on State inspections and notes that this reliance plays an important role in reducing regulatory duplication among Federal and State food safety efforts and extends FDA's inspection coverage. It has been NFI's observation that in many instances the State inspection capability to conduct inspection of high risk foods meets or exceeds that of FDA, therefore, it would be incorrect to conclude that this trend is necessarily alarming or problematic. As noted later in the report, this reliance is acceptable provided that inspector training and oversight is adequate. Both State and Federal inspection personnel need adequate training and oversight to maintain competency.

NFI takes issue with the categorization of seafood, in general, as a high-risk food. The report notes that FDA has not defined the term "high risk food firm", so, in the absence of a definition, defines high-risk food firms as those involving food products or processing technologies that have a higher potential for contamination. Historically, FDA has divided seafoods in to high and low risk by the intended use of the product after it is processed and packaged (i.e. products that are cooked before consumption versus those consumed without a terminal cook) as well as by the likelihood of contamination. Therefore, we believe that many seafood products are low risk by this definition.

Another observation and concern raised in the report is that variation exists among State inspection programs regarding: inspection classifications, enforcement authorities, inspection authorities and regulations, inspector education and training requirements and hours per inspection. NFI agrees that deficiencies in inspection and enforcement authority and inspector training and education should be addressed and, where necessary improved, because they could potentially effect the consistency of inspections conducted on behalf of FDA. However, we do not believe that differences in inspection classification reflects on the adequacy of inspection but acknowledge that it could make

comparison of inspection results between States and FDA difficult. The number of hours per inspection is not an accurate barometer of inspection quality or comprehensiveness, since it varies from industry to industry and between types of operations.

The Seafood HACCP regulation is used to illustrate the IG's concerns over the variation in State inspection authorities and regulations. However, the example provided does not reflect a variation in authority or regulation. Rather it is an example of differences that can occur in the interpretation of regulations.

Specifically, the report notes that a discrepancy occurred between FDA and a State with respect to the enforcement of controls for the potential hazard of food allergens. The seafood HACCP regulation is relatively new, hence, the inspection agencies and industry are still refining their knowledge about HACCP and its application to seafood. As a result, the guidance on hazard analysis and control measures for significant hazards is evolving. FDA had not previously identified allergens as a potential hazard in their official guidance document, entitled the "Fish and Fishery Products Hazards and Controls Guide." Therefore, many seafood operations did not initially identify allergens in their hazard analysis. Likewise, State agencies, using the same FDA guidance document, were not inclined to regulate allergens as significant hazards in a HACCP plan. FDA policy on food allergens has recently evolved and the agency now believes it is a hazard that should be controlled in a HACCP plan if it is reasonably likely to occur. Therefore, this incident resulted from a change in policy rather than a lack of State authority or regulations.

Regarding State inspector training and education, the report notes that FDA is creating a certification program for its seafood HACCP program. NFI member firms have expressed frustration with inconsistency in inspection scrutiny and interpretation of HACCP regulatory policy. Therefore, we applaud and encourage this effort and believe it is necessary to minimize inconsistency in inspections between inspectors, areas of the country and between Federal and State agencies. Although we believe the certification program can be introduced on a voluntary basis, we would like it to become mandatory in the future.

The report notes that U.S. trading partners have raised concerns about the lack of uniformity between States and FDA. In this context, NFI agrees that discrepancies should be corrected for plants and products that are involved in exportation. Products that are produced solely for in-state consumption should not be a concern to foreign governments.

The report discusses import inspection by State agencies but NFI does not believe that States are conducting imported seafood inspections at point of entry. To our knowledge these inspections are conducted entirely by the FDA, with the possible exception of molluscan shellfish which is regulated under a cooperative program between FDA and the States. Import inspection by the States should be

allowed only when a State agrees to sample and test for violations following FDA guidelines, the laboratories show adequate proficiency and inspection personnel receive adequate training.

Findings

The report finds that FDA's oversight of State food firm inspections is limited. Specifically noted are the following: on-site audits have declined, on-site audits provide limited basis for assessing the State performance, reviews of contract inspection reports lack rigor, FDA rarely seeks input from external sources to evaluate State performance. These observations reflect, in large part, the declining resources of FDA. It is understandable, although not necessarily supportable, that FDA District personnel see audits as duplicative and a low priority given they're many and varied responsibilities.

NFI agrees with the IG recommendation that FDA should shift away from conducting independent audits after State inspections occur. Such an approach is duplicative, frustrating to processors and of little value to FDA and the States. During independent audits, FDA auditors are not evaluating conditions of the plant at the same time so comparisons of inspection observations are imperfect at best. When audits are performed in conjunction with a State inspection, both the auditor and inspector will benefit from an exchange of observations and assessments of the plant. The on-site dialogue is perhaps that most useful element of the audit.

Regarding the lack of input from external sources, FDA should utilize processor evaluations to gather additional insights on the effectiveness of contract and partnership inspections. Firms can provide extensive observations to augment the limited number of FDA audits.

The IG is particularly critical of partnership inspections, saying that FDA lacks the ability to adequately direct, evaluate and critique these inspections, States are left to utilize their own authorities and regulations and audit frequency is insufficient. We agree in part with these observations, however, we agree also with the comment made by the FDA that the State partnerships are predicated on a recognition of equivalence between FDA and the State programs. It is reasonable to provide less oversight for inspection programs that have, at least, equivalent authority, regulation, and capability to implement the program effectively. Unfortunately, there is insufficient information to evaluate whether FDA is doing an adequate job of establishing equivalency prior to entering into the partnerships. NFI supports the establishment of a minimum number of audits under State contracts and partnership agreements as is done in the seafood HACCP program. The level of frequency should be adjusted up or down depending on performance.

NFI shares the IG's concern about the limited level of scrutiny afforded the State inspection reports and lack of feedback provided to the States. However, NFI is concerned about how much public disclosure is needed regarding State partnerships and contracts. We believe that the State inspections should be conducted as consistently and effectively as FDA inspections. If the inspections are conducted competently, consistently and effectively, it matters little what agency is conducting them. It would be commendable to provide the public with information on which States have inspection agreements with FDA and what type of inspections the States conduct. However, providing detailed information about the number and outcome of inspections would be counterproductive without an opportunity to place the data in the proper context. Information on FDA Inspections, irrespective of who conducts them, has never been easy to access. The FOI Act has always been the avenue to request detailed information of this type.

Recommendations

The report offers a series of seven recommendations to improve FDA oversight of State inspections:

1. FDA should work with States to achieve basic equivalency in food safety standards and laws and in inspection programs and practices.

The recommendation is logical and should serve to form a more solid foundation for agreements. Although we caution that the concept of equivalency is problematic and can become a barrier to establishing relationships if the criteria is too rigid. "Equivalent " should not be interpreted to mean "identical" for the purposes of evaluating inspection authorities, regulations and implementation strategies. Moreover, a lack of equivalency should not necessarily preclude the ability of States and FDA to enter into agreements, albeit on a prescribed limited basis or, perhaps, with an increased level of oversight. The report identifies possible models to assist in the establishment of an equivalency policy. The Interstate Shellfish Sanitation Program should be added to this list.

NFI agrees with the IG's recommendation that equivalency be phased cautiously and the believes the concept of a pilot audit as a mechanism to foster in equivalency concepts is sensible.

2. FDA should devote high priority to improving its on-site audit mechanism for evaluating the effectiveness of State inspections.

NFI supports recommendations 2a, 2b and 2c. With respect to 2c, we believe FDA should determine the frequency of State audits on the same basis they should for seafood processor inspections. The base line should be established by conducting a study to determine the effect of audit frequency on audit outcome (i.e. performance). This would theoretically establish the minimum audit

frequency needed to attain and maintain a given (minimum acceptance) level of performance. Once a base line is established, frequency should be adjusted based upon performance over time.

3. FDA should require that States routinely provide FDA with standardized information on the inspections that they conduct.

NFI agrees with recommendations 3a and 3b.

4. FDA should draw on multiple external sources of information in assessing State inspection performance.

As noted earlier, NFI concurs with the recommendation that FDA solicit industry evaluations. If FDA ability to solicit this information is encumbered by the Paperwork Reduction Act, it should utilize State agencies and trade associations to assist it in collecting this data. NFI would be interested in cooperating with FDA on such a data collection effort for seafood inspections.

5. FDA should provide substantive and timely feedback to States on their inspection performance.

NFI agrees with recommendations 5a, 5b and 5c.

6. FDA should enhance its internal capacities to conduct effective oversight.

NFI agrees with recommendations 6a through 6c but disagrees with 6d. In recommendation 6d the IG says that FDA should seek broader enforcement authorities. The report notes that many States have broader authorities than FDA and asserts that this complicates progress toward national uniformity and hinders Federal oversight because it contributes to FDA dependence on the States.

FDA's existing authorities should not create difficulty with uniformity since FDA's authorities, regulations and policy will serve as the benchmark for agreements with the States. As we mentioned earlier, equivalence should not be interpreted as meaning identical. The fact that many States have broader authority than FDA should be considered a plus for States and place them above the baseline with respect to equivalency.

We do not believe that FDA's inspection activities are compromised by over reliance on State authorities. FDA has generally received adequate support for embargoes and other actions when they have needed assistance from the States with embargo authority. FDA is capable of obtaining injunctions when necessary and can arrest violative goods with a court order. FDA should not allow its ability to oversee inspection activities to be compromised because some States have broader authorities than it does. If this issue becomes a consistent barrier to

maintaining an effective and enforceable inspection agreement than FDA should terminate the agreement.

7. FDA should increase public disclosure of its oversight of State food firms inspections.

As previously noted, NFI would support limited increases in the disclosure of State inspection information but is concerned about the possible misinterpretation or misuse of detailed inspection results.

In closing, we wish to commend the IG for providing an insightful report on FDA oversight of State inspection agreements. The analysis is thorough and the recommendations are, with a couple of noted exceptions, reasonable, rational and adaptable, given adequate resources. The latter subject, namely the allocation of additional resources is an area the report failed to address. Most of the IG's recommendations will be difficult to implement without a commitment of additional personnel and funding. The IG should consider adding to the report a concluding comment about the ability of FDA to implement its recommendations given its existing resources.

Thank you again for the opportunity to review and comment on the report. I would like to request a copy of the final document when it becomes available.

Sincerely,



Robert L. Collette
V.P of Science and Technology

CSPI Center for
Science in the
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Publisher of *Nutrition Action Healthletter*

May 1, 2000

June Gibbs Brown
Inspector General
Department of Health and Human Services
Washington, D.C. 20201

Dear General Brown:

Michael Jacobson, Executive Director of the Center for Science in the Public Interest (CSPI), asked me to review your report entitled *FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability*. This report is excellent, and provides important new information on how the Food and Drug Administration is managing its inspection responsibilities.

CSPI strongly supports your recommendation that FDA reevaluates its reliance on partnership agreements as a mechanism for conducting inspections. However, we think your recommendations should go further. We are concerned that FDA has turned over 61% of its responsibility for inspections to the states. This strikes us as an inappropriate reallocation of duties from the federal to the state governments. Rather than embracing this transfer, the report should critically evaluate whether this reallocation is appropriate.

State, county and local governments currently have major food-safety responsibilities for restaurant and all retail operations. These responsibilities extend to nursing homes, hospitals, schools, and day care centers, which serve the consumers at highest risk of serious or life-threatening food poisoning. Yet, CSPI's research suggests that many state and local governments have not adopted even basic food-safety standards, like cooking and refrigeration temperatures. (See *Dine at Your Own Risk*, at www.cspinet.org/reports/dineat.html) Therefore, we urge that your report recommend that FDA reviews the status of state/local oversight of restaurants and retail food service prior to contracting with the state to conduct food safety inspections.

Secondly, CSPI is concerned that state governments let politics and economics get in the way of "arm's length" regulatory oversight. As an example, state governments in shellfish producing states have regulated the shellfish industry for years. Due to the political power of the shellfish industry, these states have not addressed critical public health problems in this industry and shellfish remains one of the most dangerous foods on the market today.

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Michael F. Jacobson, Ph.D.
Executive Director

11-0-4

This distrust of state food safety oversight is a principle reason that state-inspected meat plants have been barred from shipping their products interstate for decades. While there is legislation in Congress to change this prohibition, the state meat inspection programs focus on the smallest meat plants, and the state programs would be subject to intensive annual audits by the US Department of Agriculture.

Therefore, we urge your report to recommend that FDA restrict state inspection of food plants to small plants producing low-risk foods. In addition, FDA should conduct annual audits of the state programs, including testing of products from state-inspected plants.

Thank you for letting us review this important new report. While the recommendations are helpful, they do not go far enough in reforming the role of states in conducting food-safety inspections in lieu of FDA inspections. Ultimately, the federal government has responsibility for ensuring the safety of food produced in this country. FDA's current food safety inspection program neither ensures equivalence nor instills confidence.

Very truly yours,



Caroline Smith DeWaal
Director of Food Safety

cc. Dr Mark Yessian at
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Endnotes

1. World Health Organization Press Release, "WHO Responds to New Challenges in Food Safety," January 25, 2000.
2. Paul S. Mead, et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases* 5 (September-October 1999) 5: pp. 607-625. The estimates of foodborne illness cited are more than twice as high as those suggested in earlier studies, which put the figure for foodborne illness at 30 million.
3. Food and Drug Administration, Food Safety Inspection Service, and Center for Disease Control and Prevention, "Healthy People 2000: Status Report Food Safety Objectives," (September 1, 1999).
4. Donna U. Vogt, "Food Safety Issues in the 105th Congress," *Congressional Research Service Issue Brief*, (August 11, 1998), p. 2.
5. Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption* (Washington: National Academy Press, 1998).
6. United States Environmental Protection Agency, United States Department of Health and Human Services, and United States Department of Agriculture, "Food Safety From Farm to Table: A National Food Safety Initiative," (Report to the President, May 1997).
7. Two States, South Carolina and West Virginia, hold two contracts each. In each State, one contract is held by the Department of Health, the other by the Department of Agriculture.
8. The President's Food Safety Initiative is supporting, among other activities, the establishment of a consortium in which all Federal agencies with risk-management responsibilities will improve the quality of risk-assessment for foods.
9. The FDA district offices oversee State contracts in accord with the Field Management Directive No. 76 (October 24, 1995); FDA district offices oversee the partnership agreements in accord with the Office of Regulatory Affairs Partnership Agreement Guidance Document (January 23, 1996).
10. The seven principles are: (1) analyze hazards, (2) identify critical control points to control identified hazards, (3) establish the point at which a preventive action must be taken, (4) establish procedures to monitor the control points, (5) establish corrective actions to be taken when monitoring shows that a critical limit has not been met, (6) establish procedures to verify that the system is working consistently, and (7) establish effective record keeping to document the

HACCP system.

11. National Food Safety System Project work groups: 1. Roles and Responsibilities, 2. Coordinating Outbreak Responses and Investigations, 3. Information Sharing and Data Collection, 4. Communication, 5. National Uniform Standards, and 6. Laboratory Operations and Coordination.

12. Speech by Joseph Levitt, Director of the FDA Center for Food Safety and Applied Nutrition at the 50-State meeting, "Meeting Challenges Together," Kansas City, Missouri, September 15-17, 1998.

13. The type of food contract we focus on in this report is the food sanitation contract.

14. These are inspections conducted under FDA's 03 project category for Foodborne Biological Hazards.

15. These programs derive their authority from the Public Health Service Act [42 U.S.C. 201 et seq.], whereby FDA's role is to provide assistance and guidance to States.

16. Based on information collected through our site visit, Texas conducted the following inspections under its contract and partnership agreements: 353 inspections under contract, 83 low-acid and acidified food inspections under partnership agreement, and 107 seafood HACCP inspections under Seafood HACCP partnership agreement. During this same time period, FDA reported that it conducted about 50 general food inspections, 13 acidified and low-acid canned food inspections, and 41 Seafood HACCP inspections.

17. The following examples illustrate the shift from low-risk to high-risk food firm inspections under contract: Fishery/seafood inspections conducted by the States increased by 178 percent over the past decade (from 269 in 1989 to 749 in 1998). During this same time period, soft drink and water inspections, which are considered low-risk, decreased by 37 percent (from 478 in 1989 to 299 in 1998); and bakery inspections, also considered low-risk, have decreased by 14 percent (from 943 in 1989 to 813 in 1998).

18. Twenty-one of the 37 partnership agreements are for Seafood HACCP inspections; 5 are for low-acid canned and acidified foods; and 2 are for cheese and dairy products. The remaining partnerships cover various general food categories.

19. Between 1989 and 1998, the number of inspections that States conducted under contract dropped from 7507 in 1989 to 4155 in 1998.

20. In 1998, FDA conducted 1,795 domestic food safety inspections (PAC 03803) ; the States conducted 1653 under partnership agreement.

21. We use the term inspector to denote all FDA personnel carrying out food firm inspections.
22. For contracted inspections, the States are required to use FDA's inspection classifications. By contrast, for inspections conducted under partnership agreement, the States can use their own classification systems.
23. FDA's consumer safety officers must have a college degree that includes 30 semester hours in one or a combination of subjects: biological sciences, chemistry, pharmacy, physical sciences, food technologies, nutrition, medical sciences, or veterinary medicine. These 30 hours may include up to 8 semester hours of statistics or coursework in computers. A combination of education and experience may be substituted for the college degree; however, FDA requires that its consumer safety officers have 30 semester hours of science.
24. At present, States generally inspect domestic food firms and domestic products under partnership agreements. The President of the Association of Food and Drug Officials recently called upon FDA to enhance its coverage of imported products through expanding the partnerships. Article by Allison Wright, "FDA's proposed international food safety activities should involve partnerships with the States," *Food Chemical News*, 8 November 1999, p.4.
25. While the number of inspections under State contract also declined during this time period, the percent of audits relative to the total number of contract inspections dropped by almost one-third. In 1993, FDA audited about 3.4 percent of total inspections conducted under contracts. In 1998, FDA audited only 2.4 percent of the total contract inspections.
26. The Field Management Directive No. 76 calls for 6 audits for contracts with up to 100 inspections, 10 audits for contracts with 101-300 inspections, 22 audits for contracts with 301-900 inspections, and 34 audits for contracts with over 901 inspections. According to the directive, "The required number of independent audits will be accomplished for a minimum of one year. If no significant performance problems are found during this period, and the overall performance is considered satisfactory by the District, the number of audits may be reduced by 50 percent to a maintenance level."
27. Those 7 district offices oversee 11 of the 38 States under contract.
28. Several district offices cited difficulties in meeting even the 30-day time frame.
29. In accordance with the Paperwork Reduction Act [P.L. 104-13], FDA cannot survey more than 10 entities without clearance from the Office of Management and Budget. The Federal Advisory Commission Act set forth the rules under which FDA can rely on information gleaned from external sources.
30. We are referring to the 03 project category for Foodborne Biological Hazards.

31. The Office of Regulatory Affairs Partnership Agreement Guidance Document identifies FDA and State responsibilities to conduct joint inspections, but does not define their function. The Model Seafood HACCP partnership agreement offers some definition, but lacks specific guidance, “joint inspections will serve training, technology and information exchange, and verification functions.”

32. We note that performance audits have been conducted of the retail side of the partnership. However, our study focuses on inspections in the manufacturing and processing arena.

33. In our analysis of five low-acid canned food partnership agreements, we identified expectations ranging from the “prompt exchange” of enforcement documentation to lack of any specifications.

34. The State contract semi-annual evaluation form can be found in the Field Management Directive No. 76, (October 24, 1995), p. 6; the partnership agreement annual evaluation form can be found in the Office of Regulatory Affairs Partnership Agreement Guidance Document (January 23, 1996), Attachment C.

35. FDA’s general information telephone hotline is 1-888-FDA-INFO. Its websites are located at www.foodsafety.gov and www.fda.gov.

36. Note that this is a result of funds provided through the President’s Food Safety Initiative to support the 1995 Seafood HACCP Regulations. While the overall number of operational FTEs has increased, the increases occurred primarily in the areas of Domestic Fish and Fishery Products and Import Seafood Products. Over the past decade, a number of other program areas lost FTEs. The most notable of these were Domestic Food Safety and Domestic Acidified and Low-Acid Canned Foods.

37. United States Environmental Protection Agency, United States Department of Health and Human Services, and United States Department of Agriculture, “Food Safety From Farm to Table: A National Food Safety Initiative,” (Report to the President, May 1997), p. 37. The report cites significant decreases in FDA’s inspectional coverage since 1981. An FDA regulated plant is inspected by FDA, on average, only once every 10 years.

38. Annual Partnership Evaluation of the Oklahoma Partnership Agreement, SW Region/Dallas District, Section 9, November 1998, “Capturing partnership inspection data into the FDA Facility Inspection System has proved to be a problem. Inspections performed under State contract were conducted using FDA forms and cover sheets, which captured all the data elements required for entry into the agency’s electronic data inspection system. Since inspections under the partnership are not being paid for and the State is receiving little monetary support from FDA for the project, we are not in a position to require the State to provide specific information in a specific format. The State uses its own inspection form to capture data elements that match its data needs.

Translation of their data for use in FDA's electronic system has resulted in some errors in the data capture in FDA's FIS. We are attempting to work through this problem with more the recent data, but it requires some time-consuming manual manipulation of the information supplied by Oklahoma State Department of Health."

39. For example, under the Oklahoma Food Safety Partnership Agreement, the Oklahoma State Department of Health conducts 100 percent of the food firm inspections in its State. In the Texas Low Acid Canned Food and Acidified Food partnership agreement, the Texas Department of Health conducts 90 percent of the acidified canned food inspections, and FDA conducts 10 percent.

40. In some of its agreements FDA has recognized the importance of retaining a minimum level of inspections to maintain its own expertise. The Model Seafood HACCP Partnership Agreement states, "FDA will conduct at least (enter the appropriate number of inspections that are to be performed by FDA under the terms of the agreement, but in no case less than 10 percent of the fish and fishery processors in the State)." The model Seafood HACCP partnership agreement cites reasons for maintenance of FDA inspectional capacity as the potential for reduced State capacity or problems that arise with the agreement, maintaining domestic and international credibility through some FDA inspectional presence in each State, and maintaining intelligence about the industry throughout the country. The California Low Acid Canned Food partnership states, "FDA may make periodic LACF inspections so that FDA investigators can maintain their expertise in the areas of LACF and acidified food inspections."

41. Department of Health and Human Services, Office of Inspector General, *FDA Food Safety Inspection*, OEI-05-90-01070, 1991.

42. The Canadian Food Inspection Agency, "Equivalence of the Fish and Fishery Products Inspection and Control Systems," Report of an Audit of the Inspection and Control System for Fish and Fishery Products of the U.S. Food and Drug Administration, (June 2, 1999).

43. Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption* (Washington: National Academy Press, 1998), p.7.

44. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, CFSAN 2000 Program Priorities, 10 February 2000.

45. FDA has developed a cost estimate of \$425,000 for fiscal year 2000 audit activity based on an audit frequency at 5 percent of 5,200 State contract inspections. The FDA estimates \$630,000 for fiscal year 2001 with a frequency of 7 percent, and \$988,000 for fiscal year 2002 with a frequency of 10 percent.

46. The model contract calls for States to report a considerable amount of information using standardized formats and FDA codes. This includes specific information that enables FDA to assess a firm's compliance with FDA regulations, which States themselves might not obtain through their own inspections. In addition, the contract states that "the inspection reports should detail the conditions found with sufficient narrative to enable an assessment of any objectionable conditions or practices found. Where microbiologically oriented inspections are conducted, a more detailed description of the manufacturing process, routes of contamination, etc., will also be made." Under partnership agreements, as we have demonstrated, FDA obtains information far below its own standards for contracts.

47. "The fourth essential feature of an ideal federal food safety system is that it be organized to be responsive to and work in true partnership with non-federal partners. These include state and local governments, the food industry, and consumers." Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption*, (Washington: National Academy Press, 1998), p.7.

48. At present, the contract document devotes only one sentence to feedback: "Results of the quality assurance review will be furnished to the contractor." The partnership agreements promote more joint work and communication.

49. In objective 6 of its Draft Preliminary Food Safety Strategic Plan, the President's Council on Food Safety calls for FDA to promote voluntary best practices developed and implemented by industry and/or State governments. President's Council on Food Safety, *Draft Preliminary Food Safety Strategic Plan for Public Review*, January 2000.

50. The ORA Division of Human Resource Development (DHRD) is developing a training course for FDA Investigators on the process and techniques for auditing State contracts and partnerships. The course is planned to be offered in September 2000.

51. In objective 5 of its Draft Preliminary Food Safety Strategic Plan, the President's Council on Food Safety calls for FDA to protect the food supply through developing additional national training and job standards. Such a program could include a credentialing system for food safety inspectors, investigators, and program reviewers. President's Council on Food Safety, *Draft Preliminary Food Safety Strategic Plan for Public Review*, January 2000.

52. Department of Health and Human Services, Office of Inspector General, *FDA Food Safety Inspection*, (OEI-05-90-01070), 1991.

53. Department of Health and Human Services, Office of Inspector General, *FDA Food Safety Inspection*, (OEI-05-90-01070), 1991.

54. FDA's Recommended National Retail Food Regulatory Program Standards (February 6, 1998) proposes a listing program of State retail programs that meet FDA standards.