

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

RETAIL FOOD SAFETY



**JANET REHNQUIST
Inspector General**

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OEI's Chicago office prepared this report under the direction of William C. Moran, Regional Inspector General and Natalie Coen, Deputy Regional Inspector General. Principal OEI staff included:

Region

Joe Penkrot, *Project Leader*
Erin Guay, *Program Analyst*
Tricia Fields, *Program Analyst*

Headquarters

Joe Rutherford, *Program Specialist*

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EXECUTIVE SUMMARY

PURPOSE

This study assesses the Food and Drug Administration's (FDA) role in States' adoption and implementation of the model Food Code and the voluntary Recommended National Retail Food Regulatory Program Standards.

BACKGROUND

Foodborne illness is a major cause of personal distress, preventable death, and avoidable economic burden. Every year, millions of Americans become sick and many die from foodborne illness, and as a result, the public has become increasingly aware and concerned about the safety of the food they eat. The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs is estimated to be in the billions of dollars.

The breadth of the retail food industry makes it an impossible task for FDA alone to monitor the safety of food at the retail level. As a result, State and local governments play a critical role in overseeing the safety of the nation's food supply. The FDA relies on more than 3,000 State and local jurisdictions to monitor retail establishments and their employees. State and local regulators conduct the vast majority of inspections for retail establishments in accordance with their own laws and authorities. In addition to many other types of food establishments that directly serve consumers, restaurants, supermarkets, and institutional food services fall under FDA's retail food protection program, a cooperative Federal-State food safety effort.

The FDA has several retail food safety initiatives underway aimed at reducing the risk factors that cause foodborne illnesses and in achieving uniformity in retail food inspections. One effort involves issuing a model Food Code every 2 years to enhance the consistency among Federal, State, and local jurisdictions, and to improve the effectiveness of retail food safety programs. The Food Code provides the most current scientific principles in conducting retail food safety inspections. Thirty States and 1 territory have voluntarily adopted a version of the Food Code, and another 15 States and 1 territory are in the process of adopting the Food Code. States and local jurisdictions may adopt particular aspects of the Food Code or use measures they deem at least equivalent to inspection techniques or procedures outlined in the Food Code. A second effort began in 1998 when FDA drafted voluntary Recommended National Retail Food Regulatory Program Standards (or the Standards) to serve as a national foundation for comprehensive retail food inspection regulatory programs and to guide the development and management of retail food inspection programs. In 1999-2000, FDA

pilot tested the Standards in 4 States and 3 local jurisdictions. Over 100 agencies volunteered to participate in the next phase-in cycle. The FDA believes that use of the Standards will be a primary focus of their dealings with retail food inspection agencies in the future.

The FDA considers States' adoption and implementation of the Food Code and the Standards as the essential elements in achieving uniformity across all jurisdictions responsible for retail food safety and reducing the incidence of foodborne illness. To determine FDA's role in assisting State and local retail food inspection agencies reach these goals, we conducted an electronic survey of all State retail food inspection agencies and met with State and local retail food inspection agencies in 10 States. In addition, we interviewed FDA's Regional Food Specialists as well as all members of the headquarters' Retail Food and Interstate Travel Team. We also conducted interviews with consumer advocates and members of the Executive Board for the Conference for Food Protection, where Food Code revisions are recommended every 2 years.

FINDINGS

OVERALL - Respondents rate FDA highly in their promotion and support of the Food Code and the voluntary Recommended National Retail Food Regulatory Program Standards

Overwhelmingly, respondents agreed that FDA has demonstrated their support for the Food Code and the Standards. Almost all respondents said that FDA encourages adoption of the Food Code, and described a variety of ways FDA supports this activity.

FOOD CODE - States face multiple barriers in adopting and implementing the Food Code

Nearly three-fourths of the States report that the biennial revisions to the Food Code act as a drawback to adopting the most recent Food Code. Respondents also indicate other drawbacks, including the feasibility of some of the provisions, the cost and time involved in adopting or implementing an updated version of the Food Code, and the need to rely on FDA to interpret Food Code provisions and provide other support.

STANDARDS - The FDA staff and State and local agency opinions differ on the most difficult standards to accept and implement, which may affect the way the Standards are implemented

While FDA regional and headquarters staff believe that retail inspection agencies will encounter more difficulty with the program standards dealing with a uniform inspection program and compliance and enforcement, State surveys point to problems with the standards relating to program assessment and program resources. State and local

agencies we visited cite standards for a trained regulatory staff and an inspection program based on the principles of hazard analysis at critical control points.

OPPORTUNITIES FOR FACILITATING IMPLEMENTATION

Develop a strategic plan outlining current and anticipated acceptance of the Standards by State and local agencies and detailing how FDA will respond to the needs of these agencies

The retail food industry, State and local agencies, and Federal respondents, all embrace the Food Code and the Standards as blueprints for developing retail food inspection practices and organizations for the future. However, respondents at every level expressed concern about implementation issues, particularly in regards to a lack of resources necessary to carry out many aspects of the Standards. Because resources are limited at all levels, collaboration among FDA, State and local agencies, and the retail food industry is essential. What FDA needs now is to develop strategic plans to map out future actions, both internally as well as for the States, and we offer numerous suggestions that we hope will be helpful in developing such strategic plans. Our suggestions include that FDA:

- < re-evaluate the frequency of revising the Food Code and consider making the Food Code a requirement by publishing the model Food Code in the Federal Register.
- < issue a user guide concurrent with the issuance of a new Food Code making the Food Code more practical.
- < widely publicize the availability of web-based training.
- < provide training to FDA staff in order for them to assist State and local agencies with program assessments.

Numerous other suggestions are included in the body of the report.

Develop a model strategic plan for the States to use as they consider acceptance and begin implementation of the Standards

In addition to the strategic plan described above that outlines activities for FDA's consideration as they begin to roll out the Standards on a national basis, it is also important that FDA provide States with a model strategic plan outlining what the States should consider in regard to accepting and implementing the Standards.

AGENCY COMMENTS

The Food and Drug Administration agrees with the recommendations in this report and will develop strategic plans and continue to work with other groups, States and localities regarding innovative ways to facilitate food safety through adoption and implementation of the Food Code and the Standards.

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INTRODUCTION

PURPOSE

This study assesses the Food and Drug Administration's (FDA) role in States' adoption and implementation of the model Food Code and the voluntary Recommended National Retail Food Regulatory Program Standards.

BACKGROUND

Foodborne illness is a major cause of personal distress, preventable death, and avoidable economic burden. Every year, millions of Americans become sick and many die from foodborne illness, and as a result, the public has become increasingly aware and concerned about the safety of the food they eat. The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs is estimated to be in the billions of dollars.

Although numerous Federal agencies are involved both directly and indirectly in the food safety system, FDA has overall Federal responsibility for all domestic and imported foods that are marketed in interstate commerce with the exception of meat and poultry products which fall under the jurisdiction of the Food Safety and Inspection Service within the United States Department of Agriculture (USDA). Both FDA and USDA, Food Safety and Inspection Service share responsibility for eggs. The Federal Food Drug and Cosmetic Act of 1938¹ established FDA's primary role in food safety as one of inspecting the conditions under which food is manufactured, processed, packaged, and stored. In addition to these inspection responsibilities, FDA assists State and local governments in the development and enforcement of food safety regulations as mandated under the Public Health Service Act.²

The breadth of the retail food industry makes it an impossible task for FDA alone to monitor the safety of food at the retail level. As a result, State and local governments play a critical role in overseeing the safety of the nation's food supply. The FDA relies on more than 3,000 State and local jurisdictions to monitor retail establishments and their employees. In addition to many other types of food establishments that directly serve consumers, restaurants, supermarkets, and institutional food services fall under FDA's retail food protection program, a cooperative Federal-State food safety effort. For

¹ 21 USC 301

² 42 USC 243

simplicity, this report uses the term “retail food establishments” to cover the entire range of facilities that fall under this cooperative program. State and local regulators conduct the vast majority of inspections of retail food establishments in accordance with their own laws and authorities.

The FDA’s Role in Ensuring Retail Food Safety

Two FDA components work toward achieving national uniformity in retail food safety programs. The Center for Food Safety and Applied Nutrition’s mission is to promote and protect the public health by ensuring that food is safe, nutritious, and wholesome. The Office of Regulatory Affairs is responsible for all FDA field activities. Both the Center for Food Safety and Applied Nutrition and the Office of Regulatory Affairs work with State and local health departments, as well as other Federal agencies, to help resolve food safety concerns and conduct training to improve consistency in science-based retail food safety inspections.

The FDA has several retail food safety initiatives underway aimed at reducing the risk factors that cause foodborne illnesses and in achieving uniform and science-based retail food inspections. One effort involves issuing a model Food Code every 2 years to enhance the consistency among Federal, State, and local jurisdictions, and to improve the effectiveness of retail food safety programs. The Food Code sets forth model regulatory requirements based on the most current scientific principles in conducting retail food safety inspections. Thirty States and 1 territory have voluntarily adopted a version of the Food Code, and another 15 States and 1 territory are in the process of adopting the Food Code. States and local jurisdictions may adopt particular aspects of the Food Code or use measures they deem at least equivalent to inspection techniques or procedures outlined in the Food Code.

A second effort began in 1998 when FDA drafted voluntary Recommended National Retail Food Regulatory Program Standards (or the Standards) to serve as a national foundation for comprehensive retail food inspection regulatory programs and to guide the development and management of retail food inspection programs. In 1999-2000, FDA pilot tested the Standards in 4 States and 3 local jurisdictions. Over 100 agencies volunteered to participate in the next phase-in cycle. The FDA believes that the Standards will be a primary focus of their dealings with retail food inspection agencies in the future.

Other efforts involve the Center for Food Safety and Applied Nutrition and the Office of Regulatory Affairs’ formation of a Retail Food Program Steering Committee to provide national leadership, enhance communication, and promote uniformity. The Steering Committee represents all FDA components involved in retail food safety. In addition, FDA established a National Retail Food Team to help improve the retail food safety system. The National Retail Food Team is comprised of all FDA regional food specialists, and headquarters retail food safety staff from the Office of Regulatory Affairs

and the Center for Food Safety and Applied Nutrition, which includes the Retail Food and Interstate Travel Team staff.

The FDA and the Department of Agriculture collaborate with the Centers for Disease Control and Prevention on FoodNet³ and PulseNet.⁴ FoodNet provides a way to respond to new and emerging foodborne diseases of national importance, monitor the prevalence of foodborne diseases, and identify the sources of specific foodborne diseases. State and local public health laboratories participating in PulseNet perform DNA “fingerprinting” on bacteria that may be foodborne and submit the patterns to the central electronic database at the Centers for Disease Control for rapid comparison.

Model Food Code

The Food Code represents the most comprehensive source of safe food practices and guidelines at the retail level and has been considered the cornerstone to achieving national uniformity. It serves as a reference document for regulatory agencies who have responsibility for overseeing food safety in retail outlets such as grocery stores and restaurants, as well as institutions like schools, hospitals, nursing homes, prisons, and day care centers. Although not federally required to do so, all levels of government may voluntarily adopt the Food Code.

The Food Code has evolved since the 1934 proposed *Restaurant Sanitation Regulations*. Prior to 1993, the recommended regulatory codes addressed separate entities of the retail food industry. Beginning in 1993, these codes were combined into a single document called the Food Code. The Conference for Food Protection, comprised of Federal, State and local agencies, the food service, retail food, and food vending industries, consumers, and academia, makes recommendations related to the Food Code to reflect the most current scientific knowledge during its biennial meeting. The FDA decides which Conference for Food Protection recommended changes to make to the Food Code and accepts those recommendations in harmony with scientific evidence, public health principles, and Federal regulations, directives, and policy.

State and local retail food inspection agencies, as well as tribal agencies and Federal Government agencies, may use the Food Code as a model to help develop or update their own food safety rules and regulations. Agencies can modify the Food Code to accommodate their existing laws, procedures, and policies. They can adopt the Food

³ The FoodNet project sites are California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, and Tennessee.

⁴ PulseNet participants include public health laboratories in California, Colorado, Georgia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Los Angeles County, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, New York City, Ohio, Oregon, Tennessee, Texas, Utah, Virginia, Washington and Wisconsin. The laboratories at the United States Department of Agriculture, Food Safety and Inspection Service and the Food and Drug Administration, Center for Food Safety and Applied Nutrition are also involved in the PulseNet network.

Code either in its entirety, or section by section, using one of the following three methods:

- < enacting the Food Code into statute,
- < promulgating the Food Code as a regulation,⁵ or
- < adopting the Food Code as an ordinance (if a local legislative body is delegated rule-making authority or regulatory powers).

State and local adoption of the Food Code is one of the primary approaches to achieving uniformity among jurisdictions, which the retail food industry strongly supports. However, some States, like Texas and Illinois, honor “home-rule” for municipal governments, making retail food safety inspection standardization more difficult to attain, and some States have a combination of home-rule and State-preempted jurisdictions. In such States, home-rule local municipalities make decisions about food safety regulations, developing and enforcing their own food safety laws, independent of State government. These local laws cannot be less stringent than State laws, but can be more strict.

Besides FDA’s efforts, the 1997 National Food Safety Initiative⁶ emphasized adoption and implementation of the Food Code to achieve coordination and better integration between the activities of the Federal, State, tribal, and local food safety agencies. In June of 1998, the Secretary of Health and Human Services and the Secretary of Agriculture jointly wrote to all State governors asking them to encourage their State agencies with retail food safety responsibilities to adopt the Food Code.

Voluntary Recommended National Retail Food Regulatory Program Standards

Although adoption of the Food Code has historically been the cornerstone in achieving uniformity among the various jurisdictions responsible for retail food safety, FDA believes that an agreed upon national standard or foundation for regulatory programs is an essential component of a comprehensive retail food safety system. In 1998, FDA formulated the Standards to assist regulatory retail food program managers in the design and management of a retail food program and provide a means of recognition for those programs that meet the Standards. Major stakeholders, including State and local regulatory officials as well as representatives from industry, trade associations, professional organizations, academia, and consumer organizations contributed to the development of the Standards.

⁵ Some States allow adoption of the Food Code by reference, a simple published statement advising that certified copies of the proposed code are available for public review. Generally, this process obviates the need for an agency’s authority to be revisited by a legislative body when the Food Code is revised.

⁶ This initiative produced interagency collaboration on food safety among the Department of Health and Human Services, the Department of Agriculture, and the Environmental Protection Agency, culminating in the report entitled “Food Safety From Farm to Table: A National Food Safety Initiative.”

The Standards represent the basic components of a retail inspection program: regulatory foundation, a trained regulatory staff, an inspection program based on hazard analysis at critical control points principles (known as HACCP), a uniform inspection program, foodborne illness investigation and response, compliance and enforcement measures, industry and community relations (previously called industry recognition), program support and resources, and program assessment. The FDA's Retail Food and Interstate Travel Team, along with other Center for Food Safety and Applied Nutrition staff and the Regional Food Specialists, provide Food Code interpretations for a uniform and reasonable application of these Standards. The Standards were developed to meet the following objectives:

- < Promote uniformity within, and provide a foundation for, the implementation of regulatory retail food programs, focused on the reduction of risk factors known to cause foodborne illness, and the Food Code's key interventions.
- < Promote, through management of a regulatory retail food program, industry's active managerial control of foodborne illness risk factors within retail food establishments.
- < Serve as a benchmark in the design and management of retail food programs.
- < Provide a means of recognition for regulatory retail food programs that meet these Standards.⁷

Early tests of the Standards have encouraged extensive expansion by FDA. Seven State and local regulatory programs participated in an FDA-sponsored pilot test designed to have the programs evaluate their ability to meet the Standards, the usefulness of the Standards in the self-assessment process, and the usefulness of the forms included in the Standards and provided as tools to the pilot agencies. Based in part on the pilot agencies' positive responses to the Standards, FDA's plans include approximately 130 additional jurisdictions phasing in the use of the Standards in calendar year 2001. In the future, FDA envisions that the Standards will be part of the Food Code, incorporated as a separate annex.

Other Studies

The Office of Inspector General conducted two previous inspections on food safety. The first, "FDA Food Safety Inspection," (OEI-05-90-01070) examined FDA's domestic food safety inspections and raised concerns about FDA's oversight of low-risk food firms. The second, "FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability," (OEI-01-98-00400) assessed FDA's oversight of food firm inspections conducted by States through contracts and partnership agreements. This inspection found that FDA's oversight of these State food firm inspections is limited, particularly for partnership agreements, and that FDA faces a number of barriers that hinder its ability to oversee States' performances.

⁷ Conference for Food Protection Accreditation Study Committee, 2000 Conference Report.

The General Accounting Office has issued reports dealing with a variety of issues regarding food safety. The General Accounting Office examined food safety in schools and FDA expenditures for food safety inspections. Currently, the General Accounting Office is in the process of conducting a survey of all State agencies responsible for food safety activities, focusing on States' resources expended for activities related to food safety.

SCOPE AND METHODOLOGY

We interviewed State and local agency management and inspectors with retail food safety responsibilities, FDA Regional Food Specialists, FDA headquarters staff in the Regional Food and Interstate Travel Team, members of the Conference for Food Protection Executive Board, and consumer advocates to gain information about the systems and processes associated with the adoption and implementation of the Food Code and the Standards. We did not attempt to measure any State's effectiveness in using the Food Code or the Standards. We did not examine the Food Code or the Standards for adequacy as they relate to retail food safety.

Throughout the inspection process, we systematically gathered both quantitative and qualitative data from the different stakeholder groups to identify issues and learn their perceptions of the systems and processes associated with the tools FDA uses to assist State retail food inspection agencies. We conducted extensive pre-inspection work to gain background knowledge and learn about pertinent issues in retail food safety.

During pre-inspection, we met with officials at FDA headquarters. We also attended FDA regional-sponsored retail food safety seminars as well as a meeting of the National Retail Food Team. We met with Office of Inspector General legal staff to discuss FDA relations with the retail food industry. We conducted on-site visits of three local and one State food safety inspection agencies. We met with four food safety experts at Kansas State University, and two team members attended a food safety course sponsored by the National Restaurant Association. We also interviewed representatives from seven industry and association groups, two consumer advocacy organizations involved with retail food safety issues, and the Joint Commission on Accreditation of Health Organizations, which inspects some institutional food services as part of its accreditation process.

We used four methods for collecting data in this evaluation. First, we conducted an electronic survey of all 66 State agencies with retail food safety responsibilities. The survey contained both open and closed ended questions about adopting the 1999 Food Code changes, overcoming barriers to Food Code adoption and/or implementation, and FDA's role in the process of adopting and implementing the Food Code. We asked similar questions regarding accepting and implementing the Standards. We also asked about improvements that need to be made to these processes with specific

emphasis on FDA's role in assisting State and local agencies to adopt and implement the Food Code and the Standards. Sixty-one State agencies completed these surveys, for a 92 percent response rate.

Second, we conducted on-site interviews with State and local retail food inspection agencies and consumer advocates involved with retail food safety issues. With all of our on-site and telephone interviews, we used a structured discussion guide to elicit information about FDA's role in the Food Code adoption process, and their views of the process of implementing the Food Code and the Standards. We also gathered information about improvements that they believe need to be made to the process and system in which they operate. We visited State and local agencies in 10 States and spoke with three consumer advocates.

State retail food inspection agency officials included program directors, program managers, and inspectors from a purposive sample in Arizona, California, Georgia, Michigan, Minnesota, Rhode Island, South Carolina, Texas, Vermont, and Wyoming. We selected these States following discussions with FDA staff and other experts and based on criteria such as geographic variability, size, differing levels of State and local involvement in retail food inspections, and status of Food Code adoption.

We conducted the site visits with these States during February and March 2001 to collect more in-depth information about the Food Code, the Standards, and the role of FDA. When applicable, we also met with local retail food safety agencies and consumer advocates to get their perceptions of the Food Code, the Standards, and FDA's role in the process of adopting and implementing the Food Code. Overall, we met with 13 State retail food inspection agencies, 11 State inspectors, 16 local retail food inspection agencies, and 11 local inspectors.

Third, we interviewed all 21 FDA Regional Food Specialists as well as all 6 members of the Retail Food and Interstate Travel Team. We conducted the interviews either in person or by telephone.

Finally, we conducted structured personal or telephone interviews with 18 of the 22 members of the Executive Board for the Conference for Food Protection for years 2000 - 2002. The Executive Board members represent the perspectives of Federal agencies, State and local regulatory bodies, industry, academia, and consumers. We spoke to three other Executive Board members during our pre-inspection or on-site activities. One member did not respond to our requests to speak on these issues.

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

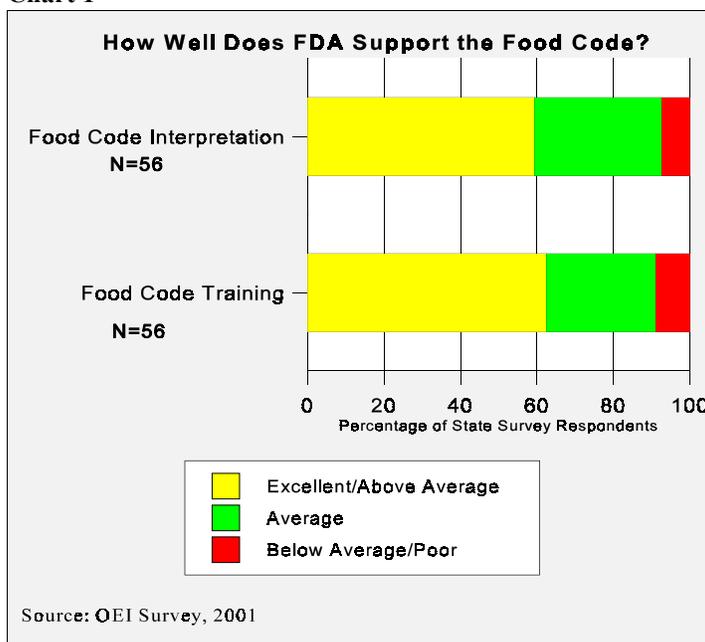
OVERALL - Respondents rate FDA highly in their promotion and support of the Food Code and the voluntary Recommended National Retail Food Regulatory Program Standards

Supporting the Food Code

Overwhelmingly, respondents agreed that FDA has demonstrated its support for the Food Code. Eighty-five of 86 respondents said that FDA encourages adoption of the Food Code and described a variety of ways FDA supports this activity. Respondents cited FDA's training and their efforts to "standardize" inspectors⁸ as well as the willingness and availability of FDA's Regional Food Specialists and headquarters staff to assist them throughout the phases of Food Code adoption and implementation. This assistance included FDA staff serving on State and local task forces, testifying at hearings and speaking at grass roots meetings, and interpreting Food Code provisions. Overall, 60 percent of the respondents characterized FDA's Food Code support as effective.

In our survey of State retail food agencies, we asked them to rate FDA's training on the Food Code and their interpreting of the Food Code. Of the 56 State agencies responding to these survey questions, 62 percent rated FDA's training as either excellent or above average, and 57 percent similarly rated their Food Code interpretation assistance. Chart 1 shows these satisfaction levels.

Chart 1



⁸ Standardization is a term FDA uses to describe the approach of training State inspectors in FDA methods. FDA standardizes State retail food inspectors by providing intensive, one-on-one training during the inspection process. Standardized inspectors learn how to inspect in accordance with the latest Food Code. They are then expected to standardize other State and local inspectors, who likewise should standardize other inspectors.

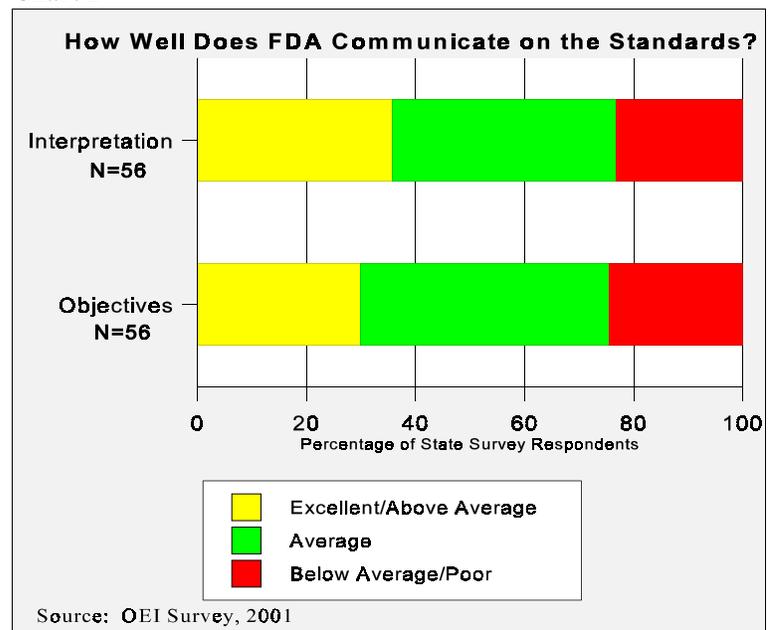
Promoting the voluntary Recommended National Retail Food Regulatory Program Standards

States surveyed indicated widespread knowledge and acceptance of the Standards.⁹ Ninety percent of the State survey respondents said they were familiar with the Standards. When we shared copies of the Standards with respondents, 96 percent believed that FDA had identified the appropriate Standards necessary for an effective retail food safety inspection agency, and 93 percent believed that the Standards were important to an agency's effectiveness in combating foodborne illnesses.

Our on-site visits at State and local retail food inspection agencies showed some differences when compared to the State survey results. During these visits, we found that while knowledge of the Standards at the State management level was high, knowledge of the Standards dropped for State inspectors. Knowledge of the Standards at the local level was lower than knowledge at the State level. Six of the 16 local agencies¹⁰ and 15 of 22 inspectors (representing both State and local agencies) visited on-site were unfamiliar with the Standards.

The relative newness of the Standards may explain why State survey respondents believe that FDA's communication of the objectives and interpretations of the Standards has been average at best. Eighty-one percent of State agencies responding to the survey said that FDA promotes the Standards, but most respondents could not comment on the effectiveness of these efforts yet. Even though FDA explained the objectives at numerous forums, on its website, and during field sanitarian courses, Chart 2 shows that most States do not believe that FDA has communicated the objectives or provided Standards interpretations at an above average level. More than half of FDA Regional

Chart 2



⁹ At the time of our data collection, Standard 7 was called Industry Recognition. Therefore, the questions on our survey and questions asked during our on-site visits refer to this standard prior to the recent change.

¹⁰ Three local agencies we visited in Texas participated in the pilot project. Those pilot agencies are very familiar with the Standards.

Food Specialists believed it is too soon to judge FDA’s performance on interpreting the Standards.

Written and web-based support for the Food Code and voluntary Recommended National Retail Food Regulatory Program Standards

Most respondents believed that FDA provided excellent or above average written materials and Internet information for the Food Code and Standards. During our on-site visits and phone interviews, we specifically asked respondents to rate FDA’s written materials and websites as they relate to supporting the Food Code and Standards. These interviews included State and local retail food inspection agency heads, Executive Board members of the Conference for Food Protection, consumer advocates, FDA’s regional Food Specialists and FDA’s Retail Food and Interstate Travel Team.

Chart 3 shows that State and local retail food inspection agencies and Conference for Food Protection Executive Board members overwhelmingly believe that FDA’s written materials provide support for the Food Code and the Standards. However, 6 of the 16 local agencies are unaware of any FDA written materials for these initiatives.

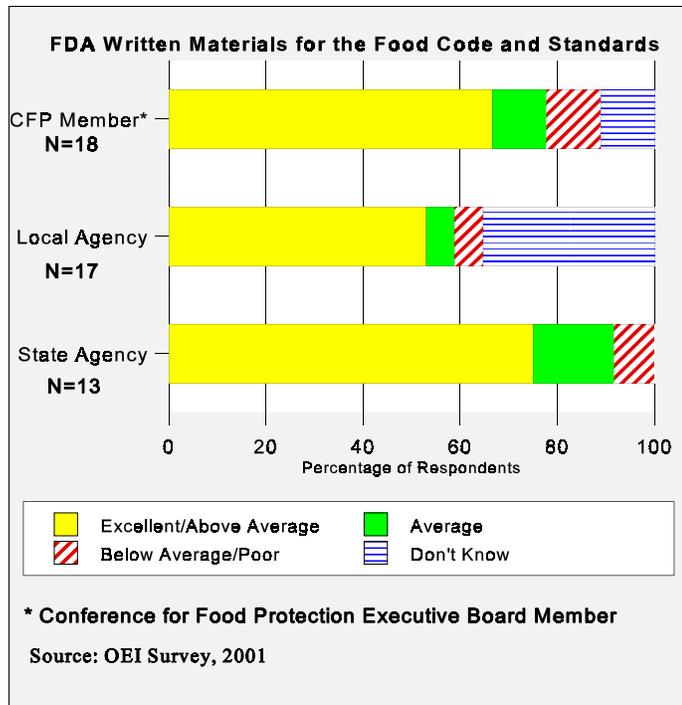
In addition, sixteen FDA respondents rated their written support as excellent or above average, four respondents rated it as average, and two as poor. Two FDA respondents said they did not know enough to give a rating,

two did not comment, and one did not give a rating but was favorable about the written support that FDA provides for both the Food Code and the Standards. Two consumer advocates called the written support above average, while one was not aware of any FDA written support for the Food Code or the Standards.

Similarly, respondents rated FDA’s website highly for providing them support for the Food Code and the Standards. Again, six of the local agencies are unaware of any FDA website information relating to these topics.

In addition to these respondents, thirteen FDA staff described their website as either excellent or above average, three called it average, and four described it as below average

Chart 3



or poor. The responses of the remaining seven FDA members could not be classified into the aforementioned ranking categories. One consumer advocate rated it above average, and one was not aware of the website.

FOOD CODE - States face multiple barriers in adopting and implementing the Food Code

Frequency of Food Code revisions a major barrier to State adoption

Seventy-two percent of States surveyed reported that frequent revisions to the Food Code act as a drawback to adopting the most recent Food Code. Similarly, during our on-site visits, many respondents told us they believed the Food Code is updated too frequently.

Sixteen of 34 States that did not update their codes to include the 1999 Food Code changes indicated that the length of time and the difficulty of the adoption process inhibits them from updating their code every 2 years. Some of these States had just finished adopting an earlier version of the Food Code and are working on implementation issues, so they did not consider adopting the 1999 Food Code. Many States report that they do not have the time and resources to update their retail food safety regulations every time the Food Code changes, especially when the new version may contain only minor changes from an earlier version of the code.

Retail Food and Interstate Travel Team staff are evenly divided on the issue of Food Code frequency. Similarly, the Conference for Food Protection Executive Board members split between thinking that the Food Code revision cycle was satisfactory or too frequent. Local retail food inspection agencies frequently take guidance from their States on Food Code adoption and are not typically involved in the Food Code revision and adoption processes.

Additional barriers to adopting and implementing the Food Code

Besides the frequency of Food Code revisions, respondents also indicate other drawbacks including the feasibility of some of the provisions, the cost and time involved in adopting or implementing an updated version of the Food Code, and the need to rely on FDA to interpret Food Code provisions and provide other support.

Fifty-four percent of State survey respondents specified that a major drawback to adopting the Food Code concerns the feasibility of some Food Code provisions. They also highlighted the political climate in the State, the reluctance to change their current retail food safety activities, and concerns about losing State control to the Federal Government as being additional barriers to Food Code adoption and implementation. In some cases, industry opposition to certain Food Code provisions inhibits changing State retail food laws.

All respondent groups identified the cost and time involved in adopting and implementing the Food Code as barriers. They explained that the adoption and implementation process was resource intensive, particularly in terms of the legislative change and associated training costs necessary to learn a new code and the corresponding inspection process.

Dependency on FDA for support, and States already having more stringent laws than the Food Code, represent other drawbacks States face when deciding to adopt and later implement the Food Code. Twenty-six percent of State survey respondents reported the need to rely on FDA for interpreting Food Code provisions and providing other implementation support as an impediment to their adopting a version of the Food Code. Based on the State responses to the survey question, we are unsure whether States are concerned that FDA does not have adequate resources to respond to requests for support or that States do not want to rely on FDA and want to be more independent.

The FDA's role in helping States overcome Food Code barriers

Seventy percent of the State survey respondents and 85 percent of the on-site respondents report that they believe FDA can play a role in helping retail food inspection agencies overcome the barriers faced in adopting and implementing the Food Code. They suggest that FDA could help States adopt the Food Code by reducing the frequency of updates to the Food Code, by making the Food Code a regulation rather than a recommendation, and improving the format of the Food Code. All respondent groups mentioned the published format of the Food Code as not being user-friendly for either inspectors or retail food operators.

In terms of how FDA can better help States implement the Food Code, the respondents suggest that FDA could devote more resources (both at the headquarters and regional level) to retail food safety and implementation issues, and expand the technical assistance and support FDA currently provides to the States. Specific suggestions relating to improved technical assistance include expanded training, additional educational and guidance materials, more timely Food Code interpretations, and marketing the importance of the Food Code.

STANDARDS - The FDA staff and State and local agency opinions differ on the most difficult standards to accept and implement, which may affect the way the Standards are implemented

Although the Standards are in draft form and have not been accepted and implemented by most retail food agencies, we asked respondents which standards they believe would be the most difficult to accept and implement. Many FDA staff said that the difficulty of implementing the Standards would vary across States, i.e. the most difficult standard for

one State could be the easiest for another. The two standards most frequently mentioned for each respondent group are displayed in Chart 4.

Chart 4

Respondent Group	Standards Most Difficult to Accept and Implement
State Agency Survey	<ul style="list-style-type: none"> • Program Assessment • Program Resources
State and Local Agencies (on-site visit respondents)	<ul style="list-style-type: none"> • Trained Regulatory Staff • Inspection Program Based on HACCP Principles
State and Local Retail Food Inspectors (on-site visit respondents)	<ul style="list-style-type: none"> • Uniform Inspection Program • Compliance and Enforcement
FDA Staff (headquarters and regional)	<ul style="list-style-type: none"> • Uniform Inspection Program • Compliance and Enforcement

Source: OEI Data, 2001

The first two respondent groups shown above in Chart 4 (State agency survey respondents and the on-site respondents from the State and local agencies) differ in terms of which Standards they believed would be most difficult to accept and implement. This difference can be attributed to the fact that we conducted on-site visits with only 10 of the 61 agencies who responded to the survey and the people that we met with on-site may not have been the person to complete the survey. In addition, the responses from our on-site visits include input from local agencies as well as from the State agencies.

In our survey, we asked State agency respondents to indicate whether certain factors represent barriers to implementing any of the Standards. Respondents who identified each factor as a barrier were then asked which standard would be the most difficult to implement because of the barrier. Chart 5 on the following page shows their responses. We list two standards if they were mentioned the same number of times.

Chart 5

Percent of State agency respondents who consider this factor a barrier	Standard most often cited by respondents as most difficult to implement because of barrier
Lack of resources (69%)	<ul style="list-style-type: none">• Trained Regulatory Staff
Feasibility (41%)	<ul style="list-style-type: none">• Trained Regulatory Staff• Inspection Program Based on HACCP Principles
Lack of industry support (34%)	<ul style="list-style-type: none">• Inspection Program Based on HACCP Principles
Lack of consistency with current State or local laws or regulations (31%)	<ul style="list-style-type: none">• Uniform Inspection Program• Compliance and Enforcement
Need to rely on FDA for interpreting (10%)	<ul style="list-style-type: none">• Uniform Inspection Program• Compliance and Enforcement

Source: OEI Survey, 2001

The FDA staff identified barriers similar to those cited by State retail food inspection agencies, including lack of resources (time, staffing, and money), training needs, and legislative challenges.

OPPORTUNITIES FOR FACILITATING IMPLEMENTATION

The retail food industry, State and local agencies, and Federal respondents, all embrace the Food Code and the Standards as blueprints for developing retail food inspection practices and organizations for the future. However, respondents at every level expressed concern about implementation issues, particularly in regards to a lack of resources necessary to carry out many aspects of the Standards.

We recognize that these resources may be hard to come by, but over time, real progress can be made to implement these measures. Because resources are limited at all levels, collaboration among FDA, State and local agencies, and the retail food industry is essential. What FDA needs now is to develop strategic plans to map out future actions, both internally as well as for the States, and we offer numerous suggestions that we hope will be helpful in developing such strategic plans. The following suggestions for FDA's consideration primarily focus on the Standards because of their relative newness as compared to the Food Code. However, we recognize that the adoption and implementation of the Food Code can be an integral part of each standard and should be considered when appropriate. We leave it to FDA to work with State and local agencies to determine how best to prioritize these actions.

Develop a strategic plan outlining current and anticipated acceptance of the Standards by State and local agencies and detailing how FDA will respond to the needs of these agencies

The strategic plan could focus on both short and long-term activities related to each of the nine standards. The widespread acceptance of the Standards by State and local retail food inspection agencies, as evidenced by their volunteering in unexpectedly high numbers to pilot the Standards, points toward the necessity of FDA devoting significant support and resources to these agencies to help them achieve some or all of the Standards. The FDA could make State and local retail food inspection agencies aware of FDA's commitment to the Standards by publishing the strategic plan. The strategic plan could specify needs, targets, and FDA commitment for each standard. The strategic plan may also help FDA improve their marketing strategies to highlight the importance of participation from all States and local jurisdictions for achieving national uniformity and reducing the incidence of foodborne illness through the use of the Food Code and the Standards.

We recognize that many standards intertwine. For example, an agency cannot have an effective compliance and enforcement program without a regulatory foundation or a trained regulatory staff. We also recognize that it is not realistic to expect that every agency can or will meet each of the Standards. We understand that implementing the

Standards will require considerable effort and support from both FDA and retail food inspection agencies. Based on these understandings and on advice from our respondents, we suggest that FDA consider the following proposals in developing their strategic plan.

Standard 1 - Regulatory Foundation

- < **Improving Adoption of the Food Code** - The FDA could re-evaluate the frequency of revising the Food Code. Publishing Food Code updates less frequently than every 2 years would remove the major barrier States currently face in adopting recent versions of the Food Code. The FDA could also consider making the Food Code a requirement rather than a regulation by publishing the model Food Code in the Federal Register. This would facilitate adoption for States that have the ability to adopt Federal regulations by reference and would help alleviate the problem of trying to keep State regulations consistent with the latest version of the Food Code. Codifying the Food Code would ultimately help achieve national uniformity.

- < **User Guide to Food Code** - The FDA could issue a user guide concurrent with the issuance of a new Food Code. The user guide would make the Food Code more practical for inspectors and retail food operators to use on a daily basis. All respondent groups mentioned the published format of the Food Code as not being user-friendly for either inspectors or retail food operators. Presently, the Food Code is written to be a regulation. Possibilities for the user guide include an abbreviated version of the Food Code which contains the critical items of the Code and consolidates all the provisions relating to one topic together in one section. The user guide should be smaller than the Food Code to facilitate its use in the field. The State of Texas publishes a Field Inspection Manual to promote uniformity in the application of their Food Establishment Rules. The manual outlines critical items and relates these items to the State inspection form. Also, the Association of Food and Drug Officials has published a Food Code Pocket Guide for Regulators that corresponds with the 1999 Food Code and includes critical items such as definitions, handwashing requirements, temperature requirements, Reduced Oxygen Packaging, and warewashing requirements. These could serve as examples for FDA. Other States may also have similar tools to assist the development of the user guide. Since retail inspection agencies frequently find non-English speaking operators and employees at retail food establishments, FDA could also make a Food Code user guide available in different languages for retail food operators.

- < **Interpretations of Food Code and Standards** - The FDA could devise a systematic way to share Food Code and Standards interpretations to help ensure consistent interpretation and enforcement. Presently, FDA responds to individual questions posed by a retail food inspection agency, usually through the Regional Food Specialist. Other Regional Food Specialists and agencies are not routinely advised of either the questions or the answers. So, when the same issues arise elsewhere, the process of trying to resolve similar questions must be repeated.

Standard 2 - Trained Regulatory Staff

- < **Need for Standardization Staff** - The FDA could determine what additional staff both in the field and in the Retail Food and Interstate Travel Team it will need to perform standardizations of retail food safety inspectors. It is reasonable to assume that demands for standardization will increase as a result of the Standards, especially with local retail food safety inspection agencies participating. The FDA could poll the volunteering agencies in the second pilot test of the Standards to get an estimate of what standardization needs those agencies will now have. The demand for FDA's standardization of retail food safety inspectors could increase exponentially with both State and local agencies using the Standards.
- < **Web-based Training** - Because inspection agencies have limited training and travel budgets, FDA could widely publicize the availability of web-based training. State and local retail food inspection agencies look forward to FDA's planned web-based training. (In fact, many respondents requested more FDA training in any form.) Web-based training will allow most inspection agencies to benefit from this valued resource.
- < **State and Local Training** - The FDA could develop more flexibility in responding to State and local training needs. State and local agencies could make their training needs known electronically, as they determine them, rather than making an annual request through the Regional Food Specialist. This process would allow local agencies more input into the training calendar.
- < **Recruitment Clearinghouse** - The FDA could develop and maintain a national clearinghouse of retail food inspection vacancies. An ongoing problem retail food inspection agencies face is staff recruitment. College students or graduates in the field could post their resumes and have a central job bank to locate positions. State and local retail food inspection agencies could post their vacant positions. The clearinghouse could be developed to be dynamic, i.e., to allow agencies and applicants to link directly to each other, or to have the resumes and vacancies time-limited, so the bank of available jobs and applicants is current.
- < **Turnover Exception** - The FDA could develop an exception for the staffing standard for agencies with well-trained staff who suddenly confront a turnover problem. With high staff turnover, some retail food safety inspection agencies cannot meet, or continually meet, this standard if it is strictly interpreted.

Standard 3 - Inspection Program Based on HACCP Principles

- < **Software Inspection Tools** - The FDA forms could be available to retail food inspection agencies in a software program compatible with hand-held computers, as FDA is doing with their uniform inspection software. The FDA developed a form for a Risk Control Plan for these retail HACCP reviews and has an inspection form for standardization purposes. Although some retail food inspection agencies

believe they perform retail HACCP inspections, the standard requires documentation in a manner consistent with HACCP principles.

Standard 4 - Uniform Inspection Program

- < **Model Inspection Forms** - Recognizing that States and local jurisdictions may have to make revisions to meet their laws, FDA could develop a model inspection form containing a common list of elements required by this standard. Jurisdictions could configure the FDA-developed software to meet local requirements.

Standard 5 - Foodborne Illness Investigation & Response

- < **Training Outreach** - The FDA could reach out to medical schools to offer training on foodborne illnesses and the appropriate responses as they have done in partnership with the American Medical Association. Several respondents pointed out that the medical community is not always trained to identify and report foodborne illnesses. The FDA could also make this training available to physicians via the Internet.
- < **Model Linkages** - The FDA could develop a model flow for foodborne illness investigation and response, clarifying what different agencies could do in certain situations. Communication links between agencies are sometimes difficult, with the State retail food inspection agency sometimes not being aware or involved until late in the process.
- < **Improved Surveillance System** - The FDA could continue to work with the Centers for Disease Control and Prevention and others to improve the surveillance of foodborne diseases. The FDA could help to raise States' awareness about FoodNet so they can access the information and use FoodNet's active surveillance system as a model in developing or improving States' foodborne illness investigation and response systems. The FDA could also promote State's awareness about and involvement in the PulseNet program. Expanded State participation in PulseNet would improve the ability to stop ongoing foodborne illness outbreaks.

Standard 6 - Compliance and Enforcement

- < **Model Programs** - Following up on Food Code violations has typically been a weak point with many agencies. The FDA could develop model programs and/or highlight "best practices" of programs similar to their own to emulate in order to help retail food inspection agencies attain this standard. These examples are very important to localities where the program leadership and/or the political climate has not been conducive for an effective compliance and enforcement program.

Standard 7 - Industry and Community Relations (Previously called Industry Recognition)

- < **Best Practices** - The FDA could evaluate and disseminate a variety of “best practice” approaches to recognizing retail food service operators. This is important because many retail food inspection agencies view themselves as enforcement agencies. For them, the notion of commending a retail food operator runs counter to that impulse.
- < **State and Local Recognition** - The FDA could also prominently recognize State and local agencies that do an exemplary job meeting some or all of the Standards.

Standard 8 - Program Support and Resources

- < **Testimony** - As FDA has done with Food Code adoption, it could assist State and local retail food safety inspection agencies by providing testimony in support of the Standards, especially relating to appropriate staff-to-facility ratios and the minimum frequencies of inspections.
- < **Practical Advice to Agencies** - The FDA could develop written materials on the Standards that explain the practical implications of the Standards to program administrators. The FDA could explain the anticipated resources and documentation necessary for each of the Standards so agencies and their employees could better understand how they will be affected.
- < **Innovative Grants** - The FDA could continue its innovative food safety grants to retail food inspection agencies who develop new ways to attack problems relating to foodborne illnesses in the retail setting and explore new funding mechanisms available for State and local agencies.
- < **Minimum Equipment Needs** - The FDA could define minimum program equipment necessary for retail food inspections as well as for compiling the data necessary to meet and carry out the Standards. The FDA should also work with agencies to help them get these necessary tools. The FDA currently lends substantial assistance to agencies in terms of training and interpretation of the Food Code and Standards. And some Regional Food Specialists have found creative ways to fund small, but important, purchases for retail food inspection agencies when no alternative local funding was possible. But many of the more than 3,000 retail food inspection agencies are very small - sometimes one person for a county - and have little equipment. For those inspectors without computers, on-line access to training is impractical and they may not have the inspection equipment to adequately perform this basic function.

Standard 9 - Program Assessment

- < **Assessment Training** - The FDA could provide training to FDA staff in order for them to assist State and local agencies with their program assessments. Program

assessment has not been featured prominently in retail food inspection agency activity in the past. Many agencies will be looking to FDA for assistance, at least initially.

- < **Audit Process** - The FDA needs to develop its own audit process to determine whether Standards are met.
- < **Certified Evaluation Officers** - The FDA needs to develop a procedure for certifying Evaluation Officers, and a plan for ensuring that an adequate number of Certified Evaluation Officers are present in the State and local jurisdictions. This standard requires that an FDA-Certified Evaluation Officer conduct an outside program validation by using FDA validation procedures every 3 years.

Develop a model strategic plan for the States to use as they consider acceptance and begin implementation of the Standards

While the above strategic plan details activities for FDA to consider as they begin to roll out the Standards on a national basis, it is also important that FDA provide States with a model strategic plan outlining what the States should consider in regard to accepting and implementing the Standards. Such a document would assist the States as they make decisions regarding the allocation of resources and determining future actions at the State level in regard to retail food safety. The FDA can use some of the suggestions we made above for their own strategic plan as well as incorporate new information as they see fit into the model State plan.

AGENCY COMMENTS

The Food and Drug Administration agrees with the recommendations in this report and will develop strategic plans and continue to work with other groups, States and localities regarding innovative ways to facilitate food safety through adoption and implementation of the Code and the Standards.

We would like to thank FDA for their assistance in conducting this study, especially for the availability of their staff at all levels to discuss their experiences and provide meaningful and insightful comments.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Memorandum

Date: AUG 23 2001

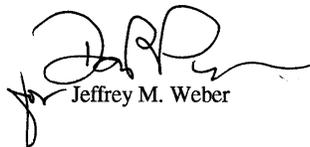
From: Acting Senior Associate Commissioner for
Management and Systems, FDA

Subject: Agency's Comments: Office of Inspector General's
Draft Report, "Retail Food Safety," OEI-05-00-00540

To: Janet Rehnquist
Inspector General

Thank you for the opportunity to review and comment on the Office of Inspector General's draft report, "Retail Food Safety," OEI-05-00-00540. The Agency prepared general and technical comments for your consideration.

If you need additional information, please contact Loretta W. Davis, (301) 827-4809.



Jeffrey M. Weber

Attachment

cc: Elise Stein

Agency Comments

FDA's Comments on the Office of Inspector General's (OIG) Draft Report Regarding the FDA's Retail Food Safety Program

FDA welcomes the OIG's draft report "Retail Food Safety" as a fair assessment of the challenges FDA faces in assisting jurisdictions in their regulation of food establishments at the retail level. Because resources are limited at all levels, collaboration is essential among FDA, State and local agencies, and the retail food industry.

As of May 16, 2001, 30 states have "adopted" the Food Code (Code) and 15 states are working on adopting the Code. We will continue to work with the states in achieving Code adoption. In addition, FDA has funded a contract with the Association of Food and Drug Officials (AFDO) to assess whether the substance of each "adoption" equals FDA's model Code expectations.

FDA agrees with the recommendations in this report. Some of the recommendations can be implemented with current resources, but others will be implemented as resources become available.

FDA will review the frequency of issuance of and codification of the Code to facilitate adoption by the States. We will also expand outreach to ethnic communities as resources become available.

Some of the recommendations are being addressed by the many organizations with which we leverage, e.g., the Conference for Food Protection (CFP), AFDO, National Environmental Health Association (NEHA), and National Association of County and City Health Officials (NACCHO). The Center for Disease Control and Prevention (CDC) and FDA have also partnered in several projects, including the Environmental Health Sanitarians (EHS)-Net program in which experienced EHS are trained and assigned to certain agencies. Their task is to assist the agencies in expanding outbreak investigations to identify precursors to the occurrence of foodborne illness risk factors and to assist in promoting the integration of the Standards in jurisdictions' regulatory schemes. FDA will continue partnering with these and other groups regarding additional and innovative ways to facilitate food safety through adoption and implementation of the Code and the **FDA's Recommended National Retail Food Regulatory Program Standards** (Standards).

Agency Comments

FDA's Response to OIG Recommendations

OIG Recommendation: Develop strategic plans.

FDA Comment: FDA agrees. The current Retail Food Steering Committee's Operational Plan includes a specific plan for fiscal years 2002 and 2003 to promote implementation of the Standards, including enrollment of a certain number of states and localities in the Standards each year, conducting regional workshops on the Standards, and other targeted efforts. We will work towards developing an expanded strategic plan. We will also develop a model strategic plan for states.

Standard 1 – Regulatory Foundation:

OIG Recommendation: Improve Adoption of the Food Code

FDA Comment: FDA acknowledges the difficulties states have had keeping pace with the two-year revision cycle. Under the rubric of the CFP, FDA is working with an ad-hoc committee to review this cycle. The ad-hoc committee is expected to report back to the CFP in April 2002.

OIG Recommendation: Codify the Code:

FDA Comment: FDA agrees in part with this recommendation. FDA is actively engaged in codifying the Code for its Interstate Travel Program (ITP) by revising 21 CFR 1240 and 1250 and inserting the Code, as it relates to interstate travel conveyances in 21 CFR 1260. FDA anticipates completing this in 2002. The FDA is also working on codifying certain model Code provisions that relate to egg safety. FDA will subsequently review the feasibility of codifying the rest of the Code.

OIG Recommendation: Issue a User Guide to the Code

FDA Comment: FDA agrees with the need to provide a “plain-speaking” guide to the Code. FDA will review the options to address this, including AFDO's Pocket Guide for Regulators or one-page compilations of key reference information for food and equipment (e.g., cooking times and temperatures, sanitizer concentrations, and lighting requirements).

OIG Recommendation: Interpretations of Code and Standards

FDA Comment: FDA agrees and is looking into posting to a web site the responses to frequently asked questions, as well as responses to less frequent inquiries.

Agency Comments

Standard 2 – Trained Regulatory Staff:

*OIG Recommendation: Need for Standardization Staff*

FDA Comment: FDA agrees and will assess the need for additional staff to provide adequate standardization opportunities sought by the regulatory agencies.

*OIG Recommendation: Web-based Training*

FDA Comment: FDA agrees with this recommendation. Web-based training is essential to leverage scarce resources and, therefore, it represents an integral part of the Agency's retail food safety game plan. FDA has initiated "Office of Regulatory Affairs University" (ORA U) which will combine face-to-face, web-based and satellite training. ORA U is being rolled out in the summer of 2001, with California, Colorado, and Texas serving as pilot participant states. The retail curriculum is consistent with Standard 2 of the Program Standards. The curriculum is being developed jointly with AFDO and is also being coordinated with a "certification" initiative by the CFP. The following web based courses are presently under development. These courses are expected to be available by spring of 2002:

- È Public Health Principles
- È Basic Food Law
- È Food Microbiology/Chemistry
- È Basics of Hazard Analysis and Critical Control Point (HACCP)
- È Investigating Foodborne Illness
- È Communications
- È Basics of Sanitation
- È Basics of Inspection

These web-based courses are being developed through a Cooperative Research and Development Agreement (CRADA) with EduNeering, a learning technology firm from Princeton, New Jersey. Through the CRADA, EduNeering will offer the same web based courses to the regulated industry.

The other component of the curriculum is face-to-face courses. In conjunction with AFDO, FDA is developing a "Basics" course to train new inspectors, as well as a higher level "retail applications" course for more experienced inspectors. Each "course-in-a-box" will include lesson plans, audiovisual materials, exercises, and exams. The FDA, AFDO, other associations, or the sponsoring agency will deliver the face-to-face courses. Such courses will be promoting a national uniform teaching vehicle, while

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simultaneously providing the opportunity for state/local agencies to include unique requirements/procedures of the state/local municipality in the course. These courses will be implemented according to available resources.

OIG Recommendation: State and Local Training

FDA Comment: FDA agrees with this recommendation and will address it through ORA U.

OIG Recommendation: Recruitment Clearinghouse

FDA Comment: FDA agrees that a national clearinghouse for retail food inspection vacancies is desirable. FDA will explore options for this.

OIG Recommendation: Turnover Exception

FDA Comment: The Standards are intended as a benchmark infrastructure and operating framework for the norm. If needed, the mechanics for addressing temporary deviations in the listing program can be discussed as part of the CFP process.

Standard 3 – Inspection Program Based on HACCP Principles:

OIG Recommendation: Software Inspection Tools

FDA Comment: FDA has been exploring new hand-held computers with the memory capacity to store the entire Electronic Inspection System (EIS). FDA plans to develop an enhanced version of this system and will explore with the developer the possibility of including forms such as the Risk Control Plan and the Inspection Report Form that is used for standardization.

OIG Recommendation: Model Inspection Forms

FDA Comment: FDA agrees and is currently working with a CFP Committee to develop “essential elements” of an inspection form.

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Standard 5 – Foodborne Illness Investigation & Response:

OIG Recommendation: Training Outreach

FDA Comment: FDA agrees and, in collaboration with the American Medical Association, the CDC, and the United States Department of Agriculture (USDA), has developed an educational tool on foodborne illness for physicians, “DIAGNOSIS AND MANAGEMENT OF FOODBORNE ILLNESS: A PRIMER FOR PHYSICIANS”, January 2001. It provides physicians with current guidelines for the diagnosis, treatment, reporting, and prevention of foodborne illness and with information for their patients on the prevention of foodborne illness.

OIG Recommendation: Model Linkages (*Flowchart foodborne illness investigation and response, clarifying what different agencies could do in certain situations.*)

FDA Comment: FDA agrees and its efforts to improve coordination and communication among public health and food regulatory officials, particularly related to foodborne illness outbreaks, include, but are not limited to the following:

1. In December 2000, FDA participated in the release of a multi-agency report entitled, **Outbreak Response and Coordination for Federal and State Agencies During Multi-State Foodborne Illness Outbreaks**. This report outlines the standard operating procedures for the rapid exchange and release of data and information during multi-state outbreaks of foodborne illness. It serves to guide federal agencies, state, or local health officials, and state food regulatory officials involved in food or waterborne outbreaks on procedures for coordinating responses during a multi-state outbreak of food or waterborne illness.
2. The National Food Safety System (NFSS) project, which includes FDA, USDA, CDC, and the Environmental Protection Agency, as well as states, contributes significantly to more effective implementation of existing food safety programs.
3. The Outbreak Coordination and Investigations Workgroup of the NFSS project issued a protocol on how to conduct multi-state outbreak investigations. This protocol, **Guidelines Manual for Coordinating Foodborne Outbreak and Traceback Investigations**, addresses greater clarity about the roles of various players in an outbreak situation.

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OIG Recommendation: Improved Surveillance System

FDA Comment: FDA has an ongoing working relationship with CDC in improving surveillance and shares resources for purposes of coordination, cross-training, and outbreak investigation. We will promote awareness amongst the states.

Standard 6 – Compliance and Enforcement:

OIG Recommendations: Model Programs and Best Practices

FDA Comment: FDA agrees. Identification of “best practices” for voluntary compliance, enforcement, and industry recognition would facilitate implementation of the Standards and enhance consumer protection. FDA will examine how best to collect and disseminate that information and will implement this as resources permit.

OIG Recommendation: State and Local Recognition

FDA Comment: FDA’s National Registry of Retail Food Protection Programs will identify states and localities that meet the requirements of the Program Standards.

Standard 8 – Programs and Resources:

OIG Recommendation: Testimony

FDA Comment: FDA has been vocally supportive of the Program Standards and State and local agencies routinely interact with FDA’s Regional Specialists who can provide targeted support.

OIG Recommendation: Practical Advice to Agencies

FDA Comment: FDA conducts outreach to spread the word about the Program Standards. At the NEHA meeting this summer, the Retail Food Steering Committee Chair provided an overview of the Standards. A video of that presentation was subsequently used at the National Association of Local Boards of Health (NALBOH) meeting. At last year's meeting of that group, the Retail Food and Interstate Travel Team Supervisor provided a face-to-face power point presentation and discussion about the Program Standards.

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OIG Recommendation: Innovative Grants

FDA Comment: FDA agrees and plans to continue food safety grants as resources permit. Current plans for FY' 02 include continuation of the Innovative Grants Program.

OIG Recommendation: Minimum Equipment Needs

FDA Comment: See the response to *Innovative Grants*.

OIG Recommendation: Assessment Training

FDA Comment: Training and assistance on the Program Standards are scheduled through workshops planned in FY' 01. Additional assistance will be provided through the Regional Food Specialists to the states and locals as resources permit.

OIG Recommendation: Audit Process

FDA Comment: FDA agrees and is premiering an audit course that will include auditing principles. A specific Program Standards Auditing Guide is scheduled for development in FY' 03. Since, after initial enrollment in the Standards, audits occur on 36-month cycles thereafter, completion of the Audit Guide in FY' 03 allows a period of time for evaluating its use and practical application.

OIG Recommendation: Certified Evaluation Officers

FDA Comment: FDA has anticipated that need and procedures for certifying Evaluation Officers are in the queue for drafting as resources become available.