United States Government Accountability Office

GAO

Report to Congressional Requesters

September 2008

# FOOD SAFETY

# Improvements Needed in FDA Oversight of Fresh Produce


GAO-08-1047

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## Improvements Needed in FDA Oversight of Fresh Produce

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Highlights

Highlights of GAO-08-1047, a report to congressional requesters

### Why GAO Did This Study

In recent years, both domestic and imported produce have been linked to reported outbreaks of foodborne illness. Contamination in produce is of particular concern because produce is often consumed raw. The Food and Drug Administration (FDA) has primary responsibility for ensuring the safety of both domestic and imported fresh produce. GAO was asked to examine (1) the resources FDA has spent on fresh produce safety and how it has allocated those resources, (2) the effectiveness of FDA's actions to oversee fresh produce safety, and (3) the extent to which FDA's planned actions to enhance fresh produce oversight address identified challenges. For this review, GAO analyzed FDA spending data and estimates and FDA activities data, reviewed FDA plans, and interviewed FDA officials and others.

### What GAO Recommends

GAO recommends, among other things, that the Commissioner of FDA update its guidance on good agricultural practices and its regulations on current good manufacturing practice for food, and seek explicit authority from the Congress to adopt preventive controls for high-risk foods and authority for enhanced access to records.

FDA agreed with most of GAO's recommendations but believed that it had sought authority from the Congress. FDA should continue to take steps to obtain these authorities so that it can conduct its oversight responsibilities.

To view the full product, including the scope and methodology, click on GAO-08-1047. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

### What GAO Found

While FDA has considered fresh produce safety a priority for many years, resource constraints and other work—including counterterrorism efforts and unplanned events such as foodborne illness outbreaks—have caused FDA to delay key produce safety activities. FDA has no formal program devoted exclusively to fresh produce and has not consistently and reliably tracked its fresh produce spending. Based on FDA estimates, FDA spent at least $20 million and 130 staff years on fresh produce in fiscal year 2007—or about 3 percent of its food safety dollars and 4 percent of its food safety staff years. In addition, FDA had few staff dedicated solely to fresh produce safety. Moreover, FDA acknowledged that it has not yet been able to conduct certain fresh produce work crucial to understanding the incidence of contamination of produce by pathogens such as *E. coli* O157:H7 or *Salmonella*, because it has lacked the resources to either fund its extramural research grant program or perform some critical research internally. Finally, FDA delayed issuing final fresh-cut produce guidance at least 6 years because it had to shift staff to counterterrorism and outbreak investigation work.

FDA has provided limited oversight of domestic and imported fresh produce. For example, while FDA has issued guidance for industry on recommended practices for reducing the risk of contamination during the processing of fresh-cut produce, it has not issued regulations requiring firms to take action to prevent contamination, even though some industry groups would like it to do so. FDA's intervention efforts have also been limited. Specifically, domestic fresh produce firms were inspected infrequently. Furthermore, FDA examined less than 1 percent of the 7.6 million fresh produce lines imported from fiscal years 2002 through 2007. Finally, FDA has improved some elements of its emergency response by, for example, partnering with California on outbreak investigations. However, it faces challenges in tracing an outbreak involving fresh produce back to its source because produce is highly perishable and may no longer be available for testing. Also, when product is available, it may be unlabeled or mixed in packages containing products from multiple sources.

FDA has proposed changes through its *Food Protection Plan* that could significantly enhance its fresh produce oversight. However, the agency is still in the planning stages for several enhancements and has not provided specific information on strategies and resources, making it difficult to assess the likelihood of success. To help prevent contamination, FDA plans to update its existing guidance on good agricultural practices and regulations on current good manufacturing practice for food, and has identified a need for explicit authority to issue preventive safety regulations for high-risk foods and enhanced access to records. To enhance intervention efforts, FDA plans to use more rigorous risk-based criteria to target domestic firm inspections and is testing a new import screening software tool. To improve response efforts, FDA is examining best practices for tracing contaminated foods to their source.

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## Figures

## Abbreviations

| | |
|---|---|
| CalFERT | California Food Emergency Response Team |
| CDC | Centers for Disease Control and Prevention |
| CFSAN | Center for Food Safety and Applied Nutrition |
| CVM | Center for Veterinary Medicine |
| FACTS | Field Accomplishment and Compliance Tracking System |
| FDA | Food and Drug Administration |
| NCTR | National Center for Toxicological Research |
| OASIS | Operational and Administrative System for Import Support |
| ORA | Office of Regulatory Affairs |
| PREDICT | Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting |
| USDA | U.S. Department of Agriculture |

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**United States Government Accountability Office**
**Washington, DC 20548**

September 26, 2008

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Barbara Boxer
United States Senate

In recent years, there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported produce. Most recently, an outbreak of *Salmonella* linked to fresh produce, which sickened at least 1,440 people in 43 states, the District of Columbia, and Canada, has become the largest foodborne illness outbreak reported in the last 10 years. According to the Centers for Disease Control and Prevention (CDC), fresh produce was linked to 7 percent of all outbreaks that had been traced to a specific food source and 14 percent of the associated illnesses from 1998 to 2004. In addition to harming human health, outbreaks of foodborne illness can undermine consumer confidence in the safety of the nation's food supply and have serious economic consequences. The 2006 outbreak of *E. coli* O157:H7 linked to bagged spinach, for example, resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry. The importance of this issue is growing because the consumption of fresh produce has increased as both health experts and the U.S. government have encouraged Americans to eat fruits and vegetables as part of a healthy diet. According to the U.S. Department of Agriculture (USDA), the average American annually consumed 13 pounds more fresh fruit and 50 pounds more fresh vegetables from 2003 through 2005 than from 1983 through 1985, an increase of about 14 percent and 41 percent, respectively. Also, more people have turned to the convenience of fresh-cut produce, such as bagged salads and cut fruit, and significant increases in imported produce have made a greater variety and volume of fresh produce available year round.

Produce is particularly vulnerable to contamination with pathogens (microorganisms that can cause disease) because it is grown in a natural environment. Moreover, it is often consumed raw, without cooking or other treatment that would reduce, control, or eliminate pathogens prior to consumption. Processing produce into fresh-cut products, the fastest

growing segment of the fresh produce market, may increase the risk of microbial contamination and growth by breaking the surface of the produce and allowing pathogens to enter the product. The contamination can then spread to other produce being processed at the same time. Fresh produce may also become contaminated after it is harvested and processed, such as during transportation, preparation, or storage.

The Food and Drug Administration (FDA) within the Department of Health and Human Services has primary responsibility for ensuring the safety of food for humans and animals. Specifically, FDA is responsible under the Federal Food, Drug, and Cosmetic Act for ensuring that domestic and imported human food (except meat, poultry, and processed egg products) and animal feed are safe, wholesome, and labeled properly. Under the Public Health Service Act, FDA has the authority to take measures to prevent the spread of disease. In addition, FDA may enter into arrangements with states to do inspections, share resources, or avoid duplication of efforts.

In January 2007, we added the federal oversight of food safety to our High-Risk Series, which is intended to raise the priority and visibility of government programs that are in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability.[1] In particular, we noted that federal spending for food safety oversight has not been commensurate with the volume of foods regulated by the agencies or consumed by the public. In November 2007, a report for FDA's science advisory board, *FDA Science and Mission at Risk*,[2] pointed out the erosion in FDA's science base. The report cited numerous management challenges that have contributed to FDA's inability to fulfill its mission that cannot be addressed with available resources, such as the lack of information sciences and infrastructure to support new science. That same month, a report by FDA, *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply*,[3] recognized the need for several changes to ensure the safety of the nation's food supply, such as shifting efforts toward prevention, and identified new authorities needed

[1]GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007).

[2]FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Washington, D.C., November 2007).

[3]Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply* (Washington, D.C., November 2007).

to implement the new strategy. We have testified that FDA's *Food Protection Plan*—which presents a three-part framework of prevention, intervention, and response—proposes some positive first steps toward enhancing FDA's oversight of food safety. We also pointed out, however, that more information about strategies and the resources FDA needs to implement the plan would facilitate congressional oversight.[4] In particular, we noted that FDA's overall resource needs and timelines for fully implementing the plan are unclear. In June 2008, we testified that FDA had implemented few of our past recommendations to improve food safety oversight. Specifically, we had made a total of 34 food safety-related recommendations to FDA since 2004, and as of May 2008, FDA had implemented 7 of those recommendations. In commenting on a draft of this report, FDA stated that an update on the status of these recommendations may allow an additional 15 recommendations to be viewed as fully implemented. FDA also stated that two recommendations would require congressional action and one would require additional funding to implement. Based on our routine update on the status of open recommendations, we agree that one additional recommendation can be considered fully implemented; however, we disagree with FDA's assessment that the remaining recommendations should be considered fully implemented.

As requested, this report examines (1) the dollars and staff years FDA has spent on fresh produce safety and how FDA has allocated those resources, (2) the effectiveness of FDA's actions to oversee domestic and imported fresh produce safety, and (3) the actions FDA plans to take to enhance fresh produce oversight and the extent to which FDA's planned actions address identified challenges.

For this report, fresh produce means fruits and vegetables in their unpeeled, natural form, as well as fruits and vegetables that have been minimally processed (e.g., peeled, sliced, or chopped) before being packaged for use by the consumer or a retail establishment. It does not include frozen or canned fruits and vegetables or fruit and vegetable juices. To conduct this review, we visited produce farms and processing facilities in California's Salinas Valley, where we interviewed growers,

[4]GAO, *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical*, GAO-08-435T (Washington, D.C.: Jan. 29, 2008) and GAO, *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*, GAO-08-909T (Washington, D.C.: June 12, 2008).

processors, and industry representatives and observed an FDA inspection of a fresh-cut produce facility. We selected the Salinas Valley because it was the source of the 2006 *E. coli* O157:H7 outbreak linked to bagged spinach. We obtained and analyzed FDA data and estimates on food safety and fresh produce safety spending in both dollars and staff years and FDA data on fresh produce oversight activities. In analyzing FDA's food safety resources, we focused on fiscal years 2000 through 2007 to update a previous GAO report that detailed food safety spending through fiscal year 1999.[5] In analyzing FDA's fresh produce resources, we limited our work to fiscal years 2005 through 2007 because FDA believed it could only provide reliable estimates of fresh produce spending for these years. We assessed the reliability of the data used in this report and found it to be sufficiently reliable for the purposes used. We reviewed FDA plans, such as its November 2007 *Food Protection Plan*, for information on proposed changes that could enhance fresh produce oversight. To assess FDA's plans, we reviewed previous GAO reports on food safety and GAO guidance for assessing key elements in agencies' performance plans, including goals, strategies, and resources.[6] We interviewed FDA officials about fresh produce resources, oversight activities, and planned changes. We also interviewed former FDA officials, food safety experts, state food safety officials, industry representatives, and others to obtain their views on FDA's current oversight activities and planned actions. Appendix I contains a detailed discussion of the scope and methodology of our review.

We conducted this performance audit from June 2007 to September 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[5]GAO, *Food Safety: Overview of Federal and State Expenditures*, GAO-01-177 (Washington, D.C.: Feb. 20, 2001).

[6]GAO, *Agencies' Annual Performance Plans under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking*, GAO/GGD/AIMD-10.1.18 (Washington, D.C.: February 1998).

## Results in Brief

Although FDA has considered fresh produce as a priority over the past decade, resource constraints and other work—including counterterrorism efforts and unplanned events such as foodborne illness outbreaks—have caused FDA to delay key fresh produce safety initiatives. Because FDA has no formal program devoted exclusively to fresh produce, it draws dollars and staff years to fresh produce from its overall food safety program. FDA has not consistently and reliably tracked its spending on fresh produce, thus limiting its ability not only to identify its actual fresh produce spending but also to plan and manage this spending. Based on FDA's estimates, our analysis indicates that spending on fresh produce safety was at least $18 million in fiscal year 2006 and at least $20 million in 2007, or approximately 3 percent of total FDA food safety spending in each year. Similarly, our analysis shows that FDA spent at least 132 staff years on produce safety in fiscal year 2006 and 130 staff years in 2007, or about 4 percent of its total food safety staff years. Additionally, FDA had few staff dedicated solely to fresh produce safety. This low level of spending relative to total food safety spending is partly the result of resource constraints and other work that have delayed fresh produce efforts. For example, officials from FDA's Center for Food Safety and Applied Nutrition (CFSAN) told us that one of the center's priorities—issuing guidance for fresh-cut produce operations—was delayed at least 6 years because they had to divert staff with the needed expertise to address counterterrorism efforts and outbreaks of foodborne illness.

FDA's actions to oversee domestic and imported fresh produce safety have generally been limited. More specifically, within FDA's *Food Protection Plan* framework of prevention, intervention, and response, we found the following:

- *Prevention.* FDA's prevention efforts have been limited, in part because gaps in scientific knowledge have impeded its ability to fully integrate science and risk into its oversight of fresh produce safety. Moreover, FDA has issued some voluntary guidance for industry, including guidelines for minimizing contamination during field and fresh-cut operations. However, it has not issued regulations requiring firms to take action to prevent contamination, even though some industry groups would like it to do so.

- *Intervention.* Inspections of domestic firms that handle fresh produce have occurred infrequently. Our analysis of FDA data showed that the 2,002 domestic firms that underwent produce-related inspections were inspected twice, on average, from fiscal years 2000 through 2007. Problems were observed in 41 percent of these inspections, but most

did not warrant further regulatory action, according to FDA. Therefore, the agency primarily relied on firms to take voluntary corrective action. We also found FDA provided minimal oversight of imported produce. Although FDA's oversight of imports relies heavily on screening products at the border, it examined less than 1 percent of the 7.6 million fresh produce import entry lines from fiscal years 2002 through 2007. Additionally, although FDA devoted more resources to import oversight, enabling it to conduct more import examinations in fiscal year 2007 than in fiscal year 2004, it has not been able to inspect a larger share of incoming fresh produce shipments.

- *Response.* FDA has improved some elements of its emergency response. Successes include improving response coordination through the creation of a new Office of Crisis Management, partnering with California on outbreak investigations, and developing a pilot program where recall notices include photographs of the recalled product. However, tracing an outbreak involving fresh produce back to its source remains challenging because produce is highly perishable and may no longer be available for testing. Also, when product is available, it may be unlabeled or mixed in packages with products from multiple sources.

FDA has proposed changes that could significantly enhance its fresh produce oversight and has reported some initial progress, but more information on strategies and resources is needed to enhance accountability and assess the likelihood of FDA's success. Specifically, through its *Food Protection Plan*, FDA proposed agency actions and identified authorities needed to better leverage its limited resources and strengthen its oversight of fresh produce, including these key actions:

- *Prevention.* FDA plans to help fill gaps in scientific knowledge and update its 1998 guidance to industry on good agricultural practices. Also, FDA has cited a need for explicit authority to issue regulations requiring preventive controls for high-risk foods, such as leafy greens, which could minimize the risk of contamination before such foods enter the market.

- *Intervention.* For domestic inspections, when deciding which domestic food facilities to inspect, FDA plans to increase the rigor of its risk-based criteria to focus on the firms of highest risk. For imports, FDA officials are also testing a new import screening software tool that uses information from a wider variety of sources to more effectively screen products at the border. Further, FDA has identified a need for explicit authority to accredit third parties to perform inspections, which could

help FDA leverage its resources, but FDA does not envision using such a program for fresh produce until the agency has established or assessed the adequacy of clear preventive standards.

- *Response.* FDA plans to improve efforts to trace contaminated products back to their source by establishing an internal working group to examine industry best practices, using new laboratory equipment, and obtaining improved records access authority during food-related emergencies. FDA also plans to organize more federal-state teams, such as the FDA-California team, to respond to outbreaks. In addition, FDA has identified the need for the authority to issue mandatory recalls when voluntary recalls are not effective and has plans to improve how it communicates risk to the public during outbreaks, with help from an external advisory group.

While these efforts have the potential to enhance food safety oversight, FDA is still largely in the planning stages for these improvements and has not provided specific information on strategies and resources. Without this information, it is difficult to assess the likelihood of success.

We are making seven recommendations to FDA, including four recommendations to enhance its oversight of fresh produce safety, such as updating its good agricultural practices guidance, two recommendations to seek authority from the Congress to make explicit FDA's authority to adopt preventive controls for high-risk foods and to provide enhanced access to firm records during food-related emergencies, and one recommendation to provide specific information to the Congress and to the public on the strategies and resources for implementing the *Food Protection Plan*. In its written comments on a draft of our report that included comments from FDA, the Department of Health and Human Services generally agreed with the report's accuracy and conclusions and with most of the report's recommendations. While FDA agreed with the importance of having explicit authority to adopt preventive controls for high-risk foods and having enhanced access to firm records during food-related emergencies, the agency believes that it has already sought such authorities by outlining legislative needs in the *Food Protection Plan* and testifying on the plan before congressional committees. We do not view these actions as seeking authority. Rather, as FDA recognized, there is a need for the agency to partner with the Congress to make the necessary changes to transform the safety of the nation's food supply. FDA should move beyond outlining needs and continue to take steps to obtain these legislative authorities, such as by suggesting language that provides FDA the necessary statutory tools to help the agency conduct its oversight

responsibilities. In addition, FDA provided technical comments that we have incorporated, as appropriate.

## Background

FDA has primary responsibility for ensuring the safety of a broad range of products, including foods, animal drugs and feeds, human medicines and vaccines, radiation-emitting devices, medical devices, blood and blood products, and cosmetics. With regard to food safety, FDA is responsible under the Federal Food, Drug, and Cosmetic Act for ensuring that all human foods introduced into interstate commerce—except meat, poultry, and processed egg products—and animal feeds are safe, wholesome, and labeled properly. To carry out its responsibilities, FDA has the authority to do such things as conduct examinations and investigations, inspect food facilities, refuse the entry of imported food that appears to be adulterated, and recommend judicial enforcement actions to the Department of Justice. Under the Public Health Service Act, FDA has the authority to take measures, such as issuing regulations, that in its judgment are necessary to prevent the spread of communicable diseases, including foodborne illness.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) amended both acts. With regard to food safety, the act

- provides FDA the authority to administratively detain a food product where there is credible evidence or information that the product presents a threat of serious adverse health consequences or death to humans or animals;
- directs FDA to issue regulations requiring information regarding food that is being imported or offered for import prior to its arrival at a U.S. port;
- directs FDA to issue regulations requiring domestic and foreign facilities engaged in manufacturing, processing, packing, or holding food for human consumption in the United States to register with FDA; and
- authorizes FDA to issue regulations requiring food firms, except farms and restaurants, to keep records on the immediate previous source and the immediate subsequent recipient of their products.

Within FDA, two centers have primary responsibility for food safety—CFSAN, which is responsible for human food, and the Center for Veterinary Medicine, which is responsible for animal feeds and drugs. In addition, FDA's Office of Regulatory Affairs (ORA) performs food safety and other field work in support of the centers' programs, and the National Center for Toxicological Research conducts food safety research, among other things. CFSAN and ORA perform most of FDA's fresh produce safety activities. CFSAN formulates regulations and guidance, conducts research, communicates information to industry and the public, and sets program priorities, while ORA carries out produce-related field activities, such as conducting inspections, collecting and analyzing samples, and taking enforcement action. Further, both CFSAN and ORA are involved in responding to emergencies involving fresh produce, such as foodborne illness outbreaks, which are coordinated by the Office of Crisis Management within the Office of the Commissioner. In addition, the Associate Commissioner for Foods, also within the Office of the Commissioner, works on food safety issues that may directly or indirectly relate to fresh produce.

Other agencies have responsibilities or programs directly or indirectly related to fresh produce safety:

- CDC within the Department of Health and Human Services conducts surveillance of foodborne illness and provides data and information to other food safety agencies, including FDA.

- Environmental Protection Agency regulates the amount of pesticide that may safely remain on food, including fresh produce.

- National Institutes of Health within the Department of Health and Human Services researches ways to prevent disease, such as foodborne illness.

- USDA conducts food safety research and also supports food safety research, education, and extension programs in the land-grant university system and other partner organizations.

In addition, FDA may enter into formal or informal arrangements with states to do inspections, share resources, or avoid duplication of efforts. Also, states may play a significant role in detecting and responding to outbreaks of foodborne illness.

Produce can become contaminated at any point in the production cycle, and the fact that it is often consumed raw without undergoing a "kill step" that would eliminate pathogens prior to consumption contributes to its potential for causing foodborne illness. At the time of our review, FDA was considering an industry request to allow, among other things, fresh produce to undergo higher doses of irradiation. In August 2008, the agency published a final rule to allow such irradiation for fresh iceberg lettuce and fresh spinach. According to an FDA official, the levels of irradiation that could be tolerated by some types of fresh produce would reduce but not completely eliminate pathogens. Produce grown outdoors is particularly vulnerable to contamination. Some factors that may contribute to contamination include the presence of animals in fields or packing areas, poor water quality, or poor worker sanitation practices. Processing produce into fresh-cut products, such as cut fruits or mixed salads, increases the risk of microbial contamination and growth by breaking down the natural exterior barrier of the produce. If pathogens are present, they can enter the product and then spread into other products being processed at the same time. Produce can also become contaminated after it is harvested and processed, such as during transportation or preparation. For example, produce can become contaminated when it is transported in unclean or improperly refrigerated trucks or when consumers place it on surfaces, such as cutting boards, that have not been thoroughly cleaned after coming into contact with raw meat or poultry. In addition to microbial pathogens, other substances, such as pesticides, may contaminate fresh produce.

According to unpublished FDA data on reported illness associated with FDA-regulated foods, from 1996 through 2006, there were at least 96 outbreaks, 10,253 illnesses, and 14 deaths associated with the consumption of fresh produce.[7] CDC officials told us that available data greatly underestimate the number of foodborne illnesses attributable to fresh produce. Many cases are not reported because the ill person does not seek medical care or the doctor does not take a lab culture. Also, according to CDC officials, in many outbreaks, the pathogen is not identified by state or local public health laboratories because of delayed or incomplete laboratory investigation, inadequate laboratory capacity, or inability to recognize a pathogen as the cause of foodborne illness. Fresh

[7]According to FDA, these data do not include (1) outbreaks and illnesses where the point of contamination is the retail food setting or home, (2) illnesses transmitted from person-to-person, and (3) illnesses or deaths that may have occurred but were not captured by the outbreak reporting process.

produce and pathogens frequently linked to foodborne illness outbreaks included sprouts (*Salmonella*), leafy greens (*E. coli* O157:H7), tomatoes (*Salmonella*), melons (*Salmonella*), herbs (*Cyclospora*), berries (*Cyclospora*), and green onions (hepatitis A). Once the pathogen is identified, laboratories may send a sample to CDC's PulseNet, a nationwide database that matches pathogen strains. Generally, state and local public health authorities conduct investigations to link the pathogen and the contaminated food. However, CDC may provide assistance. FDA becomes involved when the epidemiology indicates there is an outbreak implicating an FDA-regulated product.

## FDA Has Spent Relatively Few Resources on Fresh Produce Safety and Other Work Has Preempted Fresh Produce Efforts

Although FDA has considered fresh produce a priority area for many years, resource constraints and other work—including counterterrorism efforts and unplanned events such as outbreaks—have caused FDA to delay key fresh produce safety efforts. Because it has no formal program devoted exclusively to fresh produce, FDA allocates resources to fresh produce as part of its overall food safety planning process. Moreover, FDA has not consistently and reliably tracked its spending on fresh produce, thus limiting its ability not only to identify how much it has spent on fresh produce safety but also to plan and manage this spending. Our analysis of FDA estimates and data shows that spending on fresh produce safety was approximately 3 percent of total annual FDA food safety spending in fiscal years 2006 and 2007. Additionally, FDA had few staff solely dedicated to fresh produce.

### FDA Has Identified Fresh Produce as a Priority for Many Years but Has No Formal Fresh Produce Program

Fresh produce has been a key concern for FDA since at least 1997, when the President announced a national food safety initiative that resulted in several produce-related recommendations, such as developing fast and cost-effective methods for detecting pathogens. That same year, a presidential produce safety initiative called for FDA, among other things, to enhance its oversight of imported produce and develop guidance on good agricultural and manufacturing practices for domestic produce. Additionally, CFSAN has listed produce safety activities as priorities each fiscal year since 1999. Such priorities have included, for example, publishing guidance on fresh-cut produce operations, working with industry to develop good agricultural and manufacturing practices for commodities such as tomatoes and cantaloupes, and conducting initiatives specific to contamination in lettuce and leafy greens. CFSAN also highlighted produce safety as a critical issue in its 2004 produce safety action plan, which identified steps to prevent contamination, minimize public health impacts when contamination occurs, improve

communication about fresh produce, and facilitate and support relevant research. Additionally, FDA officials told us that fresh produce safety gained more relevance and prominence within CFSAN as a result of the *E. coli* O157:H7 outbreak in spinach in 2006.

Despite identifying fresh produce safety as a priority area, FDA has no formal program devoted exclusively to fresh produce to which it can allocate resources. Instead, FDA directs resources to fresh produce as part of the process it uses to identify overall food safety priorities, some of which include fresh produce. As part of this process, CFSAN develops and publishes its program priorities each year showing the new and ongoing work it plans to conduct during the next fiscal year. Using these priorities and the President's proposed budget as a starting point, ORA consults with CFSAN to develop its own work plans for carrying out CFSAN's field activities for the upcoming year. ORA also spells out the ideal distribution of field staff, by position and by location, needed to implement CFSAN's planned food safety priorities. However, planned priorities often shift during the year in response to outbreaks of foodborne illness, other emergencies, or resource constraints. Also, FDA's informal hiring freeze from fiscal years 2004 through mid-2007 and lower than expected congressional appropriations have meant some field locations lacked positions needed to implement planned work.

## FDA Has Not Consistently or Reliably Tracked Resources Spent on Fresh Produce Safety

In addition to lacking a formal program devoted exclusively to fresh produce, FDA has not consistently or reliably tracked the dollars or staff years it spent on fresh produce safety, thus limiting its ability to plan and manage spending. While the five FDA organizations that conducted food safety work—CFSAN, ORA, the Center for Veterinary Medicine, the National Center for Toxicological Research, and the Office of the Commissioner—were able to provide us with reliable data on their overall food safety spending for fiscal years 2000 through 2007, the three organizations that reported spending resources on fresh produce safety—CFSAN, ORA, and the Office of the Commissioner—could not provide reliable data on fresh produce. Specifically, the systems CFSAN and the Office of the Commissioner use to track their food safety spending do not consistently distinguish fresh produce work from other efforts. Consequently, CFSAN could only provide estimates for the minimum number of dollars and staff years it spent on fresh produce for fiscal years 2006 and 2007 and the Office of the Commissioner could provide no fresh produce spending data or estimates. While ORA was able to track its spending on fresh produce because staff generally enter a code to identify the product and processing method when reporting an activity in ORA's

work tracking system, officials acknowledged that not all fresh produce activities are reported as such, and thus ORA also provided estimates of fresh produce spending. Because FDA cannot identify the actual resources it spends on fresh produce, it lacks the information needed to understand whether it is allocating its resources in support of produce safety priorities in the most efficient manner. As a result, FDA's ability to effectively plan and manage its food safety resources is limited.

## Fresh Produce Has Been a Small Part of FDA's Food Safety Efforts

Our analysis of FDA's best available spending estimates shows that fresh produce amounted to at least $18 million in fiscal year 2006 and at least $20 million in 2007, or approximately 3 percent of FDA's total annual food safety spending in each year, as shown in table 1. Similarly, our analysis indicates that FDA spent at least 132 staff years on produce safety in fiscal year 2006 and 130 staff years in 2007, or about 4 percent of its total food safety staff years. Because CFSAN does not require its staff to track work on fresh produce specifically, and instead allows its staff to track fresh produce work under either a general food safety category or a produce-specific category, CFSAN dollar and staff year estimates are minimum amounts. Further, based on the estimates FDA provided, ORA spent the vast majority of FDA's fresh produce resources.

**Table 1: FDA Domestic and Imported Food Safety and Fresh Produce Spending, Fiscal Years 2006 and 2007**

Dollars in millions

| | Fiscal year | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2006 | | | | 2007 | | | |
| | Food safety | | Fresh produce[a] | | Food safety | | Fresh produce[a] | |
| Organization | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years |
| Center for Food Safety and Applied Nutrition | $150.3 | 816 | $1.5 | 10 | $157.1 | 744 | $3.6 | 23 |
| Office of Regulatory Affairs (Field work in support of the Center for Food Safety and Applied Nutrition) | 283.5 | 1,950 | 16.8 | 121 | 296.1 | 1,793 | 16.6 | 106 |
| Center for Veterinary Medicine | 54.8 | 321 | 0.0 | 0 | 58.4 | 318 | 0.0 | 0 |
| Office of Regulatory Affairs (Field work in support of the Center for Veterinary Medicine) | 33.0 | 206 | 0.0 | 0 | 34.6 | 208 | 0.0 | 0 |
| National Center for Toxicological Research[b] | 10.3 | 36 | 0.0 | 0 | 11.5 | 37 | 0.0 | 0 |
| Office of the Commissioner | 29.6 | 184 | [c] | [c] | 31.6 | 181 | [c] | [c] |
| **Total** | **$561.6** | **3,513** | **$18.3** | **132** | **$589.1** | **3,281** | **$20.2** | **130** |

Source: GAO analysis of FDA data and estimates.

Notes: Totals may not add due to rounding.

[a]According to FDA officials, fresh produce spending is estimated.

[b]Food safety spending includes some dollars spent on collaborative efforts with other federal agencies and external organizations.

[c]The Office of the Commissioner could not provide an estimate of its fresh produce spending because it could not distinguish fresh produce work from other work.

CFSAN reported fresh produce spending in two areas—produce safety and response to foodborne outbreaks—and provided an estimate of related overhead, as shown in table 2. (See app. II for a detailed listing of CFSAN's food safety spending.) The produce safety category includes efforts specific to fresh produce, such as assessing the growing practices and potential contamination pathways in leafy greens and tomatoes. However, food safety work with a fresh produce component, such as an effort to modernize current good manufacturing practice regulations for food, generally falls under the general food safety category. The response to foodborne outbreaks category includes responses to various outbreaks, such as the 2006 outbreak of *E. coli* O157:H7 in spinach. According to CFSAN officials, CFSAN attributed all of its outbreak response spending to fresh produce in fiscal years 2006 and 2007 because fresh produce spending estimates were understated under the produce safety category

and outbreak response work—which staff sometimes report more generally as food safety work—primarily involved fresh produce.

**Table 2: Minimum Estimates of CFSAN Spending on Fresh Produce, Fiscal Years 2006 and 2007**

| | Fiscal year | | | |
|---|---|---|---|---|
| | 2006 | | 2007 | |
| Activity | Dollars | Staff years | Dollars | Staff years |
| Produce safety | $1,290,696 | 9.4 | $2,330,437 | 15.9 |
| Response to foodborne outbreaks | 31,003 | 0.2 | 883,993 | 6.1 |
| Overhead[a] | 176,647 | 0.7 | 408,048 | 1.4 |
| **Total** | **$1,498,346** | **10.4** | **$3,622,478** | **23.3** |

Source: FDA estimated data.

Notes: Totals may not add due to rounding. These estimates represent the minimum resources spent on fresh produce.

[a]Overhead represents CFSAN's portion of shared services, such as human resources, information technology, management services, and telephone expenses, and excludes rent and facilities.

Similarly, ORA reports fresh produce spending across various activities. (See app. II for a detailed listing of ORA's food safety spending.) Based on ORA's estimates for fiscal years 2006 and 2007, it focused most of its produce safety resources on analyzing produce for pesticides and industrial chemicals (49 percent and 56 percent), sampling domestic and imported produce for microbial contamination (26 percent and 12 percent), implementing the general program for domestic food safety (10 percent and 9 percent), and examining imported foods (9 percent and 15 percent). Table 3 shows the dollars and staff years spent on ORA activities involving fresh produce.

**Table 3: Estimates of ORA Spending on Fresh Produce, Fiscal Years 2006 and 2007**

Dollars in millions

| | Fiscal year | | | |
|---|---|---|---|---|
| | 2006 | | 2007 | |
| **Activity** | **Dollars** | **Staff years** | **Dollars** | **Staff years** |
| **Chemical safety of foods** | | | | |
| Pesticides and industrial chemicals in domestic and imported foods | $8.2 | 58.9 | $9.2 | 59.0 |
| Radionuclides in foods | <.1 | 0.1 | 0.1 | 0.4 |
| Mycotoxins in domestic and imported foods | <.1 | 0.1 | <.1 | 0.1 |
| Food and color additives (imports) | <.1 | <.1 | <.1 | 0.1 |
| Toxic elements in foods (domestic and import) | <.1 | <.1 | 0.0 | 0.0 |
| **Microbiological safety of foods** | | | | |
| Import and domestic microbiological (produce) assignment | 4.4 | 31.9 | 2.1 | 13.2 |
| Audits of food contract inspections | <.1 | 0.1 | <.1 | 0.1 |
| Natural disasters and emergencies | <.1 | <.1 | 0.0 | 0.0 |
| **Nutrient quality and food labeling** | | | | |
| Nutrition Labeling and Education Act, nutrient sample analysis and general food labeling | 0.1 | 1.0 | 0.1 | 0.8 |
| Food economics and standards | 0.0 | 0.0 | <.1 | 0.0 |
| **Cross-cutting** | | | | |
| Domestic food safety program (general) | 1.6 | 11.7 | 1.6 | 9.9 |
| Imported foods (general) | 1.5 | 10.9 | 2.5 | 16.2 |
| Emergency response to foodborne outbreaks and illnesses | 0.4 | 3.0 | 0.6 | 3.6 |
| Counterterrorism activities | 0.3 | 2.0 | 0.2 | 1.5 |
| Consumer complaints | 0.1 | 0.7 | 0.1 | 0.5 |
| Foreign inspections and technical assistance | 0.1 | 0.7 | <.1 | 0.2 |
| Short-term assignments initiated by CFSAN, ORA headquarters, or ORA field offices | <.1 | 0.2 | 0.1 | 0.4 |
| Juice hazard analysis and critical control point program | <.1 | 0.1 | 0.1 | 0.3 |
| Miscellaneous other food safety work | 0.0 | 0.0 | <.1 | <.1 |
| **Total** | **$16.8** | **121.4** | **$16.6** | **106.2** |

Source: GAO analysis of FDA estimated data.

Notes: Totals may not add due to rounding. ORA included overhead in the dollars and staff years spent for each activity.

FDA's Office of the Commissioner also conducts work related to fresh produce, primarily through its Office of Crisis Management, which manages FDA's response to foodborne illness outbreaks and other emergencies. In addition, FDA's Commissioner created a position in 2007

within the Office of the Commissioner responsible for developing a strategic effort to better protect the nation's food supply, which includes fresh produce. However, FDA was unable to provide data or estimates on the resources spent on fresh produce by the Office of the Commissioner.

Additionally, our analysis indicates that FDA had few staff dedicated solely to fresh produce safety. Within CFSAN, two staff have worked almost full-time on fresh produce safety issues for several years, and approximately 25 staff—primarily researchers—have principally worked on fresh produce safety as part of their food safety responsibilities in fiscal year 2007. CFSAN staff have worked on a variety of fresh produce efforts, such as assessing the growing practices for leafy greens and tomatoes, conducting research on contaminants in produce, and working on foodborne illness tracebacks involving fresh produce. While no ORA field staff work solely on produce safety, they do conduct fresh produce-related work as part of other food safety efforts, such as inspecting facilities and testing products under CFSAN's domestic food safety compliance program—a general food safety program focusing on high-risk firms and products not covered by other programs. In addition, ORA has conducted some fieldwork exclusively directed at fresh produce, such as an annual assignment to collect and analyze up to 1,000 samples of domestic and imported fresh produce. While staff within the Office of the Commissioner may work on issues related to fresh produce, such as responding to outbreaks of foodborne illness linked to fresh produce, no staff work solely on fresh produce issues.

CFSAN officials acknowledged that having a critical mass of at least five staff solely working on produce safety, including an expert to lead the group, would be a more effective way of overseeing produce safety. In 2007 and 2008, CFSAN received funding to hire four additional staff to work solely on produce safety. However, CFSAN officials told us that they had not been able to fill all of the positions at the time of our review, in part due to salary limitations.

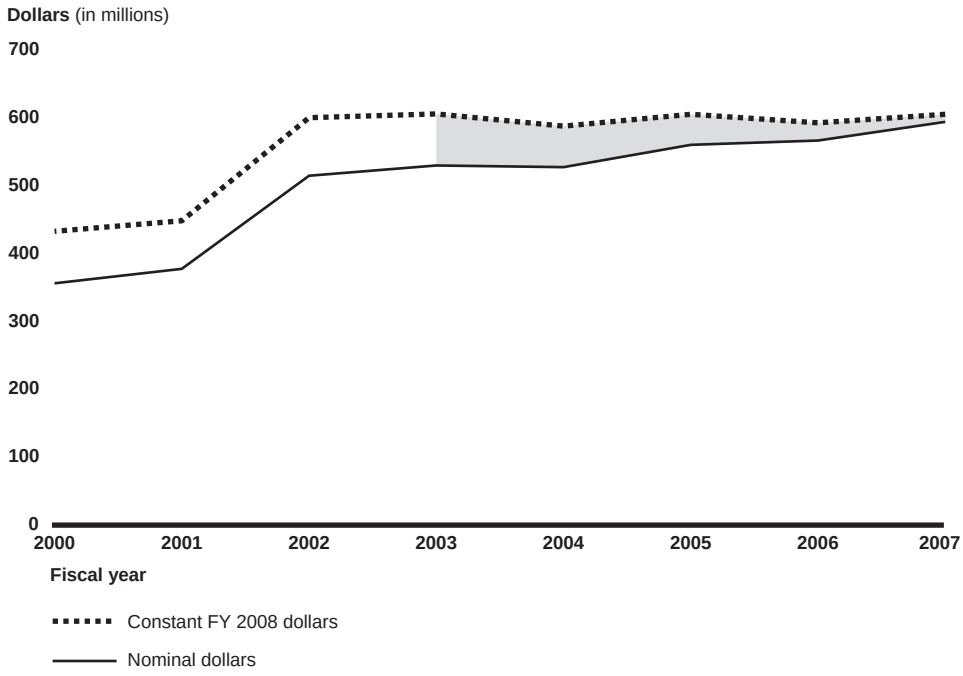
## FDA Has Delayed Key Fresh Produce Activities

Even though fresh produce safety has been a stated priority for many years, other food safety work has preempted produce safety efforts. Specifically, resource constraints and other work—including counterterrorism efforts and unplanned events such as outbreaks of foodborne illness—led FDA to delay key fresh produce safety efforts.

FDA's food safety responsibilities have increased in recent years as a result of the growth in imported food and new regulatory responsibilities,

among other things. At the same time, our analysis shows that, after adjusting for inflation, FDA's total food safety spending, which includes fresh produce, remained relatively stable in recent years, despite an initial surge after the events of September 11, 2001. Specifically, FDA's total spending on food safety dropped slightly below its peak of $600.8 million in fiscal year 2003 to $600.3 million in fiscal year 2007 (in constant fiscal year 2008 dollars), as shown in figure 1. (See app. II for FDA's food safety spending for fiscal years 2000 through 2007.)

**Figure 1: FDA Food Safety Spending in Constant and Nominal Dollars, Fiscal Years 2000 through 2007**




Source: GAO analysis of FDA data.

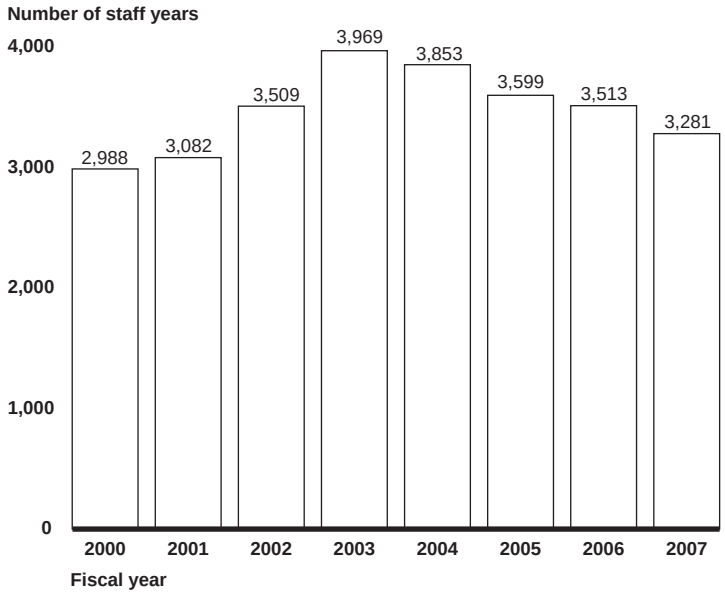
Note: Annual totals include some non-FDA funding from collaborations between the National Center for Toxicological Research and non-FDA entities.

At CFSAN, spending on food safety declined slightly from its peak of over $164 million in fiscal year 2003 to approximately $160 million in fiscal year 2007 (in constant fiscal year 2008 dollars). As a result, CFSAN had to absorb cost-of-living increases for its staff, which translated into substantial budget constraints and loss of staff years through early retirements and decisions not to fill vacated positions. CFSAN incurred these losses despite an increase in responsibilities, significantly impairing

its ability to fund its priorities, according to the document detailing the center's 2006 program priorities. ORA spending on food safety during this period remained relatively flat (in constant fiscal year 2008 dollars), translating into similar budget constraints and absorption of cost of living increases.

Our analysis also shows that staffing levels for food safety have fallen during the last 4 fiscal years, after initially increasing following September 11, 2001, as shown in figure 2. (See app. II for detailed information on FDA's food safety staffing for fiscal years 2000 through 2007.) Food safety staffing levels declined 17 percent from their peak of 3,969 staff years in fiscal year 2003 to 3,281 in fiscal year 2007. In fact, the number of staff years FDA spent on food safety had fallen below fiscal year 2002 levels by the end of fiscal year 2007. As a result, FDA lost 70 percent of the food safety staff years gained since fiscal year 2000.

**Figure 2: FDA's Total Food Safety Staffing Levels, Fiscal Years 2000 through 2007**

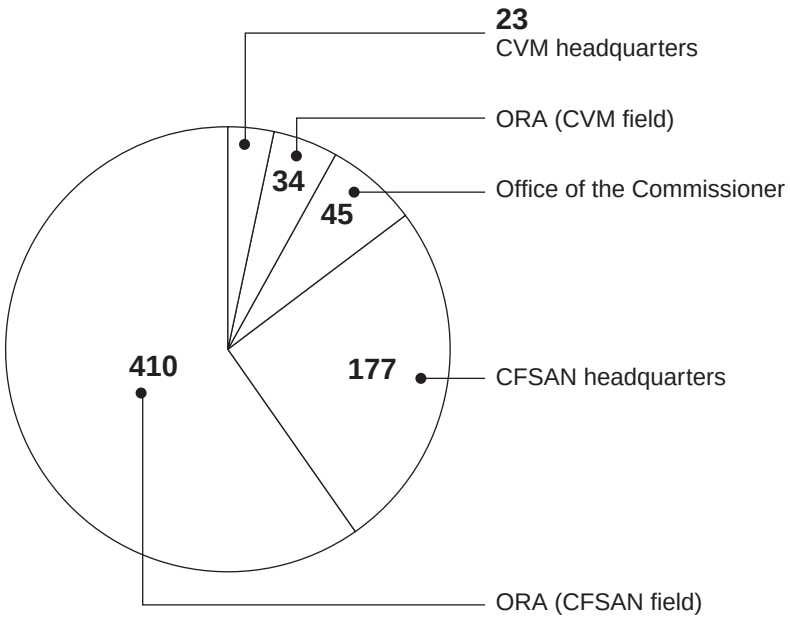



Source: FDA data.

Note: Staff years are rounded to the nearest whole number.

Specifically, FDA experienced a net decline of 689 food safety staff years between fiscal years 2003 and 2007.[8] ORA sustained the vast majority of these losses, losing 410 staff years, or more than 20 percent of the staff years it devotes to supporting CFSAN's food safety activities. CFSAN lost 177 food safety staff years during this same period, or almost 25 percent of its headquarters food safety staff years. Figure 3 shows the FDA organizations experiencing a decline in food safety staff years between fiscal years 2003 and 2007, and appendix II, table 5, shows FDA's total food safety spending, by center, during this period.

**Figure 3: FDA Organizations Experiencing a Decline in Food Safety Staff Years between Fiscal Years 2003 and 2007**




Source: GAO analysis of FDA data.

Notes: Staff years are rounded to the nearest whole number. The National Center for Toxicological Research is not included in this figure because it gained one staff year between fiscal years 2003 and 2007.

In our January 2008 testimony on FDA's *Food Protection Plan*, we noted that FDA's resources have not kept pace with an increasing food safety workload over the past decade and that funding issues are more acute for

[8]According to ORA, it hired an additional 597 people in fiscal year 2002 to help conduct work related to the Bioterrorism Act.

CFSAN than for other centers because, unlike some other FDA programs, it does not have the authority to collect and retain user fees. Similarly, CFSAN's former director testified in February 2008 that the agency's food-related funding has not kept pace with inflation, with FDA losing 800 scientists, inspectors, and other critical food safety staff since fiscal year 2004. In addition, former Secretaries of the Department of Health and Human Services and other experts have called on the Congress to dramatically increase the agency's budget for protecting the nation's food supply. FDA's Commissioner, in a May 2008 letter to the Congress, assessed the agency as immediately needing an additional $125 million to achieve its food protection goal for fiscal year 2008. However, as we testified in June 2008, the total costs to fully implement the agency's *Food Protection Plan* are not yet clear,[9] and we continue to have concerns about the agency's lack of specificity about the resources needed.

FDA officials acknowledged that, in recent years, resource constraints have led FDA to delay work on some key fresh produce safety efforts because FDA lacked enough staff with the needed expertise in areas like regulatory development, as well as enough staff with the technical and subject matter expertise to work on all food safety priorities. For example, according to FDA officials, this staff shortage caused the agency to delay two key efforts relating to fresh produce—modernizing its current good manufacturing practice regulations for food and updating its good agricultural practices guidance. In addition, FDA acknowledged that because CFSAN has lacked the resources to fund its extramural research grant program or perform some critical produce-related research internally, it has not yet been able to conduct the large-scale surveys of fresh produce that are crucial to understanding the incidence of contamination of produce by pathogens such as *E. coli* O157:H7 or *Salmonella*.

FDA officials also acknowledged that they have delayed work on fresh produce safety efforts because of other work, including counterterrorism efforts in response to the Bioterrorism Act and unplanned events such as outbreaks of foodborne illness and recalls of contaminated foods. Additionally, ORA officials repeatedly told us that responding to emergencies, such as foodborne illness outbreaks, takes precedence over other work. However, ORA stopped setting aside staff time and funding for emergencies beginning with fiscal year 2007. Consequently, during the

[9]GAO-08-909T.

2007 recall of botulism-contaminated chili, ORA diverted staff throughout the country from conducting their ongoing work to removing potentially contaminated products from store shelves. Further, agency officials stated that the February 2008 release of FDA's final guidance for fresh-cut produce operations—designed to enhance food safety in a segment of the produce industry frequently linked to foodborne illness outbreaks and listed as a CFSAN priority since fiscal year 2000—was delayed at least 6 years because CFSAN had to divert staff with the needed expertise to address counterterrorism efforts and foodborne illness outbreaks.

## FDA Has Provided Limited Oversight of Domestic and Imported Fresh Produce

FDA's oversight of domestic and imported fresh produce has generally been limited, with less focus on prevention and intervention—the first two areas of its food safety framework—than on response. This approach has limited the effectiveness of FDA's oversight. First, in terms of prevention, gaps in scientific knowledge and the lack of regulations have limited FDA's efforts to prevent microbial contamination of fresh produce. In terms of intervention, FDA has inspected domestic fresh produce firms infrequently. In addition, although FDA has allocated additional resources to import oversight, it has not been able to inspect a larger share of incoming fresh produce shipments. Finally, FDA gives top priority to responding to emergencies, such as foodborne illness outbreaks, and has had some success in improving its response, but tracing contaminated produce back to its source remains challenging.

### Gaps in Science and the Lack of Regulations Have Impeded FDA's Efforts to Take a Prevention-Based Approach

Gaps in scientific knowledge have impeded FDA's efforts to integrate science and risk analysis into its oversight of fresh produce safety. Food safety experts recommend a system that is science-based and uses risk analysis to focus preventive efforts on the foods and processes most likely to cause illness. FDA follows this approach by using available research to inform regulatory decisions and by considering the risk level of different products in making decisions about where to focus resources. However, FDA officials have noted that gaps in science have impeded their ability to make some decisions on how to regulate fresh produce. For example, cattle are known carriers of *E. coli* O157:H7, but scientists do not know exactly how *E. coli* is passed from animals to produce, and thus cannot say how far cattle should be kept from a leafy greens field. Furthermore, FDA does not have sufficient information to develop robust, science-based risk assessments that quantify the relative risks of consuming different types of produce. Lacking such information, FDA largely relies on qualitative information, such as the history of past outbreaks of foodborne illness, to rank the risk levels of fresh produce commodities.

FDA has taken steps to fill some of the gaps in scientific knowledge, but resource constraints have limited the agency's efforts. To fill some of the gaps, FDA conducts laboratory research on fresh produce commodities and their associated pathogens. For example, FDA has a study under way to improve its understanding of how one type of *Salmonella* contaminates tomatoes. However, FDA officials have acknowledged that the scope of their research needs exceeds available resources. Additionally, in response to recurring outbreaks of foodborne illness, FDA implemented a lettuce initiative in 2006 and a tomato initiative in 2007 to study farming practices and environmental conditions that could lead to contamination. These ongoing multiyear initiatives are conducted as part of a risk-based strategy that focuses on growing areas most often linked to past outbreaks—California for lettuce and leafy greens and Virginia and Florida for tomatoes. FDA typically does not inspect farms, so these initiatives also provide an opportunity to assess the extent to which growers are following the agency's recommended practices. FDA intends to use the information obtained through these initiatives to improve guidance and identify additional research or outreach needs. FDA also participates in three research centers in cooperation with academic institutions.[10] However, FDA's Science Board notes that overall output from these centers has been modest because of budget constraints at FDA. Finally, FDA directly funds projects carried out by other institutions, but agency officials noted that resource constraints led the agency to suspend its extramural research grant program for fiscal years 2006 and 2007.

Because FDA has limited resources for food safety research, it relies heavily on other federal agencies, including USDA and the National Institutes of Health, for scientific knowledge. However, a former CFSAN director told us that although FDA has worked to identify research needs and communicate them to other federal agencies, the agency has so far represented a fairly small voice in developing the research agenda, and therefore, gaps in science remain. Additionally, FDA officials acknowledged that it can be difficult to persuade other federal agencies to conduct research that meets FDA's needs. For example, obtaining baseline data on contamination levels of lettuce in different regions and in different seasons would aid FDA's regulatory work, but it is extremely expensive

[10]These centers are the National Center for Food Safety and Technology at the Illinois Institute for Technology, the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland, and the National Center for Natural Products Research at the University of Mississippi. FDA is in the process of developing a fourth center, the Western Center for Food Safety, at the University of California, Davis.

and, according to FDA officials, other agencies are uninterested in funding research to obtain such data. In addition to communicating research needs through meetings and conferences, FDA officials told us that the agency publishes a list of its research needs to communicate its priorities to other federal agencies. However, according to the director of CFSAN's Office of Regulatory Science, the most recent version was last updated 8 years ago, and many of the research priorities identified in that document still have not been addressed. Nevertheless, FDA is currently exploring ways to expand the agency's knowledge on fresh produce safety.

FDA has issued some voluntary guidance for fresh produce but has not issued enforceable regulations to prevent contamination. In 1998, for instance, FDA issued guidance for industry on good agricultural practices for reducing the risk of microbial contamination when growing, packing, and transporting fresh produce. For example, the guidance suggests practices that growers should consider to protect the quality of agricultural water. FDA has also issued guidance specifically for sprouts and for fresh-cut produce, as well as draft guidance for controlling *Listeria monocytogenes* in ready-to-eat foods, including fresh-cut produce. In addition, FDA has provided technical assistance to industry in developing guidance for melons, lettuce and leafy greens, and tomatoes, but the agency has not officially endorsed these documents. While guidance provides useful recommendations, it is voluntary and unenforceable. Finally, FDA has not issued preventive regulations for fresh produce, even though it has done so for other high-risk foods—for seafood in 1995 and for fruit juice in 2001. FDA's current good manufacturing practice regulations for food, which set out basic sanitation rules for food manufacturers, apply to fresh-cut produce, but specifically exempt raw agricultural commodities, including whole fruits and vegetables.

In the absence of preventive regulations issued by FDA, industry groups and others have undertaken other mechanisms to establish additional standards, such as the following:

- Both California leafy greens handlers and Arizona leafy greens shippers have entered into marketing agreements that regulate growing and processing practices for those who sign the agreement.

- USDA issued an advance notice of proposed rulemaking for a national marketing agreement for leafy greens.

- Florida's Department of Agriculture and Consumer Services recently adopted requirements related to safe growing and packing practices for tomatoes.

- The Association of Food and Drug Officials is developing a model fresh produce regulation for use by states.
- Some retail establishments have adopted policies requiring suppliers to meet specific, and often differing, requirements and to demonstrate adherence to these standards through inspections carried out by designated third-party auditors.

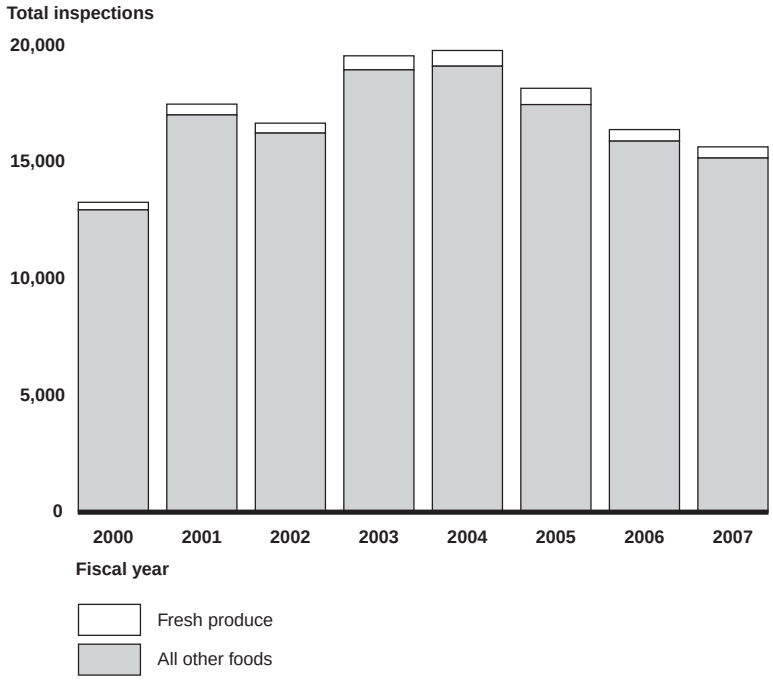
While many have praised these efforts as demonstrating a broad base of commitment to enhancing fresh produce safety, some have expressed concern that they lack national uniformity and create a patchwork of requirements that may present problems, both for growers and consumers. To address some of these problems, both industry groups and food safety experts have advocated for federal fresh produce regulations.

## FDA's Efforts to Inspect and Sample Domestic and Imported Fresh Produce Have Generally Been Limited

FDA's intervention efforts have been limited. First, FDA infrequently inspected domestic firms handling fresh produce. Additionally, FDA tested fresh produce samples more frequently for pesticides than for microbial contamination. Finally, while FDA has allocated additional resources to import oversight, it has not been able to inspect a larger percentage of imported fresh produce items.

*Domestic produce inspections have occurred infrequently*. The number of domestic fresh produce inspections conducted by FDA fluctuated from fiscal years 2000 through 2007. Our analysis of FDA data showed that the number of domestic fresh produce inspections rose from 327 in fiscal year 2000 to a peak of 699 in fiscal year 2005, and then declined to 478 inspections in fiscal year 2007. Overall domestic food inspections also fluctuated, rising from about 13,300 in fiscal year 2000 to about 19,800 in fiscal year 2004, and decreasing to about 15,700 in fiscal year 2007, as shown in figure 4.

**Figure 4: Domestic Food and Fresh Produce Inspections, Fiscal Years 2000 through 2007**




Source: FDA data.

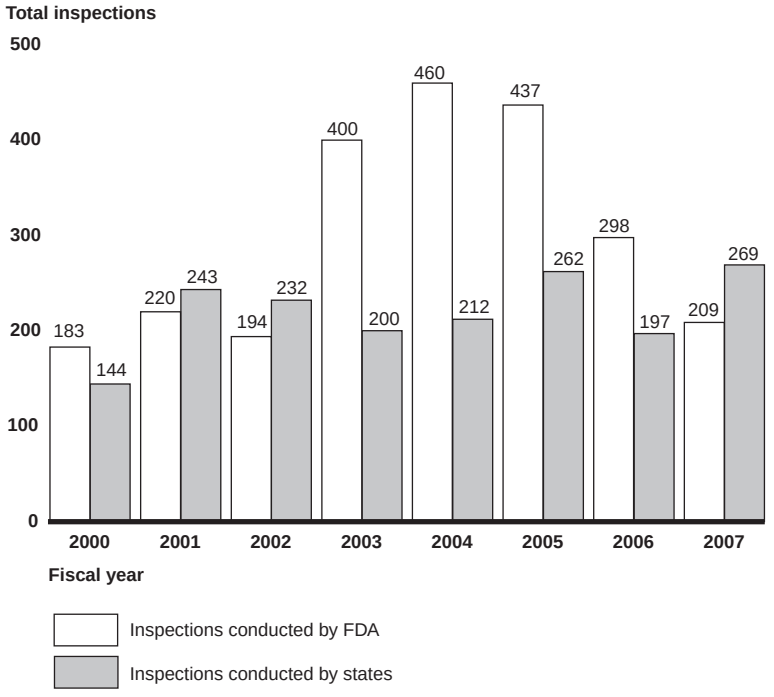
We also found that firms were inspected infrequently. Because FDA's database of registered food firms does not capture data that would identify all U.S. firms that handle fresh produce, we could not determine the percentage of fresh produce firms inspected.

However, according to our analysis, 2,002 firms had at least one produce-related inspection between fiscal years 2000 and 2007. On average, each firm was inspected twice during that period. About half of the firms had only one fresh produce-related inspection, and only 6 firms (0.3 percent) had a fresh produce-related inspection every year.

Additionally, FDA has increasingly coordinated with states to better leverage inspection resources. At the end of fiscal year 2007, FDA had contracts with 40 states to conduct food inspections on its behalf and had less formal partnership agreements with some states to coordinate food safety activities, including inspections. We found that states conducted 200 of the 600 fresh produce inspections (33 percent) in fiscal year 2003—including one conducted jointly with FDA officials—compared with 269 of

the 478 (56 percent) in fiscal year 2007, as shown in figure 5. FDA officials attributed this increase in the share of inspections conducted by states to an overall effort to better leverage resources in response to FDA staff losses and resource constraints. FDA officials also noted that the agency has tried to maintain consistent funding for state-conducted inspections. As a result, when changes in FDA funding occurred, the number of FDA-conducted inspections fluctuated more than state-conducted inspections. State officials noted that increasing the share of domestic inspections performed by the states may allow FDA to concentrate on areas where states do not have jurisdiction, such as import oversight. However, state officials also noted that they have experienced some challenges in partnering with FDA. For example, according to one state official, FDA sometimes restricts state access to the agency's inspection results because of confidentiality concerns. According to the official, such data would provide states with useful information on a firm's history and help the states' inspection efforts.

**Figure 5: Fresh Produce Inspections Conducted by FDA and States, Fiscal Years 2000 through 2007**

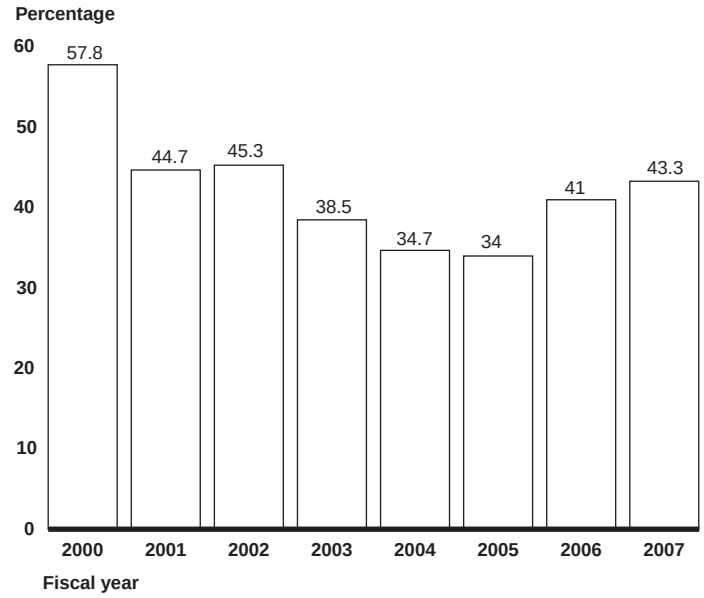



Source: GAO analysis of FDA data.

Note: State-conducted inspections include seven inspections conducted jointly with FDA.

FDA and the states found problems in approximately 41 percent of the fresh produce inspections conducted between fiscal years 2000 and 2007, as shown in figure 6. When inspections find objectionable conditions, it is FDA's practice to give firms an opportunity to take voluntary corrective action before initiating an enforcement action, unless there is significant impact on public health. FDA told us that when an inspection uncovers objectionable conditions, the firm should be reinspected within 2 to 3 years. While FDA noted that the agency is often unable to meet this goal, it also noted that serious problems that warrant regulatory action are likely to trigger a reinspection. More specifically, we were told the agency prioritizes follow-up inspections based on the severity of problems found and a firm's past history of compliance.

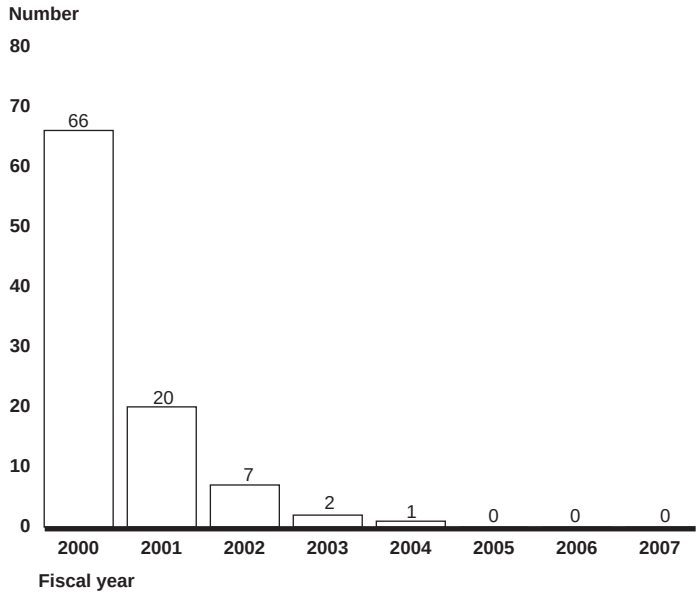
**Figure 6: Percentage of Fresh Produce Inspections Uncovering Problems, Fiscal Years 2000 through 2007**




Source: GAO analysis of FDA data.

We also found that FDA took little enforcement action.[11] Specifically, we identified 96 warning letters related to fresh produce, but their use declined substantially, with 66 issued in fiscal year 2000 and none issued in fiscal years 2005 through 2007, as shown in figure 7. During the same period, according to FDA, the agency seized no fresh produce, sought no injunctions, and prosecuted no firms for fresh produce-related violations. We could not determine the number of less formal enforcement actions taken at the FDA district level, such as sending untitled letters—informal communications used to notify firms that corrective actions are needed—or holding meetings to inform firms of objectionable conditions, because FDA had not centrally compiled such data.

**Figure 7: Fresh Produce-Related Warning Letters, Fiscal Years 2000 through 2007**




Source: GAO analysis of warning letters posted on FDA's Web site.

[11]According to FDA's Office of Chief Counsel, formal enforcement actions available to FDA include initiating a seizure of an adulterated product, obtaining an injunction to stop a company from engaging in a certain behavior, or referring a firm for criminal prosecution. Warning letters are intended to prompt voluntary corrections for violations of regulatory significance. Additionally, FDA may issue a less formal, untitled letter or request a regulatory meeting for less severe violations.

*Most of FDA's sample analysis has focused on pesticides.* In fiscal year 2007, 82 percent of all fresh produce samples were tested for pesticides, while 17 percent were tested for microbial contamination. However, the relative rates of testing differed for domestic and imported produce. FDA officials told us that in the late 1990s, outbreaks of foodborne illness led the agency to focus its domestic food safety program more heavily on microbial contamination, and as a result, the focus of its domestic sample analysis also began to shift. Specifically, in fiscal year 2000, we found that FDA tested 14 percent of domestic produce samples for microbial contamination, compared with 37 percent in fiscal year 2007. According to FDA officials, pesticides remain a larger concern for imported produce, so a significant portion of import testing continues to focus on pesticides. For example, in fiscal year 2007, 92 percent of imported produce samples were tested for pesticides. FDA officials told us that two factors have slowed the agency's shift toward microbial testing. First, pesticides are easier to detect because they are fairly evenly distributed across products, whereas microbial contamination may be sporadic. Second, pesticide testing can be more productive because available methods allow FDA to test one sample for multiple pesticide residues, whereas similar methods are considerably more difficult in microbial testing.

*FDA has provided limited oversight of imported fresh produce.* FDA primarily relies on an electronic screening process to review imported produce at the border—typically only inspecting foreign produce firms for cause, such as a potential link to an outbreak of foodborne illness. The basic import process consists of two stages—prior notice and food safety evaluation. In the first stage, FDA must receive prior notice before a food shipment arrives in the United States. Prior notice information is screened electronically by FDA's import database, the Operational and Administrative System for Import Support (OASIS), for potential risks associated with intentional contamination. Once the prior notice review has been completed, the food safety evaluation is conducted. For this evaluation, OASIS screens each entry line—or portion—of the shipment for risk factors associated with unintentional contamination to determine whether the shipment may proceed automatically or whether it requires further review.[12] In fiscal year 2007, about one-quarter of all fresh produce entry lines received a system "may proceed" designation after this step. If

[12]According to FDA, an entry line means each portion of an import shipment that is listed as a separate item on an import document. Items in an import entry having different tariff descriptions must be listed separately.

an entry line does not receive this designation, an FDA reviewer conducts an on-screen evaluation. OASIS alerts the reviewer to factors that may prompt further action, such as the existence of an import alert or a product meeting the criteria for sampling, and the reviewer then decides whether or not to allow the entry line to proceed. According to an FDA official, in 2007 this on-screen review took an average of about 45 seconds, and the vast majority of entry lines are allowed to continue into domestic commerce. In fiscal year 2007, nearly 99 percent of all fresh produce entry lines were cleared following electronic screening. Entry lines that are held by FDA may be physically examined, sampled, or detained without physical examination.

Food imports in general and fresh produce imports in particular have increased in recent years, and despite allocating additional resources, FDA has not been able to inspect a larger portion of fresh produce imports. Specifically, imported food for human consumption increased 84 percent from fiscal years 2002 through 2007, from about 5.1 million lines to about 9.4 million lines. Fresh produce imports increased about 60 percent over the same period, from about 940,000 lines in fiscal year 2002 to over 1.5 million lines in fiscal year 2007. During this period, the number of fresh produce lines that FDA examined more than quadrupled. Specifically, following the passage of the Bioterrorism Act in 2002, the agency received additional resources to oversee both domestic and imported food, which allowed it to increase the number of imported fresh produce lines examined in fiscal year 2003. Additionally, recognizing the substantial growth in imported products, the agency decided around fiscal year 2004 to shift additional resources to import oversight, according to an FDA official. Doing so enabled FDA to increase further the number and percentage of fresh produce lines it examined, but it has not been able to sustain its inspection rate at the fiscal year 2005 level. Although FDA increased fresh produce examinations from about 9,000 lines in fiscal year 2004 to about 11,000 in fiscal year 2007, the percentage of all fresh produce lines inspected remained at about 0.73 percent, as shown in table 4. Overall, FDA examined 0.77 percent and sampled 0.22 percent of the 7.6 million fresh produce lines imported from fiscal years 2002 through 2007.

**Table 4: Actions Taken on Fresh Produce Entry Lines, Fiscal Years 2002 through 2007**

| Percentage of total lines in parenthesis | | | | | | |
|---|---|---|---|---|---|---|
| | Fiscal year | | | | | |
| **Description** | **2002** | **2003** | **2004** | **2005** | **2006** | **2007** |
| Total import lines | 941,365 | 1,074,076 | 1,249,645 | 1,359,978 | 1,432,316 | 1,503,884 |
| Lines examined | 2,497 | 8,439 | 9,106 | 16,583 | 10,674 | 11,014 |
| | (0.27) | (0.79) | (0.73) | (1.22) | (0.75) | (0.73) |
| Lines sampled | 2,879 | 2,681 | 2,791 | 3,204 | 2,321 | 2,967 |
| | (0.31) | (0.25) | (0.22) | (0.24) | (0.16) | (0.20) |
| Lines detained without physical exam | 1,822 | 1,770 | 2,161 | 1,796 | 2,038 | 1,807 |
| | (0.19) | (0.16) | (0.17) | (0.13) | (0.14) | (0.12) |

Source: GAO analysis of FDA data.

Note: Percentages may be slightly overstated because some lines may have been examined more than once or detained for more than one reason and, therefore, double-counted in our annual totals.

According to FDA officials, import alerts are the agency's primary mechanism for keeping products with a history of violations out of the country, and they use them regularly. Through the use of import alerts, the agency may detain potentially adulterated products at the border without a physical exam. Additionally, import alerts place the burden on the importing firm to demonstrate that the product is safe. However, we found that import alerts covered a very small percentage of fresh produce imports from fiscal years 2002 through 2007. During that period, FDA detained 0.15 percent of all imported fresh produce lines on the basis of import alerts. Officials attributed the small proportion of imports covered by import alerts to the fact that FDA only samples a small portion of imports and only issues an import alert after it finds a problem.

## FDA Has Taken Steps to Improve Response to Outbreaks and Other Emergencies but Continues to Face Challenges

FDA has had some success in improving its response to produce-related emergencies but continues to face challenges. In particular, FDA has had success in improving coordination, partnering with California on outbreak investigations, and piloting a program involving recalled products. While FDA has taken steps to improve its ability to trace outbreaks to their source, it remains extremely difficult to do so for fresh produce. Additionally, FDA lacks authorities that could be useful in responding to food-related emergencies, including mandatory recall authority for foods other than infant formula, and access to certain records during emergencies.

FDA has taken some steps that have helped to improve the agency's response to produce-related emergencies. For example, in 2002, FDA established an Office of Crisis Management within the Office of the Commissioner. Creating this office has enhanced the agency's ability to coordinate its emergency response activities internally and with others. Also, realizing that they often performed parallel investigations for the same outbreak, FDA's Pacific Region and the California Department of Public Health decided to leverage resources by developing a joint emergency response group, called the California Food Emergency Response Team (CalFERT). CalFERT includes highly skilled and experienced investigators and scientists from FDA and California who regularly train together, allowing them to develop a working relationship before an emergency occurs. Both FDA and state officials said that CalFERT enabled them to respond quickly to the 2006 *E. coli* O157:H7 outbreak linked to spinach. Finally, in order to improve consumer awareness of recalled products, FDA started a pilot program in 2007 in which they include a photograph of the label of a recalled food product on their Web site along with the announcement of the recall. FDA is currently evaluating this program, but initial results indicate that it has been effective in helping consumers identify recalled foods.

FDA has also taken steps to improve its ability to trace outbreaks to the source of contamination, but it remains extremely difficult to do so for fresh produce. Traceback investigations are an important part of emergency response because they help identify which products should be recalled and how contamination occurred. The traceback process generally starts at the retail locations implicated in cases of illness and follows the implicated product back through the supply chain to identify a common source. Such investigations can be particularly difficult when they involve fresh produce because produce is highly perishable and may no longer be available for testing when an outbreak is identified. Even when products are available, they often are unlabeled or mixed in packages containing products from multiple sources, making it difficult to identify a specific source of contamination. For example, tomatoes can be very difficult to trace because packing houses often combine shipments from multiple domestic and foreign growers in order to create boxes of similar quality or size. To address some of these challenges, FDA has developed traceback procedures specifically for fresh produce investigations that provide techniques for determining and documenting the distribution and production chain and the source of the product implicated in an outbreak. FDA has also developed farm investigation procedures for cases where contamination may have occurred in the field. Additionally, FDA offers a course to help familiarize FDA and state

inspectors with outbreak investigation procedures on farms. Despite these efforts, traceback remains very difficult for fresh produce, and it remains uncommon for investigations to trace the product back to the field that was likely the source of contamination. CalFERT was able to do so following the 2006 outbreak of *E. coli* O157:H7 in spinach because contaminated product was found in bags with lot numbers.

However, FDA lacks some authorities that could improve its response efforts, including mandatory recall authority for foods other than infant formula and the authority to access some firm records during emergencies. FDA provides assistance to industry during voluntary recalls but does not have the authority to require a firm to issue a recall for any food other than infant formula. When industry issues a recall, FDA assists firms in notifying distributors and consumers, classifies the recall based on the potential threat to human health, and monitors the firm's recall process. Fresh produce recalls are voluntary, and FDA officials acknowledge that firms can ignore an FDA request to initiate a recall. Additionally, while FDA has the authority to access certain records, including processing and shipping records, for a product it reasonably believes is adulterated or presents a threat of serious adverse health consequences or death, it does not necessarily have the authority to access records for related products handled in the same facility. FDA officials acknowledged that they sometimes obtain records from states, since some have broader authority to access firm records. However, having to ask states to obtain records could slow an outbreak investigation.

## Proposed Actions Could Significantly Enhance Fresh Produce Oversight, but More Information Is Needed to Assess the Likelihood of Success

Through the *Food Protection Plan*, FDA has proposed actions and identified additional authorities that could significantly enhance its oversight of fresh produce within the plan's framework of prevention, intervention, and response. However, FDA has not provided sufficient information on strategies and resources for implementing the plan, which makes it difficult to assess the likelihood of success.

## FDA's Plans to Help Fill Gaps in Scientific Knowledge and Issue New Guidance and Regulations Could Enhance Prevention Efforts

To help prevent contamination of fresh produce, FDA plans to help fill gaps in scientific knowledge and issue new guidance and regulations, and has cited in its *Food Protection Plan* a need for explicit authority to issue regulations that are intended to prevent contamination. Specifically, FDA intends to:

- *Help expand scientific information on fresh produce safety*. FDA plans to expand knowledge on fresh produce safety. For example, FDA is working with researchers from several universities to carry out a USDA-funded project looking into options for reducing the risk of *E. coli* O157:H7 in leafy greens from production to packaging. Also, in June 2008, FDA announced the establishment of the Western Center for Food Safety at the University of California, Davis, which will create a research, education, and outreach program focused on the interface between agriculture and food safety. The center plans to focus its initial research on produce safety, such as safe agricultural practices for domestic and imported commodities. FDA also plans to strengthen its current qualitative risk ranking of food commodities and pathogens, starting with fresh produce items. In addition, FDA announced in June 2008 that it will fund approximately $1 million in extramural research grants that address fresh produce safety topics, such as how consumer handling of fresh-cut produce may compromise microbiological safety and problems that occur during transportation. To help shape outside research and update its 8-year-old list of research needs, FDA officials told us that CFSAN is developing a plan that outlines priority research needs, including produce safety research. According to FDA officials, CFSAN has just begun to develop this plan, and it may take several months before it is available. Finally, FDA officials told us that they would like to have voluntary access to data from producers for research purposes. For example, some fresh produce firms have testing records that show when they have found *E. coli* O157:H7 or Salmonella in product samples. FDA officials noted that they are interested in conglomerate data stripped of identifiers, but that in order to use industry data, they would need to find ways to effectively address industry members' reluctance to share such information.

- *Update existing fresh produce-related guidance and regulations*. FDA officials told us they plan to update the agency's 1998 good agricultural practices guidance to incorporate new knowledge about safe growing practices for fresh produce. FDA also has plans to update its current good manufacturing practice regulations for food, which were last updated in 1986 and which guide, among other things, domestic inspections of fresh-cut produce facilities. While both efforts could enhance FDA's oversight and assist industry in producing safe produce

items, at the time of our review, FDA officials said they had not yet started to update the agency's good agricultural practices guidance because of limited resources. Furthermore, progress on updating the current good manufacturing practice regulations for food has been slow since the effort began in 2002, and officials could not provide an estimate of their completion date.

- *Seek authority to issue preventive safety regulations for foods such as fresh produce*. FDA, in the *Food Protection Plan*, identified a need for explicit authority from the Congress to issue regulations to require preventive measures by firms producing foods that have been associated with repeated instances of serious health problems or death. FDA already has preventive regulations for seafood and juice, which require firms to analyze safety hazards and implement plans to address those hazards. According to FDA, such authority would strengthen the agency's ability to implement risk-based processes to reduce illnesses from high-risk foods. We have previously recommended the use of such preventive safety regulations for chemicals,[13] and FDA officials told us that issuing preventive regulations may be one of the most important things they can do to enhance their oversight of fresh produce. While some consumer groups, food safety experts, and producers agree that uniform standards could enhance safety for targeted foods, others have noted that preventive regulations can take a long time to develop and it may be difficult to incorporate new scientific knowledge into regulations. FDA officials expressed concern about the public health benefit of having regulations without the resources to enforce them. FDA could not provide us with information on projected costs associated with such regulations, but FDA's Science Board noted that modernizing safety standards for fresh produce and other raw foods, and implementing accompanying inspection programs could total $210 million.

## FDA Has Planned Several Actions to Enhance the Effectiveness of Its Intervention Efforts

To enhance the effectiveness of its intervention efforts, FDA plans to use more systematic, risk-based criteria to more formally target domestic inspections and introduce a new import screening tool and has identified a need for authority to accredit third parties. All these efforts have the potential to increase the effectiveness of fresh produce oversight and better leverage resources. Specifically FDA intends to:

[13]GAO, *Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food*, GAO/RCED-94-192 (Washington, D.C.: Sept. 26, 1994).

- *Use more information to target domestic inspections*. FDA plans to enhance its risk-based criteria for determining which facilities to inspect by including more information, such as a firm's previous inspection results, recalls, and association with outbreaks and adverse events. FDA officials told us that they have already begun to use some new risk-based information to plan fiscal year 2009 inspections and that, as new information from FDA's ongoing risk-ranking efforts becomes available, they will continue to incorporate that as well.

- *Use a new screening tool for imports*. FDA officials are testing a software tool called Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) that uses information sources and automated data mining techniques not available to OASIS to detect possible problems in import shipments. For example, PREDICT can use up-to-date data from FDA laboratory tests and other information, such as weather events that could affect water quality, to identify import entries for further review. PREDICT was pilot-tested on seafood imports in mid-2007 in FDA's Los Angeles district office, and the pilot test received a positive evaluation. Former FDA officials have praised PREDICT for its potential to enhance overall food safety oversight, and FDA officials noted that the tool may be particularly useful for fresh produce imports because PREDICT can make use of the agency's testing data for imported fresh produce, which is not currently used in FDA's electronic screening. FDA officials plan to increase the number of high-risk food products and test PREDICT at a border crossing by March 2009.

- *Seek authority to accredit third parties*. Obtaining the authority to accredit third parties could help FDA leverage its inspection resources, and FDA officials told us they believed third-party inspections would be especially helpful for imports, as FDA inspects few foreign food firms. However, FDA does not envision accrediting third parties for fresh produce inspections until the agency has established or assessed the adequacy of clear preventive standards. FDA has already taken this approach by accrediting third parties to inspect manufacturers of medical devices, as authorized by the Congress, and we recently reported that few inspections have been conducted under FDA's accredited programs.[14] However, FDA officials told us that an inspection program for foods could be more attractive because importers and consumers might be more willing to buy products

[14]GAO, *Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, GAO-08-428T (Washington, D.C.: Jan. 29, 2008).

certified by FDA-approved third parties, and third-party certification might expedite FDA review and the entry of perishable commodities into the United States. While third-party inspectors could provide several benefits, FDA officials told us that before consistent, reliable third-party inspections would be feasible for fresh produce, the agency would first need to establish or assess the adequacy of clear preventive standards. For this reason, they told us that FDA would likely use a third-party inspection system for items such as seafood and juice before expanding a program to fresh produce. While USDA has expressed concern that third-party inspections paid for by the companies whose facilities were being inspected may not provide effective enforcement for noncompliant firms, FDA officials noted that the use of accredited third-party inspections would be voluntary and that FDA would not waive any of its authorities.

## FDA Has Efforts Under Way That Could Improve Its Response to Emergencies

FDA has efforts under way to enhance its response to food-related emergencies, including enhancing traceback investigations, organizing more federal-state emergency response teams, and improving risk communications. The agency has also identified the need for mandatory recall authority. These efforts could increase the overall effectiveness of FDA's response to outbreaks linked to fresh produce. Specifically, FDA plans to:

- *Enhance traceback efforts.* FDA officials told us they have several efforts under way to enhance traceback investigations, including establishing a working group and purchasing new laboratory equipment. Also, the *Food Protection Plan* identifies a need for enhanced access to firm records. First, the agency has established a working group that has been meeting with industry groups and consumers to gather information and then report on key elements of effective traceback systems. Using this information, FDA plans to develop guidance for industry on traceback systems. Also, FDA has purchased equipment that will enable the agency to more rapidly screen for and accurately identify variants of *Salmonella* in fresh produce and other foods. Being able to identify *Salmonella* variants will enhance FDA's ability to investigate outbreaks. Last, FDA stated in its *Food Protection Plan* that it needs additional authorities to provide improved access to companies' records in a food-related emergency to help the agency quickly identify sources of contamination and take action.

- *Organize more federal-state emergency response teams*. FDA hopes to develop additional federal-state emergency response teams. At the time of our review, FDA was soliciting interest from states and hoped to start developing teams in six states in fiscal year 2009. According to FDA officials, training is an important part of developing these teams, and FDA is working with the Western Institute for Food Safety and Security to create an effective training program for participating states. Officials noted, however, that one of the reasons for the success of CalFERT during the 2006 outbreak was the high level of expertise of CalFERT officials and that similar results may not always be replicable in other states.

- *Improve risk communications*. In February 2008, FDA first convened an expert committee called the Risk Communication Advisory Committee to provide information on ways for FDA to enhance communications during emergencies, such as foodborne illness outbreaks linked to fresh produce. FDA also has plans to conduct studies on consumer communications. Using this information, FDA plans to update its risk communications plan. While these actions could improve FDA's methods for sharing information, the advisory committee has only met twice, and other actions have not yet been completed, so it is too early to tell what effect they will ultimately have.

- *Seek authority to order a recall*. In the *Food Protection Plan*, FDA identified the need for authority to order a recall when FDA has reason to believe that food is adulterated and presents a threat of serious adverse health consequences, which would be imposed only if a company refuses or unduly delays a voluntary recall. Currently, FDA does not have the authority to compel companies to recall contaminated food other than infant formula. FDA does have the authority, through the courts, to seize, condemn, and destroy adulterated or misbranded food and to disseminate information about food items that are believed to present a danger to public health. We have previously noted that limitations in FDA's recall authority heighten the risk that unsafe food will remain in the food supply.[15] In the case of fresh produce, FDA officials told us they were aware of no case where a fresh produce firm refused FDA's recall request, and a

[15]GAO, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Attention to Limitations in the Federal Government's Food Recall Programs*, GAO-07-785T (Washington, D.C.: Apr. 24, 2007) and GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, GAO-05-51 (Washington, D.C.: Oct. 6, 2004).

former FDA official told us that mandatory recall authority may be less useful for fresh produce items that are highly perishable and may no longer be in commerce by the time FDA becomes involved in an outbreak response.

## Limited Information on Strategies and Resources Makes It Difficult to Assess the Likelihood of FDA's Success

FDA issued its first progress report in July 2008 on its 2007 *Food Protection Plan*, and FDA officials told us that the plan has already had a positive effect on food safety by helping to increase the visibility of food protection during the agency's internal budget process. It has also aided FDA in prioritizing its efforts and has led to greater coordination within FDA to address issues that cut across different FDA centers. We have noted that public reporting is the means through which the federal government communicates the results of its work to the Congress and the American people. Such reporting is in the public interest and promotes transparency in government operations. The *Food Protection Plan* contains overarching goals to prevent foodborne contamination, intervene at critical points in the food supply chain, and respond rapidly to minimize harm. However, FDA has provided limited information on strategies and resources, making it difficult to assess the likelihood of achieving these goals. While FDA has released information on spending priorities on its short and medium term efforts for fiscal years 2008 and 2009, it has still not publicly provided information on the full costs of implementing the *Food Protection Plan* or committed to timelines for implementing produce-focused elements of the plan. Information on strategies and resources is increasingly critical, given that important elements of the plan could be highly resource-intensive. This lack of information, coupled with FDA's resource constraints and slow progress on some food protection efforts, such as updating good agricultural practices guidance or issuing guidance for fresh-cut produce operations, decreases public accountability and raises concerns about whether FDA will have the capacity to fully implement the plan.

Additionally, the *Food Protection Plan* recognizes that FDA needs to partner with the Congress to make the changes necessary to transform the safety of the nation's food supply, including legislative changes to strengthen FDA's ability to protect Americans from foodborne illness. However, as we testified in June 2008, FDA's congressional outreach strategy is general. For example, when we asked FDA officials if they had a congressional outreach strategy, they told us that they had met with various congressional committees to discuss the *Food Protection Plan*. When asked if they had provided draft language to congressional committees on the various authorities, FDA officials explained that they

only provided technical assistance, such as commenting on draft bills, to congressional staff when asked.

## Conclusions

Fresh produce is essential to a healthy diet and to the health of the industry that produces it. However, fresh produce poses particular safety challenges because it is often consumed raw without any type of treatment that would reduce or eliminate pathogens prior to consumption. FDA plays a critical role in ensuring the safety of fresh produce, yet it has struggled to fulfill that role because of resource constraints, gaps in science, and lack of legal authorities. Specifically, FDA last set its research priorities 8 years ago and has not systematically worked with others to supplement its research agenda, including research relating to fresh produce. FDA's 1998 good agricultural practices guidance has not been updated, and its current good manufacturing practice regulations for food, which includes fresh-cut produce operations, was last revised in 1986. Also, through the *Food Protection Plan*, FDA has proposed actions and identified a need for additional authorities related to preventive controls for high-risk foods and access to certain records that could significantly enhance the agency's oversight of fresh produce. However, the timelines and resources needed to fully implement the plan are unclear. To increase congressional and public confidence and fulfill its mission of protecting public health, it is imperative that FDA follow through on its planned actions to enhance fresh produce oversight, seek needed authorities from the Congress, and foster transparency and accountability by providing specific information to the Congress and to the public on strategies and resources for implementing its *Food Protection Plan*.

## Recommendations for Executive Action

We are making seven recommendations to the Commissioner of FDA.

To enhance FDA's oversight of fresh produce safety, we recommend that the Commissioner of FDA see that the agency takes the following actions:

- develop a plan for identifying research priorities and facilitating research related to fresh produce;
- identify approaches for obtaining testing and other information from industry members to inform its research agenda;
- update its good agricultural practices guidance for fresh produce to incorporate new knowledge about safe growing practices; and

- update its current good manufacturing practice regulations for food to incorporate new knowledge about the food industry and safe manufacturing, processing, and holding practices.

To enhance FDA's authority to oversee fresh produce, we recommend that the Commissioner of FDA seek authority from the Congress to

- make explicit FDA's authority to adopt preventive controls for high-risk foods, and
- provide FDA enhanced access to firm records during food-related emergencies.

To foster transparency and accountability, we recommend that the Commissioner of FDA provide specific information to the Congress and to the public on the strategies and resources for implementing the *Food Protection Plan*.

## Agency Comments and Our Evaluation

We provided a draft copy of this report to the Department of Health and Human Services for review and comment. We received a written response from the Assistant Secretary for Legislation that included comments from FDA. FDA generally agreed with the report's accuracy and conclusions and appreciated our recognition of the *Food Protection Plan* as a sound framework for advancing food safety and food defense and our use of the plan as an organizing feature for this report. FDA generally agreed with five of the report's recommendations and disagreed with two others. FDA's comments and our detailed responses are presented in appendix III of this report.

FDA agreed with our recommendation to develop a plan for identifying research priorities and facilitating research related to fresh produce. FDA said that both CFSAN and the agency, as part of the *Food Protection Plan*, were developing strategic plans for research, including fresh produce-related research. FDA said that CFSAN's plan will identify regulatory research priorities that can be addressed through intramural and extramural research, as well as future research needs that cannot be addressed due to resource limitations.

FDA also agreed with our recommendation to identify approaches for obtaining testing and other information from industry members to supplement its research agenda. FDA noted, however, that the data and information from industry would further inform, rather than supplement,

the agency's research agenda and would also be used in agency risk assessments associated with fresh produce. We revised the recommendation accordingly.

FDA agreed with our recommendation to update its good agricultural practices guidance for fresh produce to incorporate knowledge about safe growing practices. FDA said the agency recognized, when it issued the guidance in 1998, that it would need to be updated in light of new information and technological advances. FDA added that the agency has completed or is doing many of the actions necessary to update the guidance. FDA stated that it will update the guidance once it evaluates the data and information collected through these efforts.

FDA also agreed with our recommendation to update its current good manufacturing practice regulations for food to incorporate new knowledge about the food industry and safe manufacturing, processing, and holding practices. FDA said that a working group has examined the regulations and identified those areas where risk-based preventive controls would have the greatest impact on ensuring food safety.

While FDA agreed with the importance of having explicit authority to adopt preventive controls for high-risk foods and having enhanced access to firm records during food-related emergencies, the agency believes that it has already sought such authorities by outlining legislative needs in the *Food Protection Plan* and testifying on the plan before congressional committees. We do not view these actions as seeking authority. Rather, as FDA recognized, there is a need for the agency to partner with the Congress to make the necessary changes to transform the safety of the nation's food supply. FDA should move beyond outlining needs and continue to take steps to obtain these legislative authorities such as by suggesting language that provides FDA the necessary statutory tools to help the agency conduct its oversight responsibilities. FDA proposed that these recommendations be redirected to the Congress for action and refers to a prior recommendation we made that the Congress enact comprehensive, uniform, and risk-based food safety legislation. We reiterated this recommendation to the Congress most recently in our High-Risk Series[16] as one action that can help address the fragmented federal oversight of food safety and integrate the myriad food safety programs. Our recommendations to FDA are intended to enhance FDA's authority to

[16]GAO-07-310.

oversee fresh produce for which FDA has primary responsibility. We stand by these recommendations.

Finally, FDA generally agreed with our recommendation to provide specific information to the Congress and to the public on the strategies and resources for implementing the *Food Protection Plan*. FDA agreed with the need for transparency and accountability and noted that the agency has provided information to the Congress on the implementation of the *Food Protection Plan*. In addition, we believe that FDA should publicly release information on strategies and resources, including information on the full costs of implementing the *Food Protection Plan* and timelines for produce-focused elements of the plan. As stated in our report, such information would help the public assess the likelihood of achieving the goals stated in the *Food Protection Plan*.

We are sending copies of this report to interested congressional committees, the Secretary of Health and Human Services, and the Commissioner of the Food and Drug Administration. We will also provide copies to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-3841 or shamesl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix IV.

Lisa Shames
Director, Natural Resources
and Environment

# Appendix I: Objectives, Scope, and Methodology

This report examines (1) the dollars and staff years the Food and Drug Administration (FDA) has spent on fresh produce safety and how FDA has allocated those resources, (2) the effectiveness of FDA's actions to oversee domestic and imported fresh produce safety, and (3) the actions FDA plans to take to enhance fresh produce oversight and the extent to which FDA's planned actions address identified challenges. For this report, fresh produce means fruits and vegetables in their unpeeled, natural form, as well as fruits and vegetables that have been minimally processed (e.g., peeled, sliced, or chopped), with or without washing, before being packaged for use by the consumer or a retail establishment. It does not include frozen or canned fruits and vegetables or fruit and vegetable juices. Food safety includes work in support of FDA's Foods Program, excluding cosmetics, and Animal Drugs and Feeds Program, excluding medical products.

To determine the dollars and staff years FDA has spent on fresh produce safety, we obtained and analyzed FDA data on food safety and fresh produce safety spending. We used the food safety data to provide context for assessing the relative importance of fresh produce spending and the decisions leading to food safety resource allocations. For both food safety and fresh produce safety spending, some data were obtained directly from FDA databases, and others were estimated by FDA officials.

*Food safety spending.* We requested information on the dollars and staff years spent on food safety each fiscal year from 2000 through 2007, as well as detailed spending reports showing the dollars and staff years spent on specific food safety activities for each fiscal year from 2005 through 2007, by the five FDA organizations that conducted food safety work—the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the Office of Regulatory Affairs (ORA), the National Center for Toxicological Research (NCTR), and the Office of the Commissioner. The Office of the Commissioner's work in support of the agency's food safety efforts is generally considered overhead, except for specific food safety activities such as those performed by FDA's Associate Commissioner for Food and the Office of Crisis Management. We selected fiscal years 2000 through 2007 to update a previous GAO report which detailed food safety spending through fiscal year 1999.[1] Four organizations

[1]GAO, *Food Safety: Overview of Federal and State Expenditures*, GAO-01-177 (Washington, D.C.: Feb. 20, 2001).

used time and attendance and workflow management systems to identify hours spent on food safety and then converted the hours into staff years.

- CFSAN used the Resource Reporting System Via Project, its voluntary time reporting system, which captures staff hours spent on one of seven general categories, including four that fall within GAO's definition of food safety,[2] and on specific activities within these categories.

- CVM used the Activity Time Reporting system, its mandatory time reporting system.

- ORA used the Field Accomplishment and Compliance Tracking System (FACTS), its workflow management system, which captures staff time spent on domestic activities, such as inspections or sample analysis, as well as certain import activities, such as sample collections or field exams.

- NCTR used the Project Management System, which contains, among other things, staff and contractor hours downloaded from its NCTR Experiment Activity Tracking System, the center's time and attendance system, as well as contractor hours downloaded from its Task Tracking System.

The Office of the Commissioner calculated its food safety staff years to be 34.6 percent of its total staff years—the percentage it typically uses in FDA's budget justification documents.

To determine the dollars CFSAN spent on food safety, FDA ran their food safety staff years against the agency's Unified Financial Management System. To determine the dollars NCTR spent on food safety, FDA used cost data on projects from the center's Project Management System and the agency's Unified Financial Management System to summarize spending on food safety research projects. To determine dollars ORA spent on food safety, FDA ran its food safety staff years against ORA's actual budget authority dollars from the All Purpose table of the agency's annual budget justification. For the dollars CVM spent on food safety, FDA

[2]These four categories are food safety, food defense, dietary supplements, and nutrition and labeling.

used CVM's budget authority dollars from the All Purpose table to reflect GAO's definition of food safety because CVM could not isolate medical products spending from other spending. In terms of overhead, the Office of the Commissioner estimated that each year's food safety spending amounted to 34.6 percent of its annual budget authority—the percentage it typically uses in FDA's budget justification documents. Additionally, ORA and CVM included overhead in each activity's spending, while CFSAN and NCTR reported it as a separate expense.

*Produce safety spending.* We requested information on the dollars and staff years FDA spent each fiscal year from 2000 through 2007. However, due to resource constraints and other limitations within FDA that made it unlikely the agency could provide data or estimates prior to fiscal year 2005, we agreed to narrow our request to fiscal years 2005 through 2007. In addition, FDA was unable to provide its actual spending on fresh produce safety and instead developed estimates, with each of the three organizations involved in produce safety during this period—CFSAN, ORA, and the Office of the Commissioner—employing the same sources and methodology it used to prepare food safety spending data.

- CFSAN could only provide estimates of the dollars and staff years spent on fresh produce safety because its time management system is voluntary and staff are not required to report their time with the specificity needed to distinguish time spent on fresh produce activities from time spent on other food safety activities. Additionally, due to changes in its voluntary time reporting system, CFSAN could provide these estimates only for fiscal years 2006 and 2007. Further, CFSAN's spending estimates reflect only the minimum dollars and staff years spent on fresh produce because staff attributed over half of their food safety staff years to the general category called "food safety," rather than to a specific activity, such as "produce safety."

- ORA was able to track its spending at the fresh produce level for fiscal years 2005 through 2007 because field staff generally enter a commodity code into ORA's work management system as they report time spent on their work activities. However, ORA officials cautioned that their spending data were also estimates because a small number of commodities were coded as miscellaneous and certain activities, such as reviewing imported items for admissibility, do not require staff to report the specific commodity involved.

- The Office of the Commissioner could provide neither data nor estimates of its fresh produce spending. Although some staff—such as the Associate Commissioner for Foods and those in the Office of Crisis Management—work on fresh produce safety, the office's systems do not track spending at the level of specificity needed to, for example, distinguish food-related emergencies from nonfood emergencies or foodborne illness outbreaks involving fresh produce from outbreaks involving other foods.

We reviewed the methodologies FDA used to develop the data and the estimates, interviewed those staff most knowledgeable about the quality and completeness of the estimated data, and conducted tests of the data for errors and missing information. When errors or missing data were found, FDA officials corrected these errors and provided us with revised data. On the basis of this information, we assessed the reliability of the data on food safety spending and the estimates on fresh produce spending and determined that the data and estimates are sufficient and appropriate to support the conclusions reached in this report. We then summarized and analyzed the data and estimates to calculate the total dollars and staff years FDA spent each fiscal year on food safety and fresh produce safety. Due to the nature of the estimates, we were unable to assess fresh produce spending over time to determine whether spending increased or draw specific conclusions about the portion of FDA's food safety resources spent on fresh produce.

To determine how FDA has allocated its resources for fresh produce safety, we interviewed staff knowledgeable about the budget and priority-setting processes used by CFSAN, ORA, and the Office of the Commissioner; obtained and analyzed budget and planning documents on agency and center priorities and strategic plans; interviewed current and former FDA officials about the agency's food safety and fresh produce safety work, as well as the obstacles faced in implementing planned work; obtained and analyzed reports from FDA and others on the agency's food safety resources; and interviewed food safety experts and industry representatives for their perspectives on FDA's ability to ensure the safety of fresh produce.

To assess the effectiveness of FDA's actions to oversee fresh produce, we visited produce farms and processing facilities in California's Salinas Valley, where we interviewed growers, processors, and industry

representatives, and observed an FDA inspection of a fresh-cut produce facility. We selected the Salinas Valley because it was the source of the 2006 *E. coli* outbreak linked to bagged spinach. Also, we interviewed persons knowledgeable about FDA's oversight activities related to fresh produce, including current and former FDA officials, state food safety officials, industry officials, and food safety experts. We reviewed relevant FDA documents, including policies and procedures, regulations and guidance documents for industry pertaining to fresh produce, and descriptions of research needs and current research projects. We also reviewed guidance documents prepared by industry and obtained information on fresh produce safety standards promoted by other entities. We obtained and analyzed FDA data on domestic inspections and domestic and imported sample analyses from the FACTS database, and FDA data on imported fresh produce trends and activities from the Operational and Administrative System for Import Support database. We assessed the reliability of the data used in this report and found it to be sufficiently reliable for the purposes used. We also obtained and analyzed information on state contracts and partnerships from FDA officials and fresh produce-related warning letters from FDA's Web site.

To determine the actions FDA plans to take to enhance fresh produce oversight, we reviewed published information from FDA, including its *Food Protection Plan*, *Food Protection Operations Plan*, and *Federal Register* notices. We also reviewed internal FDA documents and interviewed FDA officials for additional details on published information. To assess the extent to which FDA's planned actions address identified challenges, we reviewed previous GAO reports and recommendations on food safety, food safety publications from the National Academies, and GAO guidance for assessing key elements in agencies' performance plans, including goals, strategies, and resources.[3] We also interviewed and obtained documents from former FDA officials, officials from the U.S. Department of Agriculture and state food safety agencies, academics, and representatives of industry and consumer groups to obtain information related to FDA's planned actions.

[3]GAO, *Agencies' Annual Performance Plans under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking*, GAO/GGD/AIMD-10.1.18 (Washington, D.C.: February 1998).

We conducted our work from June 2007 to September 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

# Appendix II: FDA Food Safety Spending Information for Fiscal Years 2000 through 2007

This appendix contains information provided by FDA on the dollars and staff years it spent on food safety from fiscal years 2000 through 2007. For this report, food safety includes work in support of FDA's Foods Program, excluding cosmetics, and Animal Drugs and Feeds Program, excluding medical products.

Five organizations within FDA provided food safety spending information, including

- the Center for Food Safety and Applied Nutrition (CFSAN), which administers the FDA Foods Program;
- the Center for Veterinary Medicine (CVM), which administers the Animal Drugs and Feeds Program;
- the Office of Regulatory Affairs (ORA), which conducts field work in support of FDA's centers and their programs;
- the National Center for Toxicological Research, which conducts scientific research and provides technical advice in support of FDA's centers; and
- the Office of the Commissioner, which provides direction and administrative services in managing FDA's food safety efforts.

The information provided by each organization varies in the level of detail and the time period covered.

**Table 5: Summary of FDA Food Safety Spending, by Organization, Fiscal Years 2000 through 2007**

Dollars in millions

| | 2000 | | 2001 | | 2002 | |
|---|---|---|---|---|---|---|
| **Organization** | **Dollars** | **Staff years** | **Dollars** | **Staff Years** | **Dollars** | **Staff years** |
| Center for Food Safety and Applied Nutrition (CFSAN) | $120.9 | 793 | $122.2 | 842 | $140.3 | 894 |
| ORA fieldwork in support of CFSAN | 154.2 | 1,545 | 160.5 | 1,554 | 248.9 | 1,799 |
| Center for Veterinary Medicine (CVM) | 36.5 | 271 | 48.4 | 290 | 55.7 | 323 |
| ORA fieldwork in support of CVM | 12.5 | 128 | 14.8 | 144 | 28.4 | 235 |
| National Center for Toxicological Research[b] | 3.9 | 24 | 3.0 | 19 | 8.0 | 27 |
| Office of the Commissioner[c] | 23.0 | 226 | 23.5 | 233 | 28.4 | 231 |
| **Total** | **$351.1** | **2,988** | **$372.4** | **3,082** | **$509.7** | **3,509** |

| Fiscal year | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2003 | | 2004 | | 2005 | | 2006 | | 2007 | |
| Dollars | Staff years | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years |
| $143.8 | 921 | $140.9 | 881 | $148.4 | 786 | $150.3 | 816[a] | $157.1 | 744 |
| 257.9 | 2,203 | 260.8 | 2,157 | 281.4 | 2,045 | 283.5 | 1,950 | 296.1 | 1,793 |
| 57.1 | 341 | 54.5 | 346 | 55.4 | 330 | 54.8 | 321 | 58.4 | 318 |
| 29.0 | 242 | 27.5 | 234 | 33.4 | 229 | 33.0 | 206 | 34.6 | 208 |
| 7.9 | 36 | 7.4 | 36 | 6.5 | 34 | 10.3 | 36 | 11.5 | 37 |
| 29.1 | 226 | 31.2 | 199 | 30.2 | 176 | 29.6 | 184 | 31.6 | 181 |
| **$524.8** | **3,969** | **$522.4** | **3,853** | **$555.3** | **3,599** | **$561.6** | **3,513** | **$589.1** | **3,281** |

Source: GAO analysis of FDA data.

Notes: Numbers may not add due to rounding.

[a]CFSAN's staff years spent in fiscal year 2006 exceeded its budget authority due to the inclusion of overtime and credit hours.

[b]Spending includes dollars received from other government agencies and external sources for collaborative efforts.

[c]The Office of the Commissioner developed an overhead figure of 34.6 percent of its budget authority to reflect dollars and staff years spent on food safety.

**Table 6: CFSAN Food Safety Spending, by Category, Fiscal Years 2006 and 2007**

Dollars in millions

| | Fiscal year | | | |
|---|---|---|---|---|
| | 2006 | | 2007 | |
| Category | Dollars | Staff years | Dollars | Staff years |
| Food defense | $20.6 | 113 | $22.5 | 89 |
| Food safety[a] | 102.3 | 550 | 108.4 | 531 |
| Nutrition | 4.7 | 36 | 4.3 | 26 |
| Dietary supplements | 5.1 | 26 | 5.7 | 26 |
| Overhead[b] | 17.6 | 91 | 16.2 | 71 |
| **Total** | **$150.3** | **816** | **$157.1** | **744** |

Source: FDA.

Notes: Numbers may not add due to rounding. CFSAN was not able to provide data at this level of detail prior to fiscal year 2006. Also, CFSAN's total food safety spending includes $18 million in fiscal year 2006 and $28 million in fiscal year 2007 in work conducted through major contracts—each totaling at least $200,000—with other government agencies, as well as external organizations and individuals.

[a]Food safety refers to CFSAN's traditional definition of food safety—the unintentional contamination of food.

[b]Overhead represents CFSAN's prorated share of the agency's overhead, such as human resources, information technology, management services, and telephone expenses.

**Table 7: ORA Food Safety Spending in Support of CFSAN, by Category, Fiscal Years 2005 through 2007**

Dollars in millions

| | Fiscal year | | | | | |
|---|---|---|---|---|---|---|
| | 2005 | | 2006 | | 2007 | |
| Category | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years |
| **Chemical safety of foods** | | | | | | |
| Pesticides and industrial chemicals in foods (domestic and import) | $23.2 | 181 | $19.2 | 139 | $21.3 | 136 |
| Mycotoxins in foods (domestic and import) | 5.6 | 44 | 5.7 | 41 | 5.9 | 38 |
| Food and color additives (import) | 4.7 | 37 | 5.1 | 37 | 6.1 | 39 |
| Toxic elements in foods (domestic and import) | 4.8 | 37 | 4.0 | 29 | 4.2 | 27 |
| Chemotherapeutics in seafood | 3.3 | 26 | 4.1 | 29 | 3.9 | 25 |
| Field assignment for chemical contaminants | 2.8 | 22 | 1.7 | 12 | 1.3 | 8 |
| Forensic analysis[a] | 2.1 | 16 | 2.0 | 15 | 1.4 | 9 |
| Toxic elements in foodwares (domestic and import) | 2.0 | 15 | 1.8 | 13 | 1.6 | 10 |
| Radionuclides in foods | 0.2 | 1 | 0.3 | 2 | 0.7 | 4 |
| Pet food recall (human foods) | 0.0 | 0 | 0.0 | 0 | 2.4 | 15 |
| **Microbiological safety of foods** | | | | | | |
| Cheese program (domestic and import) | 7.2 | 56 | 7.1 | 51 | 7.5 | 48 |
| Retail food protection program (general) | 5.7 | 44 | 6.5 | 47 | 7.1 | 46 |
| Interstate travel program | 5.8 | 45 | 5.7 | 41 | 6.0 | 38 |
| Domestic acidified and low acid canned food program | 4.2 | 33 | 5.2 | 38 | 5.2 | 33 |
| Microbiological assignment (domestic and import) | 4.0 | 31 | 4.9 | 35 | 2.3 | 15 |
| Interstate milk shippers program | 4.3 | 33 | 4.6 | 34 | 6.1 | 39 |
| Import acidified and low acid canned food program | 3.5 | 27 | 3.9 | 28 | 4.1 | 26 |
| Molluscan shellfish evaluation program | 3.2 | 25 | 3.6 | 26 | 4.1 | 26 |
| Audits of state food contract inspections | 1.2 | 10 | 2.0 | 14 | 2.5 | 16 |
| Natural disasters and emergencies | 0.9 | 7 | 4.7 | 34 | 0.1 | <1 |
| **Nutrient quality and food labeling** | | | | | | |
| Nutrition Labeling and Education Act, nutrient sample analysis, and general food labeling | 7.7 | 60 | 7.8 | 56 | 8.5 | 54 |
| Dietary supplements program | 3.0 | 23 | 3.0 | 22 | 2.5 | 16 |
| Medical foods (domestic and import) | 1.5 | 12 | 0.9 | 7 | 0.9 | 6 |
| Infant formula | 1.1 | 9 | 1.8 | 13 | 1.5 | 10 |
| Health fraud (foods) | 0.6 | 5 | 0.7 | 5 | 0.9 | 6 |
| Food economics and standards | 0.4 | 3 | 0.4 | 3 | 0.2 | 1 |

Dollars in millions

| | Fiscal year | | | | | |
|---|---|---|---|---|---|---|
| | 2005 | | 2006 | | 2007 | |
| Category | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years |
| **Cross-cutting** | | | | | | |
| Imported foods (general) | 58.7 | 458 | 64.2 | 464 | 72.6 | 465 |
| Domestic food safety program (general) | 23.9 | 186 | 24.9 | 180 | 22.3 | 143 |
| Domestic seafood hazard analysis and critical control point program | 23.2 | 181 | 20.9 | 151 | 20.6 | 132 |
| Imported seafood hazard analysis and critical control point program | 22.0 | 172 | 22.3 | 161 | 21.7 | 139 |
| Total diet studies | 6.8 | 53 | 8.9 | 64 | 8.6 | 55 |
| Counterterrorism activities | 6.8 | 53 | 2.8 | 21 | 2.3 | 15 |
| Consumer complaints | 4.8 | 38 | 5.0 | 36 | 4.3 | 28 |
| Methods validation and development | 4.1 | 32 | 4.4 | 32 | 4.7 | 30 |
| Juice hazard analysis and critical control point program | 3.1 | 24 | 3.9 | 28 | 4.2 | 27 |
| Short-term assignments initiated by CFSAN headquarters, ORA headquarters, or ORA field offices | 2.0 | 16 | 2.0 | 14 | 1.5 | 10 |
| Foreign inspections and technical assistance | 1.7 | 13 | 1.6 | 12 | 1.4 | 9 |
| Emergency response to foodborne outbreaks and illnesses | 0.9 | 7 | 1.2 | 8 | 7.1 | 46 |
| Miscellaneous other food safety work | 0.6 | 5 | 0.7 | 5 | 0.3 | 2 |
| Criminal investigation activities | 0.6 | 5 | 0.6 | 4 | 0.4 | 2 |
| **Subtotal** | **262.3** | **2,045** | **270.0** | **1,950** | **280.3** | **1,793** |
| State contracts and grants | 19.1 | 0 | 13.5 | 0 | 15.8 | 0 |
| **Total** | **$281.4** | **2,045** | **$283.5** | **1,950** | **$296.1** | **1,793** |

Source: GAO analysis of FDA data.

Notes: Numbers may not add due to rounding. ORA included overhead for each activity as part of the activity's total dollars and staff years spent.

[a]Spending on other forensic analysis work is included in activities where work occurred.

**Table 8: Center for Veterinary Medicine Spending on Food Safety, by Category, Fiscal Years 2000 through 2007**

Dollars in millions

| | 2000 | | 2001 | | 2002 | |
|---|---|---|---|---|---|---|
| **Category** | **Dollars** | **Staff years** | **Dollars** | **Staff Years** | **Dollars** | **Staff years** |
| **Pre-market** | | | | | | |
| Review | $14.1 | 126 | $19.2 | 141 | $21.3 | 149 |
| Applied research | 3.6 | 25 | 4.1 | 25 | 4.3 | 26 |
| Outreach/coordination | 0.9 | 12 | 0.9 | 12 | 1.0 | 12 |
| **Post-market** | | | | | | |
| Outreach coordination compliance | 11.8 | 76 | 17.4 | 79 | 21.2 | 100 |
| Applied research | 6.1 | 32 | 6.8 | 33 | 7.9 | 36 |
| **Total** | **$36.5** | **271** | **$48.4** | **290** | **$55.7** | **323** |

| Fiscal Year | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2003 | | 2004 | | 2005 | | 2006 | | 2007 | |
| Dollars | Staff years | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years |
| $21.8 | 158 | $21.4 | 176 | $21.1 | 152 | $25.2 | 145 | $27.7 | 149 |
| 4.4 | 26 | 4.1 | 26 | 4.1 | 27 | 1.7 | 9 | 1.8 | 14 |
| 1.0 | 13 | 0.8 | 12 | 0.8 | 12 | 0.5 | 4 | 0.5 | 4 |
| 21.9 | 108 | 20.6 | 97 | 21.7 | 101 | 22.0 | 132 | 22.2 | 109 |
| 8.1 | 36 | 7.6 | 35 | 7.6 | 38 | 5.3 | 31 | 6.2 | 42 |
| **$57.1** | **341** | **$54.5** | **346** | **$55.4** | **330** | **$54.8** | **321** | **$58.4** | **318** |

Source: FDA.

Note: Numbers may not add due to rounding.

**Table 9: ORA Food Safety Spending in Support of CVM, by Category, Fiscal Years 2005 through 2007**

Dollars in thousands

| | Fiscal year | | | | | |
|---|---|---|---|---|---|---|
| | 2005 | | 2006 | | 2007 | |
| Category | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years |
| Drug processing and new animal drug inspection program | $2,683 | 21 | $2,356 | 17 | $2,558 | 18 |
| Feed contaminants program | 4,154 | 33 | 3,564 | 26 | 3,440 | 25 |
| Feed manufacturing inspection program | 2,769 | 22 | 2,710 | 20 | 1,763 | 13 |
| Illegal residues in meat and poultry | 3,087 | 25 | 4,065 | 30 | 2,343 | 17 |
| Ruminant feed ban rule and BSE inspection program | 11,510 | 91 | 9,720 | 72 | 6,019 | 43 |
| Methods validation and development | 952 | 8 | 766 | 6 | 688 | 5 |
| Forensic analysis[a] | 0 | 0 | 0 | 0 | 0 | 0 |
| Audits of state contract inspections | 0 | 0 | 295 | 2 | 516 | 4 |
| Import entry review and refused entry tracking | 1,904 | 15 | 2,121 | 16 | 1,333 | 10 |
| Illegal sales, compounding, counterfeit animal drugs | 404 | 3 | 265 | 2 | 64 | 1 |
| Animal feed short-term assignments, ORA or field directed | 663 | 5 | 1,001 | 7 | 537 | 4 |
| Animal feed consumer complaints | 202 | 2 | 265 | 2 | 2,107 | 15 |
| Animal feed criminal investigation activities | 144 | 1 | 501 | 4 | 107 | 1 |
| Miscellaneous other activities | 375 | 3 | 324 | 2 | 322 | 2 |
| Pet food recall activities | 0 | 0 | 0 | 0 | 7,288 | 52 |
| **Subtotal** | **28,848** | **229** | **27,952** | **206** | **29,086** | **208** |
| State contracts and grants | 4,520 | 0 | 5,066 | 0 | 5,482 | 0 |
| **Total** | **$33,368** | **229** | **$33,018** | **206** | **$34,568** | **208** |

Source: FDA.

Notes: Numbers may not add due to rounding.

[a]Forensic analysis work is included in activities where work occurred.

**Table 10: National Center for Toxicological Research Spending on Food Safety, by Category, Fiscal Years 2000 through 2007**

Dollars in thousands

| | 2000 | | 2001 | | 2002 | |
|---|---|---|---|---|---|---|
| **Category** | **Dollars** | **Staff years** | **Dollars** | **Staff years** | **Dollars** | **Staff years** |
| Food safety | $1,015 | 12 | $325 | 3 | $694 | 7 |
| Antimicrobial resistance | 785 | 7 | 791 | 10 | 1,172 | 12 |
| Bioterrorism | 141 | 1 | 65 | 1 | 3,178 | 3 |
| Dietary supplements | 560 | 4 | 786 | 5 | 925 | 5 |
| Overhead | 1,432 | [a] | 1,010 | [a] | 2,002 | [a] |
| **Total** | **$3,933** | **24** | **$2,977** | **19** | **$7,971** | **27** |

| Fiscal year | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2003 | | 2004 | | 2005 | | 2006 | | 2007 | |
| Dollars | Staff years | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years | Dollars | Staff years |
| $293 | 8 | $1,832 | 13 | $1,463 | 10 | $3,874 | 10 | $3,718 | 7 |
| 1,114 | 17 | 1,298 | 16 | 1,404 | 17 | 1,510 | 15 | 1,682 | 17 |
| 2,842 | 6 | 424 | 2 | 113 | 1 | 551 | 5 | 797 | 7 |
| 1,126 | 5 | 1,023 | 5 | 1,530 | 6 | 1,774 | 6 | 2,439 | 6 |
| 2,518 | [a] | 2,832 | [a] | 2,033 | [a] | 2,599 | [a] | 2,848 | [a] |
| **$7,893** | **36** | **$7,409** | **36** | **$6,542** | **34** | **$10,308** | **36** | **$11,483** | **37** |

Source: FDA.

Notes: Numbers may not add due to rounding. Spending includes dollars received from other government agencies and external sources for collaborative efforts.

[a]Information not provided.

# Appendix III: Comments from the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 10 2008

Lisa Shams
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Ms. Shams:

Thank you for the opportunity to review and comment on the U.S. Government Accountability Office's (GAO) report entitled: "Food Safety: Improvements Needed in FDA Oversight of Fresh Produce" (GAO 08-1047). This is to notify you that we have reviewed the subject final report, and we have no additional comments to offer since the publication of the GAO draft report.

The Department appreciates the effort that went into this report.

Sincerely,

for Jennifer R. Lhong

Vincent J. Ventimiglia, Jr.
Assistant Secretary for Legislation

Attachment

**COMMENTS OF THE DEPPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "FOOD SAFETY — IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE" (GAO-08-1047)**

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report, *Food Safety: Improvements Needed in FDA Oversight of Fresh Produce* (GAO-08-1047). The Agency will offer both general and specific comments. Of significant importance to FDA is GAO's recognition of the Food Protection Plan (FPP) as a sound framework for advancing food safety and food defense[1] and that the GAO utilized the plan's framework as an organizing feature in this report.

In November 2007 FDA released the FPP which provides a national strategy to identify and counter potential hazards in both domestic and imported food. The FPP was developed to address the changes and challenges in protecting the U.S. food supply. The FPP places a greater emphasis on prevention by building in safety at the source of food production, regardless of whether food is produced domestically or outside the U.S. Prevention is facilitated through targeted risk-based intervention strategies that involve risk-based inspections and testing. The FPP also seeks to develop faster response and enhanced communication with stakeholders during food related events. While the focus of the current GAO report is on fresh produce safety, the elements of the FPP encompass all foods for humans and animals. Many of the specific actions in the FPP to improve prevention, intervention and response are being applied to fresh produce. Achieving the food safety enhancements identified by the FPP will require the involvement of all our food safety partners – Federal, state, local, tribal, and foreign governments; industry; academia; consumers; and Congress.

GAO's approach, using the FPP framework, helps solidify a common food vision toward protecting the food supply and provides a framework for discussion of the issues such that all stakeholders can work uniformly to advance food protection.

In this draft report, GAO makes 7 recommendations to FDA, including 4 recommendations to enhance its oversight of fresh produce safety, such as updating its good agricultural practices guidance, 2 recommendations to seek authority from Congress to make explicit FDA's authority to adopt preventive controls for high-risk foods and to provide enhanced access to firm records during food related emergencies, and one recommendation to provide specific information to Congress and to the public on the strategies and resources for implementing the FPP. As part of the FPP, FDA made 10 legislative proposals and while none of them are exclusively focused on fresh produce they are all important in ensuring that the food supply in the U.S. is protected. FDA's response to the specific GAO recommendations follows:

[1] GAO, *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan.* GAO-08-909T (Washington, D.C.: July 12, 2008).

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**COMMENTS OF THE DEPPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "FOOD SAFETY — IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE" (GAO-08-1047)**

**Recommendations to Enhance Oversight of Fresh Produce Safety**

First GAO recommendation – that FDA develop a plan for identifying research priorities and facilitating research related to fresh produce.

FDA agrees with this recommendation. Both CFSAN and the Agency, as part of the Food Protection Plan, are currently developing strategic plans for research which will include but not be limited to fresh produce related research. The Agency's regulatory food safety research needs are far broader than fresh produce; therefore, fresh produce research needs must, out of necessity, compete for limited resources. CFSAN 's plan will identify regulatory research priorities that can be addressed through (1) intramural research (2) extramural research leveraged through our Centers of Excellence or (3) through a competitive extramural research program. The plan also will identify future research needs that currently cannot be addressed due to resource (funding and expertise) limitations.

> The 2004 Produce Safety Action Plan (http://www.cfsan.fda.gov/~dms/prodpla2.html) identified broad research needs relevant to the contamination of fresh produce. CFSAN has systematically worked with our stakeholders and other research organizations (USDA, ARS and CSREES; WIFSS; NCFST and JIFSAN[2]) to leverage research resources and identify more specific research needs associated with fresh produce. These activities included participating in workshops such as the Tomato Safety Research Needs Workshop (http://www.jifsan.umd.edu/tomato_wkp2007.htm); the International Lettuce and Leafy Greens Food Safety Research Conference (http://www.unitedfresh.org/newsviews/leafy_greens_food_safety_research); and identifying appropriate research focus areas for the USDA's National Research Initiative (http://www.csrees.usda.gov/funding/nri/nri.html) and the National Integrated Food Safety Initiative (http://www.csrees.usda.gov/funding/rfas/food_safety.html) programs.

Second GAO recommendation --that FDA identify approaches for obtaining testing and other information from industry members to supplement its research agenda

> FDA agrees with the recommendation to identify approaches for obtaining testing and other information from industry members. FDA would like to note that the data and information from industry would further inform, not supplement, FDA's research agenda. Additionally, the data obtained would be used in Agency risk assessments associated with fresh produce. The Agency is aware of efforts by some produce industry associations and UC Davis's Center for Produce Safety regarding how they might serve as repositories of such data and information for the purpose of sharing with others including FDA.

[2] Acronyms: United States Department of Agriculture (USDA), Agricultural Research Service and Cooperative State Research, Education, and Education Service (ARS and CSREES), Western Institute for Food Safety and Security (WIFSS), National Center for Food Safety and Technology (NCFST), and Joint Institute for Food Safety and Nutrition (JIFSAN).

**COMMENTS OF THE DEPPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "FOOD SAFETY — IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE" (GAO-08-1047)**

Third GAO recommendation – that FDA update its good agricultural practices guidance for fresh produce to incorporate knowledge about safe growing practices

FDA agrees with this recommendation. The Agency recognized when it issued the good agricultural practices guidance in 1998 that it would need to be updated as new information and technological advances expand the understanding of those factors associated with identifying and reducing microbial food safety hazards. In the 10 years since the guidance was released, many changes have occurred in the produce industry, and a great deal of new knowledge and information has become available. In addition, the Agency now has ten years experience in implementing the guidance, and observing how and the extent to which it has been implemented.

Although at the time GAO interviewed FDA, drafting of revised guidance had not started, many of the actions necessary to update the guidance had been completed or were being done. For example, FDA held public hearings on produce safety on March 13 and April 20, 2007, where the Agency solicited input from stakeholders on risk factors associated with microbial contamination of produce. In addition, the Agency has implemented the leafy greens and tomato initiatives, whose goals include gaining knowledge on environmental factors that lead to contamination of produce, which will inform future policy or guidance.

More recently, the Agency published a notice in the Federal Register on September 2, 2008, requesting comments and scientific data and information that may assist the Agency to improve the good agricultural practices guidance. Specifically, FDA is seeking information about (1) current agricultural practices and conditions used to grow, harvest, pack, cool, and transport fresh produce; (2) risk factors for contamination of fresh produce associated with these practices; and (3) possible measures that FDA could implement that would enhance the safety of fresh produce. The Agency will update the guidance after evaluating comments it receives together with all the data and information it has collected through the other efforts mentioned above.

Fourth GAO Recommendation -- that FDA update its current good manufacturing practice regulations for food to incorporate new knowledge about the food industry and safe manufacturing, processing, and holding practices

FDA agrees with this recommendation. Beginning in late 2002, the Center for Food Safety and Applied Nutrition formed a Food Current Good Manufacturing Practice (CGMP) Modernization Working Group. The objective of the group was to examine the general food CGMP regulation in 21 CFR Part 110 (hereinafter CGMP regulation) and determine whether the regulation was in need of modernization. Also, the group was specifically tasked to focus on risk-based preventive controls, i.e. those that would have the greatest impact on ensuring food safety. The working group concluded that there have been changes in both the food industry and in the science of food safety that indicate a need for modernization.

4

See comment 1.

**COMMENTS OF THE DEPPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "FOOD SAFETY — IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE" (GAO-08-1047)**

In 2003, the working group initiated research programs to identify those areas where GMP-type controls could have the greatest impact on ensuring food safety. In 2004, the working group presented its preliminary findings from this research and engaged the public in three public meetings held across the country and through a Federal Register notice calling for comments on food CGMP modernization. This report, found at http://www.cfsan.fda.gov/~dms/cgmps.html, summarizes the public comments and details the working group's key findings.

The areas that present opportunities for modernization are training, food allergens, Listeria monocytogenes control, sanitation procedures, and application of certain CGMPs to agricultural operations, records access, and temperature control.

**Recommendations to Seek Authority from Congress**

Fifth and sixth GAO recommendations – that the Commissioner of FDA seek authority from the Congress to make explicit FDA's authority to adopt preventive controls for high-risk goods, and provide FDA enhanced access to firm records during food-related emergencies.

FDA has already sought authority from Congress for these and additional legislative proposals. These requests are highlighted in the Food Protection Plan, as well as Congressional testimony. To date, Congress has not acted on the legislative needs outlined in the Food Protection Plan. As a package, these proposals will not only enhance food safety overall but will specifically contribute to enhanced produce safety. For example, additional authority to authorize FDA to accredit highly-qualified third parties for voluntary food inspection is outlined in the Food Protection Plan, but not referenced above in the GAO recommendation. This authority would allow FDA to leverage its inspectional capabilities without relinquishing any of its regulatory or enforcement authority. As noted in the GAO report, a voluntary third party accreditation program focused on fresh produce could provide several benefits while increasing oversight of a high risk food category.

FDA refers GAO to its own outstanding recommendation that Congress enact comprehensive, uniform, and risk-based food safety legislation.[3] FDA supports GAO's recommendation for Congress to act on food safety legislation and proposes that the recommendation above be redirected to Congress for action.

[3] GAO Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, Federal Oversight of Food Safety: High-Risk Designation Can Bring Attention to the Limitations in the Government's Food Recall Programs, April 24, 2007

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**COMMENTS OF THE DEPPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "FOOD SAFETY — IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE" (GAO-08-1047)**

**Recommendation to Provide Information to Congress**

Seventh GAO recommendation - that the Commissioner of FDA provide specific information to the Congress on the strategies and resources for implementing the Food Protection Plan.

FDA agrees with the need for transparency and accountability in implementing the Food Protection Plan. FDA has provided extensive detail to Congress on the implementation plan – including resources – for the Food Protection Plan. FDA intends to continue to be as transparent as possible in its implementation of the FPP in order to enable FDA, Congress, and the public to track progress on the Food Protection Plan.

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The following are GAO's comments on FDA's written comments provided by the Department of Health and Human Service's Assistant Secretary for Legislation in a letter dated September 10, 2008.

## GAO Comments

1. FDA did not agree with our recommendations to seek authority from the Congress to make explicit FDA's authority to adopt preventive controls for high-risk foods and to provide FDA enhanced access to firm records during food-related emergencies. FDA believes that the agency has already sought authority from the Congress for these and additional legislative authorities. Specifically, FDA said that the agency has sought authority by outlining these legislative needs in the *Food Protection Plan* and highlighting them in congressional testimony. We do not view these actions as seeking authority because FDA has not drafted legislative language or formally submitted a legislative proposal to the Congress, nor has it worked directly with the Congress to help initiate these authorities. FDA proposed that these recommendations be redirected to the Congress for action and refers to a prior recommendation we made that the Congress enact comprehensive, uniform, and risk-based food safety legislation. We reiterated this recommendation to the Congress most recently in our High-Risk Series[1] as one action that can help address the fragmented federal oversight of food safety and integrate the myriad food safety programs. Our recommendations to FDA are intended to enhance FDA's authority to oversee fresh produce for which FDA has primary responsibility.

[1]GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007).

# Appendix IV: GAO Contact and Staff Acknowledgments

## GAO Contact

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## Staff Acknowledgments

In addition to the contact named above, Vondalee Hunt (Assistant Director), Kevin Bray, Candace Carpenter, Susan Malone, Kara Marshall, Katherine Raheb, Matthew Reilly, Anne Rhodes-Kline, Ben Shouse, Jena Sinkfield, and Tama Weinberg made key contributions to this report.

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