

Report to Congressional Requesters

February 2001

# FOOD SAFETY

# Overview of Federal and State Expenditures





# Contents

Letter		1
Appendix I	Objectives, Scope, and Methodology	23
Appendix II	The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures	26
Appendix III	The Food and Drug Administration's Fiscal Year 1998 and 1999 Food Safety Expenditures	38
Appendix IV	States' Fiscal Years 1998 and 1999 Food Safety Expenditures	52
Appendix V	Responses to GAO's Survey of State Agencies Responsible for Food Safety Activities	61
Appendix VI	Comments from the Food Safety and Inspection Service	75
Appendix VII	Comments from the Food and Drug Administration	79
Appendix VIII	GAO Contacts and Staff Acknowledgements	83
Tables		
	Table 1: FSIS' Expenditures and Staff Years for Food Safety Activities by Office, Fiscal Years 1998 and 1999 Table 2: Office of Field Operations Headquarters Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999	27 28

Table 3: Office of Field Operations District Office Expenditures	
and Staff Years, Fiscal Years 1998 and 1999	30
Table 4: District Office Inspection Responsibilities by	
Establishment Type, Fiscal Year 2000	31
Table 5: Office of Management Activities, Expenditures, and Staff	
Years, Fiscal Years 1998 and 1999	32
Table 6: Office of Public Health and Science Activities,	
Expenditures, and Staff Years, Fiscal Years 1998 and 1999	33
Table 7: Office of Policy, Program Development and Evaluation	
Activities, Expenditures, and Staff Years, Fiscal Years 1998	
and 1999	35
Table 8: Office of the Administrator Activities, Expenditures, and	33
Staff Years, Fiscal Years 1998 and 1999	36
Table 9: FDA's Expenditures and Staff Years for Food Safety	90
Activities by Center, Fiscal Years 1998 and 1999	39
Table 10: Number of FDA Food Safety Field Inspections,	55
Examinations, and Samples Analyzed, Fiscal Years 1998	
and 1999	41
Table 11: Food Field Activities Accounting for Over \$1 Million in	41
Expenditures and Staff Years, Fiscal Years 1998 and 1999	42
Table 12: Animal Drugs and Feeds Field Activities Accounting for	42
Over \$1 Million in Expenditures and Staff Years, Fiscal	
Years 1998 and 1999	45
Table 13: CFSAN Headquarters Activities, Expenditures, and Staff	40
	47
Years, Fiscal Years 1998 and 1999 Table 14. CVM Headquarters Activities, French ditumes, and Staff	41
Table 14: CVM Headquarters Activities, Expenditures, and Staff	40
Years, Fiscal Years 1998 and 1999	49
Table 15: Aggregate Agriculture and Health Department Food	
Safety Expenditures and Staff Years by State, Fiscal Years	70
1998 and 1999	52
Table 16: State Agriculture and Health Department Expenditures	
for Food Safety Activity Categories, Fiscal Years 1998 and	
1999	55
Table 17: Number of Food Establishments Under State Inspection	
Jurisdiction and Most Common Inspection Frequency,	F.0
Fiscal Years 1998 and 1999	56
Table 18: State Allocation of Resources to Food Safety Licensing	
and Inspection Activities, Fiscal Years 1998 and 1999	57
Table 19: State Allocation of Expenditures in Response to Food	
Safety Problems, Fiscal Years 1998 and 1999	58
Table 20: State Allocation of Expenditures for Food Safety	
Laboratory Analysis, Fiscal Years 1998 and 1999	58
Table 21: State Allocation of Expenditures for Food Safety Training	
and Technical Assistance, Fiscal Years 1998 and 1999	59

#### **Figures**

Figure 1: FSIS' and FDA's Food Safety Expenditures and Foods	
Under Each Agency's Regulatory Jurisdiction	3
Figure 2: FSIS' Expenditures for Field and Headquarters Food	
Safety Activities, Fiscal Year 1999	10
Figure 3: FDA's Expenditures for Field and Headquarters Food	
Safety Activities, Fiscal Year 1999	14
Figure 4: Aggregate State Agriculture and Health Department	
Expenditures for Food Safety Activities, Fiscal Year 1999	18

#### **Abbreviations**

CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
HHS	Department of Health and Human Services
NCTR	National Center for Toxicological Research
ORA	Office of Regulatory Affairs
USDA	U.S. Department of Agriculture



### United States General Accounting Office Washington, DC 20548

February 20, 2001

The Honorable Richard G. Lugar Chairman The Honorable Tom Harkin Ranking Member Committee on Agriculture, Nutrition, and Forestry United States Senate

The Honorable Chuck Hagel United States Senate

Foodborne illness in the United States is an extensive and expensive problem. The Centers for Disease Control and Prevention (CDC) estimates that unsafe foods cause as many as 76 million illnesses annually. The U.S. Department of Agriculture (USDA) estimates that the costs associated with foodborne illness due to seven pathogens, including salmonella, campylobacter, and E. coli O157:H7, range up to \$37 billion annually. Federal and state expenditures for activities to help ensure the safety of the nation's food supply are also significant, with federal efforts alone exceeding \$1 billion annually. While there are 12 federal agencies with food safety responsibilities, USDA's Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's (HHS) Food and Drug Administration (FDA) are the primary federal regulatory agencies responsible for food safety. FSIS is responsible for ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and marked, labeled, and packaged correctly. FDA is responsible for ensuring that (1) all foods moving in interstate and foreign commerce, except those under FSIS' jurisdiction, are safe, wholesome, and labeled properly; and (2) all animal drugs and feeds are safe, properly labeled, and produce no human health hazards when used in food-producing animals. In addition, state agencies conduct inspection and regulation activities that help ensure the safety of foods produced, processed, or sold within their borders.

To obtain a better understanding of federal and state food safety efforts, you asked us to determine for fiscal years 1998 and 1999 the amount of resources that were expended by FSIS, FDA, and the states for food safety and how the agencies used these resources.

To make this determination for FSIS and FDA, we analyzed their annual appropriations and financial documentation, which included information on actual food safety expenditures, activities and accomplishments. For food safety activities, we obtained and reviewed the associated costs and staff year levels and supplemented this information with agency programmatic documents and discussions we had with agency officials.

To determine the amounts that states expended on food safety and how they used the resources, we surveyed the agriculture and health departments of all 50 states, 3 territories, the commonwealths of Puerto Rico and North Mariana Islands, the Federated States of Micronesia, and the District of Columbia. The survey asked respondents for information on the scope of food safety activities their departments performed, the costs and staffing levels of those activities, and the scope and frequency of inspection activities. We analyzed these data to determine the extent of state food safety activities and expenditures nationwide. The survey was limited to state agriculture and health departments and did not include other state agencies or county and city agencies. Appendix I provides details on our scope and methodology.

#### Results in Brief

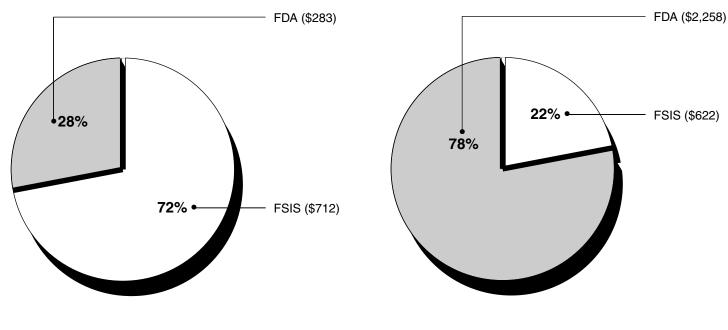
FSIS, FDA, and the state agriculture and health departments expended about \$1.3 billion in fiscal year 1999—FSIS and FDA expended about \$1 billion, and the states reported about \$300 million. The amounts and proportions of food safety expenditures for fiscal year 1998 were similar. Regarding the \$1 billion in fiscal year 1999 federal moneys, as shown in figure 1, FSIS expended about 70 percent, or \$712 million, overseeing about 20 percent of federally regulated foods and FDA expended about 30 percent, or \$283 million, overseeing about 80 percent of federally regulated foods. These expenditures reflect the regulatory approaches or inspection frequencies contained in the laws under which each agency operates.

Figure 1: FSIS' and FDA's Food Safety Expenditures and Foods Under Each Agency's Regulatory Jurisdiction

#### Food Safety Expenditures

#### **Consumer Food Expenditures by Agency Jurisdiction**





FSIS FDA

Source: Prepared by GAO from fiscal year 1999 FSIS and FDA data and fiscal year 1997 U.S. Bureau of Labor Statistics data.

FSIS food safety expenditures totaled about \$678 million in fiscal year 1998 and \$712 million in fiscal year 1999. FSIS expended about 85 percent of its resources on field activities, including in-plant inspection, compliance, administration, and supervisory activities associated with overseeing about 6,000 meat, poultry, and egg product establishments, including about 130 import establishments. FSIS' expenditures reflect its legislative mandate for continuous inspection of meat and poultry slaughter plants—including the examination of every carcass slaughtered—and of egg processing plants and its interpretation of federal law as requiring daily inspection of meat and poultry processing plants

(e.g., deboning and canning operations). About \$296 million of fiscal year 1999 inspection expenditures of \$486 million went to carcass-by-carcass slaughter inspections (inspections that cannot detect microbial pathogens, which are considered the most significant health risk, associated with foods) and about \$145 million was expended on daily inspections of processing plants regardless of risk. We previously reported that moving to a risk-based inspection system would allow for a more effective use of some of the resources currently expended on carcass-by-carcass and daily inspection activities. <sup>2</sup>

FDA's food safety expenditures in fiscal years 1998 and 1999 totaled about \$253 million and \$283 million, respectively. FDA expended about 56 percent of its food safety resources on field activities, including inspection, compliance, administration, and supervisory activities. In contrast to FSIS. FDA has no legislatively mandated inspection frequencies for foods or food firms under its jurisdiction and generally follows a regulatory approach of allowing food products to enter the market without prior approval. As such, FDA inspects the estimated 57,000 food establishments under its jurisdiction about once every 5 years, on average, and inspected less than 1 percent of the 3.7 million imported food entries in fiscal year 1999. The other 44 percent of FDA's expenditures were for headquarters-based activities, including activities associated with the evaluation and approval of certain foods such as infant formula, ingredients such as colors and additives, and animal drugs and feed before they are produced for the market, and activities such as surveillance and research on the safety of food and feed products after they enter the market.

States (used hereafter to collectively refer to state, territory, commonwealth, federated state, and the District of Columbia agriculture and health departments) reported food safety activity expenditures of about \$292 million and \$301 million in fiscal years 1998 and 1999, respectively. Over 50 percent of states' expenditures, \$142 million and \$144 million in fiscal years 1998 and 1999, respectively, were for licensing and inspection activities for a wide variety of establishments, including

<sup>&</sup>lt;sup>1</sup>The Federal Meat Inspection Act requires a post-mortem examination and inspection of the carcasses and parts of all livestock prepared at any slaughtering establishment. The Poultry Products Inspection Act requires a post-mortem inspection of each bird processed.

<sup>&</sup>lt;sup>2</sup>See Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness (GAO/RCED-98-224, Aug.6, 1998).

continuous and daily inspections at meat and poultry slaughter and processing plants under the states' jurisdictions.<sup>3</sup> Each year participating states matched the approximately \$40 million in grants FSIS provided to the states to conduct meat and poultry inspections under federal standards, including carcass-by-carcass examination. The states reported over 1 million establishments under their inspection jurisdiction, including nearly 700,000 restaurants, groceries, and other retail outlets; 90,000 dairy farms; 4,800 fish and seafood plants/farms; over 1,900 shellfish operations; and about 1,500 meat and poultry slaughter plants. In addition to state agriculture and health departments, which generally have primary food safety responsibilities at the state level, a wide variety of other state and local agencies have food safety responsibilities that were not covered in the scope of our survey.

We provided a draft of the report to FSIS and FDA for their review and comment. In commenting on the draft, both agencies generally agreed with the information contained in the report and provided additional information on specific issues. We modified the report to reflect this information as appropriate.

#### Background

The extent of foodborne illness in the United States and its associated costs are significant. CDC estimates that unsafe foods cause as many as 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually. In terms of medical costs and productivity losses, foodborne illnesses associated with seven major pathogens cost the nation between \$7 billion and \$37 billion annually, according to USDA's estimates.

According to CDC, almost 12,000 cases of foodborne illness were reported in 1997, the latest year for which data are available. Of the approximately 7,000 cases in which the food source for the illness was known, about 85 percent were associated with food products that are regulated by FDA, such as fish, shellfish, fruits, vegetables, and salads. The remaining 15 percent were associated with food products, such as meat and poultry, that fall under FSIS' jurisdiction. The relative proportion of illness

<sup>&</sup>lt;sup>3</sup>States operate federal equivalent inspection programs for intrastate meat and poultry plants.

<sup>&</sup>lt;sup>4</sup>CDC uses reported illnesses, among other sources, to estimate the extent of foodborne illnesses each year. Reported data on foodborne illnesses and related deaths are incomplete and understate the extent of the problem.

associated with foods under each agency's jurisdiction reflects consumer expenditures for food products under the jurisdiction of each. Nearly 80 percent of consumer expenditures are for foods under FDA's jurisdiction, while FSIS is responsible for the remaining 20 percent.

While 12 different federal agencies located within six federal departments conduct food safety activities, FSIS and FDA have primary regulatory responsibility for ensuring the safety of the nation's food supply. FSIS has responsibility for ensuring the safety of meat, poultry, and processed egg products, overseeing about 6,000 meat, poultry, egg product and import establishments. Under the governing inspection acts, FSIS, in effect, preapproves products before they are marketed. As such, FSIS operates under a mandated continuous inspection frequency for meat and poultry slaughter plants and egg processing plants and inspects meat and poultry processing plants daily. FSIS marks all inspected and approved meat, poultry, and egg products with a USDA inspection stamp. Without this marking, the products cannot be legally marketed.

FSIS also reviews and assesses the effectiveness of state intrastate meat, poultry, and egg product inspection programs to ensure that their standards are at least equal to federal standards. In addition, FSIS reviews and assesses foreign inspection systems and facilities that export FSIS-regulated products to the United States for equivalency with U.S. standards. In 1998, FSIS reviewed 7 of the 26 states with intrastate inspection programs for meat and/or poultry and reviewed foreign inspection programs in 22 of the 37 countries that were eligible to export

<sup>&</sup>lt;sup>5</sup>The 12 agencies are USDA's Animal and Plant Health Inspection Service, Grain Inspection, Packers and Stockyards Administration, Agricultural Marketing Service, Agricultural Research Service, and FSIS; HHS' Centers for Disease Control and Prevention and FDA; the Department of the Treasury's U.S. Customs Service and the Bureau of Alcohol, Tobacco and Firearms; the Department of Commerce's National Marine Fisheries Service; the Environmental Protection Agency; and the Federal Trade Commission. See *Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based, Inspection System* (GAO/T-RCED-99-256, Aug. 4, 1999) for information on food safety agencies' roles and responsibilities.

<sup>&</sup>lt;sup>6</sup>The Federal Meat Inspection Act regulates meat from cattle, swine, goats, sheep, and equines (horses); the Poultry Products Inspection Act defines poultry as domesticated fowl, which FSIS regulations define as chickens, turkeys, ducks, geese, and guineas. The Egg Products Inspection Act defines egg products as eggs removed from their shells for processing.

FSIS also reinspects imported meat, poultry, and egg products at ports of entry and at destination or other locations.

to the United States. In addition to the inspection activities, FSIS conducts emergency responses, including retention, detention, or voluntary recall of adulterated foods and epidemiological investigations of foodborne hazards or disease outbreaks. Furthermore, FSIS engages in developing and implementing cooperative strategies to prevent health hazards associated with animal production practices, coordinating U.S. participation in international sanitary standard-setting activities, and providing safety information to food handlers and consumers.

FDA is responsible 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. Specifically, under the Federal Food, Drug and Cosmetic Act, FDA is responsible for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and labeled properly. This includes ensuring the safety of ingredients that make up foods, such as food additives that change a food's color or taste, and reviewing and approving new additives unless they are generally recognized as being safe. In administering the act, which generally follows the regulatory approach of allowing food products to enter the market without preapproval, FDA inspects and tests domestic and imported food products. However, the act does not mandate or specify inspection frequencies for overseeing an estimated 57,000 food establishments under FDA's jurisdiction. Products under FDA's jurisdiction do not require, and FDA does not place, any inspection mark on the products before they can be legally marketed. FDA is also responsible for maintaining surveillance of all animal drugs and feeds to ensure that they are safe and labeled properly and produce no human health hazards when used in food-producing animals and for overseeing more than 9,000 animal drug and feed establishments.9

<sup>&</sup>lt;sup>8</sup>Both FDA and FSIS have implemented hazard analysis and critical control point systems that are designed to identify and control foodborne hazards that are likely to occur. In December 1997, FDA required seafood establishments to implement such systems, and in January 1998, FSIS began requiring implementation at meat and poultry establishments.

<sup>&</sup>lt;sup>9</sup>GAO's recently released report, *Food Safety: Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed* (GAO/RCED-00-255, Sept. 22, 2000) addresses concerns regarding the extent to which unsafe feed has been linked to human health problems in the United States and the actions FDA and the Department of Transportation are taking to ensure the safety of animal feed.

States all have departments that are responsible for the regulation and enforcement of their own food safety laws to ensure the safety of foods produced, processed, or sold within their borders. These responsibilities are primarily within the state departments of agriculture and health and may involve others, such as state environmental protection agencies and county departments of health. States and territories may also perform inspections for FSIS or FDA under contract or form partnerships to report their results to the federal agencies. For example, in fiscal year 1998, FDA contracted with 38 states to conduct inspections in accordance with the federal regulations. Under partnership agreements, 29 states shared the results of inspections conducted under their own standards with FDA.

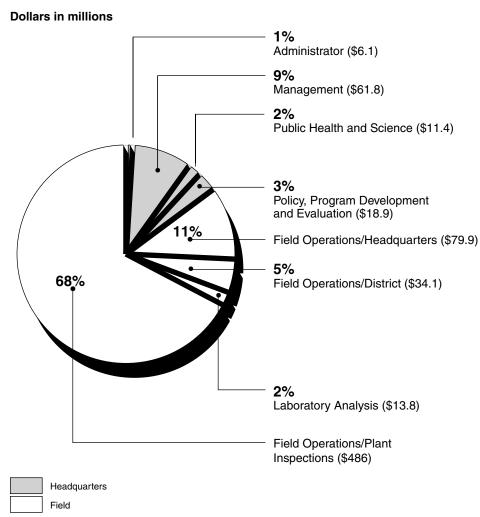
FSIS, FDA, and State Agency Food Safety Expenditures Total Nearly \$1.3 Billion FSIS was responsible for food safety expenditures of \$678 million in fiscal year 1998 and \$712 million in fiscal year 1999, or about 55 percent of the nearly \$1.3 billion fiscal year 1999 federal and state expenditures. In fiscal years 1998 and 1999, FSIS employed 11,057 and 10,951 staff years, respectively. FDA food safety activities accounted for about 22 percent of the total expenditures—\$253 million in fiscal year 1998 and \$283 million in fiscal year 1999—and employed 2,505 and 2,609 staff years, respectively. State agriculture and health departments reported food safety expenditures of about \$292 million in fiscal year 1998 and \$301 million in fiscal year 1999 and employed 5,617 and 5,717 staff years, respectively. About 85 percent of FSIS' expenditures were for field activities, while FDA's expenditures were almost evenly divided between field and nonfield activities. The federal agencies' expenditures reflect the regulatory approaches or inspection frequencies contained in the laws under which they operate.

FSIS' Field Inspection Activities Account for Most of the Agency's Food Safety Expenditures FSIS expended \$678 million in fiscal year 1998 and \$712 million in fiscal year 1999 on food safety. FSIS' food safety activities can be separated into two major components—operations conducted in the field by district offices or in direct support of those district offices and operations conducted primarily in headquarters offices. As shown in figure 2, about 85 percent of FSIS' fiscal year 1999 expenditures were for field activities and 15 percent were for headquarters office activities. See appendix II for details on FSIS' activities, expenditures, and staff years for fiscal years 1998 and 1999.

<sup>&</sup>lt;sup>10</sup>FSIS' total expenditures included about \$47 million in grants to states for inspection and other activities annually. These funds were likely reported as food safety expenditures by the state agriculture and health departments and thus may be double-counted in the federal and state total of \$1.3 billion. In addition, in commenting on a draft of this report, FSIS stated that some of its expenditures were for nonfood safety activities more related to food wholesomeness and quality issues, but provided no specific examples.

<sup>&</sup>lt;sup>11</sup>The proportion of expenditures for each category of activity varied by less than 2 percent from fiscal years 1998 to 1999.

Figure 2: FSIS' Expenditures for Field and Headquarters Food Safety Activities, Fiscal Year 1999



Note: Percentages do not add to 100 because of rounding.

Source: Prepared by GAO from FSIS' data.

In aggregate, FSIS' field activities accounted for \$614 million in fiscal year1999. Specifically:

 Inspections at more than 6,000 slaughter, processing, and import establishments accounted for \$486 million, or 68 percent, of total agency expenditures. Of the \$486 million, FSIS estimates that slaughter inspections conducted at 262 establishments accounted for about \$324 million; daily meat and poultry processing inspections at about 4,300 establishments accounted for about \$145 million; continuous inspections at 75 egg processor establishments accounted for about \$8 million; and inspections at 129 import/export establishments accounted for about \$7 million. 12 Regarding slaughter inspections, FSIS estimates that carcass-by-carcass organoleptic (see, touch, smell) inspections accounted for about \$296 million of the total inspection expenditures. FSIS does not track expenditures specifically related to Hazard Analysis and Critical Control Point system inspections and thus could not provide that information.

- Field office administration, supervision, and compliance activities, such as following-up on inspection findings, accounted for \$34.1 million, or 5 percent, of total expenditures.
- Field office management by the Office of Field Operations located in Washington, D.C., accounted for \$79.9 million, or 11 percent, of total expenditures. The largest expenditure was for grants to states for inspections, field automation, and other activities, accounting for almost \$47 million, or over half, of the office's total expenditures for fiscal year 1999.
- Field laboratory analysis services provided by the Office of Public Health and Science accounted for \$14 million of field activity expenditures, or 2 percent, of total expenditures.

FSIS' headquarters-based activities accounted for the remaining \$98 million of fiscal year 1999 expenditures, or about 15 percent, of total agency expenditures. Four program offices—Management; Public Health and Science; Policy, Program Development, and Evaluation; and the Office of the Administrator—conduct FSIS' headquarters food safety activities. Specifically:

- The Office of Management accounted for about \$61.8 million, or 9 percent, of total expenditures. The office is responsible for providing centralized administrative and support services to all other FSIS program offices, including functions such as human resource management, strategic planning, procurement, and financial management.
- The Office of Policy, Program Development, and Evaluation accounted for about \$18.9 million, or 3 percent, of total expenditures. The office is

<sup>&</sup>lt;sup>12</sup>FSIS could only provide estimates because (1) its accounting system does not track categories of inspection expenditures electronically, and to determine expenditures manually would be extremely labor-intensive, and (2) the accuracy of inspection expenditure data is questionable due to a change in accounting systems and management codes during fiscal year 1999.

responsible for, among other things, coordinating activities, such as developing and recommending domestic and international policies for FSIS; reviewing product process standards; product labeling; and developing and evaluating inspection programs.

- The Office of Public Health and Science accounted for about \$11.4 million, or 2 percent, of total expenditures. The office is responsible for conducting scientific analysis, providing scientific advice and data, and making recommendations involving all public health and science concerns relating to products under FSIS' jurisdiction. This includes mission activities such as epidemiology and risk assessment, surveillance, and response to food safety emergencies.
- The Office of the Administrator accounted for about \$6.1 million, or 1
  percent, of total expenditures. The office is responsible for managing
  agency activities such as public affairs, food safety education,
  coordinating U.S. involvement in international standard-setting for food
  safety, and maintaining liaison with trade organizations.

FSIS' large proportion of expenditures on field and supporting activities reflects the mandate of the meat and poultry acts. The two acts require that meat and poultry slaughter plants be under continuous FSIS inspection. <sup>14</sup> If a federal inspector is not present, the animals cannot be slaughtered. FSIS inspects animals both before and after slaughter. The acts also require FSIS inspectors to monitor processing plant operations, such as deboning and canning, to ensure that plants are sanitary and adhere to approved procedures and label specifications. The acts do not explicitly set inspection frequencies for meat- and poultry-processing plants; however, FSIS has interpreted the acts as requiring the daily inspection of such plants and has established its regulations accordingly. That is, an FSIS inspector must visit each meat- and poultry-processing plant for an unspecified period of time—which may be as little as an hour—each operating day. As such, the majority of FSIS expenditures are directed to conducting inspection activities based on frequencies derived from the regulatory acts, rather than on the food safety risk of a specific plant or process.

 $<sup>^{13}</sup>$ This excludes the \$14 million expended by this office for field laboratories.

<sup>&</sup>lt;sup>14</sup>There has been an ongoing debate regarding the implementation of a system under which plant workers would assume more responsibility for the carcass inspections now conducted by federal inspectors. With guidance from recent court rulings, FSIS is working to establish such a system while still meeting the requirements of the acts.

In 1998, we reported that FSIS' funds could be used more effectively if they were redirected using risk-based criteria. Specifically, the approximate \$296 million in fiscal year 1999 expenditures for organoleptic, carcass-by-carcass slaughter inspections do not optimize federal resources because these inspections do not detect the most serious public health threat associated with meat and poultry—microbial contamination. Rather, some of these funds and funds used for daily inspections of meatand poultry-processing plants could be used, for example, to increase testing for microbial and other types of contamination, risk assessment, and scientific research, or could be congressionally redirected to other food plants, such as seafood processors, based on the health risk posed. We continue to hold this view.

FDA's Food Safety Expenditures Are More Closely Divided Between Field Inspection and Headquarters Activities

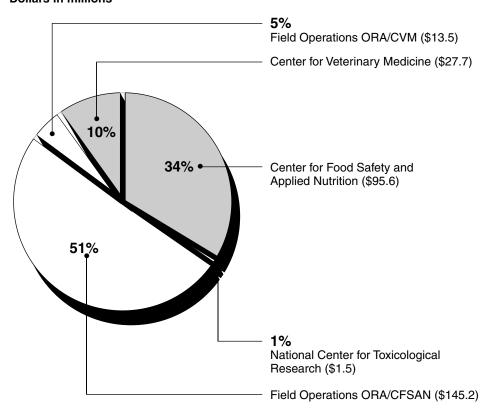
FDA expended \$253 million in fiscal year 1998 and \$283 million in fiscal year 1999 on food safety activities. These activities represent the combined efforts of FDA's three centers with food safety responsibilities: the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the National Center for Toxicological Research, as well as the field activities conducted by the Office of Regulatory Affairs in support of the centers. As with FSIS, FDA's food safety activities can be separated into two major elements: (1) inspection and enforcement operations conducted in the field by district offices or at headquarters in direct support of those district offices, and (2) operations conducted primarily in headquarters offices. As shown in figure 3, about 56 percent of FDA's fiscal year 1999 food safety expenditures were for field activities and about 44 percent were for headquarters-based activities of FDA's centers. Appendix III provides detailed information on FDA's fiscal years 1998 and 1999 activities, expenditures, and staff years.

<sup>&</sup>lt;sup>15</sup>FDA's total expenditures included nearly \$3 million of contracts to states for inspection and other activities annually. These funds were likely reported as food safety expenditures by the state agriculture and health departments and thus may be double-counted in the federal and state total of \$1.3 billion.

 $<sup>^{16}</sup>$ Each activity's proportion of total expenditures did not vary by more than 2 percent between fiscal years 1998 and 1999.

Figure 3: FDA's Expenditures for Field and Headquarters Food Safety Activities, Fiscal Year 1999

#### **Dollars in millions**





Legend:

ORA Office of Regulatory Affairs

CVM Center for Veterinary Medicine

CFSAN Center for Food Safety and Applied Nutrition

Note: Percentages do not add to 100 because of rounding.

Source: Prepared by GAO from FDA's data.

In aggregate, FDA's field activities accounted for about \$159 million in fiscal year 1999, or about 56 percent of the agency's total food safety expenditures. The Office of Regulatory Affairs (ORA) is responsible for

conducting field activities designated by the centers. ORA's compliance, inspection, and laboratory field staff manage, supervise, and conduct enforcement, compliance, inspection, sample collection and analysis activities, as well as criminal investigation, education, and outreach activities. Specifically:

- The ORA-conducted field activities in support of the Center for Food Safety and Applied Nutrition accounted for about \$145 million in expenditures for fiscal year 1999. Using these funds, FDA conducted over 14,600 domestic food establishment inspections, including those conducted by states under contract with FDA, at a cost of about \$2 million; and about 765 inspections of food importers. About \$27 million, or 19 percent, of the \$145 million went to domestic and imported seafood hazard analysis and critical control point inspection activities. Also included in these total expenditures is more than \$40 million for laboratory analysis of about 25,000 domestic and foreign product samples associated with field inspection activities.
- The ORA-conducted field activities in support of the Center for Veterinary Medicine accounted for about \$13.5 million in expenditures in fiscal year 1999. With these funds, FDA conducted nearly 3,500 domestic animal drug and feed establishment inspections, including those conducted by states under contract with FDA at a cost of about \$600,000. Also included in these expenditures is about \$2 million for laboratory analysis of about 1,800 feed samples associated with field inspection activities.

In aggregate, the headquarters-based activities of FDA's centers accounted for about \$125 million in fiscal year 1999, or 44 percent of the agency's total food safety expenditures. Specifically:

• The Center for Food Safety and Applied Nutrition's activities accounted for about \$96 million in fiscal year 1999, or 34 percent of total agency food safety expenditures. The center operates FDA's Foods Program, which is responsible for ensuring that FDA-regulated food is safe, sanitary, wholesome, and labeled properly. To attain this goal, the center implements programs that address specific food safety concerns; premarket review of food and color additives, infant formula and medical foods accounted for about \$10 million in expenditures, and postmarket monitoring and response activities accounted for about \$17 million in expenditures, and cross-cutting activities that address both premarket and postmarket concerns, such as regulatory policy development and education and outreach activities, accounted for about \$61 million in expenditures. Food safety research and risk assessment accounted for about \$32 million, or about half of cross-cutting activity expenditures.

- The Center for Veterinary Medicine's activities accounted for about \$28 million in fiscal year 1999, or 10 percent, of total agency food safety expenditures. The center operates FDA's Animal Drugs and Feeds Program, which has primary goals of ensuring that only safe and effective animal drugs, feeds, and feed additives are marketed and that foods from animals that are administered drugs and food additives are safe for human consumption. The center maintains surveillance over all animal drugs and feeds to minimize threats to human health. Premarket application review for new animal drugs accounted for the center's largest expenditures, about \$12.8 million in fiscal year 1999. In the same year, FDA reviewed 36 original new animal drug applications, approving 17, and reviewed 767 supplemental applications to change the conditions of existing approvals, approving 421.
- The National Center for Toxicological Research located in Jefferson, Arkansas, accounted for nearly \$1.5 million in fiscal year 1999, or about 1 percent of total agency expenditures. The center's mission is to conduct peer-reviewed scientific research that provides the basis for FDA to make sound, science-based regulatory decisions and to protect the public health through pre- and post-market surveillance. During fiscal year 1999, the center conducted 10 research projects that contributed to FDA's food safety mission; due to the center's research focus, it did not engage in field activities related to food safety.

FDA's relatively small proportion of expenditures on field inspection and supporting activities in comparison to FSIS' expenditures for those activities reflects the absence of specified inspection frequencies in the Federal Food, Drug and Cosmetics Act. The act, which FDA has primary responsibility for administering, generally follows the regulatory approach of allowing almost all food products to enter the market without preapproval by federal agencies. Therefore, FDA is not required to inspect foods or food firms on a given schedule. As a result, FDA inspects the more than 57,000 food establishments under its jurisdiction about once every 5 years, on average, and according to FDA officials, inspected less than 1 percent of the 3.7 million imported food entries in fiscal year 1999.

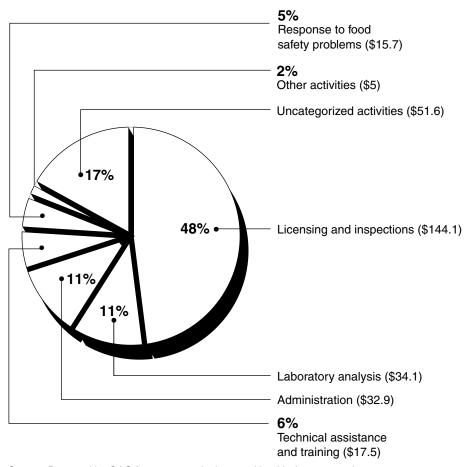
<sup>&</sup>lt;sup>17</sup>In addition, the center conducted food safety research funded through an interagency agreement with the National Institute of Environmental Health and Safety at a total cost of \$8.4 million in fiscal years 1998 and 1999.

States Report Expenditures of About \$300 Million Annually for Food Safety State agriculture and health departments reported expenditures of about \$292 million in fiscal year 1998 and \$301 million in fiscal year 1999. As shown in figure 4, nearly half of the expenditures reported by state agencies, or about \$144 million in fiscal year 1999, were for inspection and licensing activities. Appendix IV provides detailed information on the state agencies' fiscal years 1998 and 1999 expenditures and staff years for food safety activities.

<sup>&</sup>lt;sup>18</sup>Each activity's proportion of total expenditures did not vary by more than 2 percent between fiscal years 1998 and 1999. States were able to report about 83 percent of expenditures by activity category. "Uncategorized activities" represent the 17 percent of expenditures that were reported as a total amount or pooled together for multiple categories.

Figure 4: Aggregate State Agriculture and Health Department Expenditures for Food Safety Activities, Fiscal Year 1999

#### **Dollars in millions**



Source: Prepared by GAO from state agriculture and health department data.

State agriculture and health departments reported food safety expenditures in six categories: licensing and inspection, response to food safety problems, laboratory analysis, technical assistance and training, administration and support, and other expenditures. Specifically, for fiscal year 1999:

 Licensing and inspection activities for a wide variety of establishments, including meat and poultry slaughter and processing plants, fish and seafood plants, shellfish operations, dairy product and egg product plants,

- as well as groceries, restaurants, and institutions, accounted for about \$144 million, or about 48 percent, of state expenditures.
- Laboratory analysis activities, including analysis for microbial contamination, pesticides and other chemical residues, filth and/or sanitation, and food label accuracy, accounted for about \$34 million, or about 11 percent, of state expenditures.
- Administration and support for food safety activities accounted for about \$33 million, or about 11 percent, of state expenditures.
- Technical assistance and training activities for a wide variety of recipients, including farmers, producers, processors, consumers, department staff, and the staff of outside departments, accounted for about \$18 million, or about 6 percent, of state expenditures.
- Response to food safety problems, including investigation of outbreaks, recall activities, natural disasters, and regulatory enforcement activities, accounted for about \$16 million, or about 5 percent, of state expenditures.
- Other activities that did not fit into the above categories, such as committee or council activities, computer or equipment purchases, and database development, accounted for about \$5 million, or about 2 percent, of state expenditures.

State agriculture and health departments reported in aggregate over 1 million establishments under their collective inspection jurisdictions and about 2 million inspections conducted each year, not counting continuous inspections at meat and poultry slaughter plants and other establishments. Groceries, other retail outlets, and restaurants were by far the largest proportion of establishments under state inspection jurisdiction, representing more than 60 percent of all establishments under state jurisdiction. Dairy farms were the next largest group of establishments under state inspection jurisdiction, representing almost 10 percent of the establishments.

While state agriculture and health departments are generally charged with primary food safety responsibilities, a wide variety of other state and local agencies that were not included in our survey also have food safety responsibilities and associated expenditures. About half of the state departments of agriculture and health that we surveyed reported that other state departments or agencies had a role in ensuring food safety, but often only at a specific type of establishment or for a specific food product. States also reported that local governments are involved in conducting food safety inspections at some types of establishments, such as groceries and other retail outlets, restaurants, and at institutions, but are less involved in conducting laboratory analysis, responding to food safety problems, or providing technical assistance and training.

#### Agency Comments and Our Response

We provided FSIS and FDA with a draft of this report for review and comment. FSIS generally agreed with the information provided but said that the report should clearly state that FSIS' responsibilities and expenditures also involve some nonfood safety activities, such as ensuring that products meet consumer expectations for wholesomeness and quality. We believe that the report clearly identifies FSIS' responsibilities—i.e., ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and marked, labeled, and packaged correctly. Regarding nonfood safety expenditures, throughout our review, FSIS officials said that the expenditure information provided to us was for food safety or food safety-related activities. As such, we believe that the FSIS expenditures in this report are appropriately characterized as "food safety" expenditures.

FSIS also said that it would be useful if we included the size and scope of the products it regulates. We believe the report adequately describes the size and scope of FSIS' activities. For example, the report includes information on the number of meat, poultry, egg product, and import establishments FSIS oversees; the number of state and foreign programs it reviewed; and the number and type of inspections it conducted. The level of detail provided on FSIS' responsibilities and activities is similar to that provided on FDA's activities.

FSIS also said that the statistics provided in the report regarding the relative proportions of food purchases and agency food safety expenditures were misleading due to the high risk of FSIS-regulated products compared with some of the FDA-regulated products. While the relative risk of FSIS-regulated products may be greater in some cases than FDA-regulated products, it was not our intent to analyze or compare the risk of products. We believe that the data accurately reflect the proportion of each agency's expenditures and the proportion of consumer expenditures for foods under each agency's jurisdiction. The report also clearly identifies the food products for which each agency has responsibility.

Finally, FSIS said that the report should further define its responsibilities under the Federal Meat Inspection Act and Poultry Products Inspection Act. FSIS also described court actions related to its efforts to design new inspection models that would realign roles and responsibilities of industry and federal inspectors. We modified the report to clearly identify FSIS' responsibilities under the federal meat and poultry inspection acts and described its efforts, with guidance from the courts, to realign the responsibilities and roles of industry and federal inspectors.

FDA agreed with the report and said that it contained valuable information on the allocation of food safety resources. FDA applauded the report for including important information on the efforts and resources expended by states but believed that the report was incomplete because it did not include information on the expenditures and efforts of other agencies, such as USDA's Agricultural Research Service and Animal and Plant Health Inspection Service. We have previously reported on the resources and staffing of the 12 federal agencies involved in food safety activities. By design, the scope of this report was limited to FSIS and FDA food safety activities and expenditures.

FSIS and FDA also provided technical clarifications, which we incorporated into the report as appropriate. FSIS' comments and our responses are included in appendix VI; FDA's comments and our responses are included in appendix VII.

We conducted our review from March through December 2000 in accordance with generally accepted government auditing standards.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies of this report to the Honorable Ann Veneman, Secretary of Agriculture; the Honorable Bernard Schwetz, D.V.M., Ph.D., Acting Principal Deputy Commissioner of the Food and Drug Administration; the Honorable Mitchell Daniels, Jr., Director, Office of Management and Budget; and other interested parties. We will also make copies available to others upon request.

If you have any questions about this report, please contact me at (202) 512-3841. Major contributors to this report are listed in appendix VIII.

Lawrence J. Dyckman

Director, Natural Resources and Environment

# Appendix I: Objectives, Scope, and Methodology

To determine for fiscal years 1998 and 1999 the amount of resources that were expended by the Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the states for food safety and how the agencies actually used these resources, we conducted work at each of the federal agencies and mailed surveys to food safety agencies in 50 states, 3 territories, the Commonwealths of Puerto Rico and the North Mariana Islands, the Federated States of Micronesia, and the District of Columbia (hereafter referred to as states unless specified otherwise). Regarding FSIS and FDA, we obtained appropriations documentation showing the amount of funding provided to each agency. We collected records of expenditures and staff years for specific activities from each of the agencies as follows:

- FSIS provided expenditure and full-time equivalent staff-year information from its accounting system for each of its headquarters and field offices for specific food safety activities within those offices, such as inspection, education, and laboratory activities. FSIS could not provide expenditure information from its accounting system for approximately 2 weeks at the end of fiscal year 1999 because of problems created by the implementation of a new accounting system. Instead, FSIS determined the allocation of expenditures for that time period based on other expenditure records. The Office of Inspector General could not give an opinion on the U.S. Department of Agriculture's (USDA) financial statements for fiscal years 1998 and 1999 because of weaknesses in evidence and internal controls. We did not verify FSIS' accounting information, as it was the only information available, and such an audit was outside of the scope of our review.
- FDA provided records of expenditures and staff years from the agency's Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), and Office of Regulatory Affairs (ORA). Each center used its own methodology to identify and provide expenditures and staff years for specific food safety activities, using a combination of accounting system information, staff activity time records, and estimations. FDA's Office of Financial Management reviewed the information provided by the centers for accuracy and consistency and also provided us with the share of FDA central administrative costs allocable to each center. We did not verify

<sup>&</sup>lt;sup>1</sup>For the past 8 years, USDA has reported to the President that it is unable to provide reasonable assurance that its financial systems conform with certain standards and principles.

FDA's accounting information; we relied on an independent auditor's finding that FDA's accounting records fairly reported its financial position and had no internal control weaknesses in fiscal years 1998 and 1999.

At each agency, we gathered documentation and interviewed agency officials to (1) obtain additional information on the specific activities funded by the expenditures and accomplishments associated with those activities and (2) discuss the expenditure and staff-year information they provided. We also collected documentation and the transfer of funds between food safety and nonfood safety activities at each agency and discussed other financial concerns, such as FSIS' fiscal years 1997 and 1998 anti-deficiency violations caused by the over-obligation of as much as \$4 million each year.<sup>2</sup>

To determine the amounts that states expended on food safety and how they actually used the resources, we surveyed the agriculture and health departments of 50 states, 3 territories, Puerto Rico, and the District of Columbia; we surveyed the health departments of the Commonwealth of the North Mariana Islands and the Federated States of Micronesia, which do not have agriculture departments. In total, we sent out 112 surveys. The survey requested information on the scope of food safety activities performed by their departments, the costs and staffing levels of those activities, the scope and frequency of inspection activities, how the states allocated expenditures between various activities, and perceptions regarding the extent of local government involvement in food safety activities. In developing the survey, we coordinated with staff from FDA's Office of Regulatory Affairs, Division of Federal/State Relations, which is also surveying the states.

We pretested the survey at seven food safety departments in four states—Colorado, Louisiana, Pennsylvania and Virginia—to ensure that our questions were clear, unbiased, and precise and that responding to the survey did not place an undue burden on their agencies. We did not independently verify the accuracy of the state officials' responses. We also reviewed each response to identify internal data inconsistencies and other issues needing clarification, called respondents to resolve questions, and made agreed-upon changes to their responses as appropriate. We received surveys from 98 of the 100 state health and agriculture departments; 6 of

<sup>&</sup>lt;sup>2</sup>The Congress provided \$6 million in the agency's fiscal year 2001 appropriation to pay obligations associated with the 1997 and 1998 anti-deficiency violations.

Appendix I: Objectives, Scope, and Methodology

the 10 food safety agencies in the territories and other entities; and both the health and agriculture departments in the District of Columbia. Our overall response rate was 95 percent.

In completing the survey, we asked the states to obtain information from staff who are most knowledgeable about food safety activities, that they respond only for their department's activities, and that they submit only one survey reflecting the entire department's activities. Regarding expenditures, we asked that states report actual expenditures for each state fiscal year, but if these were not available, to report budget allocations and to inform us which of the two data types they provided to us. Of the responding agencies, 37 reported actual expenditures, 9 reported actual budget allocations, and 55 reported estimates. The majority of the respondents did not report all indirect costs for food safety activities or in-kind contributions, although some did.

We recognize that the total funding amounts reported for food safety activities, as well as the amounts reported for specific categories of activities, could be under- or over-reported because of differences in state department reporting, budgeting, and accounting practices. In some cases, states did not report expenditures, staff years, or establishments by the individual categories provided in the survey; rather, they may have pooled categories together or reported only a total amount. These amounts are reported as "uncategorized." A few state departments sent in several individual responses from various entities, which we consolidated into a single departmental response. Some states provided a response for only one of the two departments. The reported expenditures do not reflect the full cost of food safety activities within each state, because expenditures and activities of other state agencies, local agencies, and private industry, by design, are not included in our scope. However, we believe the information presented in the report reasonably and conservatively represents the food safety activities and expenditures of the survey respondents. Appendix V contains the survey results.

We performed our work from March through December 2000 in accordance with generally accepted government auditing standards.

# Appendix II: The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures

USDA's Food Safety and Inspection Service (FSIS) is responsible for ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and labeled and packaged correctly. The food safety activities undertaken by FSIS to attain these goals during fiscal years 1998 and 1999, the costs and staff years associated with each activity, and outcomes associated with selected activities are presented in the following sections.

# Mission, Organization, and Funding

FSIS accomplishes its mission to ensure that the nation's meat, poultry, and egg products moving interstate and into foreign commerce are safe, wholesome, and labeled and packaged correctly through five program offices located in Washington, D.C. The offices include the Office of the Administrator; Office of Public Health and Science; Office of Policy, Program Development and Evaluation; Office of Field Operations (headquarters and district offices); and Office of Management. In addition, FSIS operates a Technical Service Center in Omaha, Nebraska; three field laboratories located in Alameda, California; St. Louis, Missouri, and Athens, Georgia; and 17 district offices located throughout the United States.<sup>1</sup>

FSIS' food safety activities are funded through annual congressional appropriations, industry reimbursements, and trust funds for meat and poultry inspection. In fiscal years 1998 and 1999, funds available to FSIS totaled about \$678 million and \$714 million, respectively.

#### Food Safety Activities, Expenditures, and Staffing

For fiscal years 1998 and 1999, FSIS expended about \$678 million and \$712 million, respectively, for its food safety activities. As shown in table 1, about 84 percent of the expenditures were for the Office of Field Operations to conduct headquarters and district office food safety activities. The other four offices accounted for about 16 percent of expenditures in aggregate.

<sup>&</sup>lt;sup>1</sup>During fiscal year 1999, FSIS closed its Boston District Office, which changed the number of district offices from 18 to 17.

<sup>&</sup>lt;sup>2</sup>FSIS officials explained that the difference between fiscal year 1999 appropriations of \$714 million and expenditures of \$712 million was due to the specific planning of a \$2 million carryover. This action was taken to prevent any further anti-deficiency violations.

Table 1: FSIS' Expenditures and Staff Years for Food Safety Activities by Office, Fiscal Years 1998 and 1999

Dollars in millions				
	Expenditures (percent of total)		Staff years (percent of total)	
Office	1998	1999	1998	1999
Field Operations- Plant	\$463.4	\$486	9,441	9,330
Inspections	(68)	(68)	(85)	(85)
Field Operations- District	35.4	34.1	521	517
Compliance, Supervision, and Administration	(5)	(5)	(5)	(5)
Field Operations-	69.1	79.9	222	211
Headquarters	(10)	(11)	(2)	(2)
Field Operations -	567.9	600	10,184	10,058
Subtotal	(83)	(84)	(92)	(92)
Management	62.7	61.8	406	382
	(9)	(9)	(4)	(3)
Public Health and Science	23.9	25.2	254	281
	(4)	(4)	(2)	(3)
Policy, Program	18	18.9	149	162
Development, and Evaluation	(3)	(3)	(1)	(1)
Administrator	5.3	6.1	64	68
	(1)	(1)	(1)	(1)
<b>Headquarters Operations</b>	109.9	112	873	893
- Subtotal	(17)	(16)	(8)	(8)
Total	\$677.8	\$712	11,057	10,951
	(100)	(100)	(100)	(100)

Source: FSIS.

#### Office of Field Operations

The Office of Field Operations is responsible for managing a program of regulatory oversight and inspection for the meat, poultry, and egg product laws enforced by FSIS. As such, the office was responsible for the largest proportion of agency expenditures—\$568 million and \$600 million in fiscal years 1998 and 1999, respectively, or about 84 percent of agency expenditures and over 90 percent of staff years. The office is divided into two components—headquarters operations and field district operations. The headquarters unit located in Washington, D.C., sets policy and manages field operations. As shown in table 2, the headquarters unit accounted for about \$69 million and \$79 million in fiscal years 1998 and 1999, respectively, or about 10 percent of total FSIS expenditures. Included within this unit is the Technical Service Center, which serves as the agency's center for technical assistance and guidance for field

operations personnel and industry. The center also reviews domestic and foreign inspection programs.

Table 2: Office of Field Operations Headquarters Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands				
	Expenditures		Staff years	
Office of Field Operations - Headquarters	1998	1999	1998	1999
Grants to states – inspection and other activities	\$40,552	\$44,359	0	0
Grants to states – field automation	0	2,514	0	0
Technical Service Center – review	9,549	9,474	113	113
Field automation	8,023	13,804	0	0
Resource management	3,246	1,781	46	14
Office of Deputy	2,378	1,231	7	5
District enforcement	2,350	2,294	27	29
District inspection	1,300	1,584	15	15
Technical Service Center – training	727	2,484	4	31
Federal/state relations	507	357	5	5
Emergency programs <sup>a</sup>	424	0	5	0
Total <sup>b</sup>	\$69,057	\$79,881	222	212

<sup>&</sup>lt;sup>a</sup>In fiscal year 1999, the Emergency Planning Program was reassigned from the Office of Field Operations to the Office of Management, Planning staff.

Source: FSIS.

Three activities—grants provided to states, the Field Automation and Information Management initiative, and reviews conducted by the Technical Service Center—accounted for \$70 million, or about 88 percent, of the total office expenditures in fiscal year 1999.

- Grants to states accounted for almost 60 percent of total office expenditures. Most of the grants, about \$40 million, funded up to 50 percent of state costs to operate inspection programs for meat and poultry plants that are "equivalent to" federal programs. In fiscal year 1999, 26 states received funding through grants.
- The Field Automation and Information Management initiative accounted for about 17 percent of the Office of Field Operations headquarters expenditures for fiscal year 1999. This initiative provides for uniform automation of FSIS' inspection functions at plants inspected by FSIS and state inspectors. Expenditures were for the purchase and installation of the equipment, as well as training inspectors. For example, during fiscal

<sup>&</sup>lt;sup>b</sup>Totals may not add because of rounding.

Appendix II: The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures

- year 1999, over 750 federal inspectors were trained and 700 computers delivered to FSIS field locations. In addition, over 550 state inspectors were trained, and states received over 500 computers.
- The Technical Service Center conducted review activities that accounted for about 12 percent of field operation's headquarters expenditures for fiscal year 1999. The center is responsible for designing and implementing guidelines and procedures for review of foreign, state, and federal domestic inspection programs. The center also conducts special inquiries and reviews, such as reviews of state inspection programs, to ensure they are equivalent to the federal programs. In fiscal year 1999, the center reviewed the program documentation of 36 countries exporting to the United States to determine if they had implemented Hazard Analysis and Critical Control Point systems and Salmonella testing programs equivalent to U.S. requirements. In that same year, the center's review staff reviewed 96 state-inspected establishments in 11 states to determine their effectiveness and whether or not they were equivalent to the federal inspection programs.

The Office of Field Operation's field district offices conduct compliance and inspection activities for meat, poultry, and egg products. As shown in table 3, the field district offices accounted for expenditures of about \$499 million and \$520 million in fiscal years 1998 and 1999, respectively, or about 73 percent, of agency expenditures and about 90 percent of staff years. Within the district offices, 93 percent of their expenditures were for in-plant inspections and 7 percent for the administration of those activities and compliance activities.

Table 3: Office of Field Operations District Office Expenditures and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands					
	Expendi	tures	Staff years		
Office of Field Operations – District Office	1998	1999	1998	1999	
Jackson, MS	\$48,857	\$51,464	1,078	1,063	
Springdale, AR	47,607	52,420	992	982	
Des Moines, IA	39,698	40,766	805	801	
Atlanta, GA	39,301	41,782	828	866	
Dallas, TX	32,432	34,057	660	641	
Lawrence, KS	31,715	33,232	650	643	
Alameda, CA	30,988	32,104	583	565	
Raleigh, NC	29,973	31,585	637	635	
Beltsville, MD	26,572	28,166	569	556	
Philadelphia, PA	22,960	24,268	442	436	
Albany, NY	22,002	22,239	384	383	
Minneapolis, MN	20,943	21,560	390	379	
Chicago, IL	20,916	21,525	400	398	
Madison, WI	19,382	19,226	366	329	
Pickerington, OH	19,314	19,851	364	370	
Salem, OR	17,506	18,905	309	326	
Boulder, CO	16,180	16,230	296	295	
Boston, MA	12,426	10,751	212	180	
Total <sup>a</sup>	\$498,771	\$520,133	9,961	9,847	

<sup>&</sup>lt;sup>a</sup>Totals may not add because of rounding.

Source: FSIS.

Under the guidance and direction of the Office of Field Operation's headquarters District Inspection and District Enforcement offices, the districts manage and direct both inspection and compliance activities. As shown in table 4, the district offices direct inspections of meat and poultry slaughter plants, processing plants, and plants that have combined slaughter and processing operations, and other establishments such as egg product plants. In addition, the offices inspect these products at import points. For example, in fiscal year 1999, they inspected over 99 billion pounds of meat and poultry and 3 billion pounds of egg products at about 6,000 domestic plants and inspected 3.2 billion pounds of imported meat and poultry from 34 countries. The district offices also direct compliance reviews that are designed to (1) monitor businesses engaged in the production, distribution, and marketing of food products and (2) prevent the violation of laws and regulations. As a result of these reviews, in fiscal year 1999, the district offices detained approximately 20 million pounds of

Appendix II: The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures

adulterated meat and poultry products and initiated 118 enforcement actions to stop inspection operations in federally inspected plants.

Table 4: District Office Inspection Responsibilities by Establishment Type, Fiscal Year 2000

	Type of establishment				
District Offices	Meat and poultry slaughter	Meat and poultry processing	Meat and poultry combination slaughter and processing	Other <sup>a</sup>	Total⁵
Jackson, MS	38	142	44	30	254
Springdale, AR	7	143	70	30	250
Des Moines, IA	4	135	61	60	260
Atlanta, GA	29	336	45	49	459
Dallas, TX	10	188	48	60	306
Lawrence, KS	7	157	80	24	268
Alameda, CA	3	563	55	104	725
Raleigh, NC	14	77	27	19	137
Beltsville, MD	14	123	41	27	205
Philadelphia, PA	38	291	101	25	455
Albany, NY	46	817	74	51	988
Minneapolis, MN	6	148	75	39	268
Chicago, IL	4	314	39	32	389
Madison, WI	1	262	50	36	349
Pickerington, OH	6	217	49	20	292
Salem, OR	12	258	57	62	389
Boulder, CO	8	169	44	20	241
Total	247	4,340	960	688	6,235

<sup>&</sup>lt;sup>a</sup>Other includes egg product, import, and other establishments not included in the other categories.

Source: FSIS.

#### Office of Management

The Office of Management is responsible for providing centralized administrative and support services to all other FSIS program offices, including human resource management, strategic planning, procurement, and financial management. As shown in table 5, the office accounted for expenditures of about \$63 million and \$62 million in fiscal years 1998 and 1999, respectively, or about 9 percent, of agency expenditures and 4 percent of staff years. About 46 percent of the office's expenditures were for "central charges" attributed to the entire agency. Almost one-half of

<sup>&</sup>lt;sup>b</sup>Excludes 244 Talmadge-Aiken establishments that are staffed and inspected by state employees with FSIS oversight.

Appendix II: The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures

these charges were expenditures for benefits such as worker's compensation and unemployment. Other charges included "other services" such as contractual and consulting services, communications, utilities, and rent.

Table 5: Office of Management Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands				
	Expenditures		Staff years	
Office of Management	1998	1999	1998	1999
Central charges	\$29,563	\$27,684	0	0
Administrative services	9,824	11,304	56	49
Human resources	8,830	8,259	151	134
Budget <sup>a</sup>	5,092	1,569	103	23
Automated information services	3,738	3,673	38	29
Civil rights	1,478	1,806	16	18
Labor-management relations	997	1,345	11	18
Planning	984	1,218	14	18
Field automation and information management staff <sup>b</sup>	690	0	8	0
Reorganization	548	0	0	0
Office of Deputy	518	711	5	7
Internal control	459	496	6	6
Financial management	0	3,720	0	79
Total <sup>c</sup>	\$62,722	\$61,784	406	382

<sup>&</sup>lt;sup>a</sup>During fiscal years 1998 and 1999, the Budget and Financial Management Divisions were separated.

Source: FSIS.

## Office of Public Health and Science

The Office of Public Health and Science is responsible for conducting scientific analysis, providing advice, collecting data, and making recommendations involving all public health and science concerns relating to products under FSIS' jurisdiction. This includes mission activities such as epidemiology and risk assessment, surveillance, response to food safety emergencies, and laboratory analysis by the agency's three field laboratories. As shown in table 6, the office accounted for expenditures of about \$24 million and \$25 million in fiscal years 1998 and 1999, respectively, or about 4 percent, of agency expenditures and 2 to 3 percent of staff years.

<sup>&</sup>lt;sup>b</sup>After fiscal year 1998, Field Automation and Information Management staff expenditures were charged to the Office of Field Operations rather than the Office of Management.

<sup>°</sup>Totals may not add because of rounding.

Table 6: Office of Public Health and Science Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands				
	Expend	litures	Staff ye	ars
Office of Public Health and Science	1998	1999	1998	1999
Laboratories	\$13,325	\$13,785	175	190
Office of Deputy	4,868	5,531	10	15
Microbiology	1,689	1,876	22	23
Chemistry and toxicology	910	1,011	11	12
Food hazard surveillance	910	1,019	13	12
Emerging pathogens	853	955	10	9
Emergency response	566	621	6	8
Epidemiology & risk assessment	413	432	4	13
Research oversight <sup>a</sup>	374	0	4	0
Total <sup>b</sup>	\$23,907	\$25,231	254	281

<sup>a</sup>In fiscal year 1999, expenditures for Research oversight were charged to the Office of Public Health and Science's Office of Deputy.

Source: FSIS.

The combined expenditures for the three field laboratories and the Office of Public Health and Science's Office of Deputy accounted for 77 percent of all expenditures for that program office in fiscal year 1999.

- Three field laboratories located in Alameda, California; Athens, Georgia; and St. Louis, Missouri, accounted for more than 50 percent of the office expenditures and almost 70 percent of the staff years. These laboratories coordinate and conduct analyses in microbiology, chemistry, and pathology for food safety in meat, poultry, and egg products. Among other things, they conduct these services to (1) support both domestic and import inspections done by FSIS, (2) support the agency's Hazard Analysis and Critical Control Point initiative, and (3) identify emerging pathogens in the food supply. In addition, the laboratories provide technical assistance to FSIS field staff.
- The Office of Deputy accounted for about 22 percent of office expenditures, with the majority of these being for charges attributed specifically to the Office of Public Health and Science. Most of these charges are for "other services" such as facilities renovations, equipment, or payments to other agencies for studies. For example, in fiscal year 1999, the Office of Deputy expended \$1.2 million to repair its Eastern Laboratory in Athens, Georgia, and provided the Centers for Disease Control and Prevention (CDC) with \$1.5 million for Food Net surveys.

bTotals may not add due to rounding.

Appendix II: The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures

## Office of Policy, Program Development and Evaluation

The Office of Policy, Program Development and Evaluation is responsible for, among other things, coordinating activities such as developing and recommending domestic and international policies for FSIS; reviewing product processes, standards, and labeling; and developing and evaluating inspection programs. As shown in table 7, the office accounted for expenditures of about \$18 million and \$19 million in fiscal years 1998 and 1999, respectively, or about 3 percent, of agency expenditures and 1 percent of staff years.

Table 7: Office of Policy, Program Development and Evaluation Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands				
	Expenditures		Staff years	
Office of Policy, Program Development and Evaluation	1998	1999	1998	1999
Inspection development	\$4,562	\$4,584	30	34
Office of Deputy	2,883	3,614	22	16
Hazard analysis and critical control point initiative <sup>a</sup>	2,322	0	2	0
Labeling and standards	2,317	2,101	32	26
International policy	1,436	1,697	14	18
Animal production	1,112	2,029	6	6
Regulatory development	1,070	1,563	16	18
Evaluation and analysis	940	1,279	11	12
Compounds review <sup>b</sup>	719	0	12	0
Codex <sup>c</sup>	654	40	5	<1
Label review <sup>b</sup>	0	1,542	0	24
Management support staff <sup>d</sup>	0	500	0	7
Total <sup>e</sup>	\$18,014	\$18,949	149	162

<sup>&</sup>lt;sup>a</sup>In fiscal year 1999, the hazard analysis and critical control point initiative activity no longer existed.

Source: FSIS.

The combined expenditures of two offices in the Office of Policy, Program Development and Evaluation—the Inspection Development Division and the Office of Deputy— accounted for over 40 percent of all expenditures for that office in fiscal year 1999.

The Inspection Systems Development Division designs, develops, and tests
new or modified inspection systems for food safety. This division works
on developing specific changes to FSIS' inspection procedures, including
work related to hazard analysis and critical control point procedures. For
example, this division has contracted for the collection of microbiological
and organoleptic data in poultry and hog plants to support the proposed

<sup>&</sup>lt;sup>b</sup>In fiscal year 1999, FSIS eliminated the Compounds Review Office because the agency no longer does those reviews, and FSIS reorganized its former labeling and compounds review function.

<sup>°</sup> The Codex Office manages and coordinates U.S. involvement and participation in the Codex Alimentarius Commission, a United Nations' international standard-setting organization for food safety and public health.

<sup>&</sup>lt;sup>d</sup>At the end of fiscal year 1998, expenditures by the management support staff were not separately tracked by FSIS' accounting system.

<sup>\*</sup>Totals may not add because of rounding.

Appendix II: The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures

Hazard Analysis and Critical Control Point-based Inspection Models Project.

• The Office of Deputy accounted for about 20 percent of total office expenditures. Other than personnel expenditures, the majority of these were for "centrally administered" charges. According to FSIS officials, these are charges associated with the entire Office of Policy, Program Development and Evaluation office, rather than a specific division within that office. Most of these charges are for "other services," such as production of food safety educational materials.

#### Office of the Administrator

The Office of the Administrator is responsible for overall management of the agency and activities such as public affairs, food safety education, and coordination of U.S. involvement in international standard setting for food safety and maintaining liaisons with trade organizations. As shown in table 8, the office accounted for expenditures of about \$5 million and \$6 million in fiscal years 1998 and 1999, respectively, or about 1 percent of agency expenditures and 1 percent of staff years.

Table 8: Office of the Administrator Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands				
	Expendit	tures	Staff yea	ırs
Office of the Administrator	1998	1999	1998	1999
Education	\$2,351	\$1,822	29	24
Office of the Administrator	1,374	1,777	9	10
Executive management	1,248	1,204	21	21
The Congress and public affairs	309	578	5	7
U.S. Codex <sup>a</sup>	0	746	0	6
Total <sup>b</sup>	\$5,283	\$6,127	64	68

<sup>&</sup>lt;sup>a</sup>All Codex expenditures in fiscal year 1998 were charged to the Office of Policy, Program Development and Evaluation.

Source: FSIS.

A significant portion of the Office of the Administrator's funding, about 30 percent in fiscal year 1999, was expended on food safety education. The functions of the Food Safety Education staff are different from other units in the office because, while others primarily conduct management and policy type activities, the food safety education staff provides FSIS food safety education programs to the public. These programs are designed to educate producers, distributors, food preparers, and consumers on the prevention of foodborne illnesses. This office also operates the agency's

<sup>&</sup>lt;sup>b</sup>Totals may not add because of rounding.

Appendix II: The Food Safety and Inspection Service's Fiscal Years 1998 and 1999 Food Safety Expenditures

Meat and Poultry Hotline to answer consumer inquiries. In fiscal year 1999, this staff coordinated the agency's food safety education campaign, FightBAC!  $^{\rm tm}$ , and handled about 36,000 consumer calls to the hotline.

Food safety is one of the Health and Human Service's (HHS) Food and Drug Administration's (FDA) many responsibilities, shared by multiple units within the agency. FDA food safety activities undertaken by each unit during fiscal years 1998 and 1999, the costs and staff years associated with each activity, and outcomes associated with selected activities are presented in the following sections.

# Mission, Organization, and Funding

FDA accomplishes its mission of protecting the public health by 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 through six centers. Three of these centers are responsible for food safety activities: the Center for Food Safety and Applied Nutrition (CFSAN) for the Foods Program; the Center for Veterinary Medicine (CVM) for the Animal Drugs and Feeds Program; and the National Center for Toxicological Research (NCTR) for research into the toxicity of products. In addition, the Office of Regulatory Affairs conducts inspections and compliance reviews and collects and analyzes product samples in support of the centers. The three centers and the Office of Regulatory Affairs are also provided administrative support through numerous offices, such as the Office of the Commissioner and the Office of Management and Systems.

FDA food safety facilities are distributed nationwide. FDA headquarters and CVM are located in Rockville, Maryland, CFSAN is located in Washington, D.C., and NCTR is located in Jefferson, Arkansas. The two Centers, CVM and CFSAN, have a research facility in Beltsville, Maryland; CFSAN has a fishery research center in Dauphin Island, Alabama, and a food technology research center in Chicago, Illinois. Field facilities, primarily staffed by Office of Regulatory Affairs personnel conducting inspections and laboratory activities, are distributed across 5 regional offices, 19 district offices, and 13 laboratories, and are supported by over 120 resident posts.

FDA's appropriations for fiscal years 1998 and 1999 were about \$1.050 billion and \$1.130 billion, respectively. Each of FDA's programs received a specified amount of the total appropriation to conduct both their food safety and nonfood safety-related responsibilities. For example, in fiscal year 1999, the Foods Program received about \$235 million, of which about \$222 million was expended on CFSAN and related field food safety activities. The difference reflects that while most of the Food Program's responsibilities relate to food safety, the program also has other responsibilities and related expenditures for other activities, such as

cosmetics safety. Similarly, in fiscal year 1999, the Animal Drugs and Feeds Program received about \$43 million, of which about \$38 million was expended on CVM and related field food safety activities. The difference reflects that while the majority of the Animal Drugs and Feeds Program's responsibilities relate to food safety, the program also has responsibilities and related expenditures for nonfood animals, such as dogs and cats. The Office of Regulatory Affairs receives a specific amount of the appropriation for each program to conduct field activities in support of the centers.

## FDA Food Safety Activities, Expenditures, and Staffing

For fiscal years 1998 and 1999, as shown in table 9, about 56 percent of FDA's food safety expenditures and over 60 percent of its staff years were for food safety activities conducted in the field, and the remaining 44 percent of expenditures and nearly 40 percent of the staff years were for the headquarters-based activities of the centers.

Table 9: FDA's Expenditures and Staff Years for Food Safety Activities by Center, Fiscal Years 1998 and 1999

Dollars in millions				
_	Expenditures (percent of total)		Staff yea (percent of	
Center	1998	1999	1998	1999
Field Operations – Center for	\$127.2	\$145.2	1,426	1,535
Food Safety and Applied Nutrition	(50)	(51)	(57)	(59)
Field Operations – Center for	13.7	13.5	138	137
Veterinary Medicine	(5)	(5)	(6)	(5)
Field Operations  Subtotal	140.9	158.7	1,564	1,672
	(56)	(56)	(62)	(64)
Headquarters Operations –	85.7	95.6	733	721
Center for Food Safety and Applied Nutrition	(34)	(34)	(29)	(28)
Headquarters Operations -	25.9	27.7	203	206
Center for Veterinary Medicine	(10)	(10)	(8)	(8)
Headquarters Operations –	0.8	1.5	5	10
National Center for Toxicological Research	(<1)	(1)	(<1)	(<1)
Headquarters Operations -	112.4	124.8	941	937
Subtotal	(44)	(44)	(38)	(36)
Total	\$253.4	\$283.4	2,505	2,609
	(100)	(100)	(100)	(100)

<sup>&</sup>lt;sup>a</sup>Totals may not add because of rounding.

Source: FDA.

FDA Field Food Safety Activities for Foods and Animal Drugs and Feeds Field activity expenditures of about \$141 million and \$159 million in fiscal years 1998 and 1999, respectively, accounted for about 56 percent of total FDA food safety expenditures each year and 62 to 64 percent of FDA's staff years. CFSAN is responsible for directing field activities related to food products, and CVM is responsible for field activities related to feeds and drugs for food animals. These field activities, conducted by FDA's Office of Regulatory Affairs, include the inspection of food and animal feed and drug establishments under the agency's jurisdiction, field examination of food and feed products, and the collection and analysis of product samples to ensure that the products comply with applicable regulations. The overall results of FDA's inspection and sample analysis fieldwork are presented in table 10.

Table 10: Number of FDA Food Safety Field Inspections, Examinations, and Samples Analyzed, Fiscal Years 1998 and 1999

Activity	1998	1999
Inspections		
Food importers	940	765
Domestic food establishments <sup>a</sup>	11,922	14,680
Feed establishments <sup>b</sup>	4,182	3,128
Animal drug establishments	439	357
Total Inspections <sup>c</sup>	17,483	18,930
Field Examinations		
Imported foods	17,140	15,828
Domestic foods	2,172	1,992
Imported animal drugs/feeds	46	59
Total Field Examinations	19,358	17,879
Sample Analyses		
Import food samples	16,802	15,439
Domestic food samples	10,894	9,335
Animal drug/feed samples <sup>d</sup>	1,580	1,784
<b>Total Samples Analyzed</b>	29,276	26,558

<sup>&</sup>lt;sup>a</sup>Includes state contract inspections that are funded by the Center for Food Safety and Applied Nutrition at a cost of a little over \$2 million each year.

Source: FDA.

Field activities for foods accounted for about \$127 million in fiscal year 1998 and \$145 million in fiscal year 1999, or about 90 percent of FDA's food safety field expenditures. Table 11 lists the fiscal years 1998 and 1999 food field expenditures of \$1 million or more. FDA food field activities accounting for less than \$1 million in annual expenditures each, such as criminal investigations, emergency response to foodborne outbreaks, and various unplanned activities, represented in aggregate less than \$8 million in expenditures each year. The expenditures reflect the total cost of each activity, including inspection, investigation, field examination, sample collection, sample analysis, and other costs, such as Office of Regulatory Affairs management and administrative support expenditures, associated with each activity. FDA agencywide support expenditures accounted for about 8 percent of food product field expenditures.

<sup>&</sup>lt;sup>b</sup>Includes state contract feed mill inspections that are funded by the Center for Veterinary Medicine at a cost of \$833,000 and \$614,000 in fiscal years 1998 and 1999, respectively.

<sup>&</sup>lt;sup>c</sup>An individual importer, food, or feed establishment may be inspected more than once a year.

<sup>&</sup>lt;sup>d</sup>FDA and the states also analyzed over 200 Bovine Spongiform Encephalopathy tissue residue samples each year.

Table 11: Food Field Activities Accounting for Over \$1 Million in Expenditures and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands					
	Expend	Expenditures		ears	
Food field activities	1998	1999	1998	1999	
Imported foods general – import entry review/refused entries	\$24,939	\$26,932	312	314	
Domestic fish and fishery products inspection (hazard analysis and critical control point)	11,371	14,420	142	168	
Imported seafood products inspection (hazard analysis and critical control point)	11,283	12,755	141	149	
Domestic food safety	7,382	10,805	92	126	
Pesticides and industrial chemicals in imported foods	5,361	6,580	67	77	
Office of Regulatory Affairs/Center directed research projects	4,919	4,701	62	55	
Other domestic food safety initiative activities	4,717	1,543	59	18	
Consumer complaints	4,270	4,642	53	54	
Pesticides and industrial chemicals in domestic foods	3,597	3,436	45	40	
Total diet studies	3,516	4,447	44	52	
General retail food protection (state)	3,311	4,318	41	50	
Interstate milk shippers	3,005	3,502	38	41	
Imports – food and color additives	2,863	3,504	36	41	
Import produce assignment (fiscal year 1999)	0	3,023	0	35	
Molluscan shellfish evaluation	2,670	2,380	33	28	
Toxic elements in foods (domestic/import)	2,521	2,789	32	33	
Interstate travel sanitation	2,365	2,592	30	30	
Domestic and import cheese	2,088	1,371	26	16	
Mycotoxins in domestic foods	2,084	3,126	26	37	
State contract inspection	2,040	2,036	0	0	
Short-term assignments	1,512	2,146	19	25	
Domestic acidified and low-acid canned food	1,396	2,375	17	28	
Import acidified and low-acid canned food	1,211	1,110	15	13	
Domestic nutrition sampling	1,153	1,703	14	20	
Other activities	6,617	7,337	82	85	
Agencywide support	11,000	11,600	0	0	
Total <sup>a</sup>	\$127,191	\$145,173	1,426	1,535	

<sup>&</sup>lt;sup>a</sup>Totals may not add because of rounding.

Source: FDA.

Five of the field activities listed in table 11 accounted for about \$71 million, or almost 50 percent, of total food field expenditures in fiscal year 1999.

- Imported foods general activities accounted for about \$27 million, or about 19 percent, of food field expenditures. The objective of this activity was to ensure that imported foods comply with federal law and with guidelines for gross and microbiological filth. To attain this objective, FDA conducted import field examinations of the foods most likely to be out of compliance, collected samples, and conducted analysis for filth, decomposition, and microbiological contamination.
- The domestic fish and fish products inspection activity accounted for about \$14 million, or about 10 percent, of food field expenditures. The objective of this activity was to ensure that domestic establishments involved in the production, storage, and distribution of fish and fish products are in compliance with the applicable hazard analysis and critical control point regulations as well as with federal law. To attain this objective, FDA conducted establishment inspections, and samples were collected and analyzed when appropriate, with a priority on firms processing scombrotoxic products, smoked products, vacuum packed products, and ready-to-eat products, as well as follow-up on firms found to be in noncompliance with hazard analysis and critical control point regulations.
- The imported seafood products inspection activity accounted for about \$13 million, or about 9 percent, of food field expenditures. The objective of this activity was to ensure a safe imported seafood supply by enforcing importer compliance with the seafood hazard analysis and critical control point regulation and federal law, focusing on importers of high-risk products and firms found in noncompliance with the hazard analysis and critical control point regulations. To attain this objective, trained investigators reviewed importers' written documentation demonstrating that the product was produced under a hazard analysis and critical control point program, with priority assigned to firms processing scombrotoxic products, smoked products, vacuum packed products, and ready-to-eat products.
- The domestic food safety activity accounted for about \$11 million, or about 7 percent, of food field expenditures. The objective of this activity was to ensure that domestic establishments involved in the production, storage and distribution of food products are in compliance with federal law and that manufacturers produce products under good manufacturing practices. To attain this objective, FDA conducted inspections (including hazard analysis and critical control point) and investigations and

- necessary sample collections and analyses to document and support inspection findings.
- The pesticides and chemicals in imported foods activity accounted for about \$7 million, or about 5 percent, of food field expenditures. The objective of this activity was to determine the incidence and level of pesticides and industrial chemicals in imported food (including seafood and aquaculture products) and to prevent importation of products not meeting federal requirements. To attain this objective, FDA developed pesticide import sampling plans, collected samples, and analyzed samples for chemical contamination.

Animal drugs and feeds field activity expenditures of about \$13.7 million and \$13.5 million in fiscal years 1998 and 1999, respectively, accounted for about 10 percent of FDA's total food safety field expenditures each year. Table 12 lists the fiscal years 1998 and 1999 animal feed and drug field activity expenditures of \$1 million or more. Other field activities, such as criminal investigations, response to consumer complaints, and various unplanned activities in aggregate, accounted for just over \$3 million in expenditures each year. The expenditure amounts reflect the total cost of each activity, including inspection, investigation, field examination, sample collection, sample analysis, and other costs, such as Office of Regulatory Affairs management and administrative support expenditures, associated with each activity. FDA agencywide support expenditures accounted for about 8 percent of feed and drug field expenditures.

Table 12: Animal Drugs and Feeds Field Activities Accounting for Over \$1 Million in Expenditures and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands				
	Expend	litures	Staff ye	ars
Animal drugs and feeds field activities	1998	1999	1998	1999
Medicated feeds	\$2,316	\$2,081	27	24
Feed contaminants	2,222	2,380	26	28
Drug processing and new animal drug inspection	1,974	1,605	23	19
Illegal residues in meat and poultry	1,412	1,793	17	21
Office of Regulatory Affairs/Center directed research projects	1,207	1,213	14	14
Other field activities	3,418	3,338	31	31
Agencywide support	1,200	1,100	0	0
Total <sup>a</sup>	\$13,749	\$13,510	138	137

<sup>&</sup>lt;sup>a</sup>Totals may not add because of rounding.

Source: FDA.

Five of the field activities listed in table 12 accounted for about \$9 million, or almost 70 percent, of total animal drugs and feeds field expenditures in fiscal year 1999.

- The feed contaminants activity accounted for about \$2.4 million, or about 18 percent, of expenditures. The objective of this activity is to monitor domestic and imported animal feed and feed ingredients to prevent the widespread contamination of the nation's food supply. To attain this objective, FDA conducts inspections and investigations and collects and analyzes samples of feed and feed ingredients, including chemical and microbiological testing for mycotoxins, pesticides, industrial chemicals, metals, and microbiologicals.
- The medicated feeds activity accounted for about \$2.1 million, or about 15 percent, of expenditures. The objective of this activity is to ensure the marketing of safe and effective animal feeds. To attain this objective, FDA conducts inspections of registered medicated feed establishments, collects and analyzes feed samples, and audits the results of coordinated state inspection efforts.
- The illegal residues in meat and poultry activity accounted for about \$1.8 million, or about 13 percent, of expenditures. The objective of this activity is to ensure a safe food supply by conducting follow-up investigations and inspections when illegal residues are reported to FDA by the Food Safety

and Inspection Service, <sup>1</sup> and to initiate regulatory sanctions against those persistently causing residues. To attain this objective, FDA works cooperatively via memorandums of understanding with the Food Safety and Inspection Service and the Environmental Protection Agency, as well as through agreements or contracts with states to inspect first-time violators.

- The drug processing and new animal drug inspection activity accounted for about \$1.6 million, or about 12 percent, of expenditures. The objective of this activity is to fulfill FDA's obligation to inspect animal drug establishments that are registered with FDA, ensuring that animal drug products are being manufactured, processed, and controlled under approved conditions. To attain this objective, FDA conducts inspections of registered animal drug establishments and chemical and microbiological examinations to ensure the sterility, purity, identity, and potency of the drugs.
- Office of Regulatory Affairs/Center directed research projects accounted for about \$1.2 million, or about 9 percent, of expenditures. The objective of this activity is to develop new and/or improved methodology in support of regulatory analysis for animal drugs and feeds. To attain this objective, FDA establishes research goals in its workplan; the research results are distributed within FDA and/or published in the scientific literature.

Center for Food Safety and Applied Nutrition Headquarters Food Safety Activities CFSAN headquarters operations, which is responsible for FDA's Foods Program, accounted for expenditures of about \$86 million and \$96 million in fiscal years 1998 and 1999, respectively, or about 34 percent of total agency food safety expenditures. As shown in table 13, CFSAN's fiscal years 1998 and 1999 headquarters activities were divided into four major categories: premarket, postmarket, crosscutting, and FDA agencywide support expenditures. CFSAN expenditures for management and administrative support of food safety activities are included in the expenditure amount for each activity.

<sup>&</sup>lt;sup>1</sup>The Food Safety and Inspection Service obtains samples when it fulfills its food safety responsibilities for meat and poultry.

Table 13: CFSAN Headquarters Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands				
	Expenditures		Staff ye	ars
CFSAN headquarters activity	1998	1999	1998	1999
Premarket activities				
Food and color additives	\$6,788	\$9,062	75	73
Infant formula and medical foods	1,090	1,246	13	13
Premarket subtotal	7,878	10,308	88	86
Postmarket activities				
Planning and policy implementation for microbial contaminants	3,882	6,726	14	13
Federal/state cooperative programs	2,906	3,537	32	35
Planning and policy implementation for monitoring imports	1,177	1,184	14	13
Seafood safety (hazard analysis and critical control point)	1,177	1,511	3	3
Hazard analysis and critical control point (other than seafood)	931	1,288	7	11
Low-acid canned foods	672	637	8	7
Nutrition monitoring	589	546	4	6
Planning and policy implementation for chemical and other contaminants	447	346	3	3
Recalls, outbreak investigations and tracebacks	336	546	4	6
Planning and policy implementation for pesticide residue monitoring	302	488	2	4
Food labeling	255	157	0	0
Adverse event reporting	84	91	1	1
Postmarket subtotal	12,758	17,057	92	102
Crosscutting activities (pre- and postmarket)				
Food safety research/risk assessment (intramural)	32,112	32,343	336	310
Regulatory policy development	9,887	9,845	114	106
Education/outreach	6,719	7,560	71	76
Collaborative research with academia/industry	6,465	7,699	7	11
International activities	2,492	3,166	25	31
Crosscutting subtotal <sup>a</sup>	57,675	60,613	553	534
Agencywide support	7,400	7,600	0	0
Total <sup>b</sup>	\$85,711	\$95,578	733	721

<sup>&</sup>lt;sup>a</sup>According to FDA officials, crosscutting activity staff provide significant support to certain premarket and postmarket activities; for example, the seafood safety (hazard analysis and critical control point) activity receives support of approximately 30 staff years from various crosscutting activities.

<sup>&</sup>lt;sup>b</sup>Totals may not add because of rounding.

Source: FDA.

Premarket activities to evaluate the safety of products before they are available to consumers accounted for about 11 percent of CFSAN's headquarters expenditures in fiscal year 1999. Food and color additive activity expenditures accounted for about \$9 million, or nearly 90 percent, of premarket expenditures. In addition to its ongoing review of food additive petitions, CFSAN implemented procedures to expedite the review of food additives intended to decrease the incidence of foodborne illness through their antimicrobial actions against pathogens that may be present in food. Other activities addressed food contact substances and irradiation labeling.

Postmarket activities to evaluate the safety of products that are in the marketplace accounted for about 18 percent of CFSAN's headquarters expenditures in fiscal year 1999. CFSAN's planning and policy implementation for microbial contaminants, which accounted for \$6.7 million, or 39 percent, of postmarket expenditures, included surveillance to assess antimicrobial resistance, microbiological research, and risk assessment to develop science-based solutions to detect and control microbial contamination. Another \$3.5 million, or 21 percent, of postmarket expenditures, were for cooperative programs with states addressing the safety of retail dairy and shellfish products.

Crosscutting activities that address both premarket and postmarket food safety issues accounted for about 63 percent of CFSAN's headquarters expenditures in fiscal year 1999. CFSAN's food safety research and risk assessment, which accounted for \$32.3 million, or 53 percent of crosscutting expenditures, included activities such as the completion of draft risk assessments for *Listeria*, *Vibrio parahaemolytics*, and methylmercury and food safety research in support of the National Food Safety Initiative.

FDA agencywide support accounted for about 8 percent of CFSAN's headquarters expenditures in fiscal year 1999. These expenditures represent CFSAN's allocation for its share of central direction and administrative services to ensure that FDA's efforts are effectively managed and that resources are put to the most efficient use. Functions include agencywide policy, regulatory and legislative development, scientific coordination, planning and evaluation, consumer communication and public information, and management expertise and coordination in financial management, personnel, contracts and grants administration, and procurement.

Center for Veterinary Medicine Headquarters Food Safety Activities

CVM headquarters operations, responsible for FDA's Animal Drugs and Feeds Program, accounted for about \$26 million and \$28 million in fiscal years 1998 and 1999, respectively, or about 10 percent of total agency food safety expenditures. As shown in table 14, for fiscal years 1998 and 1999, CVM headquarters activities were divided into three major categories: premarket, postmarket, and FDA agencywide support expenditures. CVM expenditures for management and administrative support for food safety activities are included in the total cost for each activity.

Table 14: CVM Headquarters Activities, Expenditures, and Staff Years, Fiscal Years 1998 and 1999

Dollars in thousands						
	Expenditures			Staff years		
CVM headquarters activities	1998	1999		1998	1999	
Premarket activities						
Application review	\$8,097	\$8,310	82	78		
Intramural research	3,257	3,344	25	26		
Education/outreach	691	710	9	10		
Risk assessment	0	450	0	3		
Premarket subtotal	12,045	12,814	116	117		
Postmarket activities						
Epidemiology systems and surveillance	4,670	4,360	44	42		
Intramural research	3,595	3,849	25	27		
Compliance activities	1,400	2,000	15	16		
Extramural research	1,100	971	2	2		
Education and outreach	876	1,490	2	2		
Postmarket subtotal	11,641	12,670	88	89		
Agencywide support	2,200	2,200	0	0		
Total <sup>a</sup>	\$25,886	\$27,684	203	206		

<sup>&</sup>lt;sup>a</sup>Totals may not add because of rounding.

Source: FDA.

Premarket activities to ensure that products are safe before they are available to consumers, accounted for about 46 percent of expenditures each year. CVM's New Animal Drug Application review and approval process, including associated education, research and risk assessment activities, accounted for \$12.8, or 100 percent, of its premarket expenditures. CVM is implementing a phased review process, which will provide drug application sponsors with more timely feedback and early

<sup>&</sup>lt;sup>2</sup>Differing from CFSAN, CVM did not identify crosscutting activities as a category.

detection of application deficiencies. CVM approved 523 original or supplemental new and generic animal drug applications in fiscal year 1999.

Postmarket activities to ensure the safety of products that are in the marketplace accounted for about 46 percent of expenditures each year. CVM's epidemiological systems and surveillance activities, which accounted for nearly \$4.4 million, or about 34 percent, of postmarket expenditures, included collaborative efforts with other federal agencies to monitor nationwide changes in susceptibilities to 17 antimicrobial drugs through the National Antimicrobial Resistance Monitoring System and efforts to monitor and reduce drug residues in meats. Intramural research to detect microbial and chemical contaminants that may be present in animal feeds and animal food products consumed by humans and research on antibiotic resistance accounted for another \$3.6 million, or 30 percent, of postmarket expenditures. This included the development and validation of a test for detecting bovine protein in animal feeds, an important component of its Bovine Spongiform Encephalopathy regulatory strategy.

Agencywide support accounted for about 8 percent of expenditures. These expenditures represent CVM's share of central direction and administrative services, as previously described for CFSAN. These expenditures represent CVM's allocation for its share of central direction and administrative services to ensure that FDA's efforts are effectively managed and that resources are put to the most efficient use.

National Center for Toxicological Research Headquarters Food Safety Activities NCTR, FDA's center for peer-reviewed scientific research upon which the agency bases its regulatory decisions, was responsible for no more than 1 percent of agency food safety expenditures. In fiscal year 1998, NCTR expended \$842,000, including \$75,000 from CVM, and 5 staff years on eight food safety research projects. In fiscal year 1999, NCTR expended nearly \$1.5 million and 10 staff years on 10 research projects, including \$500,000 to expand food safety method development research. The annual

<sup>&</sup>lt;sup>3</sup>NCTR also conducted food safety research funded through an interagency agreement with the National Institute of Environmental Health and Safety at a total cost of \$8.4 million in fiscal years 1998 and 1999.

Appendix III: The Food and Drug
Administration's Fiscal Year 1998 and 1999
Food Safety Expenditures

expenditures include about \$100,000 for agencywide support. NCTR's expenditures do not include any field activities related to food safety.

## Appendix IV: States' Fiscal Years 1998 and 1999 Food Safety Expenditures

States (used hereafter to refer collectively to states, territories, commonwealths, federated states, and the District of Columbia) play an important role in overseeing the nation's food supply. State and local (e.g., county and city) governments conduct the majority of inspections in the United States, including food retailers, manufacturers, processors, and distributors within their state boundaries in accordance with their own laws and authorities. State agriculture departments and health departments are the two primary agencies that are responsible for food safety in states. As shown in table 15, states devoted various amounts of resources for activities to ensure the safety of foods under its jurisdiction in fiscal years 1998 and 1999.

Table 15: Aggregate Agriculture and Health Department Food Safety Expenditures and Staff Years by State, Fiscal Years 1998 and 1999

	Expenditures		Staff y	aff years	
State	1998	1999	1998	1999	
Alaska	\$4,446,800	\$4,363,300	54	55	
Alabama	11,270,784	11,833,244	126	130	
Arkansas	4,382,183	4,508,055	83	81	
American Somoa <sup>b</sup>	255	2,884	16	18	
Arizona	1,760,400	1,860,400	41	41	
California	15,843,487	17,127,897	207	222	
Colorado <sup>c</sup>	1,110,519	1,093,953	16	16	
Connecticut	679,881	788,866	39	39	
District of Columbia	1,200,000	1,250,000	10	24	
Delaware	1,251,645	1,243,527	34	34	
Florida	17,716,712	17,325,231	349	327	
Federated States of Micronesia	176,702	149,693	8	8	
Georgia	12,408,865	12,495,507	242	233	
Guam	896,034	877,331	42	43	
Hawaii	2,684,000	2,684,000	73	73	
Iowa	2,679,358	2,693,158	71	71	
Idaho	1,349,000	1,397,000	20	21	
Illinois	12,332,131	12,612,702	211	214	
Indiana	5,808,034	5,553,450	163	164	
Kansas	4,498,349	5,118,281	98	111	
Kentucky	7,372,977	7,144,475	142	143	
Louisiana	13,226,490	13,732,189	224	225	
Massachusetts	2,141,935	2,181,490	33	33	

<sup>&</sup>lt;sup>1</sup>While local agencies such as county and city health departments also play an important role in food safety, they were not included in the scope of this review.

	Expen	Expenditures		
State <sup>a</sup>	1998	1999	1998	years 1999
Maryland	2,498,984	2,509,984	20	20
Maine	1,794,000	1,938,000	35	35
Michigan	9,342,206	9,782,912	130	133
Minnesota <sup>d</sup>	5,629,701	5,627,821	77	77
Missouri	640,000	840,000	18	23
Mississippi	5,243,890	5,265,155	83	81
Montana	1,425,193	1,517,160	28	28
North Carolina	13,833,657	14,041,171	271	271
North Dakota	862,000	862,000	13	13
Nebraska	1,813,456	1,851,698	21	21
New Hampshire	777,073	868,174	26	26
New Jersey	2,161,000	2,185,000	37	37
New Mexico	887,681	962,146	14	14
Nevada	410,055	493,465	9	11
New York	19,786,927	20,083,690	504	514
Ohio	14,022,939	14,535,872	254	252
Oklahoma	5,806,533	5,722,518	117	115
Oregon	5,015,442	5,811,711	60	65
Pennsylvania	7,540,000	8,040,000	136	136
Puerto Rico	4,986,990	4,900,810	133	180
Rhode Island	2,146,539	2,342,054	33	33
South Carolina	4,899,643	5,251,946	80	85
South Dakota	1,383,051	1,517,324	38	38
Tennessee	5,390,400	5,744,310	154	159
Texas	14,225,574	15,466,741	373	368
Utah	3,953,870	4,035,571	72	74
Virginia	5,777,810	6,125,182	107	107
Vermont	905,004	1,018,423	21	21
Washington	5,439,265	5,414,274	89	87
Wisconsin	14,538,824	14,440,247	249	254
West Virginia	2,481,000	2,537,000	90	90
Wyoming	1,081,824	1,100,694	25	25
Total <sup>e</sup>	\$291,937,072	\$300,869,686	5,617	5,717

<sup>&</sup>lt;sup>a</sup>The territories of the Virgin Islands and the Commonwealth of the North Mariana Islands did not respond to the survey.

Source: GAO survey of states.

<sup>&</sup>lt;sup>b</sup>The agriculture department of American Somoa did not respond to the survey. The American Somoa Department of Health did not include staff salary and benefits in its reported expenditures.

<sup>°</sup>The agriculture department of Colorado did not respond to the survey.

<sup>&</sup>lt;sup>d</sup>The health department of Minnesota did not respond to the survey.

<sup>°</sup>Totals may not add because of rounding.

## Food Safety Activities, Funding, Expenditures, and Staffing

State food safety responsibilities can be grouped into four categories that cover a broad range of activities: licensing and inspection, response to food safety problems, laboratory analysis, and training and technical assistance. States reported a high degree of involvement in some activities within each category and little involvement with others. For example:

- Regarding licensing and inspection activities, more than 40 states reported that they were involved to a great or very great extent in registering and licensing food producers, processors, sellers, and others and inspecting dairy farms and dairy product plants. The number of states engaged in inspection activities at other types of establishments such as meat and poultry slaughter and processing plants, egg and egg product plants, groceries and restaurants varied more widely. Forty-five states reported that they engaged in little or no inspection activity at nondairy food-producing farms.
- In response to food safety problems, 48 states reported a great or very great involvement in activities to enforce food safety regulations, and 45 states reported a great or very great level of involvement in response to natural disasters that effect food safety, such as tornadoes, hurricanes, and floods.
- Regarding laboratory analysis, 41 states reported great or very great involvement in analyzing food products for microbial contamination.
   States were generally involved in laboratory analysis for pesticides and chemical residues, filth, or food labeling accuracy to a lesser extent.
- Fifty-one states reported providing training and technical assistance to a
  great or very great extent to staff employed by their own departments, and
  more than half reported providing such assistance to grocery, restaurant,
  and other retail food service workers to a great or very great extent. States
  provided training and technical assistance to farmers, processors,
  consumers, health professionals, and others to a lesser extent.

As shown in table 16, state expenditures reported for these categories of activities, as well as administrative and support, other, and uncategorized activities, were about \$292 million in fiscal year 1998 and about \$301 million in fiscal year 1999. In fiscal year 1999, federal funds accounted for 13 percent of state expenditures, other funding sources such as license fees accounted for 18 percent, and state revenues funded the remaining 65 percent of these expenditures. In aggregate, states dedicated 5,617 staff

<sup>&</sup>lt;sup>1</sup>States did not categorize the source for about 4 percent of funds each year.

years to food safety activities in fiscal year 1998 and 5,717 staff years in fiscal year 1999.

Table 16: State Agriculture and Health Department Expenditures for Food Safety Activity Categories, Fiscal Years 1998 and 1999

Dollars in thousands						
		Expenditures (percent of totals)		Staff years (percent of totals)		
Activity Category	1998	1999	1998	1999		
Licensing and inspections	\$142,163	\$144,052	3,075	3,039		
-	(49)	(48)	(55)	(53)		
Response to problems	15,361	15,701	291	343		
	(5)	(5)	(5)	(6)		
Laboratory analysis	32,871	34,070	472	467		
	(11)	(11)	(8)	(8)		
Technical assistance and	14,596	17,484	322	371		
training	(5)	(6)	(6)	(6)		
Administration and support	31,896	32,944	664	681		
	(11)	(11)	(12)	(12)		
Other <sup>a</sup>	4,642	4,978	38	37		
	(2)	(2)	(1)	(1)		
Uncategorized <sup>b</sup>	50,408	51,641	755	779		
	(17)	(17)	(13)	(14)		
Total <sup>c</sup>	\$291,937	\$300,870	5,617	5,717		
	(100)	(100)	(100)	(100)		

<sup>&</sup>lt;sup>a</sup>"Other" includes expenditures for items such as committee or council activities, computers and other equipment, and data base development.

Source: GAO survey of states.

## Licensing and Inspection Activities

State expenditures for licensing and inspection food safety activities were \$142 million in fiscal year 1998 and \$144 million in fiscal year 1999. As shown in table 17, states reported over 1 million establishments under their jurisdiction in fiscal years 1998 and 1999. This includes over 370,000 restaurants, about 300,000 groceries and other retail outlets, and about 90,000 dairy farms. States also reported their typical frequency of inspection for each type of establishment, which ranged from continuous, meaning that an inspector is onsite at all times during production, to once per year. In total, states reported that they actually conducted about 2 million inspections annually, not counting continuous inspections.

<sup>&</sup>lt;sup>b</sup>"Uncategorized" represents food safety expenditures and staff years that were reported as a total amount or pooled together for multiple categories.

<sup>°</sup>Totals may not add because of rounding.

Table17: Number of Food Establishments Under State Inspection Jurisdiction and Most Common Inspection Frequency, Fiscal Years 1998 and 1999

	inspection juriso	1999	Most common inspection frequency
Dairy farms	91,797	88,316	Quarterly
Other food producing farms	9,361	9,773	Other <sup>b</sup>
Meat and poultry slaughter plants	1,371	1,487	Continuous
Meat and poultry processing plants	2,914	2,906	Daily
Fish and seafood plants/farms	4,818	4,804	Annually
Shellfish operations	1,904	1,930	Quarterly
Dairy product plants	3,613	3,560	Quarterly
Eggs and egg product plants	834	837	Quarterly
Plants/facilities that process commercially raised or wild game for food	574	606	Annually
Other food processing plants	42,522	42,901	Annually
Feed plants for food producing animals	5,680	5,627	Annually
Groceries and other retail outlets	302,746	307,429	Twice a year
Restaurants	371,740	379,046	Other <sup>b</sup>
Institutions	47,637	50,365	Annually
Food packaging and storage facilities	31,213		Annually
Food transport (e.g., vans and tankers)	9,487	9,902	Other <sup>b</sup>
Other <sup>c</sup>	35,018	35,309	Annually
Uncategorized <sup>d</sup>	98,284	98,774	
Total	1,061,513	1,075,124	

<sup>&</sup>lt;sup>a</sup>If two departments within a state reported different inspection frequencies for a category, the highest frequency is reported in the table.

Source: GAO survey of states.

<sup>&</sup>lt;sup>b</sup>Some frequency other than continuous, daily, weekly, monthly, quarterly, twice a year, or annually.

<sup>&</sup>lt;sup>cu</sup>Other" includes establishments such as mobile food operations, daycare centers, youth camps, and civic organizations.

<sup>&</sup>lt;sup>d</sup>"Uncategorized" represents food establishments under state jurisdiction that were reported as a total amount or pooled together for multiple categories.

As shown in table 18, states reported how much of their expenditures of over \$140 million annually for food safety licensing and inspection were allocated to specific activities within the category. The activities that were allocated a large amount of resources by states include inspections at groceries and other retail outlets and restaurants.

Table 18: State Allocation of Resources to Food Safety Licensing and Inspection Activities, Fiscal Years 1998 and 1999

Activity	Number of states reporting resource expenditures	(excluding "no
Registration and licensing	54	Moderate
Inspection of:		
Dairy farms	49	Moderate
Other food producing farms	29	Small
Meat and poultry slaughter plants	36	Moderate
Meat and poultry processing plants	37	Moderate
Fish and seafood plants/farms	41	Small
Shellfish operations	31	Small
Dairy and dairy product plants	52	Moderate
Egg and egg product plants	38	Small
Plants/facilities that process commercially raised or wild game for food	31	Small
Other food processing plants	48	Moderate
Feed plants for food-producing animals	31	Moderate
Groceries and other retail outlets	53	Large
Restaurants	49	Large
Institutions	50	Moderate
Food packaging and storage facilities	52	Moderate
Food transport (e.g., vans and tankers)	51	Small

<sup>a</sup>When two agencies within a state reported different amounts of resources expended, we used the largest amount as the state response.

Source: GAO survey of states.

## Response to Problems

As shown in table 19, states reported how much of their total expenditures of about \$15 million annually to respond to food safety problems were allocated to specific activities within the category. States allocated a moderate amount of expenditures to enforcement of food safety regulations and lesser amounts to other response activities.

Table 19: State Allocation of Expenditures in Response to Food Safety Problems, Fiscal Years 1998 and 1999

Activity	Number of states reporting resource expenditures	Average (median) amount of resources reported by states for each activity (excluding "no resources") <sup>a</sup>
Tracebacks and other investigations of outbreaks	54	Small
Activities related to recalls	53	Small
Responses to natural disasters	52	Small
Enforcement activities	54	Moderate

<sup>a</sup>When two agencies within a state reported different amounts of resources expended, we used the largest amount as the state response.

Source: GAO survey of states.

### **Laboratory Analysis**

As shown in table 20, states reported how much of their total expenditures of more than \$30 million annually for food safety laboratory analysis were allocated to specific activities within the category. The activity that the states most often allocated a large amount of expenditures was laboratory analysis for microbial contamination.

Table 20: State Allocation of Expenditures for Food Safety Laboratory Analysis, Fiscal Years 1998 and 1999

Food safety laboratory analysis for:	Number of states reporting resource expenditures	
Microbial contamination	54	Large
Pesticides and other chemicals	49	Moderate
Filth and or sanitation	51	Small
Food label accuracy	46	Small to Moderate

<sup>a</sup>When two agencies within a state reported different amounts of resources expended, we used the largest amount as the state response.

Source: GAO survey of states.

## Food Safety Technical Assistance and Training

As shown in table 21, states reported how much of their annual expenditures of about \$15 million to \$17 million for food safety technical assistance and training were allocated to specific activities within the

category. The states allocated a large amount of expenditures to training and technical assistance for staff employed by their own agriculture or health department.

Table 21: State Allocation of Expenditures for Food Safety Training and Technical Assistance, Fiscal Years 1998 and 1999

Food safety training and technical assistance for:	Number of states reporting resource expenditures	(excluding "no
Farmers and producers	44	Small
Processors	51	Moderate
Grocery, restaurant, and other retail foodservice workers	53	Moderate
Institutional foodservice workers	48	Moderate
Consumers	51	Small
Health professionals	45	Small
Industry inspectors	42	Small
Staff who are employed by state departments of health or agriculture	55	Large
Staff who are employed by other state departments	46	Small
Staff who are employed by community governments	47	Moderate

<sup>a</sup>When two agencies within a state reported different amounts of resources expended, we used the largest amount as the state response.

Source: GAO survey of states.

### Role of Other State Agencies and Local Governments

Although state departments of agriculture and health generally have primary responsibility for overall food safety activities in each of the states, other state departments and local governments also have responsibility for such activities. According to the states we surveyed, these other agencies generally had responsibilities for a specific type of establishment, such as restaurants, jails or prisons, childcare facilities, and nursing homes or for specific food products. For example, in the state of Florida, restaurants are under the jurisdiction of the Department of Business and Professional Regulations. And, in several states—Delaware, Louisiana, Maine, Mississippi, New Jersey, New York, and Texas—seafood or shellfish products are the responsibility of a state agency other than agriculture or health.

Appendix IV: States' Fiscal Years 1998 and 1999 Food Safety Expenditures

States also reported that local governments have an extensive role in food safety inspection activities at certain types of establishments such as restaurants, institutions, groceries, and other retail locations. For example, although Georgia's health department has jurisdiction over almost 20,000 restaurants and institutions, county staff inspected all of those establishments under contracts with the state. In some cases, state health departments reported that local government inspections were conducted primarily through state contracts or agreements. In a few cases, states reported large expenditures by local governments. For example, the Idaho Department of Health reported that most of the state's expenditures for food safety were made by local multicounty health districts, which spent about \$1 million on food safety in fiscal year 1999, while the state spent about \$650,000.

## Appendix V: Responses to GAO's Survey of State Agencies Responsible for Food Safety Activities

United States General Accounting Office

**GAO** 

Survey of State Agencies Responsible for Food Safety Activities

#### INTRODUCTION

The U.S. General Accounting Office (GAO) is an agency that studies issues for the U.S. Congress. We are currently developing nationwide data on federal and state resources spent for certain activities related to food safety. As part of this review, we are asking all state departments of health and agriculture to complete this survey.

Your response to our survey is essential in order for us to report complete and accurate information to the Congress. You may also receive a survey from the Food and Drug Administration (FDA) concerning food safety activities. We have coordinated our efforts with FDA to minimize duplications. We encourage you to complete both surveys; they address different and important questions about food safety.

#### INSTRUCTIONS

Scope of the survey. For the purposes of this survey, food safety activities include activities which are regulated by FDA (Food and Drug Administration) and FSIS (Food Safety and Inspection Service). They do not include activities under the federal jurisdictions of APHIS (Animal and Plant Health Inspection Service) and CSREES (Cooperative State Research, Economic, and Extension Service).

**Definition of Food Safety**. For the purposes of this survey, food safety is the result of activities that help assure that food and animal feed is

- free of foodborne pathogens
- free from unacceptable levels of pesticides and other harmful chemical and drug residues
- sanitary
- wholesome
- properly labeled
- otherwise safe to eat

Reporting expenditures. Expenditures are any outlays of funds such as issuance of checks, disbursement of cash or electronic transfer of funds made to liquidate an obligation from the same year or prior years. Include expenditures for both direct and indirect costs. Please report actual expenditures. If these are not available report budget allocations and tell us which you used.

How to respond. Please have the staff in your department who are most knowledgeable about food safety activities respond to this survey for only your department's activities. Please submit only one survey that reflects the entire department's activities.

We would appreciate receiving your response within 30 days of receiving the survey if at all possible. This will enable us to give a more timely report to the Congress. Please use the enclosed business-reply envelope. If the envelope is missing or has been misplaced, our return address is

U.S. General Accounting Office Attn: Brad Dobbins 301 Howard Street, Suite 1200 San Francisco, CA 94105-2252

**Analysis Notes:** Responses from state agriculture and health departments were aggregated into a single state response in the following ways:

- (1) For questions 1, 2, 3, 4, 15, 16, 17, 18, 19, 20, 21, and 22, we used the greater of the 2 responses.
- (2) For questions 5, 7, 10, 13, and 14, we used the sum of the 2 responses.
- (3) For questions 6, 8 and 9, we did not aggregate responses; rather, we present the responses of individual agencies.
- (4) For question 12, we used the response that reported the most frequent inspection interval.

1

#### **Background Information**

1. To what extent, if at all, does your department engage in each of the following licensing and inspection activities for food safety purposes? (Check one for each.)

	Not at all	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)
Registering and licensing of food-producing farms; plants; retail outlets; food services at institutions; food packaging, storage and transport, etc.	o	2	7	17	29
Conducting inspections	1				1
2. At dairy farms	4	2	5	2	42
3. At other food-producing farms	17	28	6	1	3
4. At meat and poultry slaughter plants	17	11	2	3	22
5. At meat and poultry processing plants	9	11	9	2	24
6. At fish and seafood plants and farms	8	6	11	7	23
7. At shellfish operations	16	11	4	2	22
8. At dairy product plants	2	3	2	4	44
9. At egg and egg product plants	10	18	7	5	15
10. At plants and/or facilities that process commercially-raised or wild game for food (e.g., deer, game birds, rabbit, alligators, etc.)	11	16	9	5	14
11. At other food processing plants (e.g., grains, fruits and vegetables, beverages, bakeries)	6	3	8	11	27
12. At feed plants for food-producing animals only	22	9	7	6	11
13. At groceries and other retail outlets	0	7	9	8	31
14. At restaurants	4	12	4	3	32
<ol> <li>At institutions (e.g., cafeterias and kitchens at hospitals, nursing homes, schools, prisons, etc.)</li> </ol>	3	11	9	13	19
16. At food packaging and storage facilities	1	6	14	13	21
17. During food transport (e.g., containers, vans, tankers)	1	20	20	6	8
18. Other (Please specify.)		2	3	5	6

2. To what extent, if at all, does your department engage in each of the following activities in response to food safety problems that have been identified? (Check one for each.) (22-26)

		Not at all	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)
1.	Tracebacks and other investigations of outbreaks	0	2	9	13	31
2.	Activities related to recalls	0	5	11	17	22
3.	Responses to natural disasters (e.g., fires, tornados, hurricanes, floods, etc.)	0	5	5	14	31
4.	Enforcement activities	0	0	7	10	38
5.	Other (Please specify.)		1	2	0	2

 To what extent, if at all, does your department engage in each of the following types of laboratory analysis of food products for food safety purposes? (Check one for each.)

		Not at all	Some extent	Moderate extent (3)	Great extent (4)	Very great extent (5)
1.	For microbial contamination	1	3	10	14	27
2.	For pesticides and other chemical residues	3	9	16	10	17
3.	For filth and/or sanitation	2	10	9	9	25
4.	For food label accuracy	4	12	11	18	10
5.	Other (Please specify.)		3	2	3	6

4. To what extent does your department provide training and technical assistance for food safety purposes to each of the following groups? (Check one for each.)

		Not at all	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)
1.	Farmers and producers	2	20	20	8	5
2.	Processors	1	6	28	11	9
3.	Grocery, restaurant and other retail foodservice workers	0	9	13	21	12
4.	Institutional foodservice workers	4	6	17	17	11
5.	Consumers	0	19	25	6	5
6.	Health professionals (e.g., nurses, doctors, dieticians, etc.)	8	26	13	4	4
7.	Industry inspectors	4	20	15	6	10
8.	Staff who are employed by your department	0	1	3	12	39
9.	Staff who are employed by other state departments	3	23	23	5	1
10.	Staff who are employed by community governments (e.g., city, county, township, parish, etc.)	5	10	13	8	19
11.	Other (Please specify.)		3	1	1	0

5. About how much did your department expend in state fiscal years 1998 and 1999 on the food safety activities described in Questions 1-4 above? Please treat these categories of activity as non-overlapping expenditure categories. (Enter amount or zero for each, rounded to whole dollars.)

#### FY 1998 Expenditures for Food Safety

2(4-59)

- A. \$ 142,162,536 Licensing and inspections (see Question 1)
- B. \$ 15,360,849 Response to problems (see Question 2)
- C. \$ 32,871,412 Laboratory analysis (see Question 3)
- D. \$ 14,596,155 Technical assistance and training (see Question 4)
- E. \$ 31,896,062 Administration and support (not included in A to D)
- F. \$ 4,641,533 Other (Please specify.)
- G. \$ 291,937,072 TOTAL EXPENDITURES

#### **FY 1999 Expenditures for Food Safety**

3(4-59)

- H. \$ 144,051,669 Licensing and inspections (see Question 1)
- I. \$ 15,701,372 Response to problems (see Question 2)
- J. \$ 34,070,044 Laboratory analysis (see Question 3)
- K. \$ 17,483,585 Technical assistance and training (see Question 4)
- L. \$ 32,943,637 Administration and support (not included in H to K)
- M. \$ 4,977,504 Other (*Please specify*.)
- N. \$ 300,869,686 TOTAL EXPENDITURES

Note: Frequencies for Question 8 are number of agencies.  $\rightarrow \rightarrow \rightarrow \rightarrow \rightarrow$ 

6. What basis did you use to calculate the amounts in Question 5? (Check one.)

(60)

(68)

- 11 Actual expenditures in each category
- 26 Actual expenditures for the totals, estimated expenditures for each category
- \_\_30 Estimated expenditures for categories and totals
- 1 Actual budget allocations for each category
- Actual budget allocations for the totals, estimated budget allocations for each category
- 12 Estimated budget allocations for categories and totals
- 13 Other (Please explain.)

#### Note: Frequencies for Q6 are number of agencies

 For state fiscal years 1998 and 1999, how much of the total expenditures that you reported in Question 5 came from state, federal, and other funding sources? (Enter amounts or zero on each line.)

		FY 1998 (1)	FY 1999 (2)			
1.	State funds	190,218,758	195,992,341			
2.	Federal funds	39,738,358	39,947,722			
3.	Other funding (Please specify.)					
		49,991,881	52,921,561			
4.	TOTAL FUNDS (should equal totals from Questions 5G and 5N)	291,937,073	300,869,686			

- 8. Do the amounts you reported in Question 5 include indirect costs (costs incurred for common purposes that benefit both food safety and other activities, such as costs for operating and maintaining facilities used jointly by food safety and other workers)? (Check one.)
  - 38 Amounts include no indirect costs
  - 31 Amounts include some indirect costs
  - 32 Amounts include all identifiable indirect costs

5

Appendix V: Responses to GAO's Survey of State Agencies Responsible for Food Safety Activities

9.	Do the amounts you reported in Question 5 include in-kind contributions (donated space, equipment, supplies and services provided from public or private sources at no cost to your department)? (Check one.)  85 Amounts include no in-kind contributions  8 Amounts include some in-kind contributions  7 Amounts include all identifiable in-kind contributions	<ul> <li>10. In state fiscal years 1998 and 1999, about how man of your department's staff years (full-time equivalents) were devoted to the food safety activities you identified in Questions 1-4? (Enternumber for each.)</li> <li>Full-time equivalent (FTE) means one or more employees who collectively complete a full-time work year. For example, two half-time employees who world 52 weeks equals one full-time equivalent.</li> </ul>	
Note: Frequencies for Q9 are number of agencies.		FY 1998 FTEs for Food Safety	5(4-31)
8		A. 3,075.06 Licensing and inspections (see Question 1)	
		B. 291.28 Response to problems (see Question 2)	
		C. 471.58 Laboratory analysis (see Question 3)	
		D. 322.08 Technical assistance and training (see Question 4)	
		E. 663.63 Administration and support (not included in A to D)	
		F. 38.19 Other (Please specify.)	
		G. 5,617.29 TOTAL FTES	
		FY 1999 FTEs for Food Safety	(32-59)
		H. 3,039.47 Licensing and inspections (see Question 1)	
		I. 342.81 Response to problems (see Question 2)	
		J. 466.90 Laboratory analysis (see Question 3)	
		K. 370.51 Technical assistance and training (see Question 4)	
		L. 680.99 Administration and support (not included in H to K)	
		M. 37.00 Other (Please specify.)	

N. 5,716.55 TOTAL FTES

	About what percentage of your total expenditure food safety activities in 1998 and 1999, reported Question 5, were for payroll and benefits for all staff you identified in Question 10? (Enter percefor each.)	l in the									
,	% for 1998										
	% for 1998										
	% for 1999										
12.	On average, how often, if at all, does your depareach of the following types of food or feed estables.	olishme	ent? (C	heck or	ne for e	rach.)	/	/.	o John (8)	7	n 6(4-20)
	Dairy farms	5	0	1	2	2	22	14	3	6	
	Other food-producing farms	28	1	1	0	0	1	2	8	14	
	Meat and poultry slaughter plants	21	14	9	2	0	1	2	4	2	
	Meat and poultry processing plants	12	8	15	3	0	3	5	7	2	
	5. Fish and seafood plants and farms	13	0	0	3	5	8	10	13	3	
	6. Shellfish operations	18	0	0	2	2	14	7	10	2	
	7. Dairy product plants	2	0	1	2	9	35	3	2	1	
	8 Figgs and egg product plants	15	3	4	3	3	14	5	6	2	

Plants and/or facilities that process commercially-raised or wild game for

11. Feed plants for food-producing animals

15. Food packaging and storage facilities

10. Other food processing plants

12. Groceries and other retail outlets

food

13. Restaurants

14. Institutions

16. Food transport17. Other (*Please specify*.)

9 16

5 18

9 12

13. How many, if any, establishments were under your department's inspection jurisdiction in fiscal years 1998 and 1999? (Enter number for each.)

7(4-73) 8(4-73) 9(4-43)

		FY 1998 (1)	FY 1999 (2)
1.	Dairy farms	91,797	88,316
2.	Other food-producing farms	9,361	9,773
3.	Meat and poultry slaughter plants	1,371	1,487
4.	Meat and poultry processing plants	2,914	2,906
5.	Fish and seafood plants and farms	4,818	4,804
6.	Shellfish operations	1,904	1,930
7.	Dairy product plants	3,613	3,560
8.	Eggs and egg product plants	834	837
9.	Plants and/or facilities that process commercially-raised or wild game for food	574	606
10.	Other food processing plants	42,522	42,901
11.	Feed plants for food-producing animals	5,680	5,627
12.	Groceries and other retail outlets	302,746	307,429
13.	Restaurants	371,740	379,046
14.	Institutions	47,637	50,365
15.	Food packaging and storage facilities	31,213	31,552
16.	Food transport (e.g., containers, vans, tankers)	9,487	9,902
17.	Other (Please specify.)		
		35,018	35,309
18.	TOTAL ESTABLISHMENTS	1,061,513	1,075,124

14. In total, how many inspections, not counting continuous inspections, did your department conduct in fiscal years 1998 and 1999 in the establishments reported in Question 13? (Enter number for each.) (44-59)

2,000,377 in 1998

2,081,035 in 1999

15. To answer the following question, please refer back to your responses for Question 1 and Questions 5A and 5H. For fiscal years 1998 and 1999 combined, about how much of your expenditures for food safety licensing and inspections were dedicated to each of the following activities? (Check one for each.)

	Check one box for each row.					
	No resources (1)	Small amount (2)	Moderate amount (3)	Large amount (4)	Most or almost all resources (5)	
Registering and licensing activities	0	15	20	17	2	
Conducting inspections						
2. At dairy farms	5	7	18	23	1	
3. At other food-producing farms	26	21	6	2	0	
4. At meat and poultry slaughter plants	19	16	5	13	2	
5. At meat and poultry processing plants	18	15	7	13	2	
6. At fish and seafood plants and farms	14	29	6	6	0	
7. At shellfish operations	24	19	8	4	0	
8. At dairy and dairy product plants	3	11	17	22	2	
9. At egg and egg product plants	17	23	6	7	2	
At plants and/or facilities that process commercially-raised or wild game for food	24	22	5	4	0	
11. At other food processing plants	7	8	22	17	1	
12. At feed plants for food-producing animals	24	14	11	6	0	
13. At groceries and other retail outlets	2	9	13	27	4	
14. At restaurants	6	11	5	22	11	
15. At institutions	5	18	20	7	5	
16. At food packaging and storage facilities	3	22	21	8	1	
17. During food transport (e.g., containers, vans, tankers)	5	38	10	2	1	
18. Other (Please specify.)		5	4	2	1	

16. To answer the following question, please refer back to your responses for Question 2 and Questions 5B and 5I. For fiscal years 1998 and 1999 combined, about how much of your expenditures in response to food safety problems that have been identified were dedicated to each of the following activities? (Check one for each.)

		Check one box for each row.						
		No resources	Small amount (2)	Moderate amount (3)	Large amount (4)	Most or almost all resources (5)		
1.	Tracebacks and other investigations of outbreaks	1	29	18	3	4		
2.	Activities related to recalls	2	37	14	2	0		
3.	Responses to natural disasters	3	34	16	1	1		
4.	Enforcement activities	1	4	26	21	3		
5.	Other (Please specify.)		0	2	2	0		

17. To answer the following question, please refer back to your responses for Question 3 and Questions 5C and 5J. For fiscal years 1998 and 1999 combined, about how much of your expenditures for food safety laboratory analysis were dedicated to each of the following activities? (Check one for each.)

		Check one box for each row.						
		No resources (1)	Small amount (2)	Moderate amount (3)	Large amount (4)	Most or almost all resources (5)		
1.	Analysis for microbial contamination	1	9	15	21	9		
2.	Analysis for pesticides and other chemical residues	6	19	16	14	0		
3.	Analysis for filth and/or sanitation	4	27	19	5	0		
4.	Analysis for food label accuracy	9	23	15	8	0		
5.	Other (Please specify.)							
			4	2	3	1		

18. To answer the following question, please refer back to your responses for Question 4 and Questions 5D and 5K. For fiscal years 1998 and 1999 combined, about how much of your expenditures for food safety training and technical assistance were dedicated to each of the following activities? (Check one for each.) (14-24)

			Check o	ne box for ea	ch row.	
		No resources (1)	Small amount (2)	Moderate amount (3)	Large amount (4)	Most or almost all resources (5)
1.	Farmers and producers	10	25	13	6	0
2.	Processors	3	22	23	5	1
3.	Grocery, restaurant and other retail foodservice workers	1	14	19	16	4
4.	Institutional foodservice workers	6	23	17	7	1
5.	Consumers	3	37	10	4	0
6.	Health professionals	9	35	6	4	0
7.	Industry inspectors	12	23	14	4	1
8.	Staff who are employed by your department	0	4	20	26	5
9.	Staff who are employed by other state departments	8	37	8	1	0
10.	Staff who are employed by community governments	7	23	13	9	2
11.	. Other (Please specify.)		0	2	1	0

### Food Safety Activities of Community Governments

Please base your answers to the following questions on your knowledge of the food safety activities of community governments (e.g., county, city, township, parish) within your state.

19. To what extent are these community governments engaging in each of the following licensing and inspection (25-42) activities? (Check one for each.)

	Not at all	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)	Do not know (6)
Registering and licensing activities	4	10	10	9	22	0
Conducting inspections						
2. At dairy farms	45	5	1	2	2	0
3. At other food-producing farms	44	8	1	2	0	0
4. At meat and poultry slaughter plants	45	6	2	2	0	0
5. At meat and poultry processing plants	41	9	3	2	0	0
6. At fish and seafood plants and farms	37	11	5	2	0	0
7. At shellfish operations	48	4	2	1	0	0
8. At dairy product plants	40	10	1	4	0	0
9. At egg and egg product plants	46	7	2	0	0	0
10. At plants and/or facilities that process commercially-raised or wild game for food	42	11	0	0	2	0
11. At other food processing plants	26	19	5	3	2	0
12. At feed plants for food-producing animals only	50	1	0	2	1	1
13. At groceries and other retail outlets	10	8	9	7	20	0
14. At restaurants	8	4	4	10	29	0
15. At institutions	9	7	9	13	17	0
16. At food packaging and storage facilities	21	15	12	4	3	0
17. During food transport	23	24	4	3	1	0
18. Other (Please specify.)		2	1	1	1	4

20. To what extent are these community governments engaging in each of the following activities in response to food safety problems that have been identified? (Check one for each.)

		Not at all	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)	Do not know (6)
1.	Tracebacks and other investigations of outbreaks	7	12	10	13	13	0
2.	Activities related to recalls	11	25	6	6	7	0
3.	Responses to natural disasters (e.g., fires, tornados, hurricanes, floods, etc.)	7	9	10	13	16	0
4.	Enforcement activities	4	11	12	11	17	0
5.	Other (Please specify.)		1	1	1	0	5

21. To what extent are these community governments engaging in each of the following types of laboratory analysis for food safety purposes? (Check one for each.) (48-52)

		Not at all	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)	Do not know (6)
1.	For microbial contamination	18	29	4	3	1	0
2.	For pesticides and other chemical residues	38	12	3	1	1	0
3.	For filth and/or sanitation	22	21	7	5	0	0
4.	For food label accuracy	34	17	2	2	0	0
5.	Other (Please specify.)		0	1	0	0	6

	Not at all	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)	Do not know (6)
Farmers and producers	40	13	1	0	0	1
2. Processors	36	15	2	2	0	(
Grocery, restaurant and other retail foodservice workers	7	9	17	7	15	(
4. Institutional foodservice workers	8	14	15	7	10	1
5. Consumers	7	23	18	5	1	1
6. Health professionals (e.g., nurses, doctors, dieticians, etc.)	22	16	13	3	0	1
7. Industry inspectors	30	16	5	2	1	
Staff who are employed by your department	28	19	4	3	1	
<ol><li>Staff who are employed by other state departments</li></ol>	34	18	2	0	0	-
<ol> <li>Staff who are employed by community governments (e.g., city, county, township, parish, etc.)</li> </ol>	11	16	3	5	6	:
11. Other (Please specify.)		2	0	0	o	,
Are there state departments other than safety activities identified in this surve  28 Yes  Name of agency	y? (Check on	nts of healtle.)		ure that hav	e responsibili	ty for food

24. Comments. Please provide any additional comments you may have on topics covered by this questionnaire.

Thank you for your cooperation.

14

\_\_\_27\_ No

(65)

## Appendix VI: Comments from the Food Safety and Inspection Service

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



Food Safety and Inspection Service Washington, D.C. 20250

JAN 3 1 2001

Mr. Lawrence J. Dyckman Director United States General Accounting Office Washington, DC 20548

Dear Mr. Dyckman:

We appreciate the opportunity to review the draft U.S. General Accounting Office (GAO) report entitled: Food Safety: Overview of Federal and State Expenditures (GAO-01-177). The Food Safety and Inspection Service (FSIS) generally agrees with the subject report.

However, FSIS would like to offer the following general comments:

### **General Comments**

1. Page 8 - Paragraph 3, "Results in Brief". We suggest that FSIS' expenditures be put into full context by adding language that clearly states that FSIS' responsibilities involve more than food safety. As written, the statements incorporate and report all FSIS expenditures as food safety expenditures. The Acts under which we administer meat, poultry, and processed egg inspection programs provide for the Agency to undertake both food safety activities and non-food safety activities associated with assuring that products meet consumer expectations for wholesomeness and quality issues. The dollars reflected here are used by FSIS to meet its full statutory responsibilities for both food safety and non-food safety activities. Additionally, it would be useful to lay out that the size or scope of the products regulated by FSIS (i.e., meat, poultry, processed egg products).

While the report notes that the expenditures reflect the regulatory approaches or inspection frequencies contained in the laws under which each agency operates, it would also be helpful to point out that these regulatory approaches are distinctly different. The fact that the products we inspect are relatively high risk products as opposed to many of the products (e.g., fruits and vegetables, sodas) that come under FDA. Thus the statistics on percent of food supply and percent of expenditures are misleading. These differences make the global (e.g., summary) level comparison of expenditures somewhat a case of comparing apples and oranges. We suggest that the comparison be re-characterized to note these differences.

See comment 1.

See comment 2.

See comment 3.

Lawrence J. Dyckman

2

2. Page 10 – Paragraph 1, Line 1, "We previously reported that moving to a risk-based inspection..." FSIS feels that this statement needs further definition to state that the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) require inspectors appointed by USDA to perform a post-mortem inspection of the carcasses and parts of all livestock and birds processed for human consumption. Specifically, the FMIA requires "a post-mortem examination and inspection of the carcasses and parts" of all livestock "prepared at any slaughtering" establishment. The PPIA requires "a post-mortem inspection of the carcass of each bird processed."

In 1998, FSIS began to design new inspection models that would realign the HACCP-based roles and responsibilities of both the industry and the federal inspection force. In 1999, FSIS began testing the models under which HACCP concepts are extended to the inspection of slaughter activities in volunteer plants. Plants sort carcasses to remove food safety and non-food safety conditions and must meet performance standards established by FSIS for these defects. Under the original design, FSIS inspectors would be removed from fixed positions on the slaughter line and would oversee and verify plant HACCP activities. While no system is perfect, the models project is an attempt to reduce and eliminate defects that pass through traditional inspection.

On November 3, 2000 FSIS published performance standards for food safety and non-food safety conditions that slaughter plants participating in the HACCP-based Inspection Models Project must meet. The performance standards for young chickens, which account for the majority of participating plants, were previously released at a public meeting held in March; the standards for young hogs and turkeys have not been released previously. Under the models project, performance standards are based on improving what is achieved under the current, traditional method of inspection. When plants enter the project, they must improve their process in order to meet the new, tougher standards. Preliminary data from FSIS' HACCP-based Inspection Models Project (HIMP) indicate that the new system dramatically improves the safety of poultry products and increases overall consumer protection as well.

A group of FSIS inspectors, their union (AFGE) and a consumer group filed a lawsuit challenging the models project. On June 30, 2000, the Court of Appeals for the District of Columbia Circuit ruled that the type of "oversight inspection" performed by federal government inspectors in the models project violated the FMIA and PPIA. The Court stated that "both statutes [the FMIA and the PPIA] clearly contemplate that when inspections are done, it will be federal inspectors - rather than private employees - who will make the critical determination of whether a product is adulterated or unadulterated." The Court continued, "To the extent federal employees are doing any systematic inspecting under the Models Project, they are inspecting people, not carcasses. Delegating the task of inspecting carcasses to plant employees violates the clear mandates of the FMIA and PPIA."

See comment 4.

Lawrence J. Dyckman

3

Following the Court of Appeals' ruling, FSIS, in September 2000, redesigned the models project to position an FSIS carcass inspector in a fixed location on each slaughter line. The redesigned project was under consideration by the District Court and on January 18, 2001, Judge Lamberth of the District Court recently ruled supporting the United States Department of Agriculture's Food Safety and Inspection Service efforts to improve the inspection of meat and poultry.

The Court has determined that the project, which includes up to 30 plants and was modified in August 2000, complies with the statutes. This decision keeps the door open to our efforts of constant improvement, and will allow the success of inspection modifications to be determined on their merits. While the current inspection system in place in meat and poultry plants nationwide is good, it can be better. FSIS remains committed to our pilot project to improve the safety of the meat and poultry in the American marketplace.

Enclosed also are specific editorial and technical comments. If you have any questions, please contact Ronald F. Hicks, Deputy Administrator, Office of Management at (202) 720-4425.

Sincerely,

(THOMAS J. BILLY Administrator

Enclosure

### **GAO's Comments**

- 1. The report clearly identifies FSIS' responsibilities—i.e., ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and marked, labeled, and packaged correctly. Regarding nonfood safety expenditures, FSIS officials assured us during the review that the expenditure information that they provided was for food safety or primarily food safety related activities. As such, we believe the FSIS expenditures in this report are sufficiently related to food safety to be appropriately characterized as "food safety" expenditures.
- 2. We believe the report adequately describes the size and scope of FSIS activities. For example, the report includes information on the number of meat, poultry, egg product, and import establishments FSIS oversees; the number of state and foreign programs it reviewed; and the number and type of inspections it conducted. The level of detail provided on FSIS' responsibilities and activities is similar to that provided on FDA activities.
- 3. It was not our intent to analyze or compare the relative risks of products under the jurisdiction of FSIS and FDA. While the relative risk of FSIS-regulated products may be greater in some cases than FDA-regulated products, we believe that the data accurately reflect the proportion of each agency's expenditures and the proportion of consumer expenditures for foods under each agency's jurisdiction. The report also clearly identifies the food products for which each agency has responsibility.
- 4. We modified the report to clearly identify FSIS' responsibilities under the federal meat and poultry inspection acts and to describe its efforts, with guidance from the courts, to realign the responsibilities and roles of industry and federal inspectors.

# Appendix VII: Comments from the Food and Drug Administration

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



### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration Rockville MD 20857

JAN 23 2001

Mr. Lawrence J. Dyckman
Director, Resources, Community,
and Economic Development Division
Food and Agricultural Issues
United States General Accounting Office
441 G Street, Northwest, Room 2T23
Washington, D.C. 20548

Dear Mr. Dyckman:

Please find the enclosed comments from the Food and Drug Administration on the General Accounting Office (GAO) draft report entitled, Food Safety: Overview of Federal and State Expenditures (GAO-01-177).

Sincerety,

Melinda K. Plaisier Associate Commissioner for Legislation

Enclosure

FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: OVERVIEW OF FEDERAL AND STATE EXPENDITURES GAO/01-177

### GENERAL COMMENTS

FDA welcomes the General Accounting Office's draft report titled "Food Safety: Overview of Federal and State Expenditures." The report provides much valuable information about the allocation of food safety resources. The FDA has six points to emphasize in response to the draft report.

- 1. FDA agrees with GAO that there is a major resource disparity in food safety resources allocated between the Food Safety Inspection Service (FSIS) and the Food and Drug Administration (FDA). On page 9 of the draft report, GAO correctly states that FDA has responsibility for ensuring the food safety for 78 percent of consumer food expenditures, and yet the FDA only receives 28 percent of the food safety resources. In contrast, GAO documents that FSIS has received 72 percent of the food safety resources to ensure the safety of only 22 percent of consumer food expenditures. In reality, the disparity is even greater because, since FY '93, FDA has not received funding for mandatory cost-of-living increases (about five percent per year), whereas FSIS has. In absorbing these cost-of-living expenses, FDA's capacity is reduced accordingly.
- 2. Nevertheless, it is equally clear that, as FDA food safety resources have increased, beginning in FY '98, along with that of other Government food safety programs, foodborne illness has declined. According to CDC, in three years (1996-99), the level of foodborne illness has declined by 20 percent for the nine most common foodborne pathogens. This includes even higher declines in E. coli O157:H7 (down 22 percent); Campylobacter (down 26 percent); Shigella (down 44 percent); Salmonella Enteritidis (down 48 percent); and Cyclospora (down 70 percent). These data show the food safety programs are working, but that more is needed.
- 3. Given its limited resources, FDA has recognized the importance of adopting a risk-based regulatory approach towards food safety. In FY 2001, FDA intends to inspect all food firms whose products are at high risk of microbiological contamination, something it was not able to accomplish in previous fiscal years. This will be accomplished, with additional funding, and reflects FDA's recognition that a targeted, risk-based approach yields greater food safety

## Appendix VII: Comments from the Food and Drug Administration

benefits. FDA's inspections also benefit from a workforce that has scientific training, including its frontline inspectors. In this context, FDA agrees with GAO's support of using funds to increase testing for microbial and other types of contamination, risk assessment and scientific research as consistent with our shifting focus to a risk-based system.

- 4. FDA agrees with GAO that the statutes governing FDA and FSIS have set their respective regulatory approaches and, in large measure, have been the determining factor used by the Congress in setting resource allocation levels. FDA has no legislatively mandated inspection frequency for foods or food firms under its jurisdiction. In contrast, as GAO reports, FSIS' resource levels reflect its legislative mandates, including that for continuous inspection of meat and poultry plants and egg processing plants.
- 5. FDA applauds GAO for including the important States' efforts and resources expended, as the States are a critical element in improving food safety. The States have the primary role for ensuring food safety in retail establishments, as well as for molluscan shellfish and interstate milk safety. The States also play an essential role in outbreak response and act as an extension of FDA in the inspection of food processors. FDA is currently instituting a strengthened program for auditing state food inspections to assure the same level of protection for American consumers. FDA believes that a clearer identification of State-level funding for activities related to foods under FDA jurisdiction, relative to meat and poultry, would aid in Congress having a full picture of how food safety resources are expended.
- 6. Finally, the GAO report, while an important contribution to identifying food safety resources, did not fully reflect the totality of the food safety effort or the accompanying food safety resources. USDA's Agricultural Research Service (ARS) and Cooperative Research Extension Education Service (CSREES) have significant research and education programs in the food safety arena. USDA's Animal and Plant Health Inspection Service (APHIS) also contributes to food safety. In addition, the Centers for Disease Control (CDC) is a major player in the foodborne illness surveillance and outbreak response arena. Lastly, EPA also plays a critical role in food safety through pesticide regulation. FDA believes that GAO's report would be more complete if all of these resources were tabulated and included.

See comment 1.

2

Appendix VII: Comments from the Food and Drug Administration

### **GAO's Comments**

1. By design, the scope of this report was limited to FSIS and FDA food safety activities and expenditures. However, the report recognizes that 12 federal agencies conduct food safety activities and cites our testimony *Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based, Inspection System* (GAO/T-RCED-99-256, Aug. 4, 1999), which provides the fiscal year 1998 funding and staffing levels for these federal agencies.

# Appendix VIII: GAO Contacts and Staff Acknowledgements

GAO Contacts	Lawrence Dyckman (202) 512-3841 Keith Oleson (415) 904-2218
Staff Acknowledgements	In addition to those named above, Brad Dobbins, Kathy Colgrove-Stone, John Nicholson, and Carolyn Boyce made key contributions to this report.

## **Ordering Information**

The first copy of each GAO report is free. Additional copies of reports are \$2 each. A check or money order should be made out to the Superintendent of Documents. VISA and MasterCard credit cards are also accepted.

Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

### Orders by mail:

U.S. General Accounting Office P.O. Box 37050 Washington, DC 20013

### Orders by visiting:

Room 1100 700 4<sup>th</sup> St., NW (corner of 4<sup>th</sup> and G Sts. NW) Washington, DC 20013

### Orders by phone:

(202) 512-6000 fax: (202) 512-6061 TDD (202) 512-2537

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (202) 512-6000 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

### **Orders by Internet**

For information on how to access GAO reports on the Internet, send an e-mail message with "info" in the body to:

Info@www.gao.gov

or visit GAO's World Wide Web home page at:

http://www.gao.gov

## To Report Fraud, Waste, and Abuse in Federal Programs

### Contact one:

- Web site: http://www.gao.gov/fraudnet/fraudnet.htm
- E-mail: fraudnet@gao.gov
- 1-800-424-5454 (automated answering system)

