



Testimony

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FOOD SAFETY

Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures

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Mr. Chairman and Members of the Committee:

We are pleased to be here today to provide an overview of food safety expenditures by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's Food and Drug Administration (FDA).¹ As you know, FSIS and FDA are the two agencies with primary responsibility for food safety in the United States. FSIS is responsible for ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, labeled and packaged. FDA is responsible for ensuring that (1) all foods moving in interstate and foreign commerce, except those under FSIS' jurisdiction, are safe, wholesome and properly labeled; and (2) all animal drugs and feeds are safe, properly labeled, and produce no human health hazards when used in food-producing animals.

As this Committee and Senator Hagel requested, we are conducting a review to determine, for fiscal years 1998 and 1999, the amount of resources available to FSIS and FDA for food safety activities, how these resources were expended by the agencies, and how much the states, territories, and District of Columbia expended on food safety activities. My testimony today presents an overview of the results of work to date on the federal agencies' expenditures. We cannot yet report on nonfederal expenditures because our surveys of the states, territories, and the District of Columbia are still ongoing.

In summary, FSIS and FDA in aggregate expended almost \$1 billion in fiscal year 1998 and again in fiscal year 1999 on food safety activities. In fiscal year 1999, FSIS expended about \$712 million, of which 16 percent was for headquarters activities and 84 percent for field activities associated with overseeing more than 6,000 meat, poultry, egg product and import establishments. FDA expended about \$260 million on food safety activities in

¹ GAO has previously reported on food safety resources. See *Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness* (GAO/RCED-98-224, August 6, 1998).

fiscal year 1999, of which 44 percent was for headquarters activities and 56 percent for field activities associated with overseeing an estimated 57,000 food establishments and over 9,000 animal drug and feed establishments, and ensuring the safety of FDA-regulated imported foods. We found similar expenditures for FSIS and FDA in fiscal year 1998.

Background

Foodborne illness in the United States is an extensive and expensive problem. The Centers for Disease Control and Prevention estimates that unsafe foods cause as many as 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually.² In terms of medical costs and productivity losses, foodborne illnesses cost the nation between \$7 billion and \$37 billion annually, according to USDA's estimates.

According to the Centers for Disease Control and Prevention, 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 of illnesses were associated with food products, such as meat and poultry, which fall under FSIS' jurisdiction.

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 food supply.³ FSIS has responsibility for ensuring the safety of meat,

² Reported data on foodborne illnesses and related deaths are incomplete and may understate the extent of the problem. The Centers for Disease Control uses reported illnesses, among other sources, to estimate the extent of foodborne illnesses each year.

³ 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 Tobacco, Alcohol 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) for information on food safety agency roles and responsibilities.

poultry, and processed egg products.⁴ Under the governing meat, poultry, and egg products inspection acts, FSIS, in effect, preapproves products under its jurisdiction 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, such as those that run deboning and canning operations, 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.

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. With regard to food safety, FDA is responsible under the Federal Food, Drug, and Cosmetic Act for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. In administering the act, which generally follows the regulatory approach of allowing food products to enter the market without preapproval, FDA inspects domestic establishments that manufacture, process, pack or hold food, and inspects and tests imported food products. However, the act does not mandate or specify inspection frequencies. As such, 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. 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 properly labeled, and produce no human health hazards when used in food-producing animals.⁵

⁴ The meat act regulates meat from cattle, swine, goats, sheep, and equines (horses); the poultry act defines poultry as domesticated fowl, which FSIS regulations define as chickens, turkeys, ducks, geese, and guineas. Egg products are eggs removed from their shells for processing.

⁵ Both FDA and FSIS have implemented Hazard Analysis and Critical Control Point (HACCP) systems that are designed to identify and control foodborne hazards that are likely to occur. In December 1997 FDA required seafood establishments to implement HACCP and in January 1998 FSIS began requiring that meat and poultry establishments implement HACCP.

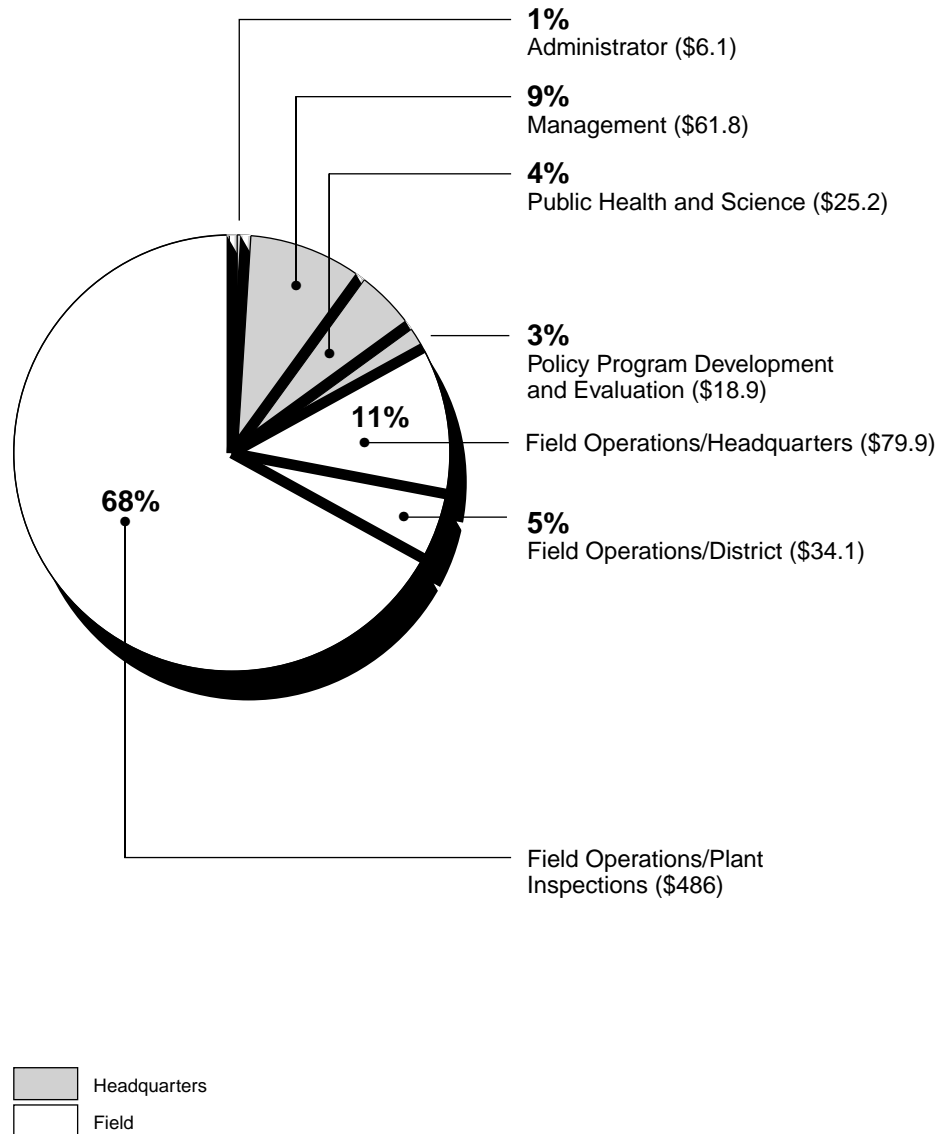
States, territories, and the District of Columbia also have food safety responsibilities and operate agencies that regulate and enforce their own food safety laws to ensure the safety of foods produced, processed, and/or sold within their borders. These responsibilities generally lie within the departments of agriculture and health, and may involve others, such as state environmental protection agencies or county health departments. States and territories may also perform inspections for FSIS or FDA under contract or partnership agreements and report their inspection results to the federal agencies.

FSIS' Food Safety Expenditures

FSIS expended about \$678 million and \$712 million in fiscal years 1998 and 1999, respectively, on food safety activities. 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 1, about 84 percent of FSIS' fiscal year 1999 expenditures were for field activities, and 16 percent were for headquarters office activities. Each activity's proportion of the total expenditures did not vary by more than 1 percent from fiscal year 1998 through fiscal year 1999. (See app. I for detailed information on expenditures, staff years, and activities for fiscal years 1998 and 1999.)

Figure 1: FSIS' Expenditures for Field and Headquarters Activities, Fiscal Year 1999

Dollars in millions



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

In aggregate, FSIS' field activities accounted for \$600 million in fiscal year 1999, or 84 percent of total agency expenditures. Inspections at slaughter, processing, and import establishments accounted for \$486 million, or 68 percent, of total expenditures; and field office administration, supervision and compliance activities accounted for

\$34.1 million, or 5 percent of total expenditures. In addition, the Office of Field Operations, the Washington D.C. headquarters office that manages field activities, accounted for \$79.9 million, or 11 percent of total expenditures. The largest expenditure of the field operations office was for grants to states for inspection activities, accounting for \$44.4 million, or about 57 percent of its total expenditures in fiscal year 1999. This office also funds the Technical Service Center, located in Omaha, Nebraska, which serves as the agency's center for technical assistance and guidance for field operations personnel and industry and conducts reviews of domestic and foreign inspection programs.

In aggregate, FSIS' headquarters-based activities accounted for \$112 million in fiscal year 1999, or 16 percent of total agency expenditures. FSIS' headquarters food safety activities are conducted by four offices—management; public health and science; policy, program development, and evaluation; and the office of the administrator. Specifically:

- The Office of Management accounted for about \$61.8 million, or 9 percent, of total expenditures. The management 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 Public Health and Science accounted for about \$25.2 million, or 4 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. Almost half or \$16.6 million of its expenditures were for laboratory analyses by the agency's three field laboratories.
- The Office of Policy, Program Development, and Evaluation accounted for about \$18.9 million, or 3 percent, of total expenditures. The policy and program office is

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

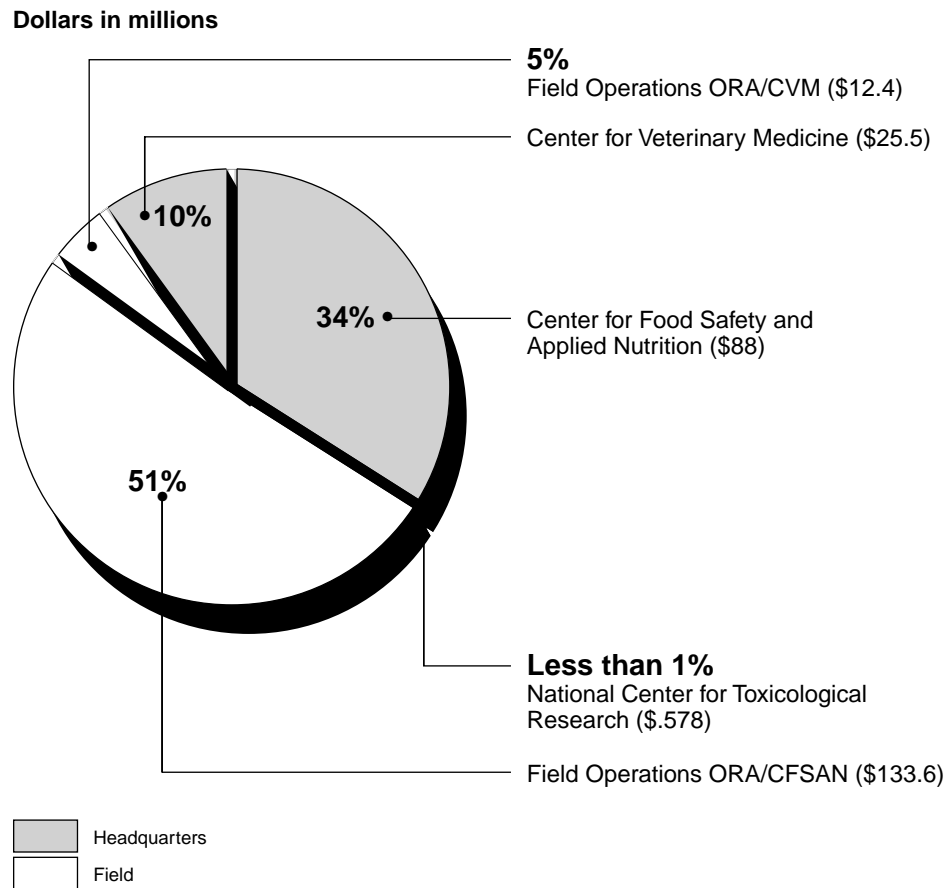
- The Office of the Administrator accounted for about \$6.1 million, or 1 percent, of total expenditures. The office is responsible for management of agency activities such as public affairs, food safety education, coordination of U.S. involvement in international standard-setting for food safety, and maintaining liaison with trade organizations.

FDA's Food Safety Expenditures

FDA expended about \$231 million and \$260 million in fiscal years 1998 and 1999, respectively, on food safety activities.⁶ These expenditures represent the combined activities of the three FDA 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 for these centers by the Office of Regulatory Affairs. As with FSIS, FDA's 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 56 percent of FDA's fiscal year 1999 expenditures were for field activities, and about 44 percent were for headquarters office activities. Each activity's proportion of total expenditures did not vary by more than 1 percent from fiscal year 1998 to 1999. (See app. II for detailed information on fiscal year 1998 and 1999 expenditures, staff years, and activities.)

⁶ These figures exclude central agency support costs, which FDA is in the process of determining.

Figure 2: FDA's Expenditures for Field and Headquarters Activities, Fiscal Year 1999



Legend:

- ORA Office of Regulatory Affairs
- CVM Center for Veterinary Medicine
- CFSAN Center for Food Safety and Applied Nutrition

In aggregate, FDA's field activities accounted for \$146 million in fiscal year 1999, or 56 percent of total agency expenditures. FDA's 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. For fiscal year 1999, the ORA-conducted field component of the Center for Food Safety and Applied Nutrition's food

safety activities accounted for \$133.6 million in expenditures and the ORA-conducted field component of the Center for Veterinary Medicine's food safety activities accounted for \$12.4 million in expenditures.

In aggregate, headquarters-based activities accounted for \$114 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 headquarters component accounted for \$88 million in fiscal year 1999, or 34 percent of total expenditures. The center operates FDA's Foods Program, which is responsible for ensuring that FDA-regulated food is safe, sanitary, wholesome, and honestly labeled. To achieve this goal, the center implements programs that address specific food safety concerns, such as food and color additives, infant formula, medical foods, and seafood. The center also engages in regulatory policy development and education and outreach activities, and manages federal/state cooperative programs. Food safety research and risk assessment accounted for the center's largest expenditures, about \$32 million each year.
- The Center for Veterinary Medicine's headquarters component accounted for \$25.5 million in fiscal year 1999, or 10 percent of total 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 headquarters expenditures, about \$12.8 million.
- The National Center for Toxicological Research, located in Jefferson, Arkansas, accounted for \$578,000 in fiscal year 1999, or less than 1 percent of total 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 years 1998 and 1999, the center conducted research projects that contributed to FDA's food safety mission. It did not engage in field activities related to food safety.

Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions you or Members of the Committee may have.

Contact and Acknowledgement

For future contacts regarding this testimony, please contact Lawrence J. Dyckman at (202) 512-5138. Individuals making key contributions to this testimony were Keith Oleson, Brad Dobbins, Kathy Colgrove-Stone, and John Nicholson.

Appendix I

**Food Safety and Inspection Service’s Food Safety Expenditures and Staff Years,
Fiscal Years 1998 and 1999**

For fiscal years 1998 and 1999, the Food Safety and Inspection Service (FSIS) expended about \$677.8 and \$712 million, respectively, for its food safety activities. As shown in table 1, 84 percent of the expenditures were for field office operation, compliance, and inspection activities, while the remainder were expended for FSIS headquarters office activities. Each activity’s proportion of the total expenditures did not vary by more than 1 percent between the 2 fiscal years.

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

Dollars in millions

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

^aTotals may not add because of rounding.

Appendix I

FSIS' field activities include inspections of establishments under the agency's jurisdiction and compliance work to ensure that the establishments are following applicable regulations. Table 2 presents selected results from FSIS' inspection and compliance field work.

Table 2: Number of Establishments Inspected by FSIS and Selected Compliance Activities, Fiscal Years 1998 and 1999

Activity	1998	1999
Inspections		
Slaughter establishments	254	262
Processing establishments	4,297	4,343
Combination slaughter and processing establishments	985	968
State agreements ^a	256	254
Import establishments	135	129
Egg product establishments	78	75
Total establishments inspected	6,005	6,031
Compliance activities		
Compliance reviews	26,176	43,976
Warnings issued	1,520	2,778
Suspensions for Hazard Analysis and Critical Control Point violations	77	118

^aFunded through FSIS' headquarters Office of Field Operations at a cost of \$40.6 million and \$44.4 million in fiscal years 1998 and 1999, respectively.

Appendix II

**Food and Drug Administration’s Food Safety Expenditures and Staff Years,
Fiscal Years 1998 and 1999**

For fiscal years 1998 and 1999, the Food and Drug Administration (FDA) expended about \$231.3 and \$260 million, respectively, for its food safety activities. As shown in table 3, about 56 percent of the expenditures were for field office operation, compliance and inspection activities, while the remainder were expended for FDA headquarters office activities. Each activity’s proportion of the total expenditures did not vary by more than 1 percent between the 2 fiscal years 1998 to 1999.

Table 3: FDA’s Fiscal Year 1998 and 1999 Expenditures and Staff Years for Food Safety Activities by Center, Fiscal Years 1998 and 1999

Dollars in millions

Center	Expenditures (percent of total)		Staff Years (percent of total)	
	1998	1999	1998	1999
Field Operations— Office of Regulatory Affairs/ Center for Food Safety and Applied Nutrition	\$116.2 (50)	\$133.6 (51)	1,426 (57)	1,535 (59)
Field Operations— Office of Regulatory Affairs/Center for Veterinary Medicine	12.5(5)	12.4 (5)	138 (5)	137 (5)
Field Operations— Subtotal	128.7 (56)	146 (56)	1,564 (62)	1,672 (64)
Headquarters Operations—Center for Food Safety and Applied Nutrition	78.3 (34)	88 (34)	733 (29)	721 (28)
Headquarters Operations - Center for Veterinary Medicine	23.7 (10)	25.5 (10)	203 (8)	206 (8)
Headquarters Operations— National Center for Toxicological Research	.6 (<1)	.6 (<1)	4 (<1)	4 (<1)
Headquarters Operations— Subtotal	\$102.6 (44)	\$114 (44)	940 (38)	931 (36)
Total^a	\$231.3 (100)	\$260 (100)	2,503 (100)	2,603 (100)

^aTotals may not add because of rounding.

Appendix II

FDA's field activities include inspections of establishments under the agency's jurisdiction and analysis of product samples to ensure that the products are in compliance with applicable regulations. Table 4 presents selected results from FDA's inspection and sample analysis field work.

Table 4: Selected FDA Food Safety Inspection and Sample Analysis Activity, Fiscal Years 1998 and 1999

Activity	1998	1999
Inspections		
Food importers	940	765
Domestic food establishments ^a	11,922	14,680
Feed establishments ^b	4,182	3,128
Total inspections^c	17,044	18,573
Sample Analysis		
Domestic food samples	10,894	9,335
Import food samples	16,802	15,439
Feed samples	1,580	1,784
Total samples analyzed	29,276	26,558

^aIncludes 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.

^bIncludes 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.

^cAn individual importer, food or feed establishment may be inspected more than once in a year.

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