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FOOD SAFETY

U.S. Needs a Single Agency
to Administer a Unified,
Risk-Based Inspection
System

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the need to revamp the federal food safety system. Each year, millions of people become ill and thousands die from eating unsafe foods. As we have stated in previous reports and testimonies, fundamental changes to the food safety system are needed, including moving to a uniform, risk-based inspection system, administered by a single agency. (See Related GAO Products.). My testimony today provides an overview of our work on the problems resulting from the current fragmented food safety system and discusses our views on where in the federal government food safety inspection responsibilities should reside.

In summary, the structure of the current food safety system—which costs the federal treasury more than \$1 billion annually—hampers efforts to address public health concerns associated with existing and newly identified food safety risks. The fragmented system was not developed under any rational plan but was patched together over many years to address specific health threats from particular food products. Efforts to address food safety concerns—particularly changing health risks—are hampered by inconsistent and inflexible oversight and enforcement authorities, inefficient resource use, and ineffective coordination.

A single food safety inspection agency responsible for administering a uniform set of laws is the most effective way for the federal government to resolve these long-standing problems, deal with emerging food safety issues, and better ensure a safe food supply. While we believe that this would be the most effective approach, we recognize that there are short term costs and other considerations associated with setting up a new government agency. A second option, though less desirable, would be to consolidate food safety activities in an existing department. In such an event, consolidating these activities—either in the U.S. Department of Agriculture (USDA) or the Department of Health and Human Service's (HHS) Food and Drug Administration—presents benefits and drawbacks. Regardless, it is unlikely that fundamental, long-lasting improvements in food safety will occur until food safety activities are consolidated under a single agency and the current patchwork of food safety legislation is altered to make it uniform and risk-based.

Background

Twelve different agencies administer as many as 35 laws that make up the federal food safety system. Two agencies account for most federal

spending on, and regulatory responsibilities for, food safety: The Food Safety and Inspection Service (FSIS), under USDA, is responsible for the safety of meat, poultry, and some eggs and some egg products, while FDA is responsible for the safety of most other foods. Other agencies with food safety responsibilities and/or programs include HHS' Centers for Disease Control and Prevention; USDA's Agricultural Marketing Service, Animal and Plant Health Inspection Service, Agricultural Research Service, and Grain Inspection, Packers, and Stockyards Administration; the Department of Commerce's National Marine Fisheries Service; the Department of the Treasury's U.S. Customs Service and Bureau of Alcohol, Tobacco, and Firearms; the Environmental Protection Agency (EPA); and the Federal Trade Commission. Appendix I describes the food safety roles and responsibilities of these 12 agencies and shows each agency's food safety funding and staffing level for fiscal year 1998.

Despite the more than \$1 billion spent annually on the current food safety system, food safety remains a concern. For example, in late 1998, 101 people became ill from eating hot dogs contaminated with listeria—a pathogenic bacterium. Of those who became ill, 15 died and 6 suffered a miscarriage or stillbirth. In May and June of this year, about 120 people became ill in the Richmond, Virginia, area because they ate at a local restaurant where some of the food contained eggs contaminated with the pathogenic bacterium *Salmonella Enteritidis*. Because many cases of foodborne illness go undiagnosed, estimates of the actual number of incidents that occur nationally each year cover a wide range—from a low of 6 million cases to a high of 33 million cases, leading to about 9,000 deaths annually, according to CDC. In medical costs and productivity losses, foodborne illness costs the nation between \$7 billion and \$37 billion per year, according to USDA estimates.

Current Federal Food Safety System Needs Overhaul

During the past 25 years, we and other organizations, such as the National Academy of Sciences, have issued reports detailing problems with the federal food safety system and made numerous recommendations for change. While many of these recommendations have been acted upon, improvement efforts have fallen short, largely because the separate agencies continue to operate under the different regulatory approaches implicit in their basic authorities. Consequently, it is unlikely that fundamental, lasting improvements in food safety will occur until systematic legislative and structural changes are made to the entire food safety system.

The federal regulatory system for food safety evolved haphazardly. As the understanding of foodborne hazards grew, food safety concerns changed. Addressing one new worry after another, legislators amended old laws and enacted new ones. Programs emerged piecemeal, typically in response to particular health threats or economic crises. The laws not only assigned specific food commodities to particular agencies but also provided the agencies with different authorities and responsibilities, reflecting significantly different regulatory approaches. The resulting inflexible and inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts have hampered and continue to impede efforts to address the public health concerns associated with existing and newly identified food safety risks. The following examples represent some of the problems we have found in reviewing the nation's food safety system:

- Federal agencies are not using their inspection resources efficiently. Because the frequency of inspection is based on the agencies' regulatory approach, some foods and establishments may be receiving too much attention while others may not be receiving enough. Firms that process food products posing similar health risks to the public are inspected at widely different frequencies, depending on which agency—and thus which regulatory approach—governs them. Although the level of health risk is similar for all animal products, meat and poultry plants regulated by FSIS are inspected at least daily, while firms that are under FDA's jurisdiction such as, processors of rabbit, venison, and quail, are generally inspected, on average once every ten years. Furthermore, food establishments are sometimes inspected by more than one federal agency because they participate in programs or process foods that are under the jurisdiction of different agencies.
- Responsibilities for the oversight of chemical residues in foods are fragmented among FDA, USDA, and EPA. As a result, chemicals posing similar risks may be treated differently by the agencies because they operate under different laws and regulations. Furthermore, the states use different methodologies for determining the amount of fish that can be safely consumed. For example, under the Clean Water Act, EPA is required only to consider risks to human health and aquatic life when conducting water quality assessments. However, under the Federal Food, Drug, and Cosmetic Act, FDA is allowed to consider both health risks and benefits in establishing tolerances for chemical contaminants in food. Therefore, as we reported in 1994,¹ FDA standards for some chemicals are often less

¹Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994).

stringent than those developed by EPA. This inconsistency is often reflected in the methodology the states use to determine the levels of fish consumption considered safe. According to EPA officials as of 1998, about 30 states use a methodology similar to EPA's and about 20 states use a different methodology such as one similar to FDA's.² Thus a fish considered unsafe to eat in one state may become safe to eat if it swims to another state.

- Enforcement authorities granted to the agencies also differ. USDA agencies have the authority to (1) require food processors to register so that they can be inspected, (2) presume that food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, and (4) temporarily detain any suspect foods. Conversely, FDA, without such authority, is often hindered in overseeing food processors.
- Oversight of imported food is inconsistent and unreliable.³ To ensure the safety of meat and poultry imports, FSIS has a statutory mandate to require that each of the countries exporting meat and poultry to the United States demonstrate that it has a food safety system that is equivalent to the United States' system. Under the equivalency requirement, FSIS has shifted most of the responsibility for ensuring product safety to the exporting country. The exporting country performs the primary inspection, allowing FSIS to leverage its resources by focusing its reviews on verifying the efficacy of the exporting countries' systems. In contrast, FDA lacks the legal authority to require that countries exporting foods to the United States have food safety systems equivalent to ours. Without such authority FDA must rely primarily on its port-of-entry inspections, which covered less than 2 percent of shipments in 1997, to detect and bar unsafe foods. Such an approach has been widely discredited as resource-intensive and ineffective.
- Fragmented federal responsibilities also cause problems for the food industry because communication about health risks associated with contaminated food products is impaired. As we reported in April 1998,⁴ nearly every day during May, June, and early July 1997, officials from FDA, FSIS, and the Environmental Protection Agency participated in conference calls to discuss the latest developments in the investigation of animal feeds contaminated with dioxin (a suspected carcinogen) to determine

²EPA officials stated that further review of the 20 states using a methodology different than EPA's may reveal that some of them are actually using a methodology similar to EPA's.

³Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998).

⁴Food Safety: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors (GAO/RCED-98-104, Apr. 10, 1998).

what actions, if any, the agencies needed to take to protect consumers. While FDA and FSIS worked together to make decisions on the preferred course of action, each agency was responsible for communicating its decisions to the producers or processors under its jurisdiction. However, complete information was not communicated to all affected parties. For example, when officials from FDA, the agency responsible for regulating animal feed, met with meat and poultry producers, their primary concern was with the contaminated feed, not with the animals that had consumed it. Thus, they did not necessarily tell these producers of the actions they should take for their affected animals. FSIS, the agency responsible for regulating meat and poultry processors, sent word of the testing requirements to meat and poultry processors and to trade associations, but it did not notify meat and poultry producers. FSIS has jurisdiction over processing plants, but not producers.

- The agencies have made attempts to coordinate their activities to overcome the fragmentation and avoid duplication or gaps in coverage, but history has shown that as time passes, such efforts frequently prove to be ineffective. We have reported in the past that unsafe conditions in food processing plants have gone unaddressed because the notifications required by coordination agreements do not always take place or the problems referred to the responsible agency are not promptly investigated.⁵ As we testified before this Subcommittee last month, egg safety remains questionable, despite FSIS' and FDA's efforts to coordinate their activities on egg and egg product safety—a shared responsibility between the two agencies.⁶ In 1991, an amendment to the Egg Products Inspection Act mandated that federal regulations be issued requiring the refrigeration of shell eggs. Eight years later, FSIS regulations, effective August 27, 1999, set refrigeration requirements for eggs from the packing plant through transportation to the retail level. However, FDA, which has responsibility for egg safety at the retail level has not enacted similar regulations; therefore, refrigerating eggs at the retail level is not yet required.⁷

These problems, which apply to many food products, are clearly illustrated in the regulation of pizza. Figure 1 shows the federal

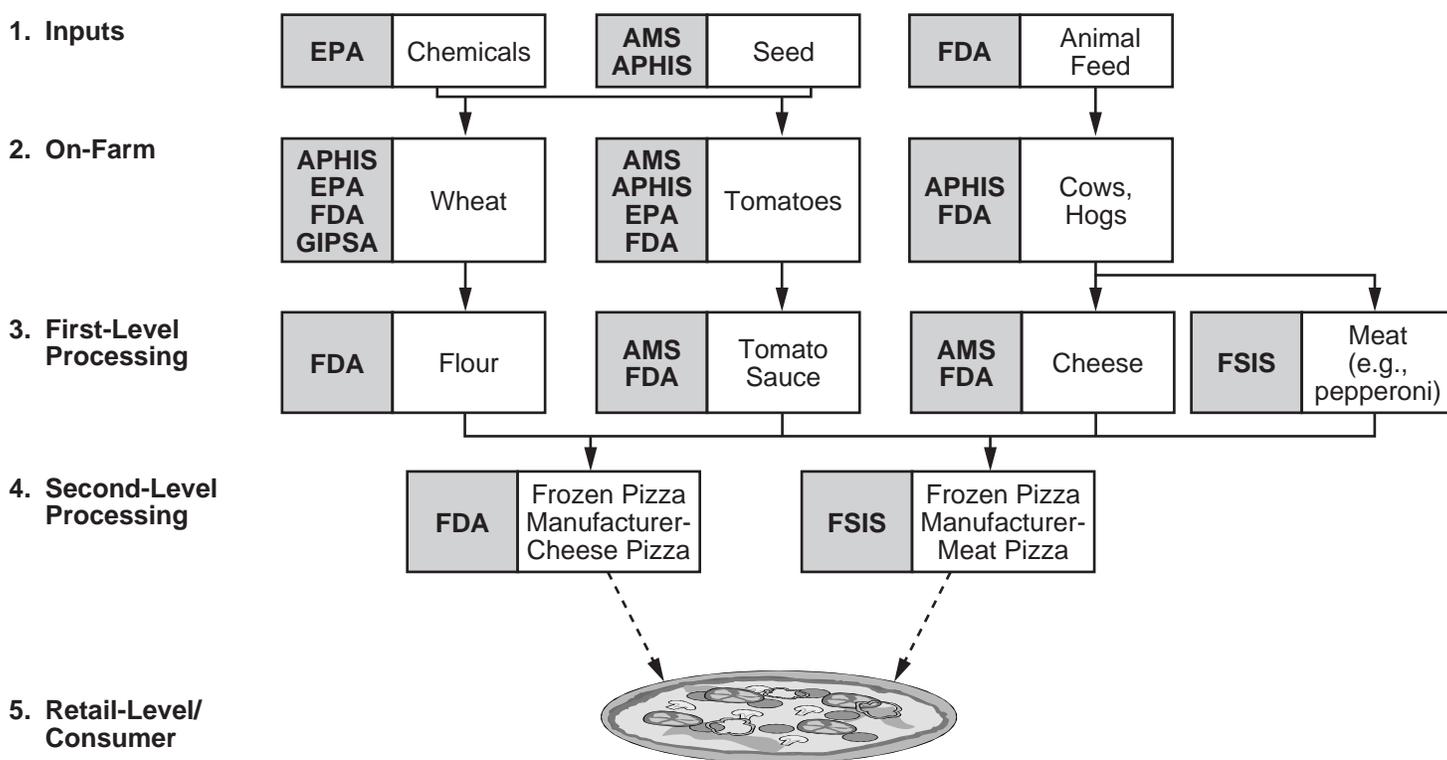
⁵Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

⁶Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety (GAO/RCED-99-184, July 1, 1999).

⁷On July 1, 1999, FDA announced proposed regulations for ensuring the safety of eggs that contained, among other things, refrigeration requirements for eggs at the retail level.

responsibilities for ensuring the safety of a frozen meat pizza and a frozen cheese pizza.

Figure 1: Federal Agencies Responsible for Ensuring Safe Pizza



A Single Agency Would Enhance Food Safety

The most effective solution to the current fragmentation of the federal food safety system is consolidating food safety programs under a single agency with uniform authority. Consolidating food safety activities is hardly a new concept. Such a concept was debated in 1972 in connection with a proposed bill to transfer FDA's responsibilities, including its food safety activities, to a new independent agency, called the Consumer Safety Agency. This new agency was to be responsible for, among other things, ensuring the safety of the nation's food supply, although meat and poultry inspection was to remain in USDA.

Whether an independent single agency is preferable to a component of an existing department, as we testified in 1972,⁸ is a matter of judgment upon which opinions differ. However, we continue to believe, as we testified in 1994,⁹ that a single independent food safety agency administering a unified, risk-based food safety system is the preferred approach, although we recognize the difficulties in establishing a new government agency. Regardless of where a single agency is housed, what is most important are certain principles, including a clear commitment by the federal government to consumer protection, a system that is founded on uniform laws that are risk-based, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency. Although these principles can be influenced by organizational placement, commitment to them probably depends more on public and political concern for the importance of the mission.

In this regard, we recently reported on the experiences of four countries that have consolidated or are in the process of consolidating their food safety responsibilities.¹⁰ Two of the four—Great Britain and Ireland—were responding to heightened public concerns about the safety of their food supplies and chose to consolidate responsibilities in the agencies that report to their ministers of health. For example, the British plan to consolidate food safety activities into a single agency was largely a result of the government’s perceived mishandling of an outbreak of Bovine Spongiform Encephalopathy (commonly referred to as “mad cow” disease). Public opinion viewed the agriculture ministry, which had dual responsibilities to promote agriculture and the food industry and to regulate food safety, as slow to react because it was too concerned about protecting the cattle industry.

The other two countries—Canada and Denmark—were more concerned about program effectiveness and cost saving and accordingly consolidated activities in agencies that report to their ministers of agriculture, who already control most of the food safety resources. For example, Canada did not face a loss of public confidence, as did Great Britain and Ireland, but instead faced a budgetary crisis; it therefore sought ways to reduce federal expenditures. By combining the various elements of its food

⁸Hearings on the Consumer Safety Act of 1972 before the Subcommittee on Executive Reorganization and Government Research, Senate Committee on Government Operations (1972).

⁹Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994).

¹⁰Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems (GAO/RCED-99-80, Apr. 20, 1999).

inspection services, Canada expected to save about 13 percent of its food inspection budget, or \$44 million Canadian (\$29 million U.S.) per year.

We are not alone in calling for fundamental changes to the federal food safety system. In an August 1998 report, the National Academy of Sciences concluded that the current fragmented federal food safety structure is not well equipped to meet emerging challenges.¹¹ As such, the Academy report recommended that the Congress establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and has the responsibility for, and control of, resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

According to the Academy report, many members of the committee believed that the most viable means of achieving food safety goals would be to create a single, unified agency headed by a single administrator—an agency that would incorporate the several relevant functions now dispersed, and in many instances separately organized, among three departments and a department-level agency. However, designing the structure and assessing the associated costs involved were not possible in the timeframe given the committee, nor were these tasks included in the committee's charge. As such, the committee did not recommend a specific organizational structure but instead provided several possible configurations for illustrative purposes. These were

- forming a Food Safety Council of representatives from the agencies, with a central chair appointed by the President, reporting to the Congress and having control of resources;
- designating one current agency as the lead agency and making the head of that agency the responsible individual;
- establishing a single agency reporting to one current cabinet-level secretary; and
- establishing an independent single agency at the cabinet level.

In response to the National Academy's report, the President established a Council on Food Safety and directed it to provide him with an assessment of the Academy report within 180 days.¹² The council was also charged

¹¹Ensuring Safe Food From Production to Consumption (Institute of Medicine, National Research Council, National Academy Press, Washington, D.C., Aug. 1998).

¹²The President's Council on Food Safety comprises, among others, the Secretaries of Agriculture, Health and Human Services, and Commerce, and the Administrator of EPA.

with developing a comprehensive strategic plan for federal food safety activities and making recommendations to the President on how to implement the plan.

In its March 1999 report to the President,¹³ the Council agreed with the goal of the Academy's recommendation that there should be a fully integrated food safety system and undertook to assess structural models and other mechanisms that could strengthen the federal food safety system through better coordination, planning, and resource allocation. In its analysis, the council said it plans to determine whether certain models of reorganization would have advantages for coordination and allocation of resources while also considering how each agency's responsibilities that are not driven by food safety might affect food safety responsibilities.

To conclude, Mr. Chairman, as the United States prepares to enter a new millenium, we believe the Congress has an opportunity to transform our present food safety system into one that better protects consumers' health. Creating a single agency to administer food safety activities that are uniform and risk-based is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and better ensure the safety of our country's food supply. This completes our prepared statement. We would be happy to respond to any questions.

Contacts and Acknowledgements

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 and John Nicholson.

¹³President's Council on Food Safety Assessment of the NAS Report: Ensuring Safe Food from Production to Consumption, (President's Council on Food Safety, Mar. 1999).

Food Safety Responsibilities and Fiscal Year 1998 Funding and Staffing Levels at 12 Federal Agencies

Dollars in millions

Agency	Fiscal year 1998 funding ^a	Fiscal year 1998 staffing
Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), is responsible for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. The Federal Food, Drug, and Cosmetic Act, as amended, is the major law governing FDA's activities to ensure food safety and quality. The act also authorizes FDA to maintain a surveillance of all animal drugs, feeds, and veterinary devices to ensure that drugs and feeds used in animals are safe and properly labeled, and produce no human health hazards when used in food-producing animals.	\$254 ^b	2,796 ^b
Centers for Disease Control and Prevention (CDC), within HHS, is charged with protecting the nation's public health by providing leadership and direction in preventing and controlling diseases and responding to public health emergencies. CDC conducts surveillance for foodborne diseases; develops new epidemiological and laboratory tools to enhance the surveillance and detection of outbreaks; and performs other activities to strengthen local, state, and national capacity to identify, characterize, and control foodborne hazards. CDC engages in public health activities related to food safety under the general authority of the Public Health Service Act, as amended.	15	50
Food Safety and Inspection Service (FSIS), within the U.S. Department of Agriculture (USDA), is responsible for ensuring that meat, poultry, and some eggs and egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, labeled, and packaged. FSIS carries out its inspection responsibilities under the Federal Meat Inspection Act, as amended, the Poultry Products Inspection Act, as amended, and the Egg Products Inspection Act, as amended.	676	9,702
Animal and Plant Health Inspection Service (APHIS), within USDA, is responsible for ensuring the health and care of animals and plants. APHIS has no statutory authority for public health issues unless the concern to public health is also a concern to the health of animals or plants. APHIS identifies research and data needs and coordinates research programs designed to protect the animal industry against pathogens or diseases that are a risk to humans to improve food safety.	c	c
Grain Inspection, Packers and Stockyards Administration (GIPSA), within USDA, is responsible for establishing quality standards and providing for a national inspection system to facilitate the marketing of grain and other related products. Certain inspection services, such as testing corn for the presence of aflatoxin, enable the market to assess the value of a product on the basis of its compliance with contractual specifications and FDA requirements. GIPSA has no regulatory responsibility regarding food safety. Under a memorandum of understanding with FDA, GIPSA reports to FDA certain lots of grain, rice, pulses, or food products (which were officially inspected as part of GIPSA's service functions) that are considered objectionable under the Federal Food, Drug, and Cosmetic Act, as amended, the U.S. Grain Standards Act, as amended, and the Agriculture Marketing Act of 1946, as amended.	c	c
Agricultural Marketing Service (AMS), within USDA, is primarily responsible for establishing the standards of quality and condition and for grading the quality of dairy, egg, fruit, meat, poultry, seafood, and vegetable products. As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. AMS carries out its wide array of programs to facilitate marketing under more than 30 statutes—for example, the Agricultural Marketing Agreement Act of 1937, as amended; the Agricultural Marketing Act of 1946, as amended; the Egg Products Inspection Act, as amended; the Export Apple and Pear Act, as amended; and the Export Grape and Plum Act, as amended. AMS is largely funded with user fees.	10 ^d	42 ^d
Agricultural Research Service (ARS), within USDA, is responsible for conducting a wide range of research relating to the Department's mission, including food safety research. ARS carries out its programs under the Department of Agriculture Organic Act of 1862; the Research and Marketing Act of 1946, as amended; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended.	55	167

(continued)

**Appendix I
Food Safety Responsibilities and Fiscal Year
1998 Funding and Staffing Levels at 12
Federal Agencies**

Dollars in millions

Agency	Fiscal year 1998 funding^a	Fiscal year 1998 staffing
National Marine Fisheries Service (NMFS), within the Department of Commerce, conducts its voluntary seafood safety and quality inspection programs under the Agricultural Marketing Act of 1946, as amended, and the Fish and Wildlife Act of 1956, as amended. In addition to the inspection and certification services provided for fishery products for human consumption, NMFS provides inspection and certification services for animal feeds and pet foods containing a fish base.	13 ^d	174 ^d
Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or distributed in the United States and setting maximum allowed residue levels—tolerances—for pesticides on food commodities and animal feed. EPA's activities are conducted under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Federal Food, Drug, and Cosmetic Act, as amended.	127	970
Federal Trade Commission (FTC) enforces the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. FTC's food safety objective is to prevent consumer deception through the misrepresentations of food.	e	e
U.S. Customs Service, within the Department of the Treasury, is responsible for collecting revenues and enforcing various customs and related laws. Customs assists FDA and FSIS in carrying out their regulatory roles in food safety.	e	e
Bureau of Alcohol, Tobacco, and Firearms, within the Department of the Treasury, is responsible for administering and enforcing laws covering the production (including safety), use, and distribution of alcoholic beverages under the Federal Alcohol Administration Act and the Internal Revenue Code.	e	e
Total	\$1,150	13,901

^aFiscal year 1998 appropriated funds.

^bFDA's data includes funding and staffing for various programs across FDA that are involved with food safety activities, including the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the field components for these centers, as well as overall agency-wide support.

^cThe agency did not specify its food safety resources.

^dAgencies' funding and staffing levels are for both safety and quality inspection activities.

^eWe did not obtain these agencies' food safety budgets due to the small amount of funds for these activities in previous years.

Source: GAO's analysis of federal agencies' data.

Related GAO Products

Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety (GAO/RCED-99-184, July 1, 1999).

Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems (GAO/RCED-99-80, Apr. 20, 1999).

Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness (GAO/RCED-98-224, Aug. 6, 1998).

Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998).

Food Safety: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors (GAO/RCED-98-104, Apr. 10, 1998).

Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994).

Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994).

Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994).

Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

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