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Testimony

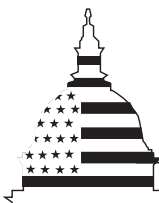
Before the Subcommittee on Oversight of
Government Management, Restructuring
and the District of Columbia, Committee
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FOOD SAFETY AND SECURITY

Fundamental Changes Needed to Ensure Safe Food

Statement of Robert A. Robinson, Managing Director,
Natural Resources and Environment



G A O

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the federal food safety system and whether the system's current design can meet the food safety challenges of today. While the food supply is generally safe, each year tens of millions of Americans become ill and thousands die from eating unsafe foods, according to the Centers for Disease Control and Prevention (CDC). As we have stated in previous reports and testimonies, fundamental changes are needed to ensure a safer food supply. My testimony today provides an overview of the nation's fragmented food safety system, the problems that it causes, and the changes necessary to create lasting improvements. In addition, I want to bring to your attention some work GAO has done addressing deliberate food contamination and federal research on and preparedness for bioterrorism in light of the tragic events of September 11, 2001.

In summary, the current food safety system is a patchwork structure that hampers efforts to adequately address existing and emerging food safety risks, whether those risks involve inadvertent or deliberate contamination. The current system is not the product of a comprehensive planning process; rather, it was cobbled together over many years to address specific health threats from particular food products. The resulting fragmented organizational and legal structure causes inefficient use of resources, inconsistent oversight and enforcement, and ineffective coordination, which together hamper federal efforts to comprehensively address food safety concerns. Many states modeled their organizational structure for food safety on the federal system and thus face the same issues.

It is now widely recognized that food safety issues must be addressed comprehensively—that is, by preventing contamination through the entire food production cycle, from farm to table. A single, food safety agency responsible for administering a uniform set of laws is needed to resolve the long-standing problems with the current system; deal with emerging food safety issues, such as the safety of genetically modified foods or deliberate acts of contamination; and ensure a safe food supply. While we believe that an independent agency could offer 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 would be to consolidate food safety activities in an existing department, such as the U.S. Department of Agriculture (USDA) or the Department of Health and Human Service (HHS). Regardless, however, choosing an organizational structure only represents half the job. For any

single food safety agency to be ultimately successful, it will also be necessary to rationalize the current patchwork of food safety legislation to make it uniform and risk-based.

Background

Despite spending more than \$1 billion annually on the federal food safety system, food safety remains a concern. For example, between May and November 2000, sliced and packaged turkey meat contaminated with *Listeria monocytogenes* caused 29 individuals in 10 states to become ill. In April and May of this year, imported cantaloupes contaminated with a pathogenic strain of *Salmonella* were linked to 54 illnesses and 2 deaths in 16 states, and in June six people in California were sickened, two of whom died, from eating oysters contaminated with *Vibrio vulnificus*. CDC estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year. In medical costs and productivity losses, foodborne illnesses related to five principal pathogens cost the nation about \$6.9 billion annually, USDA estimates.¹

Twelve different agencies administer as many as 35 laws that make up the federal food safety system. Two agencies account for most federal food safety spending and regulatory responsibilities: the Food Safety and Inspection Service (FSIS), in USDA, is responsible for the safety of meat, poultry, and processed eggs, while the Food and Drug Administration (FDA), in HHS, 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 (AMS), Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), and Grain Inspection, Packers and Stockyards Administration (GIPSA); 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 2000.

State and local governments also conduct inspection and regulation activities that help ensure the safety of foods produced, processed, or sold

¹The five principal pathogens are *Campylobacter* spp., *Salmonella* (nontyphoidal), *E. coli* O157:H7, *E. coli* non-O157 STEC, and *Listeria monocytogenes*.

Fragmented System Hampers the Effectiveness of Food Safety Efforts

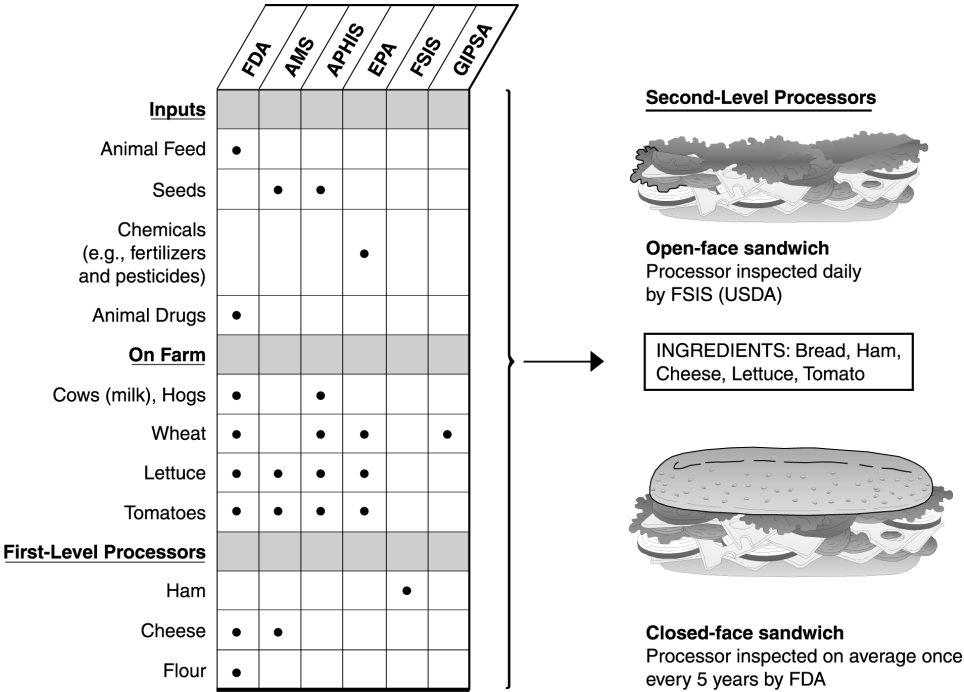
within their borders. State and local governments would generally be the first to identify and respond to deliberate acts of food contamination.

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 have made numerous recommendations for change. While many of these recommendations have been acted upon, food safety problems persist, largely because food safety responsibilities are still divided among several agencies that continue to operate under different regulatory approaches.

The federal regulatory system for food safety did not emerge from a comprehensive design but rather evolved piecemeal, typically in response to particular health threats or economic crises. Addressing one new worry after another, legislators amended old laws and enacted new ones. The resulting organizational and legal patchwork has given responsibility for specific food commodities to different agencies and provided them with significantly different regulatory authorities and responsibilities.

The number of agencies involved in regulating a sandwich illustrates the fragmented nature of the current food safety system. Figure 1 shows the federal responsibilities for regulating production and processing of a packaged ham and cheese sandwich and its ingredients. The responsible regulatory agency as well as the frequency with which inspections occur depends on how the sandwich is presented. FSIS inspects manufacturers of packaged open-face meat or poultry sandwiches (e.g., those with one slice of bread), but FDA inspects manufacturers of packaged closed-face meat or poultry sandwiches (e.g., those with two slices of bread). According to FSIS officials, the agency lacked the resources to inspect all meat and poultry sandwich manufacturers, so it was decided that FSIS would inspect manufacturers of the less common open-face sandwich, leaving inspection of other sandwich manufacturers to FDA. Although there are no differences in the risks posed by these products, wholesale manufacturers of open-face sandwiches sold in interstate commerce are inspected by FSIS daily, while wholesale manufacturers of closed-face sandwiches sold in interstate commerce are generally inspected by FDA on average once every 5 years. (See app. II for a list of other food products with similar risks that have different inspection frequencies because they are regulated by different agencies.)

Figure 1: Federal Agencies Responsible for Safety of Packaged Ham and Cheese Sandwich

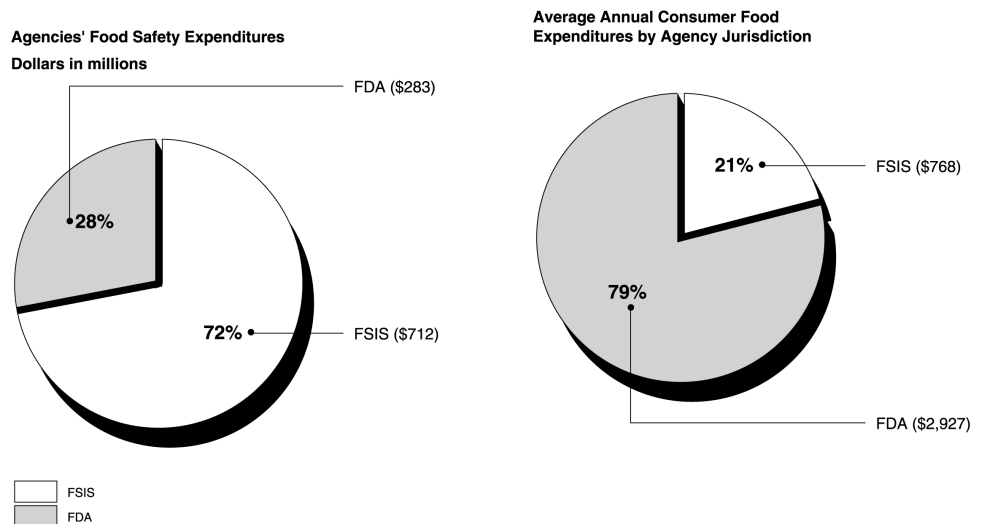


Because the nation’s food safety system evolved piecemeal over time, the nation has essentially two very different approaches to food safety—one at USDA and the other at FDA—that have led to inefficient use of resources and inconsistencies in oversight and enforcement. These problems, along with ineffective coordination between the agencies, have hampered and continue to impede efforts to address public health concerns associated with existing and emerging food safety risks. The following examples represent some of the problems we identified during our reviews of the nation’s food safety system.

- **Federal food safety expenditures are based on legal requirements, not on risk.** As shown in figure 2, funding for ensuring the safety of products is disproportionate to the level of consumption of those products because the frequency of inspection is based not on risk but on the agencies’ legal authority and regulatory approach. Likewise, funding for ensuring the safety of products is disproportionate to the percentage of foodborne illnesses linked to those products. For example, to ensure the safety of meat, poultry, and processed egg products in fiscal year 1999,

FSIS spent about \$712 million to, among other things, inspect more than 6,000 meat, poultry, and egg product establishments and conduct product inspections at 130 import establishments. FSIS' expenditures reflect its interpretation of federal law as requiring daily inspection of meat and poultry processing plants and its traditional implementation of its statutory inspection mandate through continuous government inspection of every egg products plant and every meat and poultry slaughter plant, including the examination of every carcass slaughtered. These plants account for about 20 percent of federally regulated foods and 15 percent of reported foodborne illnesses. In comparison, FDA, which has responsibility for all foods except meat, poultry, and processed egg products and has no mandated inspection frequencies, spent about \$283 million to, among other things, oversee some 57,000 food establishments and 3.7 million imported food entries. These establishments and entries account for about 80 percent of federally regulated foods and 85 percent of reported foodborne illnesses.²

Figure 2: FSIS' and FDA's Food Safety Expenditures and Consumers' Annual Food Expenditures by Agency Jurisdiction



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

²*Food Safety: Overview of Federal and State Expenditures* (GAO-01-177, Feb. 20, 2001) and *Food Safety: Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures* (GAO/T-RCED-00-300, Sept. 20, 2000).

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- **Federal agencies' authorities to enforce food safety requirements differ.** USDA agencies have the authority to (1) require food firms to register so that they can be inspected, (2) prohibit the use of processing equipment that may potentially contaminate food products, and (3) temporarily detain any suspect foods. Conversely, FDA lacks such authority and is often hindered in its food oversight efforts. For example, both USDA and FDA oversee recalls when foods they regulate are found to be contaminated or adulterated.³ However, if a USDA-regulated company does not voluntarily conduct the recall, USDA can detain the product for up to 20 days while it seeks a court order to seize the food. Because FDA does not have detention authority, it cannot ensure that tainted food is kept out of commerce while it seeks a court-ordered seizure. As another example, while FDA is responsible for overseeing all seafood-processing firms operating in interstate commerce, the agency does not have an effective system to identify the firms subject to regulation because there is no registration requirement for seafood firms. As a result, some firms may not be subjected to FDA oversight, thus increasing the risk of consumers' contracting a foodborne illness from unsafe seafood.⁴
 - **USDA and FDA implementation of the new food safety approach is inconsistent.** Since December 1997, both USDA and FDA have implemented a new science-based regulatory approach—the Hazard Analysis and Critical Control Point (HACCP) system—for ensuring the safety of meat, poultry, and seafood.⁵ The HACCP system places the primary responsibility on industry, not government inspectors, for identifying and controlling hazards in the production process. However, as we discussed in previous reports,⁶ FDA and USDA implemented the HACCP system differently. While USDA reported that in 1999, 96 percent of federally regulated plants were in compliance with the basic HACCP requirements for meat and poultry, FDA reported that less than half of federally regulated seafood firms were in compliance with HACCP requirements. In addition, while USDA collects data on *Salmonella*

³ *Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls* (GAO/RCED-00-195, Aug. 17, 2000).

⁴ *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204, Jan. 31, 2001).

⁵ In January 2001, FDA finalized regulations requiring HACCP for fruit and vegetable juices.

⁶ *Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System* (GAO/RCED-00-16, Dec. 8, 1999) and *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204, Jan. 31, 2001).

contamination to assess the effectiveness of its HACCP system for meat and poultry, FDA does not have similar data for seafood. Without more effective compliance programs and adequate performance data, the benefits of HACCP will not be fully realized.

- **Oversight of imported food is inconsistent and unreliable.** As we reported in 1998, the meat and poultry acts require that, before a country can export meat and poultry to the United States, FSIS must make a determination that the exporting country's food safety system provides a level of safety equivalent to the U.S. system.⁷ 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 addition, until FSIS approves release of imported meat and poultry products into U.S. commerce, they generally must be kept in an FSIS-registered warehouse. In contrast, FDA lacks the legal authority to require that countries exporting foods to the United States have food safety systems that provide a level of safety equivalent to ours. Without such authority, FDA must rely primarily on its port-of-entry inspections to detect and bar the entry of unsafe imported foods. Such an approach has been widely discredited as resource-intensive and ineffective. In fiscal year 2000, FDA inspections covered about 1 percent of the imported food entries under its jurisdiction. In addition, FDA does not control imported foods or require that they be kept in a registered warehouse prior to FDA approval for release into U.S. commerce. As a result, some adulterated imports that were ultimately refused entry by FDA had already been released into U.S. commerce. For example, in 1998 we reported that in a U.S. Customs Service operation called "Bad Apple," about 40 percent of the imported foods FDA checked and found in violation of U.S. standards were never redelivered to Customs for disposition. These foods were not destroyed or reexported as required and presumably were released into U.S. commerce.
- **Claims of health benefits for foods may be treated inconsistently by different federal agencies.** Because three federal agencies are charged with enforcing different statutes, a product's claim of health

⁷ *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable* (GAO/RCED-98-103, Apr. 30, 1998).

benefits might be denied by one agency but allowed by another.⁸ FDA, the Federal Trade Commission, and USDA share responsibility for determining which claims regarding health benefits are allowed in labeling and advertising of foods and dietary supplements. FDA has authorized only a limited number of specific health claims for use on product labels. However, the Federal Trade Commission may allow a health claim in an advertisement as long as it meets the requirements of the Federal Trade Commission Act, even if FDA has not approved it for use on a label. Furthermore, USDA has not issued regulations to adopt any of the FDA-approved health claims for use on the products that it regulates, such as pot pies, soups, or prepared meals containing over a certain percentage of meat or poultry. Rather, USDA reviews requests to use a health claim, including those approved by FDA, on a case-by-case basis.

- **Effective enforcement of limits on certain drugs in food-producing animals is hindered by the regulatory system's fragmented organizational structure.** FDA has regulatory responsibility for enforcing animal-drug residue levels in food producing animals. However, FDA in conjunction with the states have only investigated between 43 and 50 percent of each year's USDA animal-drug residue referrals made between fiscal year 1996 and 2000. According to FDA officials, the agency lacks the resources to conduct prompt follow-up investigations and does not have an adequate referral assignment and tracking system to ensure that investigations are made in a timely manner. FDA has relied on the states, through contracts and cooperative agreements, to conduct the bulk of the investigations. FDA only has resources to investigate repeat violators. As a result, animal producers not investigated may continue to use animal drugs improperly putting consumer health at greater risk.

In the absence of a unified food safety system, federal agencies have attempted to coordinate their efforts to overcome fragmentation and avoid duplication or gaps in coverage. While we believe that interagency coordination is important and should be continued, history has shown that such efforts are difficult to conduct successfully. The following examples represent some of the coordination problems we have found.

- **Fragmented organizational structure poses challenges to U.S. efforts to address barriers to agricultural trade.** The organizational

⁸ *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods"* (GAO/RCED-00-156, July 11, 2000).

structure for food safety complicates U.S. efforts to address foreign sanitary and phytosanitary (SPS) measures. SPS measures are designed to protect humans, animals, or the territory of a country from the spread of a pest or disease, among other things. However, the U.S. Trade Representative and USDA are concerned that some foreign SPS measures may be inconsistent with international trade rules and may unfairly impede the flow of agricultural trade. In 1997, we reported that the federal structure for addressing foreign SPS measures was complex because 12 federal agencies had some responsibility for addressing problems related to SPS measures and that no one agency was directing federal efforts.⁹ We found, among other things, that the involvement of multiple agencies with conflicting viewpoints made it difficult to evaluate, prioritize, and develop unified approaches to address such measures. While, the U.S. Trade Representative and USDA took some actions to respond to our report, including establishing mechanisms to improve interagency coordination and decision-making, it remains to be seen whether such actions will effectively address the coordination problems over the long run.

- **Different statutory responsibilities may limit the ability of agencies to coordinate successfully.** As we reported in August 1998, because FDA and FSIS have different statutory responsibilities, important information about animal feed contaminated with dioxin (a suspected carcinogen) and animals that had consumed this feed was not effectively communicated to the food industry.¹⁰ FDA and FSIS worked together to decide on the preferred course of action for handling the contaminated feed and animals, and each agency was responsible for communicating its decisions to producers or processors under its jurisdiction. However, the agencies did not necessarily communicate all required actions 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 about the actions they should take for their affected animals. FSIS, the agency responsible for regulating meat and poultry processors, sent word of dioxin-testing requirements to the processors and trade associations but did not notify meat and poultry producers, over which it has no jurisdiction.

⁹*Agricultural Exports: U.S. Needs a More Integrated Approach to Address Sanitary/Phytosanitary Issues* (GAO/NSIAD-98-32, Dec. 11, 1997)

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

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- **The need for extensive coordination may impede prompt resolution of food safety problems.** Despite FSIS' and FDA's efforts to coordinate their efforts on egg safety, more than 10 years have past since the problem of bacterial contamination of intact shell eggs was first identified and a comprehensive safety strategy has yet to be implemented. In 1988, for the first time, some intact shell eggs were discovered to be contaminated internally with the pathogenic bacteria *Salmonella enteritidis*. In 1992, we reported that due to coordination difficulties resulting from the split regulatory structure for eggs, the federal government had not agreed on a unified approach to address this problem.¹¹ In July 1999, we reported that the federal government still had not agreed on a unified approach to address the problem.¹² In July 2000, FDA and FSIS issued a "current thinking" paper identifying actions that would decrease the food safety risks associated with eggs. However, as of September 2001, comprehensive proposed regulations to implement these actions had not yet been published.
 - **Continuity of coordination efforts is hampered by changes in executive branch leadership.** The President's Council on Food Safety, created in 1998, was tasked with developing a comprehensive strategic plan for federal food safety activities. In August 2000, the council agreed to initiate an interagency process to address our recommendation that FDA and the Department of Transportation,¹³ among others, enhance food safety protections by developing a strategy to regulate animal feed while in transport. While the council published its strategic food safety plan in January 2001 that included numerous "action items" and recommendations for improving the federal food safety system, the council did not address a transport strategy for animal feed. Moreover, the council has not met since publishing the strategic plan, and it remains to be seen whether the new administration will act on the council's recommendations. For example, the council's strategic plan included an action item to allocate enforcement resources based on the potential risk to public health, but the President's fiscal year 2002 budget showed little change in the allocation of food safety resources among agencies.

¹¹*Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination* (GAO/RCED-92-69, Apr. 21, 1992).

¹²*Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety* (GAO/RCED-99-184, July 1, 1999).

¹³*Food Safety: Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed* (GAO/RCED-00-255, Sept. 22, 2000).

Fundamental Changes Needed to the Federal Food Safety System

We continue to believe, as we testified in 1999,¹⁴ that a single, independent food safety agency administering a unified, risk-based food safety system is the most effective solution to the current fragmentation of the federal food safety system. While there are difficulties involved in establishing a new government agency and opinions differ about the best organizational model for food safety, there is widespread national and international recognition of the need for uniform laws and consolidation of food safety activities under a single organization. Both the National Academy of Sciences and the President's Council on Food Safety have joined us in calling for fundamental changes to the federal food safety system, including a reevaluation of the system's organizational structure. Likewise, several former senior-level government officials that were responsible for federal food safety activities have called for major organizational and legal changes. Internationally, four countries—Canada, Denmark, Great Britain, and Ireland—have each recently consolidated their food safety responsibilities under a single agency. Several other countries or government organizations may be considering this option as well, including Argentina, Chile, Hong Kong, the Netherlands, and the European Union.

In an August 1998 report, the National Academy of Sciences concluded that the current fragmented federal food safety system is not well equipped to meet emerging challenges.¹⁵ The academy found that “there are inconsistent, uneven, and at times archaic food statutes that inhibit use of science-based decision-making in activities related to food safety, and these statutes can be inconsistently interpreted and enforced among agencies.” As such, the academy concluded that to create a science-based food safety system current laws must be revised. Accordingly, it recommended that the Congress change federal statutes so that food safety inspection and enforcement are based on scientific assessments of public health risks. The academy also recommended that food safety programs be administered by a single official in charge of all federal food safety resources and activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

¹⁴*Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based, Inspection System* (GAO/T-RCED-99-256, Aug. 4, 1999).

¹⁵*Ensuring Safe Food from Production to Consumption* (Institute of Medicine, National Research Council, National Academy Press, Washington, D.C., August 1998).

According to the academy's report, many members of the committee tasked to conduct the study believed that a single agency headed by one administrator was the best way to provide the central, unified framework critical to improving the food safety system. However, assessing alternative organizational approaches was not possible in the time available or part of the committee's charge. Therefore, 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.

The committee also proposed that a detailed examination of specific organizational changes be conducted as a part of a future study. Such a study would be in keeping with the Congress' intent, as expressed in the fiscal year 1998 conference report on food safety appropriations. This conference report directed that if the academy's study recommended an independent food safety agency,¹⁶ a second study be conducted to determine the agency's responsibilities to ensure that the food safety system protects the public health.

In response to the academy's report, the President established a Council on Food Safety and charged it to develop a comprehensive strategic plan for federal food safety activities, among other things.¹⁷ The Council's Food

¹⁶*Making Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies' Programs for the Fiscal Year Ending September 30, 1998, and for Other Purposes*, Conference Report (H. Rept. 105-252, Sept. 17, 1997).

¹⁷The President's Council on Food Safety comprises, among others, the Secretaries of Agriculture, Health and Human Services, and Commerce; the Administrator of the Environmental Protection Agency; and the Assistant to the President for Science and Technology.

Safety Strategic Plan, released on January 19, 2001, recognized the need for a comprehensive food safety statute and concluded that “the current organizational structure makes it more difficult to achieve future improvements in efficiency, efficacy, and allocation of resources based on risk.”¹⁸ The council analyzed several organizational reform options. Two of the options involved enhanced coordination within the existing structure, and the other two involved consolidation of responsibilities, either within an existing organization or a stand-alone food safety agency. The council’s analysis of the options found that coordination may lead to marginal improvements but do little to address the fragmentation, duplication, and conflict inherent in the current system. The council concluded that consolidation could eliminate duplication and fragmentation, create a single voice for food safety, facilitate priority setting and resource allocation based on risk, and provide greater accountability. The council recommended the development of comprehensive, unifying food safety legislation to provide a risk-based, prevention-oriented system for all food, followed by the development of a corresponding organizational reform plan.

Former key government food safety officials at USDA and FDA have acknowledged the limitations of the current regulatory system. As shown in table 1, many former government officials recognize the need for and support the transition to a single food safety agency. Some of these officials believe the single agency could be consolidated within an existing department, and others favor an independent agency. Regardless, they all recognize the need for legislative overhaul to provide a uniform, risk-based approach to food safety.

¹⁸The Food Safety Strategic Plan is available on the Internet at <http://www.foodsafety.gov/~fsg/cstrpl-4.html>

Table 1: Former Food Safety Officials Who Support Legislative Reform and Consolidation of Food Safety Activities

Name	Former government position and agency	Period of service
Mr. Dan Glickman	Secretary of Agriculture, USDA	1995-2001
Dr. Jane Henney	Commissioner, FDA, HHS	1998-2001
Dr. Catherine Woteki	Under Secretary for Food Safety, USDA	1997-2001
Dr. David Kessler	Commissioner, FDA, HHS	1990-1997
Mr. Michael Taylor	Administrator, FSIS, USDA and Deputy Commissioner for Policy, FDA, HHS	1994-1996 1991-1994
Dr. Russell Cross	Administrator, FSIS, USDA	1992-1994
Dr. Lester Crawford	Administrator, FSIS, USDA	1987-1991
Ms. Carol Tucker-Foreman	Assistant Secretary for Food and Consumer Services, USDA	1977-1981

Source: GAO

Although in the past the U.S. food safety system has served as a model for other countries, recently Canada, Denmark, Great Britain, and Ireland have taken the lead by consolidating much of their food safety responsibilities in a single agency in each country. As we reported in 1999,¹⁹ responding to heightened public concerns about the safety of their food supplies, Great Britain and Ireland chose to consolidate responsibilities in agencies that report to or are represented by their ministers of health. The British consolidated food safety activities into an independent agency, represented before Parliament by the Minister of Health, largely because of the agriculture ministry'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 the dual responsibilities of promoting agriculture and the food industry and regulating food safety, as slow to react because it was too concerned about protecting the cattle industry.

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 controlled 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. Denmark reorganized the whole Ministry of Agriculture, and all food regulation is now in the newly created Ministry of Food, Agriculture, and Fisheries.

¹⁹*Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems* (GAO/RCED-99-80, Apr. 20, 1999).

Bioterrorism and Deliberate Acts of Food Contamination

Recent events have raised the specter of bioterrorism as an emerging risk factor for our food safety system. Bioterrorism is the threatened or intentional release of biological agents (viruses, bacteria, or their toxins) for the purpose of influencing the conduct of government or of intimidating or coercing a civilian population. These agents can be released through food as well as the air, water, or insects. To respond to potential bioterrorism, federal food safety regulatory agencies need to be prepared to efficiently coordinate their activities and respond quickly to protect the public health. Under the current structure, we believe that there are very real doubts about the system's ability to detect and quickly respond to any such event.

To date, the only known bioterrorist act in the United States involved deliberate contamination of food with a biological agent. In 1984, a religious cult intentionally contaminated salad bars in local restaurants in Oregon to prevent people from voting in a local election. Although no one died, 751 people were diagnosed with foodborne illnesses. Since then federal officials identified only one other act of deliberate food contamination with a biological agent that affected 13 individuals in 1996, but numerous threats and hoaxes have been reported. Both FDA and FSIS have plans and procedures for responding to deliberate food contamination incidents,²⁰ but the effectiveness of these procedures is largely untested for contamination involving biological agents. Therefore, we recommended in 1999 that FDA and FSIS test their plans and procedures using simulated exercises that evaluate the effectiveness of federal, state, and local agencies' and industry's responses to various types of deliberate food contamination with a biological agent.²¹

Moreover, in September 2001 we reported that coordination of federal terrorism research, preparedness, and response programs is fragmented.²² Separately, we reported that several relevant agencies have not been

²⁰A number of federal, state, and local agencies have responsibility for responding to deliberate acts or threats of food contamination. Besides FDA and FSIS, other federal agencies include CDC, the Federal Bureau of Investigation, and USDA's Office of Inspector General.

²¹*Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination* (GAO/RCED-00-3, Oct. 27, 1999).

²²*Combating Terrorism: Selected Challenges and Related Recommendations* (GAO-01-822, Sept. 20, 2001).

included in bioterrorism-related policy and response planning.²³ For example, USDA officials told us that their department was not involved, even though it would have key responsibilities if terrorists targeted the food supply.

Conclusions

To conclude, Mr. Chairman, we believe that creating a single food safety agency to administer a uniform, risk-based inspection system is the most effective way for the federal government to resolve long-standing problems; address emerging food safety issues, including acts of deliberate contamination involving biological agents; and ensure the safety of the nation's food supply. In addition, the National Academy of Sciences and the President's Council on Food Safety have reported that comprehensive, uniform, and risk-based food safety legislation is needed to provide the foundation for a consolidated food safety system. While we believe the case for a single food safety agency has been compelling for some time, recent events make this action more imperative. Numerous details, of course, remain to be worked out but it is essential that the fundamental decision to create such an agency be made and the process for resolving outstanding technical issues be started.

Matters for Congressional Consideration

To provide more efficient, consistent, and effective federal oversight of the nation's food supply, we recommend that the Congress consider

- enacting comprehensive, uniform and risk-based food safety legislation and
- commissioning the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational food safety structures and report the results of such an analysis to the Congress.

Recommendation for Executive Action

Pending Congressional action to establish a single food safety agency and enact uniform, risk-based legislation, we recommend that the Secretary of Agriculture, the Secretary of Health and Human Services, and the Assistant to the President for Science and Technology, as joint chairs of the President's Council on Food Safety, reconvene the council to facilitate interagency coordination on food safety regulation and programs.

²³ *Bioterrorism: Federal Research and Preparedness Activities* (GAO/01-915, Sept. 28, 2001).

Contact and Acknowledgments

For future contacts regarding this testimony, please contact Robert A. Robinson at (202) 512-3841. Individuals making key contributions to this testimony included Lawrence J. Dyckman, Keith W. Oleson, Stephen D. Secrist, Diana P. Cheng, Maria C. Gobin, Natalie H. Herzog, and John M. Nicholson Jr.

Appendix I: Food Safety Responsibilities and Fiscal Year 2000 Funding and Staffing Levels at 12 Federal Agencies

Dollars in millions		
Agency	Fiscal year 2000 funding ^a	Fiscal year 2000 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 conduct surveillance of all animal drugs, feeds, and veterinary devices to ensure that drugs and feeds used in animals are safe, effective, and properly labeled and produce no human health hazards when used in food-producing animals.	\$323 ^b	2,828 ^b
Centers for Disease Control and Prevention (CDC), within HHS, is charged with protecting the nation's public health by leading and directing the prevention and control of diseases and responding to public health emergencies. CDC conducts surveillance for foodborne diseases; develops new epidemiological and laboratory tools to enhance 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.	29	66
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.	649 ^c	9,545
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 to protect the animal industry against pathogens or diseases that are a risk to humans to improve food safety.	d	d
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 and starlink, 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.	d	d
Agricultural Marketing Service (AMS), within USDA, is primarily responsible for establishing quality and condition standards and for grading the quality of dairy, fruit, vegetable, livestock, meat, poultry, and egg products. As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. AMS also runs a voluntary pesticide data program and carries out a wide array of programs to facilitate marketing. It carries out these programs under more than 50 statutes, including 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; the Export Grape and Plum Act, as amended; the Federal Seed Act; and the Food Quality Protection Act. AMS is largely funded with user fees.	13 ^e	26 ^e

Dollars in millions		
Agency	Fiscal year 2000 funding ^a	Fiscal year 2000 staffing
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.	82	222
National Marine Fisheries Service (NMFS), within the Department of Commerce, conducts 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. NMFS provides inspection and certification services for fishery products for human consumption, as well as for animal feeds and pet foods containing a fish base.	^f	165 ^f
Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or distributed in the United States and setting maximum allowed residue levels for pesticides on food commodities and animal feed. EPA conducts these activities under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Federal Food, Drug, and Cosmetic Act, as amended.	171	1,076
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 misrepresentation of food.	^g	^g
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.	^g	^g
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.	^g	^g
Total	\$1,267	13,928

^aFiscal year 2000 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 National Center for Toxicological Research, and the field components for these centers.

^cFSIS' total funding for fiscal year 2000 was \$751 million, which includes appropriated funds, reimbursements, and trust funds.

^dThe agency did not specify its food safety resources.

^eAMS' funding and staffing are for Food Quality Protection Act information gathering only.

^fNMFS' activities were funded through \$12.4 million in user fees, not appropriated funds. Funding and staffing levels are for both safety and quality inspection activities.

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

Source: Federal agencies' data.

Appendix II: Differences in Inspection Frequency of Manufacturers of Similar Products

Manufacturing plant inspected daily by FSIS	Manufacturing plant inspected on average about once every 5 years by FDA
Open-face meat and poultry sandwiches	Closed-face (traditional) meat and poultry sandwiches
Hot dog in pastry dough	Hot dog in a roll
Corn dog	Bagel dog
Dehydrated chicken soup	Dehydrated beef soup
Beef broth	Chicken broth
Spaghetti sauce with meat stock	Spaghetti sauce without meat stock
Beans with bacon (2 percent or more bacon)	Pork and beans (no limit on amount of pork)
Pizza with meat topping	Pizza without meat topping
Soups with more than 2 percent meat or poultry	Soups with less than 2 percent meat or poultry

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

Related GAO Products

Food Safety: CDC Is Working to Address Limitations in Several of Its Foodborne Disease Surveillance Systems ([GAO-01-973](#), Sept. 7, 2001).

Food Safety: Overview of Federal and State Expenditures ([GAO-01-177](#), Feb. 20, 2001).

Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers ([GAO-01-204](#), Jan. 31, 2001).

Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls ([GAO/RCED-00-195](#), Aug. 17, 2000).

Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and “Functional Foods” ([GAO/RCED-00-156](#), July 11, 2000).

Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System ([GAO/RCED-00-16](#), Dec. 8, 1999).

Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination ([GAO/RCED-00-3](#), Oct. 27, 1999).

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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).

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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).

Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination ([GAO/RCED-92-69](#), Apr. 21, 1992).