

GAO

Testimony

Before the Subcommittee on Civil Service
and Agency Organization, Committee on
Government Reform, House of
Representatives

For Release on Delivery
Expected at 3:00 p.m. EST
Tuesday, March 30, 2004

FEDERAL FOOD SAFETY AND SECURITY SYSTEM

Fundamental Restructuring Is Needed to Address Fragmentation and Overlap

Statement of Lawrence J. Dyckman, Director
Natural Resources and Environment





Highlights of [GAO-04-588T](#), testimony before the House Subcommittee on Civil Service and Agency Organization, Committee on Government Reform

Why GAO Did This Study

The safety of the U.S. food supply is governed by a highly complex system of more than 30 laws administered by 12 agencies. In light of the recent focus on government reorganization, it is time to ask whether the current system can effectively and efficiently respond to today's challenges.

At the request of the Subcommittee on Civil Service and Agency Organization, we reviewed and summarized our work on the safety and security of the food supply regarding (1) the fragmented legal and organizational structure of the federal food safety system, (2) the consequences of overlapping and inconsistent inspection and enforcement, and (3) options for consolidating food safety functions.

What GAO Recommends

GAO suggests that the Congress consider (1) enacting comprehensive, uniform, and risk-based food safety legislation and (2) establishing a single, independent food safety agency. Alternatively, GAO suggests that the Congress consider modifying existing laws to designate one current agency as the lead agency responsible for all food safety inspection matters.

This testimony is based on dozens of GAO products issued since 1992 and ongoing reviews related to food safety and security efforts. A list of GAO reports and testimonies is contained in appendix III.

www.gao.gov/cgi-bin/getrpt?GAO-04-588T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lawrence J. Dyckman at (202) 512-3841 or dyckmanl@gao.gov.

FEDERAL FOOD SAFETY AND SECURITY SYSTEM

Fundamental Restructuring Is Needed to Address Fragmentation and Overlap

What GAO Found

As we have stated in numerous reports and testimonies, the federal food safety system is not the product of strategic design. Rather, it emerged piecemeal, over many decades, typically in response to particular health threats or economic crises. The result is a fragmented legal and organizational structure that gives responsibility for specific food commodities to different agencies and provides them with significantly different authorities and responsibilities.

The existing food safety statutes create fragmented jurisdictions between the two principal food safety agencies, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). As a result, there are inconsistencies in the frequency of the agencies' inspections of food facilities and the enforcement authorities available to these agencies. In short, which agency has jurisdiction to regulate various food products, the regulatory authorities they have available to them, and how frequently they inspect food facilities is determined by disparate statutes or by administrative agreement between the two agencies, without strategic design as to how to best protect public health. In many instances, food processing facilities are inspected by both FDA and USDA. Furthermore, federal food safety efforts are based on statutory requirements, not risk. For example, funding for USDA and FDA is not proportionate to the amount of food products each agency regulates, to the level of public consumption of those foods, or to the frequency of foodborne illnesses associated with food products.

A federal food safety system with diffused and overlapping lines of authority and responsibility cannot effectively and efficiently accomplish its mission and meet new food safety challenges. These challenges are more pressing today as we face emerging threats such as mad cow disease and the potential for deliberate contamination of our food supply through bioterrorism.

Therefore, fundamental changes are needed. First, there is a need to overhaul existing food safety legislation to make it uniform, consistent, and risk based. Second, consolidation of food safety agencies under a single independent agency or a single department is needed to improve the effectiveness and efficiency of the current federal food safety system. Integrating the overlapping responsibilities for food safety into a single agency or department can create synergy and economies of scale, as well as provide more focused and efficient efforts to protect the nation's food supply.

Madam Chairwoman and Members of the Subcommittee:

I am pleased to be here today before the Committee on Government Reform's Subcommittee on Civil Service and Agency Organization to discuss the Subcommittee's interest in streamlining the federal government. Today, I will discuss our work on the federal food safety system and whether its current design provides sufficient protection for consumers while ensuring logical and effective use of scarce government resources. In recent testimony before this Subcommittee, the Chairman of the National Commission on the Public Service, Mr. Paul Volcker, recommended that government programs that are designed to achieve similar outcomes be combined into one agency and that agencies with similar or related missions be combined into large departments that encourage cooperation, achieve economies of scale in management, and facilitate responsiveness to political leadership. He noted that important health and safety protections fail when responsibility for regulation is dispersed among several departments, as is the case with our federal food safety system.

At GAO we concur with this view. In his September 2003 testimony, the Comptroller General stressed the importance of beginning to take steps to achieve fundamental reorganization of the federal government into a limited number of mission-related executive departments. His testimony pointed out that redundant, unfocused, and uncoordinated programs waste scarce resources, confuse and frustrate program customers, and limit overall program effectiveness. Based on GAO's substantive body of work on the federal food safety system and as we have testified in the past, we believe that overhauling existing food safety statutes, consolidating food safety agencies under a single independent agency or a single department, and streamlining inspection and enforcement efforts would improve the effectiveness and efficiency of the current federal food safety system.

While the food supply is generally safe, each year tens of millions of Americans become ill and thousands die from eating unsafe food. The federal government spends about \$1.3 billion annually¹ to ensure the safety of domestic and imported foods, and estimates that the costs associated with foodborne illnesses are about \$7 billion, including medical costs and

¹Based on 2003 food safety expenditures of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

productivity losses from missed work. As we have stated in previous reports and testimonies, the nation's food safety system is a patchwork structure that hampers efforts to address the risks of inadvertent or deliberate food contamination. Fundamental changes are needed to correct deficiencies in the system, reduce overlap and duplication, and ensure a safer food supply. In summary, a system with diffused and overlapping lines of authority and responsibility cannot effectively and efficiently accomplish its mission and meet new food safety challenges. These challenges are more pressing today as we face emerging threats associated with diseases like bovine spongiform encephalopathy (BSE), better known as mad cow disease, and the potential for the deliberate contamination of our food supply through bioterrorism.

My testimony today provides an overview of the government's fragmented food safety system, the consequences of overlapping and inconsistent inspection and enforcement, and options for consolidating food safety functions. I will also provide a brief overview of the agencies' roles in addressing the emerging threat of a bioterrorism act against the nation's food supply and for protecting the U.S. from mad cow disease. This testimony draws upon our wide-ranging, ongoing, and completed work on food safety and upon completed work and previous testimonies on issues related to government organization and transformation. We used updated data on agency expenditures and numbers of employees and establishments that we obtained from the agencies. We used consumer expenditures data from the Bureau of Labor Statistics (BLS) and analyzed foodborne illness outbreaks data from the Centers for Disease Control and Prevention (CDC). To assess the reliability of these data, we reviewed existing documentation about the data and the systems that produced them and interviewed agency officials knowledgeable about the data; we determined that the data were sufficiently reliable for the purposes of this testimony. We conducted our work in accordance with generally accepted government auditing standards.

Background

The safety and quality of the U.S. food supply is governed by a highly complex system that is based on more than 30 laws and administered by 12 agencies. In addition, there are over 50 interagency agreements to govern the combined food safety oversight responsibilities of the various agencies. The federal system is supplemented by the states, which have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products. The United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), have most of the

regulatory responsibilities for ensuring the safety of the nation's food supply and account for most federal food safety spending. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, USDA is responsible for the safety of meat, poultry, and certain egg products. FDA, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, regulates all other foods, including whole (or shell) eggs, seafood, milk, grain products, and fruits and vegetables.² Appendix I summarizes the agencies' responsibilities.

Existing statutes give the agencies different regulatory and enforcement authorities. For example, food products under FDA's jurisdiction may be marketed without the agency's prior approval. On the other hand, food products under USDA's jurisdiction must generally be inspected and approved as meeting federal standards before being sold to the public. Although recent legislative changes have strengthened FDA's enforcement authorities, the division of inspection authorities and other food safety responsibilities has not changed.

As we have reported, USDA traditionally had more comprehensive enforcement authority than FDA; however, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 has granted FDA additional enforcement authorities that are similar to USDA's. For example, FDA can now require all food processors to register with the agency so that they can be inspected. FDA can also temporarily detain food products when there is credible evidence that the products present a threat of serious adverse health consequences, and FDA can require that entities such as the manufacturers, processors, and receivers of imported foods keep records to allow FDA to identify the immediate previous source and the immediate subsequent recipients of food, including its packaging. This record keeping authority is designed to help FDA track foods in the event of future health emergencies, such as terrorism-related contamination. In addition, FDA now has the authority to require advance notice of imported food shipments under its jurisdiction. Despite the additional enforcement authorities recently granted to FDA, important differences between the agencies' inspection and enforcement authorities remain.

²Under the Egg Products Inspection Act, the Secretary of Health and Human Services regulates whole eggs, while the Secretary of Agriculture regulates egg products.

Finally, in addition to their established food safety and quality responsibilities, following the events of September 11, 2001, the federal agencies began to address the potential for deliberate contamination of agriculture and food products. In 2001, by Executive Order, the President added the food industries to the list of critical infrastructure sectors that need protection from possible terrorist attack. As a result of this Executive Order, the Homeland Security Act of 2002 establishing the Department of Homeland Security, and subsequent Presidential Directives, the Department of Homeland Security provides overall direction on how to protect the U.S. food supply from deliberate contamination. The Public Health Security and Bioterrorism Preparedness and Response Act also included numerous provisions to strengthen and enhance food safety and security.

Fragmented System Hampers the Efficiency and Effectiveness of Food Safety Efforts

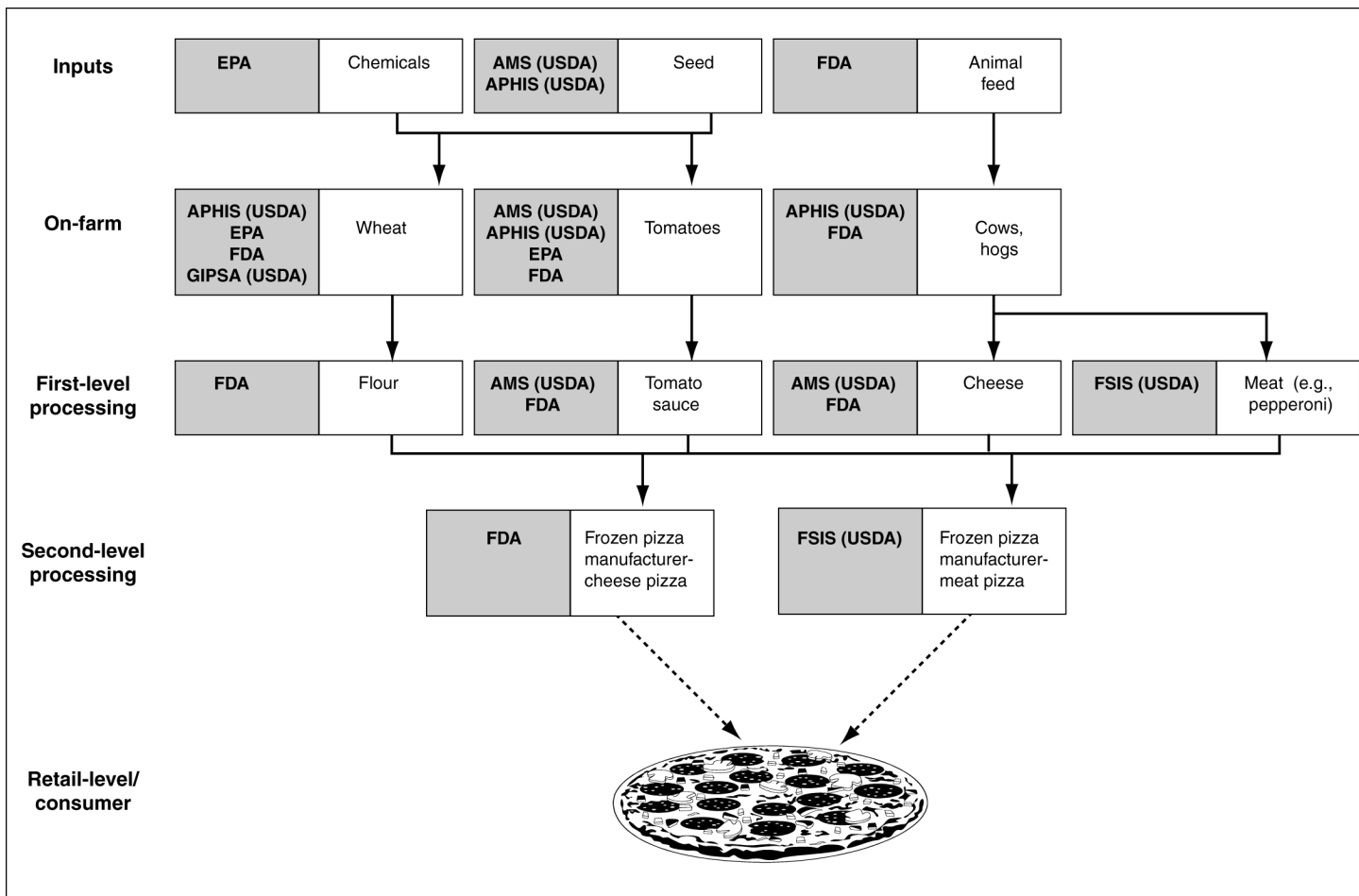
As we have stated in numerous reports and testimonies, the fragmented federal food safety system is not the product of strategic design.³ Rather, it emerged piecemeal, over many decades, typically in response to particular health threats or economic crises. In short, what authorities agencies have to enforce food safety regulations, which agency has jurisdiction to regulate what food products, and how frequently they inspect food facilities is determined by the legislation that governs each agency, or by administrative agreement between the two agencies, without strategic design as to how to best protect public health. It is important to understand that the origin of this problem is historical and, for the most part, grounded in the federal laws governing food safety. We and other organizations, including the National Academies, have issued many 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, problems in the food safety system persist, largely because food safety responsibilities are still divided among agencies that continue to operate under different laws and regulations. As a result there is fragmentation, inconsistency, and overlap in the federal food safety system. These problems are manifested in numerous ways as discussed below.

- **Federal agencies have overlapping oversight responsibilities.** Agency jurisdictions either assigned by law over time or determined by agency agreements result in overlapping oversight of single food products.

³Appendix III lists relevant GAO reports and testimonies.

For example, which agency is responsible for ensuring the safety of frozen pizzas depends on whether or not pepperoni is used as a topping. Figure 1 shows the agencies involved in regulating the safety of frozen pizza.

Figure 1: Federal Agencies Responsible for Ensuring Safe Pizza



Sources: GAO (analysis); CorelDraw (clip art).

In other instances, such as canned soups, it is the amount of a particular ingredient contained in the food product that governs whether it is subject to FDA or USDA inspection. As a result, canned soup producers are also subject to overlapping jurisdiction by the two food safety agencies.

- **Overlap and duplication result in inefficient use of inspection resources.** Food processing establishments may be inspected by more than one federal agency because they process foods that are regulated

under different federal laws or because they participate in voluntary inspection programs. As of February 2004, FDA's records show that there are about 2,000 food processing facilities in the United States that may handle foods regulated by both FDA and USDA because their products include a variety of ingredients. Multi-ingredient products that are regulated by both FDA and USDA include pizza, canned soups, and sandwiches. GAO found that 514 of the 8,653 FDA inspections conducted in six states between October 1987 and March 1991, duplicated those of other federal agencies. For example, FSIS had five inspectors assigned full time to a plant that processed soups containing meat or poultry, yet FDA inspected the same plant because it also processed soups that did not contain meat or poultry. Thus, rather than having the full-time inspectors assigned to the plant conduct inspections for all the plant's products, additional inspectors from another agency were required to conduct separate inspections of products as a result of the different ingredients contained in the product.

Moreover, there is also inefficient use of federal inspection resources dedicated to overseeing the safety of seafood products. FDA has responsibility for ensuring the safety of domestic and imported seafood products. However, as we reported in January 2004, the NOAA Seafood Inspection Program also provides fee-for-service safety, sanitation, and/or product inspections for approximately 2,500 foreign and domestic firms annually. Thus, both FDA and NOAA's programs duplicate inspections of seafood firms. To make more efficient use of federal inspection resources, we have recommended that FDA work toward developing a memorandum of understanding that leverages NOAA's Seafood Inspection Program resources to augment FDA's inspection capabilities.

- **Federal agencies' different authorities result in inconsistent inspection and enforcement.** Despite the additional enforcement authorities granted to FDA by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, differences between the agencies' inspection and enforcement authorities remain. For example, when FSIS inspectors observe serious noncompliance with USDA's food safety regulations, they have the authority to immediately withdraw their inspection services. This effectively stops plant operations because a USDA inspector must be present and food products under USDA's jurisdiction generally must be inspected and approved as meeting federal standards before being sold to the public. This ensures more timely correction of problems that could affect the safety of meat and poultry products. In contrast, food products under FDA's jurisdiction may be marketed without the agency's prior approval. Thus, while FDA may temporarily detain food products when there is credible evidence that the

products present a threat of serious adverse health consequences, FDA currently has no authority comparable with USDA's allowing it to stop plant operations. As a result, problems identified during FDA inspections may take longer to correct.

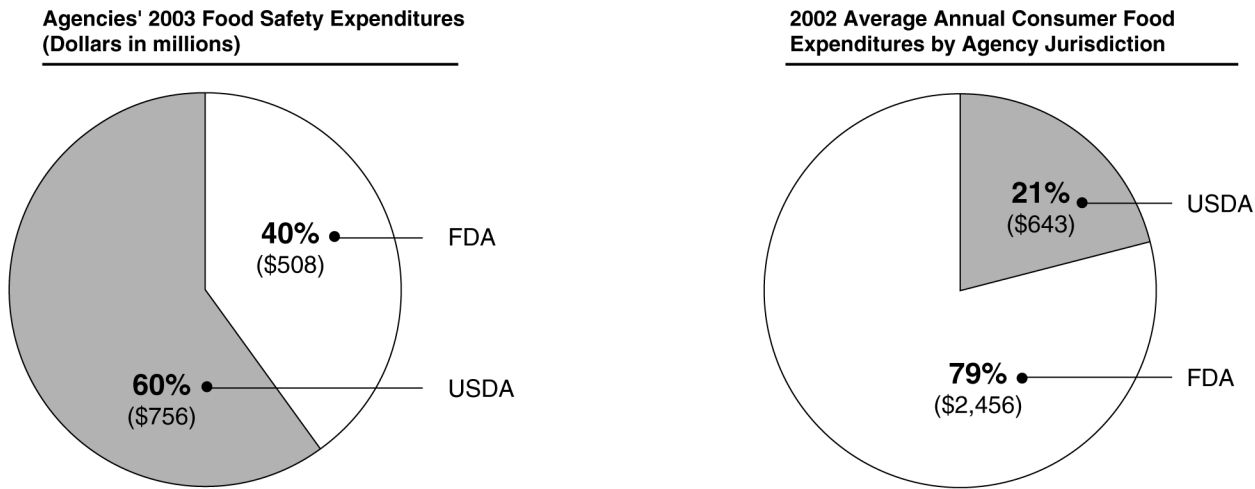
- **Federal agencies' different authorities to oversee imported foods also result in inconsistent efforts to ensure safety.** A significant amount of the food we consume is imported; yet, as we have testified in the past, the same fragmented structure and inconsistent regulatory approach is being used to ensure the safety of imported foods. For example, more than three-quarters of the seafood Americans consume is imported from an estimated 13,000 foreign suppliers in about 160 different countries.⁴ As we have reported, however, FDA's system for ensuring the safety of imported seafood does not sufficiently protect consumers. For example, the agency inspected about 100 of roughly 13,000 foreign firms in 2002 and tested slightly over 1 percent of imported seafood products. In January 2004, we reported that despite some improvements, FDA is still able to inspect only a small proportion of U.S. seafood importers and visit few seafood firms overseas yearly. As we have previously recommended, a better alternative would be to strengthen FDA's ability to ensure the safety of imported foods by requiring that all food eligible for importation to the United States be produced under equivalent food safety systems. USDA has such authority. In fact, USDA is legally required to review certifications made by other countries that their meat and poultry food safety systems ensure compliance with U.S. standards and USDA must also conduct on-site inspections before those products can be exported to the United States. At this time, 37 countries are approved to export meat and poultry products to the United States.
- **Frequency of inspections is not based on risk.** Under current law, USDA inspectors maintain continuous inspection at slaughter facilities and examine each slaughtered meat and poultry carcass. They also visit each processing plant at least once during each operating day. For foods under FDA jurisdiction, however, federal law does not mandate the frequency of inspections. The differences in inspection frequencies are, at times, quite arbitrary, as in the case of jointly regulated food products. For example, as we testified in 2001, federal responsibilities for regulating the production and processing of a packaged ham and cheese sandwich

⁴The CDC's foodborne outbreak data shows that contaminated seafood accounts for about 15 percent of the documented foodborne illness outbreaks—a greater percentage than either meat or poultry, even though meat and poultry are consumed at 8 and 6 times the rate of seafood, respectively.

depends on whether the sandwich is made with one or two slices of bread, not on the risk associated with its ingredients. As a result, facilities that produce closed-faced sandwiches are inspected on average once every 5 years by FDA, whereas facilities that produce open-faced sandwiches are inspected daily by FSIS.

- **Federal expenditures are not based on the volume of foods regulated, consumed, or their risk of foodborne illness.** FDA and FSIS food safety efforts are based on the respective legislation governing their operation. As a result, expenditures for food safety activities are disproportionate to the amount of food products each agency regulates and to the level of public consumption of those food products. FDA is responsible for ensuring the safety of approximately 79 percent of the foods Americans consume annually, while its budget represented only 40 percent (\$508 million) of the approximately \$1.3 billion spent on food safety oversight during fiscal year 2003. In contrast, FSIS inspects approximately 21 percent of the foods Americans consume annually, while its food safety budget represented 60 percent (\$756 million) of the federal expenditures for food safety in 2003. Figure 2 shows the imbalance between the dollar amounts that the agencies spend on food safety activities and the volume of foods Americans consume annually.

Figure 2: Comparison of Agencies' Food Safety Expenditures Versus Consumers' Annual Food Expenditures⁵

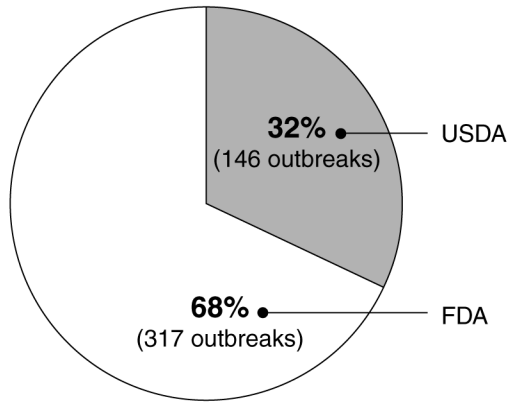


Sources: (left to right): GAO analysis of USDA and FDA data; GAO analysis of Bureau of Labor Statistics data.

Perhaps more importantly, the agencies' food safety expenditures are disproportionate to the percentage of foodborne illnesses linked to the food products they regulate. For example, according to foodborne illness data compiled by the CDC, USDA-regulated foods account for about 32 percent of reported foodborne outbreaks with known sources. Conversely, FDA-regulated foods account for about 68 percent of these outbreaks. (See fig. 3.) Yet, USDA's food safety expenditures are about 49 percent more than FDA's.

⁵FDA's percentage of the total food safety budget has increased since our 2001 testimony due to supplemental food security funding.

Figure 3: Percentage of Foodborne Outbreaks Associated with Products Regulated by FDA and USDA from 1993-1997

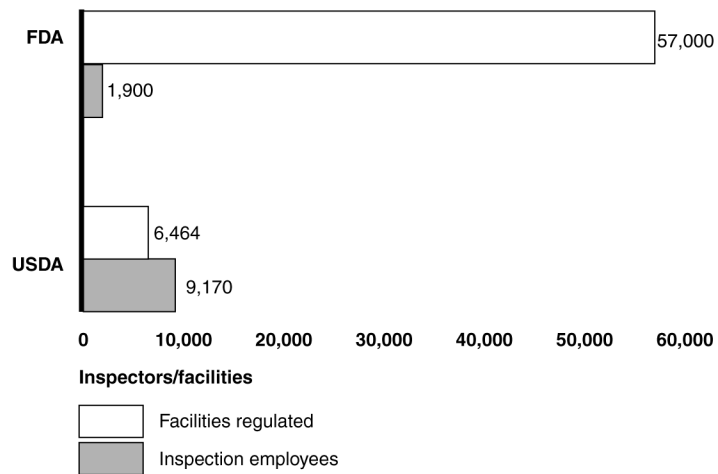


Source: GAO analysis of CDC data.

Note: Only major food categories under each agency's jurisdiction are included.

Finally, as figure 4 shows, FSIS has 9,170 employees that are, by law, responsible for daily oversight of approximately 6,464 meat, poultry, and egg product plants. FDA has roughly 1,900 food inspection employees who, among other things, inspect about 57,000 food establishments.

Figure 4: FDA and USDA Fiscal Year 2003 Inspection Resources Versus Facilities Regulated by Each Agency

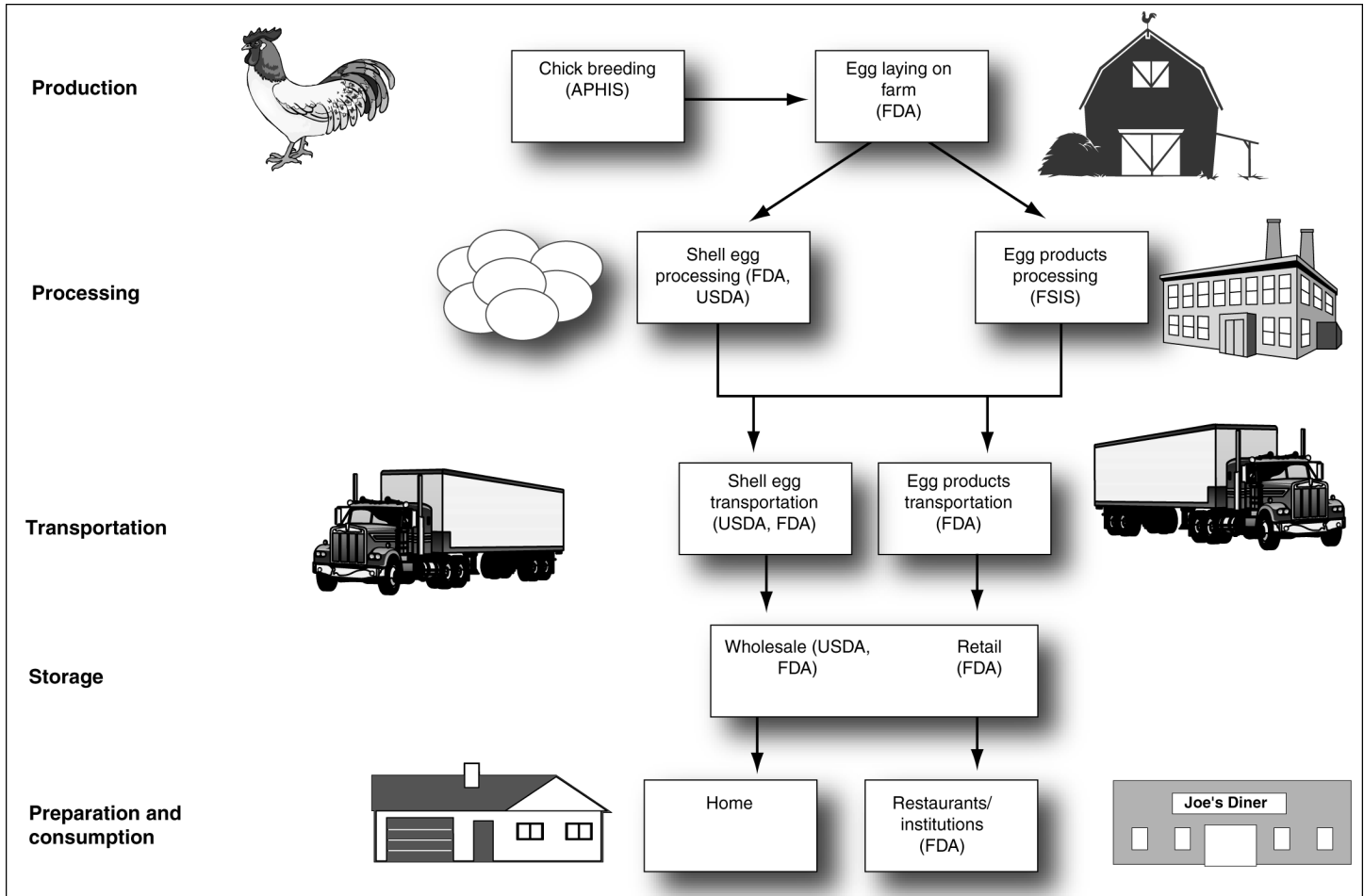


Source: GAO analysis of FDA and USDA data.

- Overlaps in egg safety responsibility compromise safety.**

Overlapping responsibilities have resulted in extensive delays in the development of a comprehensive regulatory strategy to ensure egg safety. As we have reported, no single federal agency has overall responsibility for the policies and activities needed to ensure the safety and quality of eggs and egg products. Figure 5 shows the overlapping responsibilities of multiple agencies involved in overseeing the production, processing, and transportation of eggs and egg products.

Figure 5: Federal Oversight of Egg Production, Processing and Transportation



Sources: GAO (analysis); CorelDraw (clip art).

As shown in figure 5, FDA has the primary responsibility for the safe production and processing of eggs still in the shell (known by industry as shell eggs), whereas FSIS has the responsibility for food safety at the

processing plants where eggs are broken to create egg products. Despite FSIS and FDA attempts to coordinate their efforts on egg safety, more than 10 years have passed since the problem of bacterial contamination of intact shell eggs was first identified, and a comprehensive safety strategy has yet to be implemented. Agency representatives serving on the President's Council on Food Safety developed an Egg Safety Action Plan in 2000 and identified egg safety as one component of food safety that warranted immediate federal, interagency action. As of March 2004, comprehensive regulations to implement the actions the agencies identified in the Action Plan have not been published.⁶

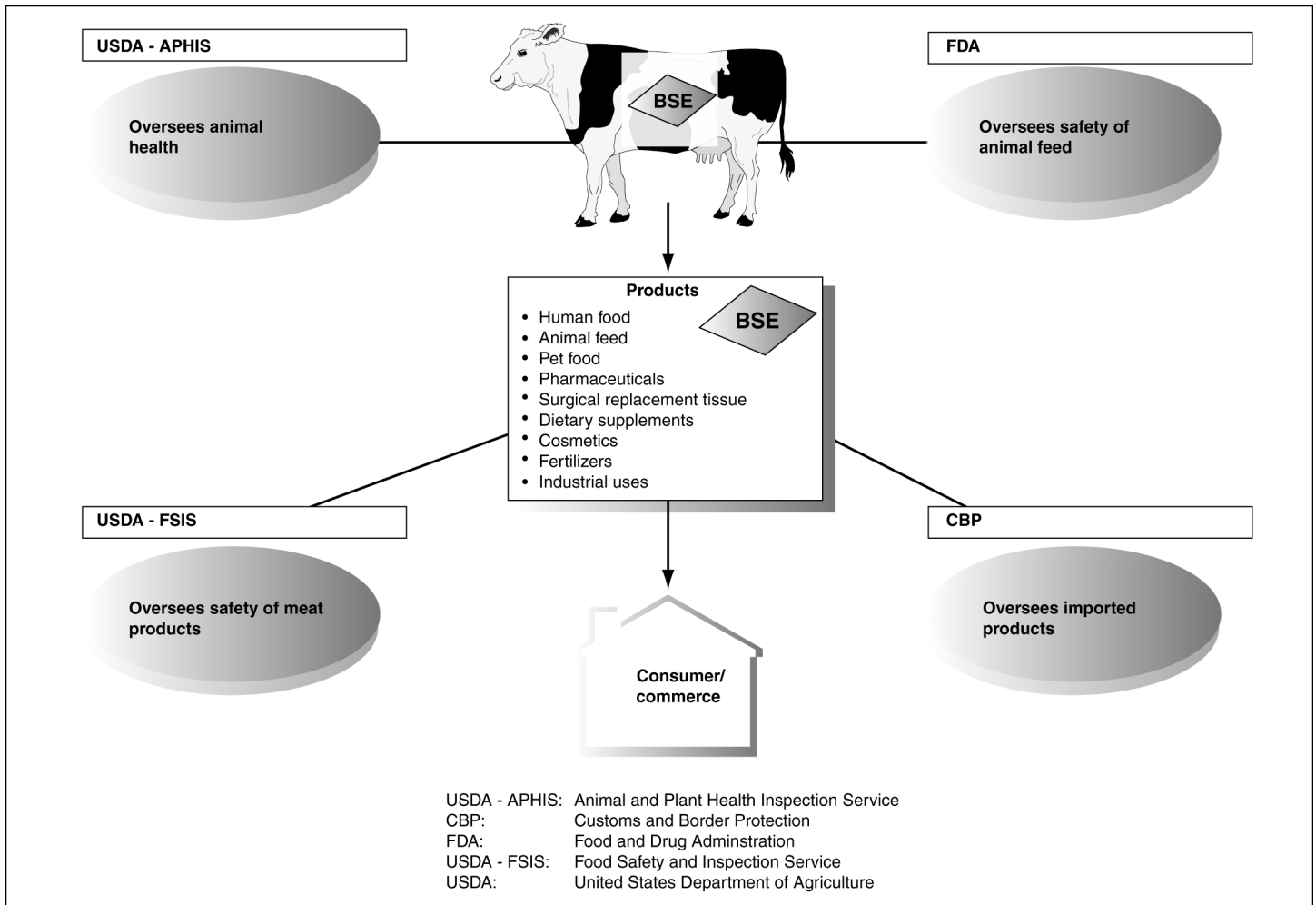
- **Claims of health benefits for foods may be treated inconsistently by different federal agencies.** Overlaps also exist in the area of health benefit claims associated with certain foods and dietary supplements. FDA, USDA, and the Federal Trade Commission (FTC) share responsibility for determining what types of health benefit claims are allowed on product labels and in advertisements. The varying statutory requirements among the agencies can lead to inconsistencies in labeling and advertisements. As a result, the use of certain health benefit claims on a product might be denied by one agency but allowed by another. For example, the FTC 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. Similarly, USDA reviews requests to use health claims on a case-by-case basis, regardless of whether or not FDA has approved them. Thus, consumers face a confusing array of claims, which may lead them to make inappropriate dietary choices.
- **Multiple agencies must respond when serious food safety challenges emerge.** Inconsistent food safety authorities result in the need for multiple agencies to respond to emerging food safety challenges. This was illustrated recently with regard to ensuring that animal feed is free of diseases, such as bovine spongiform encephalopathy (BSE), or mad cow disease. A fatal human variant of the disease is linked to eating beef from cattle infected with BSE. As we reported in 2002, four federal agencies are responsible for overseeing the many imported and domestic products that

⁶USDA officials report that rulemaking for shell eggs will be separate from rulemaking for egg products because shell egg packing facilities lack the capacity to respond to a Hazard Analysis and Critical Control Point (HACCP) rule at present. USDA officials explain that they will likely propose HACCP and sanitation performance standard regulations for egg product plants, while shell egg facilities will likely receive guidance and training materials related to HACCP and sanitation standards.

pose a risk of BSE. One, the U.S. Customs and Border Protection, screens all goods entering the United States to enforce its laws and the laws of 40 other agencies. The second, USDA's Animal and Plant Health Inspection Service (APHIS), protects livestock from animal diseases by monitoring the health of domestic and imported livestock.⁷ The third, USDA's FSIS, monitors the safety of imported and domestically produced meat and, at slaughterhouses, tests animals prior to slaughter to determine if they are free of disease and safe for human consumption. Finally, FDA monitors the safety of animal feed—animals contract BSE through feed that contains protein derived from the remains of diseased animals. During the recent discovery of an infected cow in Washington state, FDA investigated facilities that might have handled byproducts from the infected animal to make animal feed. Figure 6 illustrates the fragmentation in the agencies' authorities.

⁷On March 1, 2003, APHIS's Agriculture Quarantine and Inspection force became part of the Department of Homeland Security.

Figure 6: Federal Government Agencies Involved in Bovine Spongiform Encephalopathy (BSE) Oversight



Sources: GAO (analysis); CorelDraw (clip art).

When we issued our report in 2002, BSE had not been found in U.S. cattle. However, we found a number of weaknesses in import controls. Because of those weaknesses and the disease’s long incubation period—up to 8 years—we concluded that BSE might be silently incubating somewhere in the United States. Then, in May 2003, an infected cow was found in Canada, and in December 2003, another was found in the state of Washington. USDA’s Animal and Plant Health Inspection Service operates the surveillance program that found the infected U.S. cow, while FDA must ensure that the disease cannot spread by enforcing an animal feed ban that prohibits the use of cattle brains and spinal tissue, among other things, in cattle feed. With regard to the meat from the BSE-infected

animal found in Washington state, FSIS conducted a recall of meat distributed in markets in six states. Both USDA and FDA have reported that meat from the cow was not used in FDA-regulated foods. However, had the meat been used, for example, in canned soups that contained less than 2 percent meat, FDA—not FSIS—would have been responsible for working with companies to recall those foods. (As app. II shows, the agencies' oversight responsibilities for food products vary depending on the amount of beef or poultry content.) Neither FDA nor USDA has authority under existing food safety laws to require a company to recall food products.⁸ Both agencies work informally with companies to encourage them to initiate a recall, but our ongoing work shows that each agency has different approaches and procedures. This can be confusing to food processors involved in a recall. Overlapping responsibilities in responding to mad cow disease highlight the challenges that government and industry face when responding to the need to remove contaminated food products from the market. As part of work currently underway, we are looking at USDA and FDA food recalls—including USDA's oversight of the BSE-related recall and FDA's oversight of the feed ban. We are also monitoring both USDA's and FDA's BSE-response activities.

There are undoubtedly other federal food safety activities where overlap and duplication may occur. For example, in the areas of food safety research, public outreach, or both FDA, and USDA's Economic Research Service, FSIS and the Cooperative State Research, Education and Extension Service have all received funding to develop food safety-related educational materials for the public. In addition, responsibility for regulating genetically modified foods is shared among FDA, USDA, and the Environmental Protection Agency (EPA). However, we have not yet examined the extent to which these and other areas of overlap and duplication impact the efficiency of the food safety system.

⁸FDA, however, does have legislative authority to require recalls that involve infant formula.

Emerging Terrorist Threats Highlight the Need to Reorganize the Federal Food Safety System

The fragmented legal and organizational structures of the federal food safety system are now further challenged by the realization that American farms and food are vulnerable to potential attack and deliberate contamination. As we recently reported in a statement for the record before the Senate Committee on Governmental Affairs,⁹ bioterrorist attacks could be directed at many different targets in the farm-to-table continuum, including crops, livestock, food products in the processing and distribution chain, wholesale and retail facilities, storage facilities, transportation, and food and agriculture research laboratories. Experts believe that terrorists would attack livestock and crops if their primary intent were to cause severe economic dislocation. Terrorists could decide to contaminate finished food products if their motive were to harm humans. Both FDA and USDA have taken steps to protect the food supply against a terrorist attack, but it is, for the most part, the current food safety system that the nation must depend on to prevent and respond to bioterrorist acts against our food supply.

For example, in February 2003, we reported that FDA and USDA determined that their existing statutes empower them to enforce food safety, but do not provide them with clear authority to regulate all aspects of security at food-processing facilities. Neither agency feels that it has authority to require processors to adopt physical facility security measures such as installing fences, alarms, or outside lighting. Each agency, independently of one another, developed and published guidelines that food processors may voluntarily adopt to help them identify security measures and mitigate the risk of deliberate contamination at their production facilities. However, while food inspectors were instructed to be vigilant, they have not been asked to enforce, monitor, or document their actions regarding the extent to which security measures are being adopted. As a result, neither FDA nor USDA can fully assess the extent to which food processors are following the security guidelines that the agencies developed. Officials note, however, that they have taken many steps to address deliberate food contamination. Both agencies have distributed food security information to food processors under their jurisdictions and are cochairing the Food Emergency Response Network, which integrates the nation's laboratory infrastructure for the detection of threat agents in food at the local, state, and federal levels. Among other things, USDA established the Office of Food Security and Emergency

⁹*Bioterrorism: A Threat to Agriculture and the Food Supply*, [GAO-04-259T](#) (Nov. 19, 2003).

Preparedness, enhanced security at food safety laboratories, and trained employees in preparedness activities. Similarly, FDA revised emergency response plans and conducted training for all staff, as well as participated in various emergency response exercises at FDA's Center for Food Safety and Applied Nutrition.

Another GAO report documented vulnerabilities in federal efforts to prevent dangerous animal diseases from entering the United States. Our 2002 report on foot-and-mouth disease concluded that because of the sheer magnitude of international passengers and cargo that enters this country daily, completely preventing the entry of foot-and-mouth disease may not be feasible. During the 2001 outbreak of foot-and-mouth disease in Europe, poor communication between USDA and Customs officials caused delays in carrying out inspections of international passengers and cargo arriving from disease-affected countries.

Fundamental Changes Needed to Improve Effectiveness and Efficiency of the Federal Food Safety System

To address the problems I have just outlined, a fundamental transformation of the current food safety system is necessary. As the Comptroller General has testified, there are no easy answers to the challenges federal departments and agencies face in transforming themselves. Changes, such as revamping the U.S. food safety system, will require a process that involves key congressional stakeholders and administration officials as well as others, ranging from food processors to consumers. There are different opinions about the best organizational model for food safety, but there is widespread national and international recognition of the need for uniform laws and the consolidation of food safety activities.

Establishing a single food safety agency responsible for administering a uniform set of laws would offer the most logical approach to resolving long-standing problems with the current system, addressing emerging threats to food safety, and ensuring a safer food supply. This would ensure that food safety issues are addressed comprehensively by better preventing contamination throughout the entire food cycle—from the production and transportation of foods through their processing and sale until their eventual consumption by consumers. In our view, integrating the overlapping and duplicative responsibilities for food safety into a single agency or department can create synergy and economies of scale that would provide for more focused and efficient efforts to protect the

nation's food supply. A second option would be to consolidate all food safety inspection activities, but not other activities,¹⁰ under an existing department, such as USDA or HHS. Other measures have not proven successful. For example, the Farm Security and Rural Investment Act of 2002 mandated the creation of a 15-member Food Safety Commission charged with making specific recommendations to improve the U.S. food safety system and delivering a report to the President and the Congress within a year. The Congress has thus far not provided funding for the commission.

Simply choosing an organizational structure will not be sufficient, however. For the nation's food safety system to be successful, it will also be necessary to reform the current patchwork of food safety legislation and make it uniform, consistent, and risk-based. As table 1 shows, five of eight former senior food safety officials with whom we discussed the matter in preparation for this testimony concur with this view.

Table 1: Former Food Safety Officials Who Support Changes to the Current System

Name	Former government position and agency	Period of Service	Consolidation of food safety activities	Creation of independent food safety agency	Legislative reform
Dan Glickman	Secretary of Agriculture, USDA	1995-2001	X		X
Jane Henney	Commissioner, FDA, HHS	1998-2001	X		X
Catherine Woteki	Under Secretary for Food Safety, USDA	1997-2001	X	X	X
Michael Taylor	Administrator, FSIS, USDA and Deputy Commissioner for Policy, FDA, HHS	1994-1996 1991-1994	X		X
Carol Tucker-Foreman	Assistant Secretary for Food and Consumer Services, USDA	1977-1981	X	X	X

Three officials had different views on the best approach to address problems with the current food safety system. Joseph Levitt, director of the FDA's Center for Food Safety and Applied Nutrition from 1998 to 2003,

¹⁰These include, for example, CDC's foodborne illness surveillance functions and EPA's chemical residue tolerance responsibilities.

recommends that the existing agencies be fully funded. Thomas Billy, administrator of USDA's FSIS from 1996 to 2001 and director of FDA's Office of Seafood between 1990 and 1994, believes that no changes should take place until a presidential commission evaluates the problems, identifies the alternatives, and recommends a specific approach and strategy for consolidating food safety programs. However, Mr. Billy supports incremental legislative steps to fix current shortcomings. Finally, Caren Wilcox, USDA's deputy under secretary for Food Safety from 1997 to 2001, believes that creating a single food safety agency would be advisable, but only under certain circumstances.

In 1998, the National Academies similarly recommended modifying the federal statutory framework for food safety to avoid fragmentation and to enable the creation and enforcement of risk-based standards.¹¹ Moreover, our 1999 report on the experiences of countries that were then consolidating their food safety systems indicated that foreign officials are expecting long-term benefits in terms of savings and food safety. Five countries—Canada, Denmark, Great Britain, Ireland, and New Zealand—have each consolidated their food safety responsibilities under a single agency. For example, New Zealand's Food Safety Authority was created in July 2002 to reduce inconsistencies and lack of coordination in food safety management by two separate agencies—the Ministry of Health and the Ministry of Agriculture and Forestry. The new authority anticipates an effective use of scarce resources and a reduction in duplication of effort.

Conclusions

In conclusion, given the risks posed by new threats to the food supply, be they inadvertent or deliberate, we can no longer afford inefficient, inconsistent, and overlapping programs and operations in the food safety system. It is time to ask whether a system that developed in a piecemeal fashion in response to specific problems as they arose over the course of several decades can efficiently and effectively respond to today's challenges. 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, and better ensure the safety of the nation's food supply. This integration can create synergy and economies of scale,

¹¹*Ensuring Safe Food From Production to Consumption*, National Research Council (Washington, D.C.: 1998).

and provide more focused and efficient efforts to protect the nation's food supply.

The National Academies 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. We recognize that consolidating federal responsibilities for food safety into a single agency or department is a complex process. Numerous details, of course, would have to be worked out. However, it is essential that the fundamental decision to create more uniform standards and a single food safety agency to uphold them is made and the process for resolving outstanding technical issues is initiated.

Matters for Congressional Consideration

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

- enacting comprehensive, uniform, and risk-based food safety legislation and
- establishing a single, independent food safety agency at the Cabinet level.

If the Congress does not opt for an entire reorganization of the food safety system, we suggest that as an alternative interim option it consider

- modifying existing laws to designate one current agency as the lead agency for all food safety inspection matters.

Madam Chairwoman, this completes my prepared statement. I would be pleased to respond to any questions that you or other Members of the Committee may have at this time.

Contacts and Staff Acknowledgments

For further information about this testimony, please contact Lawrence J. Dyckman, Director, Natural Resources and Environment, (202) 512-3841. Maria Cristina Gobin, Katheryn Summers Hubbell, Kelli Ann Walther, Amy Webbink, and John Delicath made key contributions to this statement.

Appendix I: Federal Agencies' Food Safety Responsibilities

	Agency	Responsible for
Department of Health and Human Services	Food and Drug Administration (FDA)	All domestic and imported food products except meat, poultry, and processed egg products
	Centers for Disease Control and Prevention (CDC)	Protecting the nation's public health
U.S. Department of Agriculture	Food Safety and Inspection Service (FSIS)	All meat, poultry, and processed egg products that are imported or involved in interstate commerce
	Animal and Plant Health Inspection Service (APHIS)	The health and care of all animals and plants
	Grain Inspection, Packers and Stockyards Administration	Establishing quality standards, inspection procedures, and marketing of grain and other related products
	Agricultural Marketing Service (AMS)	Establishing quality and condition standards for dairy, fruit, vegetable, livestock, meat, poultry, and egg products
	Agricultural Research Service (ARS)	Conducting food safety research
Department of Commerce	National Oceanic and Atmospheric Administration (NOAA)	Examining seafood for safety and quality
Environmental Protection Agency		Regulating the use of pesticides and maximum allowable residue levels on food commodities and animal feed
Federal Trade Commission		Prohibiting unfair or deceptive acts or practices
Department of the Treasury	Bureau of Alcohol, Tobacco, and Firearms	Enforcing laws covering the production, use, and distribution of alcoholic beverages
Department of Homeland Security		Coordinating all agencies' security activities
	U.S. Customs and Border Protection	Collecting revenues and enforcing various Customs laws.

Source: GAO.

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

Manufacturer inspected by FSIS daily	Manufacturer inspected by FDA on average about once every 5 years
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: GAO.

Appendix III: Related GAO Products

Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed. [GAO-04-246](#). Washington, D.C.: January 30, 2004.

Bioterrorism: A Threat to Agriculture and the Food Supply. [GAO-04-259T](#). Washington, D.C.: November 19, 2003.

Combating Bioterrorism: Actions Needed to Improve Security at Plum Island Animal Disease Center. [GAO-03-847](#). Washington, D.C.: September 19, 2003.

Results-Oriented Government: Shaping the Government to Meet 21st Century Challenges. [GAO-03-1168T](#). Washington, D.C.: September 17, 2003.

School Meal Programs: Few Instances of Foodborne Outbreaks Reported, but Opportunities Exist to Enhance Outbreak Data and Food Safety Practices. [GAO-03-530](#). Washington, D.C.: May 9, 2003.

Agricultural Conservation: Survey Results on USDA's Implementation of Food Security Act Compliance Provisions. [GAO-03-492SP](#). Washington, D.C.: April 21, 2003.

Food-Processing Security: Voluntary Efforts Are Under Way, but Federal Agencies Cannot Fully Assess Their Implementation. [GAO-03-342](#). Washington, D.C.: February 14, 2003.

Meat and Poultry: Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses. [GAO-02-902](#). Washington, D.C.: August 30, 2002.

Foot and Mouth Disease: To Protect U.S. Livestock, USDA Must Remain Vigilant and Resolve Outstanding Issues. [GAO-02-808](#). Washington, D.C.: July 26, 2002.

Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced. [GAO-02-566](#). Washington, D.C.: May 23, 2002.

Food Safety: Continued Vigilance Needed to Ensure Safety of School Meals. [GAO-02-669T](#). Washington, D.C.: April 30, 2002.

Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts. [GAO-02-183](#). Washington, D.C.: January 25, 2002.

Food Safety: Weaknesses in Meat and Poultry Inspection Pilot Should Be Addressed Before Implementation. [GAO-02-59](#). Washington, D.C.: December 17, 2001.

Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food. [GAO-02-47T](#). Washington, D.C.: October 10, 2001.

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

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

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

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

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

School Meal Programs: Few Outbreaks of Foodborne Illness Reported. [GAO/RCED-00-53](#). Washington, D.C.: February 22, 2000.

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

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

Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System. [GAO/T-RCED-99-256](#). Washington, D.C.: August 4, 1999.

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

Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems. [GAO/RCED-99-80](#). Washington, D.C.: April 20, 1999.

Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness. [GAO/RCED-98-224](#). Washington, D.C.: August 6, 1998.

Food Safety: Federal Efforts to Ensure Imported Food Safety Are Inconsistent and Unreliable. [GAO/T-RCED-98-191](#). Washington, D.C.: May 14, 1998.

Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable. [GAO/RCED-98-103](#). Washington, D.C.: April 30, 1998.

Food Safety: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors. [GAO/RCED-98-104](#). Washington, D.C.: April 10, 1998.

Food Safety: Fundamental Changes Needed to Improve Food Safety. [GAO/RCED-97-249R](#). Washington, D.C.: September 9, 1997.

Food Safety: Information on Foodborne Illnesses. [GAO/RCED-96-96](#). Washington, D.C.: May 8, 1996.

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

Food Safety: A Unified, Risk-Based Food Safety System Needed. [GAO/T-RCED-94-223](#). Washington, D.C.: May 25, 1994.

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

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

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

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The General Accounting Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through the Internet. GAO's Web site (www.gao.gov) contains abstracts and full-text files of current reports and testimony and an expanding archive of older products. The Web site features a search engine to help you locate documents using key words and phrases. You can print these documents in their entirety, including charts and other graphics.

Each day, GAO issues a list of newly released reports, testimony, and correspondence. GAO posts this list, known as "Today's Reports," on its Web site daily. The list contains links to the full-text document files. To have GAO e-mail this list to you every afternoon, go to www.gao.gov and select "Subscribe to e-mail alerts" under the "Order GAO Products" heading.

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. General Accounting Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
 TDD: (202) 512-2537
 Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Public Affairs

Jeff Nelligan, Managing Director, NelliganJ@gao.gov (202) 512-4800
U.S. General Accounting Office, 441 G Street NW, Room 7149
Washington, D.C. 20548