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OVERSEEING THE U.S. FOOD SUPPLY

Steps Should be Taken to Reduce Overlapping Inspections and Related Activities

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Highlights of [GAO-05-549T](#), a testimony to the Subcommittee on the Federal Workforce and Agency Organization, Committee on Government Reform, House of Representatives

Why GAO Did This Study

GAO has issued many reports documenting problems resulting from the fragmented nature of the federal food safety system—a system based on 30 primary laws. This testimony summarizes GAO's most recent work on the federal system for ensuring the safety of the U.S. food supply. It provides (1) an overview of food safety functions, (2) examples of overlapping and duplicative inspection and training activities, and (3) observations on efforts to better manage the system through interagency agreements. It also provides information on other countries' experiences with consolidation and the views of key stakeholders on possible consolidation in the United States.

What GAO Recommends

In the past, GAO has recommended that the Congress consider fundamental restructuring to ensure the effective use of scarce government resources. In the report that the Subcommittee is releasing today, GAO recognizes that, short of reorganization, other improvements can be made to help reduce overlap and duplication and to leverage existing resources. For example, the Food and Drug Administration (FDA) could use existing authority to commission U.S. Department of Agriculture (USDA) inspections of dual jurisdiction establishments.

www.gao.gov/cgi-bin/getrpt?GAO-05-549T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robert A. Robinson at (202) 512-3841 or robinsonr@gao.gov.

OVERSEEING THE U.S. FOOD SUPPLY

Steps Should Be Taken to Reduce Overlapping Federal Inspections and Related Activities

What GAO Found

USDA and FDA have primary responsibility for overseeing the safety of the U.S. food supply; the Environmental Protection Agency (EPA) and the National Marine Fisheries Service also play key roles. In carrying out their responsibilities, these agencies spend resources on a number of overlapping activities, particularly inspection/enforcement, training, research, and rulemaking, for both domestic and imported food. For example, both USDA and FDA conduct similar inspections at 1,451 dual jurisdiction establishments—facilities that produce foods regulated by both agencies, as shown below.

To better manage the fragmented federal system, these agencies have entered into at least 71 interagency agreements—about a third of them highlight the need to reduce duplication and overlap or make efficient and effective use of resources. The agencies do not take full advantage of these agreements because they do not have adequate mechanisms for tracking them and, in some cases, do not fully implement them.

Selected industry associations, food companies, consumer groups, and academic experts disagree on the extent of overlap, on how best to improve the federal system, and on whether to consolidate food safety-related functions into a single agency. However, they agreed that laws and regulations should be modernized to more effectively and efficiently control food safety hazards.

As GAO recently reported, Canada, Denmark, Ireland, Germany, the Netherlands, New Zealand, and the United Kingdom also had fragmented systems. These countries took steps to consolidate food safety functions—each country modified its food safety laws and established a single agency to lead food safety management or enforcement of food safety legislation.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to address the Subcommittee's interest in examining the potential for reorganizing the federal system for ensuring the safety of the U.S. food supply. As the Comptroller General recently testified, there is a need to bring government and its programs in line with 21st century realities.¹ He noted that many, if not most, current federal programs and policies, were designed decades ago to respond to trends and challenges that existed at the time. These programs can be updated and modernized by improving their targeting and efficiency through, among other things, consolidating facilities and programs and streamlining and reengineering operations and processes. The Comptroller General specifically cited the federal food safety system as an area where opportunities for crosscutting program integration exist.

In testimony last year before this Subcommittee, we described the fragmented nature of our federal food safety system—one based on 30 principal laws related to food safety that are administered by 15 agencies.² We stated that the patchwork nature of the system governing inspection and related activities hampers efforts to address the risks of inadvertent or deliberate food contamination. Under this system, different agencies are responsible for specific food commodities and have significantly different authorities for carrying out these responsibilities. As a result, federal agencies are spending resources on similar activities to ensure that the food supply is safe, wholesome, and appropriately labeled. For example, Food and Drug Administration (FDA) inspectors examine seafood processors; U.S. Department of Agriculture (USDA) inspectors examine meat- and poultry-processing facilities; and both agencies inspect the same food-processing facilities if the facilities produce food products under the jurisdiction of both agencies. For example, USDA inspects a canning facility that produces soup containing meat or poultry; if the facility also produces soup containing seafood, FDA inspects it as well. USDA spent \$665 million and FDA spent \$219 million, totaling \$884 million—and dedicated 8,787 and 1,844 full-time equivalent staff, respectively—for inspection and enforcement activities in fiscal year 2003. USDA and FDA provided updated expenditures for fiscal year 2004 totaling \$958 million—

¹GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, [GAO-05-352T](#) (Washington, D.C.: Feb. 16, 2005).

²GAO, *Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap*, [GAO-04-588T](#) (Washington, D.C.: Mar. 30, 2004).

and dedicated 8,733 and 1,812 full-time equivalent staff, respectively, for these activities.³

We have recommended changes to the federal system for ensuring the safety of our food supply. In particular, we recommended that the Congress consider enacting comprehensive, uniform, and risk-based food safety legislation to streamline inspection and enforcement efforts, and consolidate food safety functions by establishing a single, independent food safety agency or by designating one current agency as the lead agency for all food safety inspection matters. Such an overhaul would enable the federal system to more effectively and efficiently accomplish its mission and meet new food safety challenges, such as the emerging concerns about the deliberate contamination of our food supply through bioterrorism.

In my testimony today, I will discuss GAO's most recent work conducted at the request of this Subcommittee and other Congressional requesters. This GAO report, which is being released today, examines the need to reduce overlap and better leverage resources.⁴ It provides (1) an overview of the government's food safety functions, activities, and expenditures, (2) specific examples of overlapping and, at times, duplicative inspection and training activities, and (3) observations on the agencies' efforts to manage this fragmented system through dozens of interagency agreements. At your request, I will also provide a synopsis of selected industry and other stakeholders' views on the current federal approach to food inspection. Finally, I will offer some observations on the experiences of several countries that have recently undertaken consolidation efforts to achieve more effective and efficient management of their food safety programs; these observations are based on our recent report on foreign countries' experiences consolidating food safety functions and activities.⁵ My

³In 2003, USDA inspected about 6,500 meat, poultry, and egg-product facilities, and FDA inspected approximately 57,000 food-processing facilities. In 2004, the agencies inspected about 6,000 and 62,000 facilities, respectively.

⁴GAO, *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, [GAO-05-213](#) (Washington, D.C.: Mar. 30, 2005).

⁵GAO, *Food Safety: Experiences of Seven Countries in Consolidating Their Food Safety Systems*, [GAO-05-212](#) (Washington, D.C.: Feb. 22, 2005). The information on other countries' food safety systems, including descriptions of laws, is based almost exclusively on interviews with and documentation provided by high-level food safety officials from the seven countries we examined, as well as representatives from the food industry and consumer groups.

testimony also draws on our wide-ranging past reports and testimonies on the fragmented nature of the federal system and upon completed work and previous testimonies on issues related to government organization and transformation. (See app. II.) We conducted our work in accordance with generally accepted government auditing standards.

In the interest of clarity, I want to note at the outset that we are defining overlaps as similar food safety-related activities being performed by more than one agency—such as the training of food inspectors. We are defining duplication as essentially identical activities performed by more than one agency—such as inspecting the same food-processing facility for compliance with sanitation and/or good manufacturing practices requirements.

Background

The safety and quality of the U.S. food supply is governed by a highly complex system stemming from 30 principal laws related to food safety that are administered by 15 agencies. In addition, dozens of interagency agreements are intended to address a wide range of food safety-related activities. 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. USDA and FDA, within the Department of Health and Human Services, 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.⁶ Appendix 1 summarizes the agencies' food safety responsibilities.

The existing statutes also 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

⁶Under the Egg Products Inspection Act, the Secretary of Health and Human Services regulates whole eggs, while the Secretary of Agriculture regulates egg products.

the public. Under current law, USDA inspectors maintain continuous inspection at slaughter facilities and examine each slaughtered meat and poultry carcass. They also visit each processing facility at least once during each operating day. For foods under FDA's jurisdiction, however, federal law does not mandate the frequency of inspections (which FDA typically conducts every 1 to 5 years). 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 has had more comprehensive enforcement authority than FDA; however, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 granted FDA additional enforcement authorities that are similar to USDA's.⁷ For example, FDA now requires all food processors to register with the agency so that they can be inspected. FDA also has the authority to temporarily detain food products when it has credible evidence that the products present a threat of serious adverse health consequences. Moreover, FDA requires that entities such as the manufacturers, processors, and receivers of imported foods keep records so that FDA can identify the immediate previous source and the immediate subsequent recipients of food. 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 requires advance notice of imported food shipments under its jurisdiction. Despite these additional authorities, important differences remain between the agencies' inspection and enforcement authorities. For example, the Federal Meat Inspection Act and the Poultry Products Inspection Act require that meat and poultry products be inspected and approved for sale (i.e., stamped by USDA inspectors). The Federal Food, Drug and Cosmetic Act does not require premarket approval, in general, for FDA-regulated food products.

Finally, following the events of September 11, 2001, in addition to their established food safety and quality responsibilities, 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 industry to the list of critical infrastructure sectors that need protection from possible terrorist attack. As a result of this order, the Homeland Security Act of 2002 establishing the Department of Homeland

⁷Pub. L. No. 107-188, 116 Stat. 594 (2002).

Security, and subsequent presidential directives, the Department of Homeland Security provides overall coordination on how to protect the U.S. food supply from deliberate contamination. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 also included numerous provisions to strengthen and enhance food safety and security.

Many proposals have been made to consolidate the U.S. food safety system. In 2001, parallel Senate and House bills proposed consolidating inspections and other food safety responsibilities in a single independent agency. In 2004 and 2005, legislation was again introduced in the Senate and the House to establish a single food safety agency. This proposed legislation would combine the two food safety regulatory programs of USDA and FDA, along with a voluntary seafood inspection program operated by the National Marine Fisheries Service (NMFS) in the Department of Commerce. In addition, in 1998, the National Academy of Sciences recommended integrating the U.S. food safety system and suggested several options, including a single food safety agency.⁸ More recently, the National Commission on the Public Service recommended that government programs designed to achieve similar outcomes be combined into one agency and that agencies with similar or related missions be combined into large departments.⁹ The commission chairman testified before the Congress that important health and safety protections fail when responsibility for regulation is dispersed among several departments, as is the case with the U.S. system.

Federal Agencies’ Food Safety-Related Functions, Activities, and Expenditures

The four agencies we examined—USDA, FDA, the Environmental Protection Agency (EPA), and NMFS—are involved in key program functions related to food safety. These functions include inspection and enforcement, research, risk assessment, education and outreach, rulemaking and standard setting, surveillance and monitoring, food security, and administration. These agencies spend resources on similar food safety activities to ensure the safety of different food products. Table 1 illustrates similar activities that these agencies conduct.

⁸National Research Council and Institute of Medicine, *Ensuring Safe Food From Production to Consumption* (Washington, D.C.: 1998).

⁹Report of the National Commission on the Public Service, *Urgent Business For America: Revitalizing the Federal Government For the 21st Century* (Washington, D.C.: 2003).

Table 1: Examples of Similar Food Safety Activities

Food safety program function	Activity	USDA	FDA	EPA	NMFS
Inspection/Enforcement	Inspection of domestic food-processing facilities	•	•		•
	Visits to foreign countries or firms to conduct inspections and/or evaluate foreign food safety systems	•	•		•
	Inspection of imported food at ports of entry	•	•		
	Training inspectors	•	•		•
	Maintenance of inspection record database	•	•		•
	Support to state enforcement efforts (retail-level food safety)	•	•	•	
	Laboratory analysis of samples collected at food-processing facilities (to identify potential contamination)	•	•		•
Research	Research on pathogen reduction	•	•		•
	Research on foodborne chemical contaminants (such as pesticides or dioxins) or biological contaminants (such as e-coli or salmonella)	•	•	•	•
Risk assessment	Risk assessment of food contaminants	•	•	•	•
	Sample collection and/or analysis of pesticide residues to inform risk assessment	•	•		•
Education/Outreach	Development and delivery of consumer education (such as consumer hotlines or pamphlets)	•	•	•	•
	Development and delivery of industry guidance (such as guidance regarding regulations)	•	•	•	•
	International harmonization of standards	•	•	•	•
Surveillance/Monitoring	Participation in FoodNet (active surveillance for foodborne diseases)	•	•		
	Participation in PulseNet (early warning system for food illness outbreak)	•	•		
Rulemaking/Standard setting	HACCP rule development and promulgation ^a	•	•		• ^b

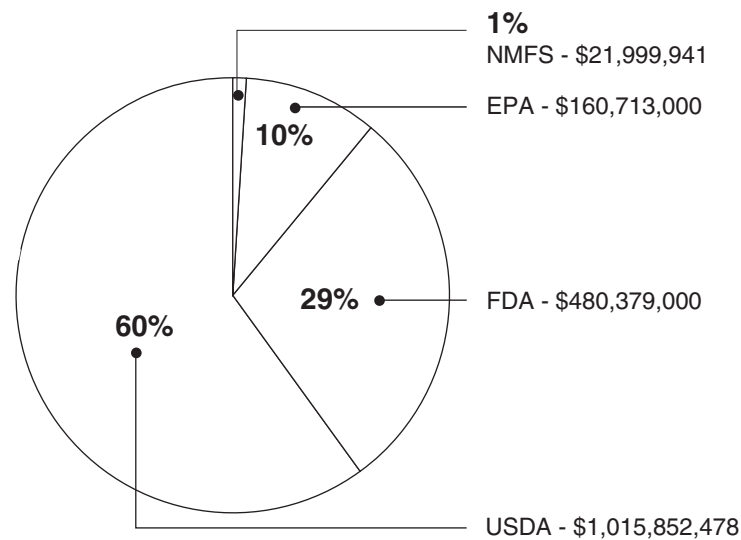
Source: GAO analysis of documents obtained from, and discussions with, USDA, FDA, EPA, and NMFS officials.

^aHazard Analysis and Critical Control Point (HACCP) regulations require food processors to maintain a plan identifying critical points in the production line where contamination is more likely to occur and adopt control techniques to prevent or reduce contamination. Currently, USDA requires all meat- and poultry-processing facilities to comply with mandatory HACCP regulations, and FDA requires that seafood- and juice-processing facilities comply with mandatory HACCP regulations.

^bNMFS participated in developing FDA's seafood HACCP rule.

In fiscal year 2003, the four federal agencies spent nearly \$1.7 billion on food safety-related activities.¹⁰ As figure 1 shows, USDA and FDA together are responsible for nearly 90 percent of federal expenditures for food safety.

Figure 1: USDA, FDA, EPA, and NMFS Food Safety-Related Expenditures, Fiscal Year 2003



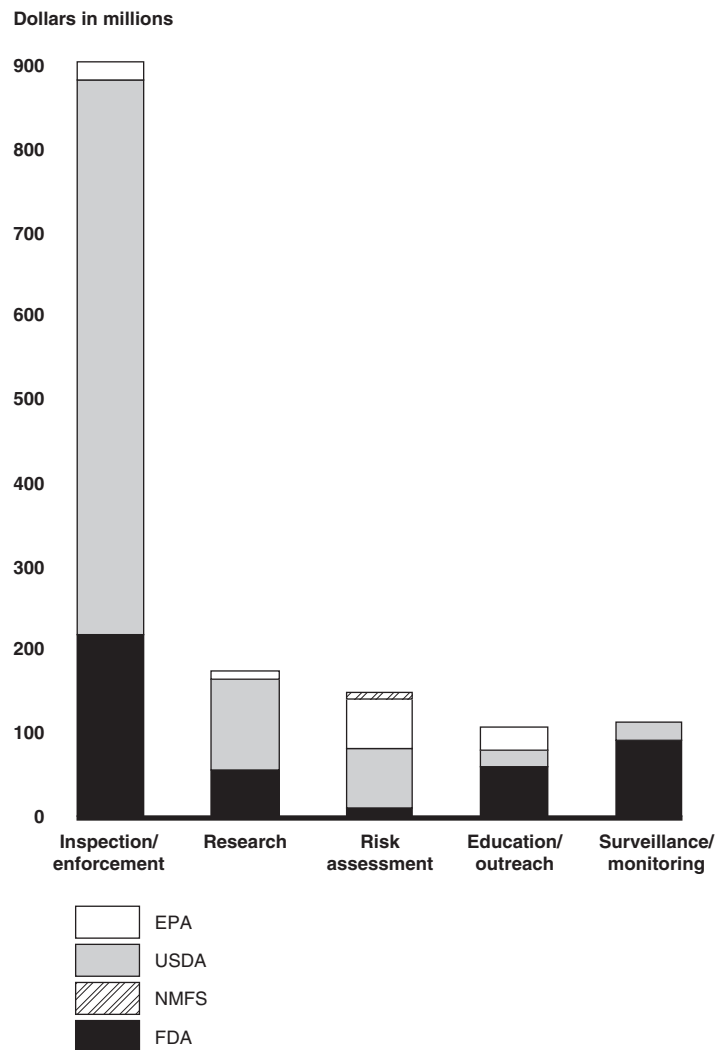
Source: GAO analysis of data obtained from, and discussions with, USDA, FDA, EPA, and NMFS officials.

As figure 2 shows, most of the agencies' expenditures were incurred for inspection/enforcement activities, including inspections of domestic and imported food. However, these expenditures are not based on the volume of foods regulated by the agencies or consumed by the public. USDA's activities account for almost three-quarters of the agencies' inspection and enforcement expenditures. That is, the majority of federal expenditures

¹⁰The total food safety expenditures provided in this testimony are derived by summing data for specific food safety activities (monitoring/surveillance, inspection/enforcement, education/outreach, research, and risk assessment) presented in the National Academy of Sciences' 1998 report *Ensuring Safe Food From Production to Consumption*. To capture other relevant activities, we included three additional activities—administration, food security, and rulemaking/standard setting—in the agencies' expenditures. At the time GAO initiated its review in May 2004, the agencies could only provide complete expenditures by these categories for fiscal year 2003. Because the agencies generally do not track expenditures in this manner, we were only able to update some of these data to reflect fiscal year 2004 expenditures.

for food safety inspection are directed toward USDA's programs for ensuring the safety of meat, poultry, and egg products; however, USDA is responsible for regulating about 20 percent of the food supply. In contrast, FDA, which is responsible for regulating about 80 percent of the food supply, accounted for only about 24 percent of these expenditures.

Figure 2: Food Safety Expenditures by Agency and Function, Fiscal Year 2003



Source: GAO analysis of data obtained from, and discussions with, USDA, FDA, EPA, and NMFS officials.

Federal Food Safety Agencies Conduct Overlapping Activities

As a result of the multiple laws governing food safety, several federal agencies conduct activities—inspections of domestic and imported foods, training, research, risk assessment, education, and rulemaking—that can serve overlapping, if not identical, purposes.

USDA and FDA Inspections of Jointly Regulated Facilities Overlap

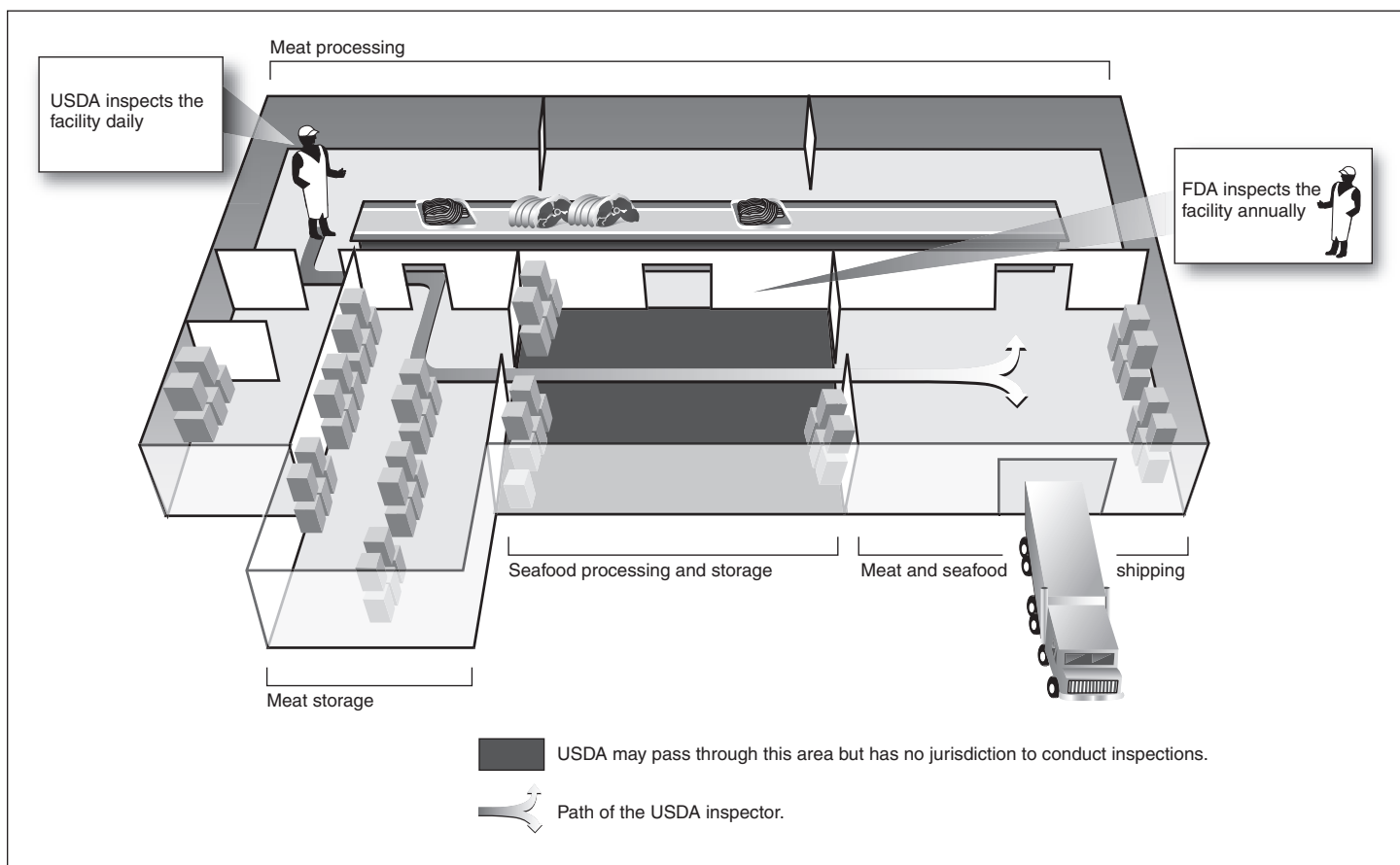
USDA and FDA conduct overlapping, and even duplicative, inspections at more than 1,400 domestic facilities that produce foods such as canned goods and frozen entrees. Both agencies inspect these facilities because each has statutory responsibility for the safety of different foods or food ingredients. USDA inspects canning facilities at least daily if the company produces canned beans containing meat and poultry. If the facility produces canned beans without meat or poultry, FDA also inspects it, with a frequency ranging from 1 to 5 years. USDA and FDA inspections have common features—both agencies spend inspection resources to verify that facilities are sanitary and follow good manufacturing practices, such as verifying that facilities do not have rodent or insect infestations.

At jointly regulated facilities, both USDA and FDA inspectors verify that HACCP systems are in place. In these instances, each agency verifies that the facility has created and implemented a HACCP plan specific to the products that the agency regulates. Each agency's regulations require the facility to maintain separate HACCP plans for each product and to develop separate analyses of critical control points and separate strategies to mitigate or eliminate food contaminants. While separate HACCP plans are generally necessary to address the specific hazards associated with specific food products, maintaining these separate plans, and the associated inspections and documentation that each agency requires, can be burdensome. For example, at a facility we visited that produces both crab cakes and breaded chicken, the manager must maintain a seafood HACCP plan and a poultry HACCP plan. He said that although both plans have similar elements, each agency's inspectors expect different levels of detail for the plans—something the manager finds confusing and difficult to comply with.

USDA and FDA inspections of the same food-processing facility represent, in our view, an inefficient use of scarce government resources. For example, at a plant that produces both meat and seafood products, a USDA inspector told us that as part of his daily, routine inspections he walks through the seafood processing and storage section of the plant. (See fig. 3.) However, because FDA regulates seafood, the USDA inspector does not monitor or inspect the seafood storage section. The inspector noted that, with minimum training on seafood temperature controls, he

could inspect this section of the plant as well. USDA headquarters officials said the agency’s inspectors are capable of taking on FDA’s inspection responsibilities at jointly regulated facilities, given the proper resources and training.

Figure 3: Diagram of a Jointly Regulated Food-Processing Facility



Source: GAO observation of a jointly regulated establishment.

USDA and FDA have new tools that could help reduce overlap in inspections. Under the Bioterrorism Act, FDA could commission USDA inspectors, who are present every day at these jointly regulated facilities,

to inspect FDA-regulated food.¹¹ In doing so, FDA could reduce overlapping inspections and redirect resources to other facilities for which it has sole jurisdiction. While they did not disagree in principle with the benefits of such an arrangement, FDA officials said that the savings would be somewhat offset because FDA would likely have to reimburse USDA for the costs of those inspections. Furthermore, FDA officials said that they do not currently plan to pursue this option and have not conducted any analyses of the costs or savings associated with it. USDA officials commented that their inspectors are fully occupied and that they would need to be trained before conducting joint inspections.

FDA and NMFS Inspections of Domestic Seafood Processors Overlap

Overlaps also occur at seafood processing facilities that both FDA and NMFS inspect. NMFS currently inspects approximately 275 domestic seafood facilities, and FDA inspects some of these plants as part of FDA's surveillance program. NMFS conducts safety and sanitation inspections, as well as other product quality inspections, on a fee-for-service basis. NMFS inspectors verify sanitation procedures, HACCP compliance, and good manufacturing practices—many of the same components of an FDA inspection. Although the two agencies' seafood safety inspections are similar, FDA does not take into account whether NMFS has already inspected a particular facility when determining how frequently its inspectors should visit that same facility.

FDA officials said they do not rely on NMFS inspections for two reasons. First, FDA officials believe that NMFS has a potential conflict of interest because companies pay NMFS for these inspections; and therefore, as a regulatory agency, FDA should not rely on them. NMFS officials disagreed, stating that their fee-for-service structure does not affect their ability to conduct objective inspections. Furthermore, they noted, when NMFS inspectors find noncompliance with FDA regulations, they refer companies to FDA and/or to state regulatory authorities. NMFS officials stated that companies that contract with NMFS need the agency's certification in order to satisfy their customers. Second, FDA officials believe, it is difficult for FDA to determine which facilities NMFS inspects at any given time because NMFS' inspection schedules fluctuate often, according to changes in NMFS' contracts with individual companies.

¹¹Under the act, the agencies would have to enter into a memorandum of understanding that would include provisions to ensure adequate training of USDA officials and to address reimbursement.

However, we believe that if FDA were to recognize the results of NMFS' inspection findings in targeting its resources, it could decrease or eliminate inspections at facilities that NMFS inspectors find are in compliance with sanitation and HACCP regulations.

USDA and FDA Both Inspect Imported Food

Both USDA and FDA maintain inspectors at 18 U.S. ports of entry to inspect imported food but do not share inspection resources. In fiscal year 2004, USDA spent almost \$16 million on imported food inspections, and FDA spent about \$121 million. According to USDA inspectors we interviewed, FDA-regulated imported foods are sometimes handled and stored in USDA-approved import inspection facilities. Although USDA inspectors are present at these ports more often than FDA inspectors, USDA inspectors have no jurisdiction over FDA-regulated products and, therefore, the FDA-regulated products may remain at the facilities for some time awaiting FDA inspection.

FDA and USDA are also not sharing information they gather during their respective evaluations and/or visits to foreign countries to assess food safety conditions. For example, USDA evaluated 34 countries in 2004 to determine whether these countries' food safety systems for ensuring the safety of meat and poultry are equivalent to that of the United States. FDA conducted inspections in 6 of these countries, but officials said they do not take USDA's evaluations of the foreign countries' food safety systems into account when determining which countries to visit and that USDA's findings would be of little use to FDA because they relate to products under USDA's jurisdiction.¹²

USDA and FDA Have Similar Training Programs for Food Inspectors

Both USDA and FDA spend resources to provide similar training to food inspection personnel. USDA spent about \$13.4 million and FDA spent about \$1.7 million in fiscal year 2004. We found that, to a considerable extent, food inspection training addresses the same subjects—such as plant sanitation, good manufacturing practices, and HACCP principles, albeit for different food products. FDA's online curriculum includes over 106 courses that address topics common to both USDA and FDA, as well as courses that are specific to FDA's regulations and enforcement authorities. NMFS currently uses 74 of these courses to train its seafood

¹²The countries that both USDA and FDA visited were Brazil, Costa Rica, Germany, Hungary, Mexico, and Canada.

inspectors. NMFS officials cite benefits to using FDA’s online training, such as accessibility to training materials at times other than when their inspectors are “on duty,” as well as cost savings attributable to reduced expenses for course materials and management.

Interagency Agreements Are Not Reducing Overlaps

We identified 71 interagency agreements that the principal food safety agencies—USDA, FDA, EPA, and NMFS—have entered into to better protect the public health by addressing jurisdictional boundaries, coordinating activities, reducing overlaps, and leveraging resources. About one-third (24) of the agreements highlight the need to reduce duplication and overlap or make efficient and effective use of resources. However, the agencies cannot take full advantage of these agreements because they do not have adequate mechanisms for tracking them and, in some cases, do not effectively implement them. Agency officials had difficulty identifying the food safety agreements they are party to, and in many instances, the agencies did not agree on the number of agreements they had entered into.

In addition, for the two comprehensive inspection-related agreements that we examined in detail, the agencies are not ensuring that their provisions are adhered to or that the overall objectives of the agreements are being achieved. For example:

- USDA and FDA are not fully implementing an agreement to exchange information about jointly regulated facilities in order to permit more efficient use of both their resources and contribute to improved public health protection. Under this agreement, the agencies are to share inspection information, but FDA does not routinely consider compliance information from USDA when deciding how to target its inspection resources. Also, the agreement calls for the agencies to explore the feasibility of granting each other access to appropriate computer-monitoring systems so that each agency can track inspection findings. However, the agencies maintain separate databases and the inspectors with whom we spoke continue to be largely unaware of a facility’s history of compliance with the other agency’s regulations. Inspectors told us that compliance information might be helpful when inspecting jointly regulated facilities so they could focus on past violations.
- An agreement between FDA and NMFS recognizes the agencies’ related responsibilities at seafood-processing establishments. The agreement details actions the agencies can take to enable each to discharge its responsibilities as effectively as possible, minimizing FDA inspections at these facilities. However, we found that FDA is not using information from

NMFS inspections, which could allow it to reduce the number of inspections at those facilities. Also, FDA rarely notifies NMFS of seizure actions it takes against NMFS-inspected plants, as outlined in the agreement. Although FDA is not implementing the agreement, it has recognized the potential benefits of working with NMFS to leverage resources. In a January 2004 letter to the Under Secretary of Commerce for Oceans and Atmosphere,¹³ the then-Commissioner of FDA noted, among other things, that using NMFS inspectors could be cost effective because the NMFS inspectors may already be on-site and the FDA inspector therefore would not have to travel to conduct an inspection.

Stakeholders Disagree on the Significance of Overlapping Activities and on How to Improve the Federal Structure for Performing Food Safety Inspections and Related Activities

The stakeholders we contacted—selected industry associations, food-processing companies, consumer groups, and academic experts—disagree on the extent to which overlaps exist and on how best to improve the federal structure. Most of these stakeholders agree that the laws and regulations governing the system should be modernized so that scientific and technological advancements can be used to more effectively and efficiently control current and emerging food safety hazards. However, they differed about whether to consolidate food safety inspection and related functions into a single federal agency.

- *Industry Associations:* Representatives of industry associations do not see the need to consolidate food safety-related functions, but they see the need for minor changes within the existing regulatory framework to enhance communication and coordination among the existing agencies.
- *Food Processing Companies:* Representatives from the individual food companies inspected by USDA and FDA believe that consolidation would improve the effectiveness and efficiency of the system and ensure that food safety resources are distributed based on the best available science. They also said that overlaps can be burdensome or confusing. The representatives did not see the added value of FDA's once-a-year (or less) inspections because USDA inspectors already visit their plants daily. At one company, USDA and FDA inspectors gave the plant manager contradictory instructions—the USDA inspector did not want the company to paint sterilization equipment because he determined that paint chips could contaminate the food; whereas the FDA inspector told the

¹³NMFS is located within the Department of Commerce's National Oceanic and Atmospheric Administration.

company to paint the same equipment because he determined that it would be easier to identify sanitation problems on lightly painted surfaces.

- *Academics and Consumer Groups:* Academics and consumer groups support consolidating food safety inspection and related functions into a single agency. One group stated that the laws do not build prevention into the farm-to-table continuum and divide responsibility and accountability for food safety among federal agencies. Further, according to this group, the laws prevent risk-based allocation of resources across the federal food safety agencies.

Other Countries Have Modified Laws and Consolidated Food Safety Functions

The division of responsibility among several government agencies responsible for food safety is not unique to the United States. According to food safety officials in seven countries whose consolidations of food safety systems we examined, they faced similar fragmentation and division of responsibilities in their systems. As reported in February 2005,¹⁴ we examined the efforts of Canada, Denmark, Ireland, Germany, the Netherlands, New Zealand, and the United Kingdom to streamline and consolidate their food safety systems. We found that, in each case, these countries (1) modified existing laws to achieve the necessary consolidation and (2) established a single agency to lead food safety management or enforcement of food safety legislation.

We acknowledge that these countries have smaller populations than the United States, but they face several similarities in their efforts to ensure safe food. These countries, like the United States, are high-income countries in which consumers have very high expectations about the safety of their food supplies.¹⁵ In addition, U.S. consumers' spending on food as a percentage of total spending is somewhat similar to that of these seven countries, ranging from about 10 percent in the United States to over 16 percent in Ireland and the United Kingdom. In general, high-income countries tend to spend a smaller percentage of their income on food than low-income countries.

¹⁴GAO, *Food Safety: Experiences of Seven Countries in Consolidating Their Food Safety Systems*, [GAO-05-212](#) (Washington, D.C., Feb. 22, 2005).

¹⁵All seven countries, as well as the United States, are in the World Bank's high-income category.

The seven countries' approaches for modifying their systems, of course, differed. For example, Denmark created a new federal agency in which it consolidated almost all food safety functions and activities, including inspections, which were previously distributed among several government agencies. In contrast, Germany's new food safety agency functions as a coordinating body to lead food safety management, while the German federal states continue to be responsible for overseeing food inspections performed by local governments. These countries had two primary reasons for consolidating their food safety systems—public concern about the safety of the food supply and the need to improve program effectiveness and efficiency. In addition, an important factor motivating the European Union (EU) countries' consolidations has been the need to comply with recently adopted EU legislation. These EU changes aim to harmonize and simplify its food safety legislation and to create a single, transparent set of food safety rules that is applicable to all EU-member countries.

As we previously reported, Canada reorganized its food safety system in 1997. As part of its consolidation of food safety functions, Canada also assigned responsibilities for animal disease control and feed inspections to the Canadian Food Inspection Agency (CFIA). As a result, CFIA is responsible for detecting animal diseases that may affect human health, such as mad cow disease in cattle as well as for preventing the introduction and spread of the disease through animal feed.¹⁶

Not unexpectedly, the countries faced challenges in implementing their new systems. Many countries had to determine (1) whether to place the new agency within the existing health or agriculture ministry or establish it as a stand-alone agency and (2) what responsibilities the new agency would have. For example, Ireland chose to place its new independent food

¹⁶In the United States, USDA is primarily responsible for detecting mad cow disease, and FDA is primarily responsible for preventing its introduction and spread through animal feed. As we recently reported, FDA has not always notified USDA when it has discovered that cattle may have consumed feed containing prohibited material. This lapse has been occurring even though FDA's guidance calls for such communication (GAO, *Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness*, GAO-05-101 (Washington, D.C.: Feb. 25, 2005)). Despite this lapse in communication regarding animal feed, an international panel that reviewed USDA's epidemiological investigation conducted in response to an animal that tested positive for mad cow disease in the United States in December 2003 found that USDA's investigation conformed to international standards. A separate international panel stated that Canada's investigation of its first case of the disease was comprehensive, thorough, and timely.

safety agency under its existing Department of Health and Children, in part, to separate food safety responsibilities from the promotion of the food industry, which is the responsibility of the Department of Agriculture and Food. On the other hand, to separate food safety regulation from political pressures, New Zealand established a semi-autonomous food safety agency attached to the Ministry of Agriculture and Forestry. Officials in several countries also cited challenges in helping employees assimilate into the new agency's culture and support its priorities.

As expected, most countries incurred start-up costs in reorganizing, including the costs associated with acquiring buildings and purchasing new laboratory equipment. Some countries also reported that they experienced a temporary reduction in the quantity of food safety activities performed due to consolidation-related disruptions.

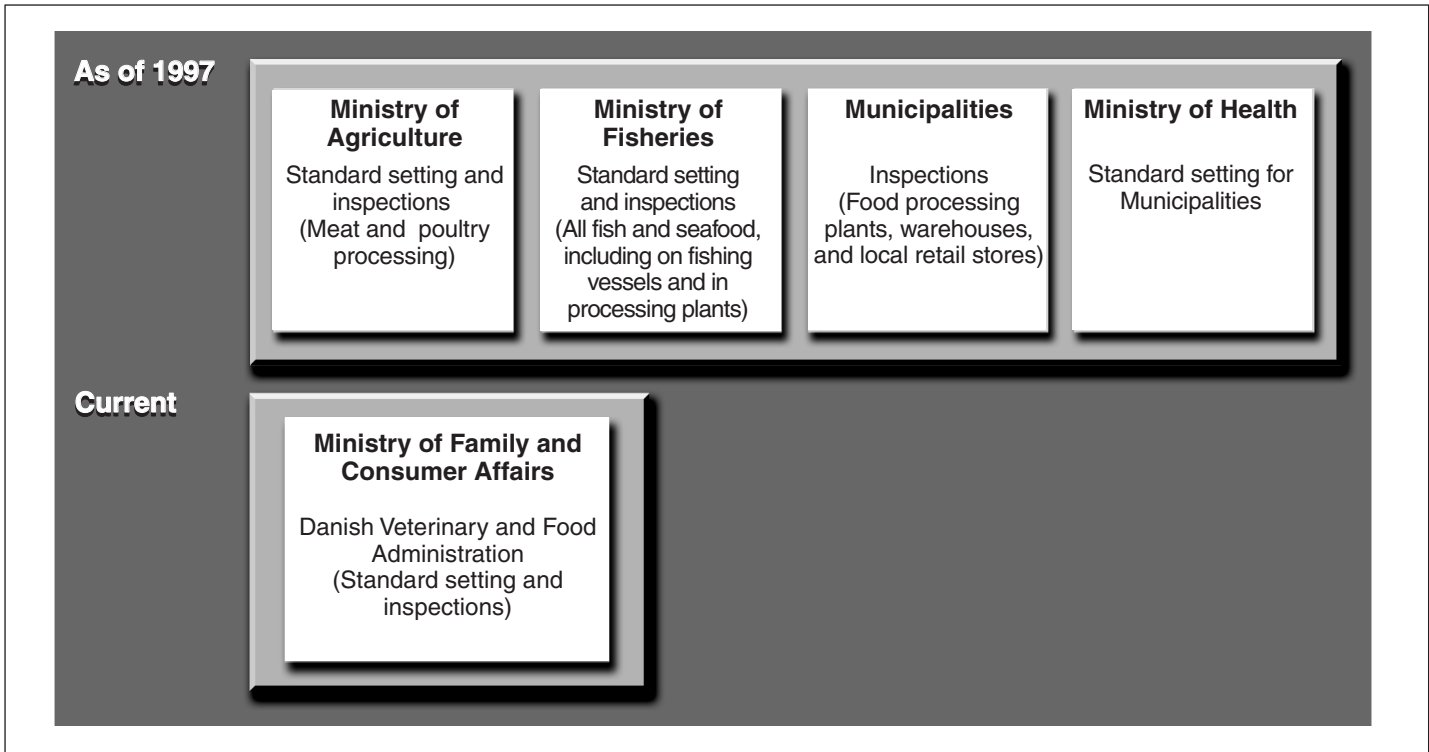
None of the countries has conducted an analysis to compare the effectiveness and efficiency of its consolidated food safety system with that of the previous system. However, government officials in these countries as well as other stakeholders consistently stated that consolidation of their systems has led to significant qualitative improvements in operations that enhance effectiveness or efficiency. According to these officials, the benefits included reduced overlaps in inspections, more targeted inspections based on food safety risk, more consistent or timely enforcement of food safety laws and regulations, and greater clarity in responsibilities.

Danish officials stated that consolidation and the accompanying reform of food safety laws facilitated risk-based inspections. The frequency of most inspections is now based on an individual food product's safety risk and on an individual company's food safety record, not on agencies' jurisdiction, as was the case before consolidation. As a result, the frequency of inspections at some food processing plants and of lower risk food products has been reduced, making more resources available for inspections of higher risk companies and foods.

Government officials in Canada, the Netherlands, and Denmark stated that some cost savings may be achieved as a result of changes that have already taken place or are expected from planned changes needed to complete their consolidation efforts. For example, Dutch officials said that reduced duplication in food safety inspections would likely result in decreased spending. In addition, they anticipate savings from an expected 25-percent reduction in administrative and management personnel and from selling excess property.

Figures 4 and 5 illustrate key functions and activities that the governments of Denmark and Canada decided to consolidate in order to achieve more efficient food safety systems.

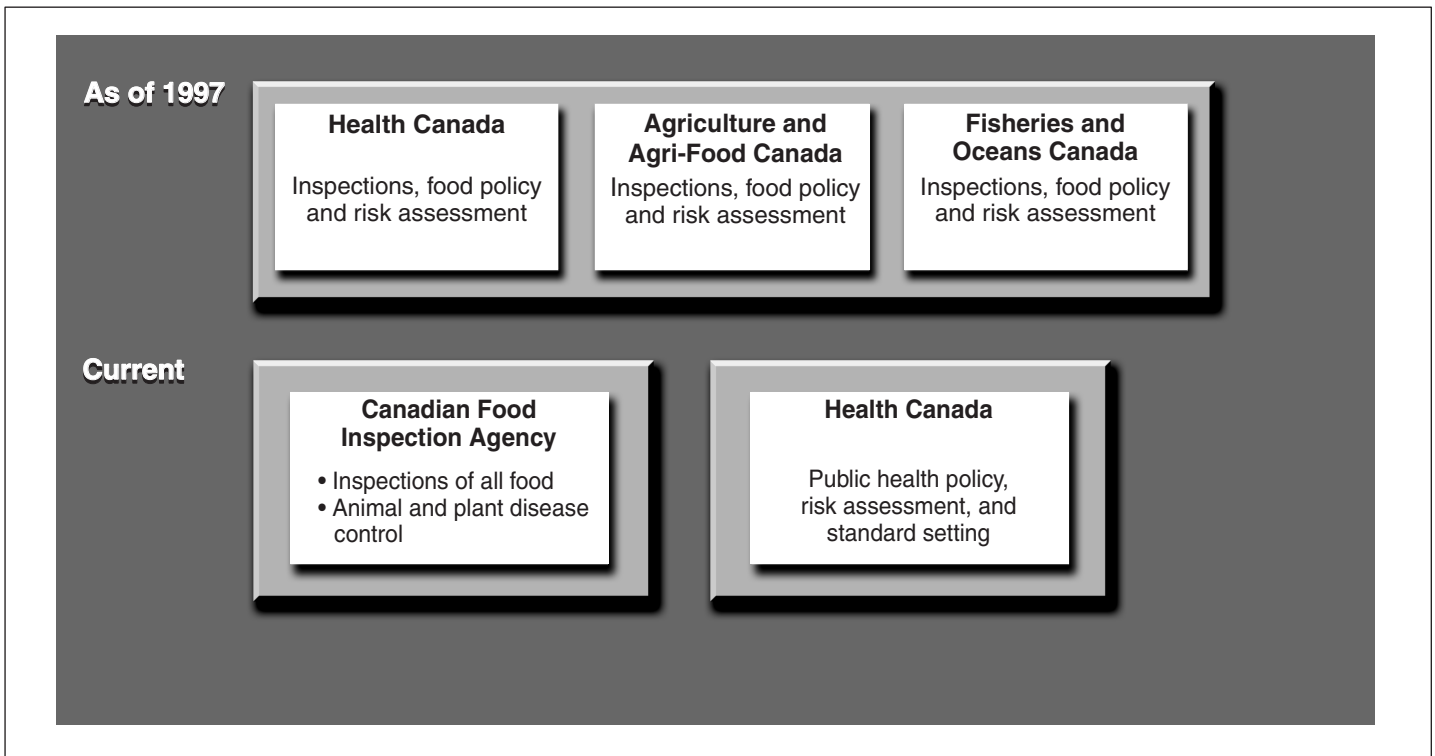
Figure 4: Consolidation of Food Safety Entities in Denmark



Source: GAO diagram based on information provided by Danish Food Safety Officials.

Note: The Danish Veterinary and Food Administration is responsible for almost all food safety responsibilities. Exceptions are the Plant Directorate, which is responsible for animal feed inspections, and the Directorate for Fisheries, which is responsible for inspection of fish on ships. These two agencies are in the Ministry of Food, Agriculture, and Fisheries.

Figure 5: Consolidation of Food Safety Entities in Canada



Source: GAO diagram based on information provided by Canadian Food Safety Officials.

Note: The Canadian Food Inspection Agency is responsible for all inspection/compliance activities, including inspections of imported/domestic products, laboratory and diagnostic support, crisis management and product recalls, and export certification. In addition to the responsibilities listed above, Health Canada is responsible for research and setting limits on the amount of a substance allowed in a food product.

Conclusions

In recent years, many proposals from the Congress and others have been made to reform existing laws and consolidate the governmental structure for ensuring the safety of the food supply. As we have reported in the past, the current system is fragmented and causes inefficient use of resources, inconsistent oversight and enforcement, and ineffective coordination. We have recommended that the Congress consider statutory and organizational reforms, and we continue to believe that the benefits of establishing a single national system for the regulation of our food supply outweigh the costs. In making these recommendations, we fully recognize the time and effort needed to develop a reorganization plan and to transfer authorities, as necessary, under such a reorganization.

We also recognize that improvements short of restructuring the current system can be made to help reduce overlaps and duplication, and to leverage existing resources. Therefore, in the report that you are releasing today, we make several recommendations to that end. For example, if cost effective, we recommend that FDA, as authorized under the Bioterrorism Act, commission USDA inspectors to carry out inspections of FDA-regulated foods at food establishments that are under their joint jurisdiction. We also recommend that USDA and FDA examine the feasibility and cost effectiveness of establishing a joint training program for their food inspectors.

Contacts and Staff Acknowledgements

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Appendix I: Federal Agencies with Food Safety Responsibilities

Table 2: Federal Agencies' Food Safety Responsibilities

Department and/or agency		Responsible for
U.S. Department of Agriculture	Food Safety and Inspection Service	All domestic and imported meat, poultry, and processed egg products
	Animal and Plant Health Inspection Service	Protecting the health and value of U.S. agricultural resources (e.g., 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) ^a	Establishing quality and condition standards for dairy, fruit, vegetable, livestock, meat, poultry, and egg products
	Agricultural Research Service	Conducting food safety research
	Economic Research Service	Providing analyses of the economic issues affecting the safety of the U.S. food supply
	National Agricultural Statistics Service	Providing statistical data, including agricultural chemical usage data, related to the safety of the food supply
	Cooperative State Research, Education and Extension Service	Supporting food safety research, education, and extension programs in the land-grant university system and other partner organizations
Department of Health and Human Services	Food and Drug Administration (FDA)	All domestic and imported food products except meat, poultry, or processed egg products
	Centers for Disease Control and Prevention (CDC)	Protecting the nation's public health, including foodborne illness surveillance
Department of Commerce	National Marine Fisheries Service	Voluntary, fee-for-service examinations of seafood for safety and quality
Environmental Protection Agency		Regulating the use of pesticides and maximum allowable residue levels on food commodities and animal feed
Department of the Treasury	Alcohol and Tobacco Tax and Trade Bureau	Enforcing laws covering the production, use, and distribution of alcoholic beverages
Department of Homeland Security ^b		Coordinating agencies' food security activities
Federal Trade Commission		Prohibiting false advertisements for food

Source: GAO.

^aAccording to USDA, AMS has no statutory authority in the area of food safety. However, the agency performs some functions related to food safety for several foods. For example, AMS graders monitor a shell egg surveillance program that identifies cracked and dirty eggs. In addition, AMS performs functions related to food safety for the National School Lunch Program.

^bIn 2001, by executive order, the President stated that the then Office of Homeland Security, as part of its efforts to protect critical infrastructures, should coordinate efforts to protect livestock, agriculture, and food systems from terrorist attacks. In 2002, Congress enacted the Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002), setting out the department's responsibility to protect and secure critical infrastructures and transferring several food safety-related responsibilities to the Department of Homeland Security. As a result of the 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 coordination on the protection of the U.S. food supply from deliberate contamination.

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