

March 2005

# OVERSIGHT OF FOOD SAFETY ACTIVITIES

## Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources



G A O

Accountability \* Integrity \* Reliability



Highlights of [GAO-05-213](#), a report to congressional requesters

### Why GAO Did This Study

GAO has documented many problems resulting from the fragmented nature of the federal food safety system and recommended fundamental restructuring to ensure the effective use of scarce government resources. In this report, GAO (1) identified overlaps in food safety activities at USDA, FDA, EPA, and NMFS; (2) analyzed the extent to which the agencies use interagency agreements to leverage resources; and (3) obtained the views of stakeholders.

### What GAO Recommends

Recognizing the statutory constraints under which the agencies operate, GAO, among other things, recommends that (1) if cost effective, FDA use available authority to enter into an agreement to commission USDA inspectors at jointly regulated facilities; (2) USDA and FDA consider joint training programs; and (3) USDA, FDA, EPA and NMFS inventory, evaluate, and update active interagency agreements. USDA generally did not appear to agree with GAO's recommendations but recognized the benefits of joint training for food inspectors. HHS (FDA) agreed with GAO's recommendations to inventory, evaluate, and update the interagency agreements and with GAO's recommendation to use USDA's foreign country evaluations, but it disagreed with others. NMFS agreed with GAO's recommendations, and EPA took no position.

[www.gao.gov/cgi-bin/getrpt?GAO-05-213](http://www.gao.gov/cgi-bin/getrpt?GAO-05-213).

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](mailto:robinsonr@gao.gov).

# OVERSIGHT OF FOOD SAFETY ACTIVITIES

## Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources

### What GAO Found

Several statutes give responsibility for different segments of the food supply to different agencies to ensure that the food supply is safe. The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) have the primary responsibility for regulating food safety, with the Environmental Protection Agency (EPA) and the National Marine Fisheries Service (NMFS) also involved. In carrying out their responsibilities, with respect to both domestic and imported food, these agencies spend resources on a number of overlapping activities, such as inspection/enforcement, training, research, or rulemaking. For example, both USDA and FDA conduct similar inspections at 1,451 dual jurisdiction establishments—facilities that produce foods regulated by both agencies. Under authority granted by the Bioterrorism Act of 2002, FDA could authorize USDA inspectors to inspect these facilities, but it has not done so. Furthermore, USDA and FDA maintain separate training programs on similar topics for their inspectors that could be shared. Ultimately, inspection and training resources could be used more efficiently.

### Common Elements of USDA and FDA Inspections

Hazard Analysis and Critical Control Point:	Sanitation:	Good Manufacturing Practices:
<ul style="list-style-type: none"> <li>Check to ensure facility maintains a HACCP plan that identifies potential sources of food contamination</li> <li>Check to ensure the facility is implementing its HACCP plan</li> </ul>	<ul style="list-style-type: none"> <li>Check food contact surfaces</li> <li>Check for pests</li> <li>Check the facility's hand-washing area</li> </ul>	<ul style="list-style-type: none"> <li>Check cleanliness of employees' outer garments and gloves</li> <li>Check equipment design to see if it is cleanable and properly maintained</li> </ul>

Source: GAO analysis of FSIS and FDA documents.

GAO identified 71 interagency agreements that the agencies entered into to better protect public health and to coordinate their food safety activities. However, the agencies have weak mechanisms for tracking these agreements that, in some cases, lead to ineffective implementation. Specifically, USDA and FDA are not fully implementing an agreement to facilitate the exchange of information about dual jurisdiction establishments, which both agencies inspect. In addition, FDA and NMFS are not implementing an agreement designed to enable each agency to discharge its seafood responsibilities effectively.

GAO spoke with selected industry associations, food companies, consumer groups, and academic experts, and they disagree on the extent of overlap and on how best to improve the food safety system. Most of these stakeholders agreed that laws and regulations should be modernized to more effectively and efficiently control food safety hazards, but they differed about whether to consolidate food safety functions into a single agency.

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**Abbreviations**

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CBP	Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
CSREES	Cooperative State Research, Education and Extension Service
CVM	Center for Veterinary Medicine
DJE	Dual Jurisdiction Establishment
DOC	Department of Commerce
EPA	Environmental Protection Agency
ERS	Economic Research Service
GIPSA	Grain Inspection, Packers and Stockyards Administration
ISSC	Interstate Shellfish Sanitation Conference
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point (system)
NASS	National Agricultural Statistics Service
NCTR	National Center for Toxicological Research
NMFS	National Marine Fisheries Service
ORA	Office of Regulatory Affairs
USDA	U.S. Department of Agriculture

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United States Government Accountability Office  
Washington, D.C. 20548

March 30, 2005

The Honorable George V. Voinovich  
Chairman, Subcommittee on Oversight of Government  
Management, the Federal Workforce, and the District of Columbia  
Committee on Homeland Security and Governmental Affairs  
United States Senate

The Honorable Jon Porter  
Chairman, Subcommittee on the Federal Workforce  
and Agency Organization  
Committee on Government Reform  
House of Representatives

The Honorable Jo Ann Davis  
House of Representatives

The statutory framework underlying the U.S. federal food safety system gives responsibility for specific food commodities to different agencies and provides them with significantly different authorities and responsibilities. As a result, federal agencies are spending resources on similar activities to ensure that the food supply is safe, wholesome, and appropriately labeled. Over the years, we have documented many problems resulting from the fragmented nature of the federal food safety system and have recommended streamlining food safety statutes and consolidating food safety functions into a single agency.<sup>1</sup> As the Comptroller General noted in testimony before the Congress, redundant, unfocused, and uncoordinated programs waste scarce resources, confuse and frustrate program customers, and limit overall program effectiveness.<sup>2</sup> The food safety challenges are more pressing today as we face the potential threat of deliberate contamination of our food supply.

Multiple federal agencies are involved in food safety activities, but four agencies play key roles and invest the largest share of resources to ensure the safety and quality of food. These agencies—the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), the

<sup>1</sup>GAO, *Federal Food Safety and Security System: Fundamental Restructuring Is Needed to Address Fragmentation and Overlap*, [GAO-04-588T](#) (Washington, D.C.: Mar. 30, 2004).

<sup>2</sup>GAO, *Results-Oriented Government: Shaping the Government to Meet 21<sup>st</sup> Century Challenges*, [GAO-03-1168T](#) (Washington, D.C.: Sept. 17, 2003).

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Environmental Protection Agency (EPA), and the National Marine Fisheries Service (NMFS)—expended nearly \$1.7 billion and devoted nearly 15,000 staff in fiscal year 2003,<sup>3</sup> the most recent year for which the agencies could provide complete expenditure data, on activities that included (1) inspecting food manufacturers, processors and warehouses; (2) researching and implementing methods to reduce the prevalence of foodborne pathogens; (3) assessing risks posed by various food contaminants; and (4) educating industry about new regulatory requirements and the public about food safety issues. These agencies operate under 30 primary laws underpinning the legal framework for ensuring the safety and quality of the food supply. (See app. IV.)

Of the federal agencies involved in food safety activities, USDA and FDA have most of the regulatory responsibility for overseeing industry's compliance with federal regulations to ensure food safety and also account for most federal spending in this area. USDA is responsible for ensuring the safety of meat, poultry, and certain egg products under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FDA is responsible for ensuring the safety of all other food—including whole shell eggs, seafood, milk, grain products, and fruits and vegetables—under the Federal Food, Drug and Cosmetic Act and the Public Health Service Act. In addition, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) gave FDA the authority to commission other federal officials to inspect FDA-regulated foods.<sup>4</sup> USDA and FDA enforce their respective Hazard Analysis and Critical Control Point (HACCP) regulations. These regulations require that food processors 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. EPA and NMFS also have related food safety and quality responsibilities. EPA sets pesticide tolerances for food under the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug and Cosmetic Act and issues fish consumption advisories under the Clean Water Act. NMFS conducts voluntary, fee-for-service inspections of seafood-processing facilities and seafood products under the Federal Agricultural Marketing Act of 1946, the Fish and Wildlife Act of 1956, and Reorganization Plan No. 4 of 1970.

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<sup>3</sup>USDA, FDA, EPA and NMFS devoted a combined 14,690 full-time equivalents to food safety-related activities in fiscal year 2003.

<sup>4</sup>Section 314 of the Bioterrorism Act outlines FDA's authority to commission other federal officials to conduct inspections. Pub. L. No. 107-188, § 314, 116 Stat. 594, 674 (2002).

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To coordinate activities across jurisdictional boundaries, these federal agencies have entered into dozens of interagency agreements that address a wide range of food safety-related activities.<sup>5</sup> The agreements concern numerous functions and activities, including how the agencies carry out inspections, public education and outreach, and research projects.

Because of your continuing interest in the efficient and effective use of government resources, you asked us to (1) identify overlaps that may exist in federal food safety functions and activities, (2) examine the extent to which federal food safety agencies are using interagency agreements to leverage existing resources and reduce any such overlaps, and (3) obtain the views of regulated industry and other stakeholders regarding opportunities to reduce overlap by consolidating federal food safety functions.

In addressing these questions, we defined overlaps as similar activities being performed by more than one agency—such as training food inspectors—and 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. To identify overlaps, we obtained and analyzed agency budget data—including actual expenditures and staffing levels for fiscal year 2003, the most recent year for which data were complete—and contacted agency budget and program officials to help us identify what activities the agencies perform and to determine whether similar activities were performed by more than one agency. To examine the extent of interagency coordination, we identified and reviewed all active interagency agreements. We selected two inspection-related interagency agreements for in-depth review because the agencies spend most of their resources on inspection activities; one agreement that pertains to dual jurisdiction establishments and one that pertains to inspections of fishery products. In addition, these agreements encompassed a broad range of intended coordination efforts between the agencies involved. To obtain information about the agreements' implementation, we conducted site visits to USDA and FDA field offices in three locations. To identify key stakeholders and obtain their views on overlapping agency functions and potential

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<sup>5</sup>Interagency agreements include memoranda of understanding, memoranda of agreement, and other agreements between agencies. FDA defines interagency agreements as those that involve an exchange of funds, personnel, or property. We did not include this type of agreement in our analysis.



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consolidation of these functions, we relied on our previous work and on the four agencies' recommendations. Based on this information, we compiled a list of 35 stakeholders from the major industry associations, consumer groups, and food safety experts from academia and conducted structured interviews with them. In addition, we interviewed two to four company representatives in the three states where we conducted field work. We performed our work between May 2004 and March 2005 in accordance with generally accepted government auditing standards, which included an assessment of data reliability and internal controls. Appendix I describes our methodology in greater detail.

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## Results in Brief

We identified several overlapping food safety activities that occur at multiple agencies because the agencies operate under different statutes, which give them responsibility for conducting similar activities for different food products, and different regulatory and enforcement authorities. As a result, federal agencies are spending resources on overlapping food safety activities designed to ensure the safety and quality of domestic and imported food. In some cases, the agencies conduct these activities at the same locations. For example:

- *Domestic inspections.* In fiscal year 2003, USDA and FDA spent most of their food safety resources—about \$900 million—on inspection and enforcement activities. A portion of these activities included overlapping and even duplicative inspections of 1,451 domestic food-processing facilities that produce multi-ingredient foods, such as canned goods and frozen entrees. Both agencies inspect these facilities, because each agency has statutory responsibility for the safety of different foods or food ingredients. For example, 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. Although neither USDA nor FDA could estimate the total costs associated with inspecting these facilities, FDA estimates that it spends about \$4,000 per inspection. According to some industry officials, having two different regulatory agencies inspect a single facility can be burdensome. At a facility we visited that produces crab cakes and breaded chicken, the manager told us that he must maintain separate seafood and poultry HACCP plans and that separate inspections are required for each. The manager said this duplication is

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confusing because the agencies are using the same model, but their expectations for the plans' content differ. Under the Bioterrorism Act, FDA could commission USDA officials to perform food inspections on its behalf at those establishments under the jurisdiction of both agencies, thereby making better use of its resources and reducing industry burden. FDA has not yet exercised this authority with respect to commissioning USDA officials.

- *Import inspections.* USDA and FDA both inspect shipments of imported food at ports of entry and also visit foreign countries that export food to the United States. We found that both USDA and FDA maintain inspectors at 18 U.S. ports of entry to inspect imported food. In fiscal year 2003, USDA spent almost \$16 million on imported food inspections, and FDA spent more than \$115 million. The two agencies do not share inspection resources at these ports. For example, USDA officials told us that all USDA-import inspectors are assigned to, and located at, a USDA-approved import inspection facility. They also told us that some of these facilities handle and store FDA-regulated products, but USDA has no jurisdiction over these FDA-regulated products. Although USDA maintains a daily presence at these facilities, the FDA-regulated products may remain at the facilities for some time awaiting FDA inspection. FDA also conducted inspections in 6 of the 34 countries that USDA evaluated in 2004 to determine whether their food safety systems for ensuring the safety of meat and poultry are equivalent to that of the United States. FDA officials said they do not use USDA's evaluations of the foreign countries' food safety systems and that USDA's findings would be of little use to FDA because they relate to products under USDA's jurisdiction.
- *Inspectors' training.* Both USDA and FDA spend resources to provide similar training to food inspection personnel. USDA spent \$7.8 million and FDA spent about \$1.6 million in fiscal year 2003. We found that, to a considerable extent, food inspection training addresses the same subjects—such as plant sanitation, good manufacturing practices, and HACCP principles. However, the programs differ in that they include HACCP training on specific products, such as seafood or poultry. While taking into consideration product-specific training differences, the agencies could explore opportunities to merge training resources, as has been done by consolidating federal law enforcement training in the Federal Law Enforcement Training Center.

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- *Other overlapping activities.* We identified overlapping activities in research and risk assessments, development of education materials for industry and consumers, and rulemaking. For example, USDA and FDA each developed and issued separate HACCP rules, which are based on the same model but applied to different food products. Because different food products present different risks, separate HACCP plans may be required to address individual food products. These rules require companies to maintain a plan that identifies hazards that are most likely to contaminate food in the production process and establish appropriate control mechanisms to reduce those hazards. FDA estimates that it spent between \$650,000 and \$1 million to develop and promulgate its 1995 seafood HACCP rule; NMFS spent \$5 million in efforts that supported FDA's seafood HACCP rule. USDA was unable to calculate how much it spent to develop its meat and poultry HACCP rule.

We also identified 71 interagency agreements that the principal food safety agencies—USDA, FDA, EPA, and NMFS—have entered into that are designed to better protect the public health by addressing jurisdictional boundaries, coordinating activities, reducing overlaps, and leveraging resources. However, the agencies' ability to take full advantage of these agreements is hampered by the absence of adequate mechanisms for tracking them and, in some cases, by ineffective implementation of the agreements' provisions. 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. 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 to permit more efficient use of both agencies' resources at jointly regulated facilities. 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. Furthermore, an inspection agreement between FDA and NMFS recognizes the agencies' related responsibilities at seafood-processing establishments that are inspected by FDA and also inspected by NMFS under contractual arrangements. The agreement details actions the agencies can take to enable each agency to discharge its responsibilities as effectively as possible and minimize FDA inspections at these facilities. However, contrary to the terms of the agreement, FDA is not using information from NMFS inspections, which could allow it to reduce the number of inspections at those facilities.

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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 food safety system. However, 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, but they differed about whether to consolidate food safety functions into a single federal agency. Specifically, the academics and consumer groups support consolidating food safety functions into a single food safety agency. These groups believe that consolidation would improve the effectiveness and efficiency of the system and ensure that food safety inspections are based on the best available science. Representatives from the individual food companies that both USDA and FDA inspect concurred with that assessment. In contrast, the industry association representatives do not see the need to consolidate federal food safety functions. Proponents and opponents also cited several roadblocks to consolidation, including the need to maintain food security during any transition.

We have previously recommended that the Congress consider streamlining food safety statutes to make them more uniform and risk based and consolidating federal food safety functions under a single agency. We also recognize, however, that improvements short of reorganizing the food safety system can be made to help reduce overlaps and duplication, and to leverage existing resources. In this report, 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 FDA's inspection responsibilities 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.

In commenting on a draft of this report, USDA did not specifically agree or disagree with the report's recommendations, but the agency's general comments on the report appear to indicate that the agency disagrees. USDA asserted that our report oversimplifies food safety authorities, regulations, inspections, and training activities, exaggerates the economic impact of overlaps, and does not accurately address coordination efforts and agreements between USDA and FDA. We disagree with USDA's characterization. Our report is based on numerous discussions with knowledgeable officials as well as a thorough review of the agencies'

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authorities, regulations, inspections, and training activities; but it does not assess the economic impact of overlapping activities. The report provides specific examples of those activities and information on the expenditures each agency incurred to conduct these activities. One of USDA's comments indicates that USDA recognizes the benefits of joint training for food inspectors—one of our report's recommendations. USDA added, however, that several factors affect the feasibility of conducting joint training activities, such as the differences in classification of the job series of individuals performing inspection duties. USDA also commented that our report inaccurately characterizes the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). We disagree. As the report states, FDA is authorized under the act to enter into an agreement to commission other agency officials, including USDA officials, to carry out inspections on its behalf—for FDA-regulated foods—at establishments under the jurisdiction of both agencies. USDA also provided technical comments, which we incorporated in our report, as appropriate. USDA's comments and our detailed response are contained in appendix V.

In commenting on a draft of this report, HHS agreed with three of the report's seven recommendations that the agency (1) use USDA's foreign country evaluations, (2) identify and inventory all food safety-related interagency agreements, and (3) evaluate and update the agreements. FDA stated that it has taken steps to inventory these agreements. HHS disagreed with our recommendation regarding joint training of FDA and USDA food inspectors. The agency commented on, but did not agree or disagree with, our recommendation regarding utilization of the Bioterrorism Act authority to commission USDA officials. Finally, HHS partially concurred with two other recommendations dealing with implementation of two interagency agreements. In its comments, HHS raised concerns about our terminology regarding overlapping activities and said that the report overstated similar activities without specifying the differences. For example, HHS noted that training programs for food inspectors are vastly different due to the fact that USDA inspectors and FDA investigators have very different academic backgrounds and conduct very different inspections. We disagree with HHS's comment. Our report clearly explains the use of terminology as well as the differences in the agencies' activities. HHS also provided technical comments, which we have incorporated in this report, as appropriate. HHS's comments and our detailed response are contained in appendix VI.

EPA did not provide official written comments, but the agency commented that it will consider our recommendation for better tracking of interagency

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agreements when EPA sets priorities for future investments in information technology.

The National Oceanic and Atmospheric Administration (NOAA) provided written comments and agreed with the report's recommendations that pertain to NMFS. NOAA also commented that our report does a fair and thorough job of describing NMFS's food safety activities. NOAA's comments are contained in appendix VII.

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## Background

Many federal agencies, as well as state and local entities, play a part in the U.S. food safety regulatory system. While the federal agencies regulate the food production chain from farms to food manufacturers, state and local agencies primarily regulate food safety in retail food establishments. Table 1 summarizes the food safety responsibilities of the federal agencies. In addition to their established food safety and quality responsibilities, following the events of September 11, 2001, these agencies began to address the potential for deliberate contamination of agriculture and food products, with the Department of Homeland Security providing overall coordination on how to protect the food supply from deliberate contamination.

**Table 1: Federal Agencies' Food Safety Responsibilities**

<b>Department and/or agency</b>	<b>Responsible for</b>	
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) <sup>a</sup>	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 <sup>b</sup>		Coordinating agencies' food security activities
Federal Trade Commission		Prohibiting false advertisements for food

Source: GAO.

<sup>a</sup>According 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.

<sup>b</sup>In 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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The agencies' food safety authorities stem from 30 principal laws related to food safety. For a listing of the principal food safety laws, see appendix IV. As a result of this division of responsibility, the federal food safety system is fragmented. In some instances, agencies perform nearly identical activities—both USDA and FDA inspect food-processing facilities that produce foods under the regulatory responsibility of each agency, referred to as dual jurisdiction establishments (DJE). DJEs are those that manufacture or process food products that contain ingredients regulated by more than one federal agency. For example, both USDA and FDA inspect facilities that make canned baked beans with 2 percent or more bacon (a USDA-regulated food) and canned baked beans without meat (an FDA-regulated food). While these agencies each perform food safety inspections, the frequency of their inspections varies.<sup>6</sup> Generally, USDA inspectors have a more regular presence at DJEs. As another example, both FDA and NMFS inspect seafood-processing facilities, although NMFS's inspections are conducted at the request of the facility through a contract between the facility and NMFS.

Four agencies—USDA, FDA, EPA, and NMFS—are involved in key program functions related to food safety—including inspection and enforcement, research, risk assessment, education and outreach, rulemaking and standard setting, surveillance and monitoring, food security, and administration. Examples of activities under these functions include:

- inspecting domestic food-processing facilities and imported food items at U.S. ports of entry;
- researching foodborne chemical and biological contaminants, as well as reducing foodborne pathogens;
- conducting risk assessments of foodborne physical, chemical, and biological contaminants to inform rulemaking, allocation of agency resources, or risk communication;
- developing and distributing guidance to consumers and industry related to food safety topics such as appropriate food temperatures; and

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<sup>6</sup>Under its statutes, USDA inspects meat and poultry processing facilities at least daily, whereas FDA can determine how often it inspects facilities. FDA's goal is to inspect high-risk facilities at least annually and other facilities every 3 to 5 years.

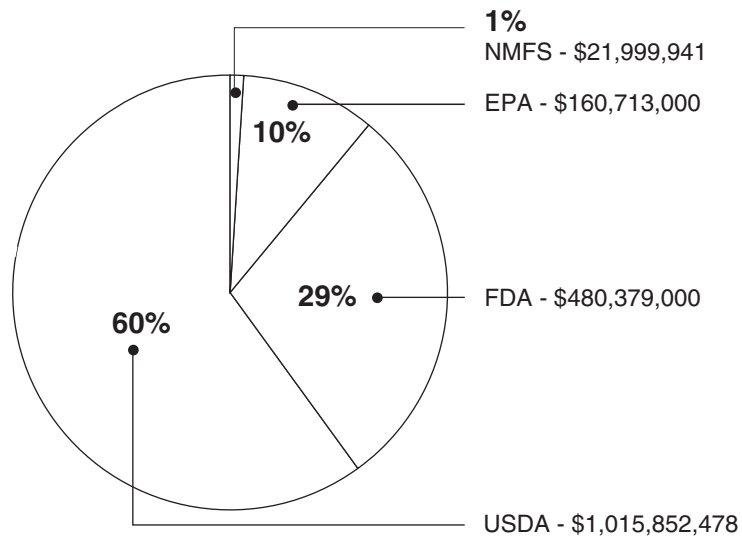


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- issuing/promulgating HACCP, sanitation, and good manufacturing practices regulations.

In fiscal year 2003, the four federal agencies spent nearly \$1.7 billion on food safety-related activities. USDA and FDA are responsible for most federal food safety resources (as fig. 1 shows).

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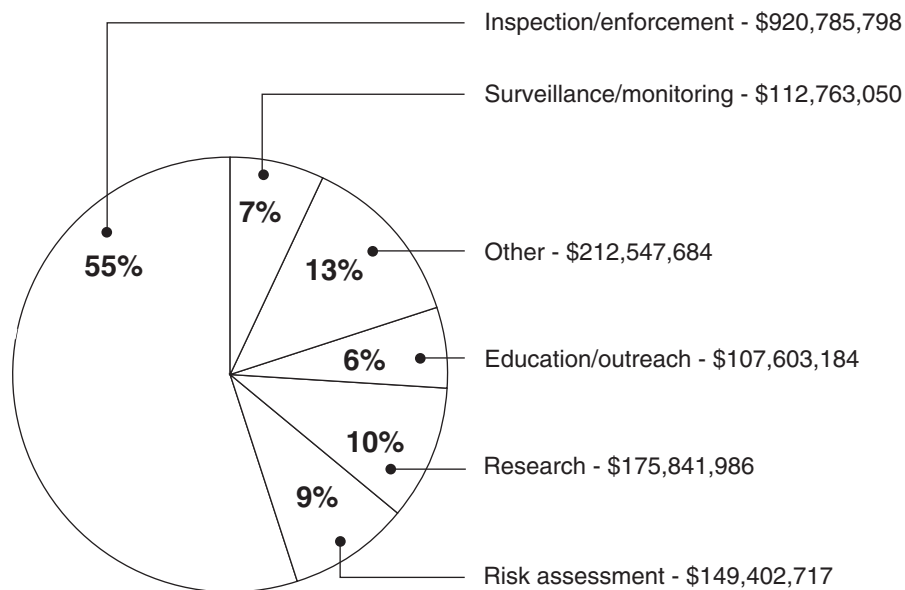
**Figure 1: USDA, FDA, EPA, and NMFS Food Safety Expenditures, Fiscal Year 2003**



Source: GAO analysis of USDA, FDA, EPA, and NMFS expenditures.

These agencies spent about \$921 million (55 percent) in fiscal year 2003 on inspection/enforcement functions, including inspections of domestic and imported food (as fig. 2 shows).

**Figure 2: USDA, FDA, EPA, and NMFS Food Safety Expenditures by Program Function, Fiscal Year 2003**



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

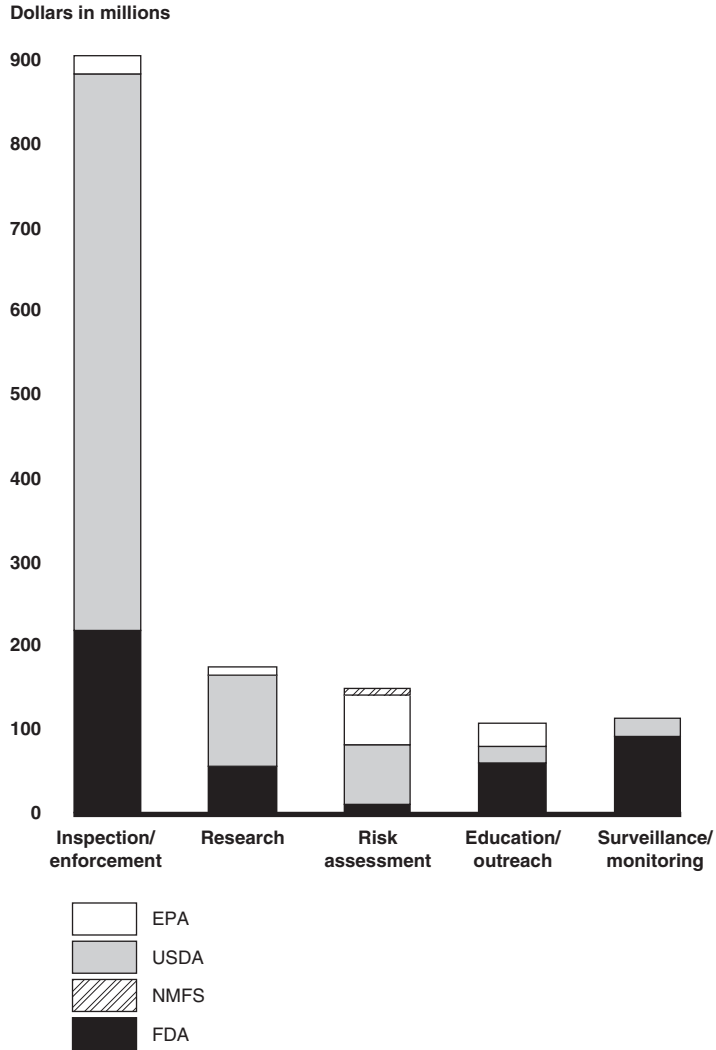
Notes: Program functions are based on the National Academy of Science's 1998 report *Ensuring Safe Food*.<sup>7</sup> These categories include: monitoring/surveillance, inspection/enforcement, education/outreach, research, and risk assessment. To capture other relevant activities, we include three additional functions—administration, food security, and rulemaking/standard setting—in the function “other.” Expenditures for these functions were provided by some agencies, but not others. The agencies that did not provide estimates of these expenditures reported that they are distributed among other functions.

USDA's Food Safety and Inspection Service did not provide Surveillance expenditure data.

The agencies' expenditures vary by program function (as shown in fig. 3). For example, USDA's inspection/enforcement expenditures made up almost three-quarters of the total spent by these agencies for that program function. That is, the majority of federal food safety inspection expenditures are directed toward USDA's programs for ensuring the safety of meat, poultry, and egg products. In contrast, FDA accounts for more than half of the agencies' expenditures for food safety education/outreach programs.

<sup>7</sup>National Research Council and Institute of Medicine, *Ensuring Safe Food: From Production to Consumption* (Washington, D.C.: 1998).

**Figure 3: Food Safety Expenditures (dollars) by Agency and Function, Fiscal Year 2003**



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

Appendix II provides detailed information on the agencies' expenditures and staffing levels devoted to the various program functions in fiscal year 2003.

## Federal Food Safety Agencies Spend Resources on Overlapping Food Safety Activities

As a result of the multiple laws and regulations governing food safety, several federal agencies conduct activities—inspections of domestic and foreign foods, training, research, risk assessment, education, and rulemaking—that can serve overlapping, if not identical, purposes. As a result, federal agencies spend resources on similar food safety activities. Table 2 illustrates similar activities conducted by the four federal agencies we examined. These activities, such as laboratory analysis and risk assessment, may be product specific.

**Table 2: 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	•	•		• <sup>a</sup>

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

<sup>a</sup>NMFS participated in development of FDA's seafood HACCP rule.

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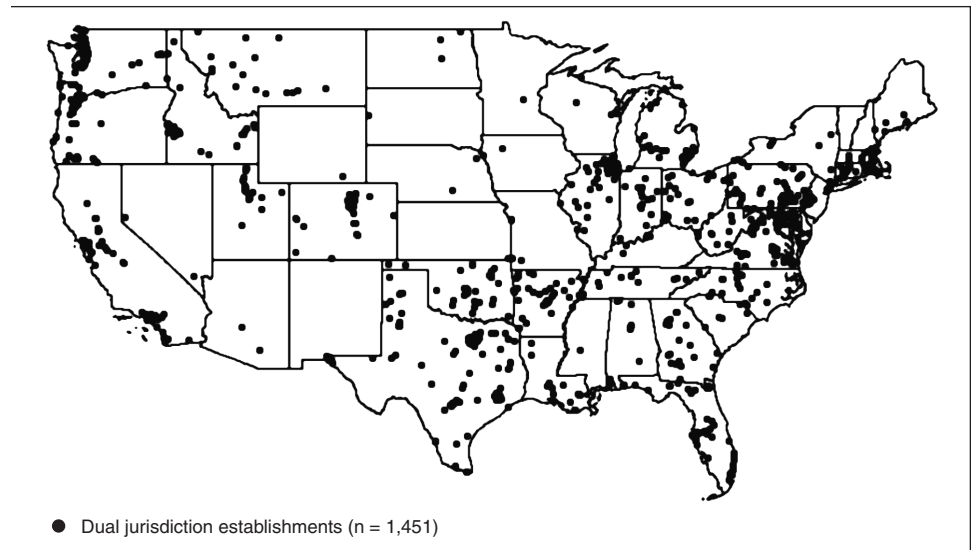
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## Agencies Conduct Overlapping Inspections at Jointly Regulated Food-Processing Facilities

USDA and FDA spent \$884 million in fiscal year 2003 on inspection and enforcement activities—roughly 60 percent of their total food safety expenditures. Neither USDA nor FDA has estimated the total costs associated with inspecting jointly regulated facilities. FDA estimated that it spends about \$4,000 per inspection. As figure 4 shows, USDA and FDA both inspect 1,451 known DJEs located across the country.<sup>8</sup> USDA and FDA inspect these establishments with different frequencies. For example, USDA inspects a canning facility at least daily if it produces food containing meat and poultry. If the facility also produces canned soups containing beans or seafood, FDA inspects it every 1 to 5 years.

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**Figure 4: Location of Food Manufacturers, Warehouses, and Other Types of Food Establishments Inspected by Both USDA and FDA**



Source: GAO analysis of USDA and FDA establishment data.

Note: DJEs in Puerto Rico (39), Hawaii (10), and Alaska (18) are not shown in the figure.

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<sup>8</sup>According to FDA officials, these establishments include 772 food manufacturers, 539 warehouses, and 140 other types of establishments such as retailers, importers, packers, and labelers. The agency is verifying about 400 potential additional DJEs.

Because of their split jurisdiction, each agency is responsible for inspecting different food products at these facilities; but the agencies' inspections have common key elements, including verifying the facilities' compliance with sanitation standards (as defined by USDA) or good manufacturing practices (as defined by FDA). For example, both agencies' inspectors verify that facilities do not have rodent or insect infestations. Figure 5 summarizes some of the common elements of USDA and FDA inspections.

**Figure 5: Common Elements of USDA and FDA Inspections**

Hazard Analysis and Critical Control Point:	Sanitation:	Good Manufacturing Practices:
<ul style="list-style-type: none"> <li>• Check to ensure facility maintains a HACCP plan that identifies potential sources of food contamination</li> <li>• Check to ensure the facility is implementing its HACCP plan</li> </ul>	<ul style="list-style-type: none"> <li>• Check food contact surfaces</li> <li>• Check for pests</li> <li>• Check the facility's hand-washing area</li> </ul>	<ul style="list-style-type: none"> <li>• Check cleanliness of employees' outer garments and gloves</li> <li>• Check equipment design to see if it is cleanable and properly maintained</li> </ul>

Source: GAO analysis of FSIS and FDA documents.

At jointly regulated facilities, USDA and FDA inspectors also 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. The 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.<sup>9</sup> For example, at a facility we visited that produces both crab cakes and breaded chicken, the manager is required to maintain a seafood HACCP plan and a poultry HACCP plan. The manager 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 have new tools that could help reduce overlaps in inspections. Under the Bioterrorism Act, FDA could allow USDA

<sup>9</sup>Separate HACCP plans are generally necessary to address the specific hazards associated with specific food products.

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inspectors, who are present every day at these jointly regulated facilities, to inspect FDA-regulated food.<sup>10</sup> 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. 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 authorizing USDA officials to conduct FDA inspections at these facilities. USDA officials commented that their inspectors are fully occupied and that they would need to be trained before conducting joint inspections.

Overlaps also occur at seafood-processing facilities that both FDA and NMFS inspect. NMFS currently inspects approximately 275 domestic seafood facilities that FDA also inspects. NMFS safety and sanitation inspections, as well as other product quality inspections are conducted 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 NMFS and FDA 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 disagree with FDA's viewpoint, stating that their fee-for-service structure does not affect their ability to conduct objective inspections. NMFS officials said that, 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, 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's contracts with individual companies. If FDA were to recognize the

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<sup>10</sup>Under 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.

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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.

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## USDA and FDA Conduct Inspections of Food Imports

Both USDA and FDA maintain inspectors at 18 U.S. ports of entry to inspect imported food products. In fiscal year 2003, USDA spent almost \$16 million on these inspections, and FDA spent more than \$115 million.<sup>11</sup> FDA spends about 7 times as much on import inspections because the agency is responsible for about 80 percent of the U.S. food supply, including imports from about 250 countries, compared with USDA's responsibility for inspecting imports that come from 34 countries. However, the agencies are not leveraging inspection resources at these ports. USDA officials told us that FDA-regulated, imported foods are sometimes stored in USDA-approved inspection facilities at these ports. USDA inspectors have no authority to inspect FDA-regulated products, although USDA inspectors are present at these ports more often than FDA inspectors. As a result, some FDA-regulated products may remain at the facility for some time awaiting inspection. FDA has the authority to commission federal officials to conduct inspections at jointly regulated facilities. In 2003, FDA exercised this authority to conduct inspections by entering into an agreement with the Department of Homeland Security's Customs and Border Protection (CBP) so Customs' officials can help FDA inspect products at ports and other facilities subject to CBP jurisdiction.

FDA could also leverage USDA's efforts to ensure the safety of imported food by using information that USDA compiles in its determinations that exporting countries' food safety systems are equivalent to the U.S. system. Under the Meat and Poultry Products Inspection Acts, the Secretary of Agriculture is required to certify that countries exporting meat and poultry

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<sup>11</sup>Ports of entry at which USDA and FDA inspectors are each present include Baltimore/Dundalk, Maryland; Blaine, Washington; Boston, Massachusetts; Buffalo, New York; Champlain, New York; Detroit, Michigan; Eastport/Porthill, Idaho; Houston, Texas; Jacksonville, Florida; Laredo, Texas; Los Angeles, California; New Orleans, Louisiana; New York, New York; Newark, New Jersey; Pembina, North Dakota; Savannah, Georgia; Seattle/Tacoma, Washington; and Sweetgrass, Montana.



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to the United States have equivalent food safety systems for producing meat and poultry products that are exported to the United States.<sup>12</sup> That information could inform FDA's decision making about which countries to visit for its overseas inspections. Currently, FDA visits foreign countries to inspect individual food-processing firms. In 2004, USDA determined that the food safety systems of 34 countries it evaluated were equivalent to that of the United States. A substantial portion of what USDA evaluates—sanitation procedures and compliance with HACCP rules—could be useful to FDA in deciding what countries to visit when conducting inspections of foreign firms that export products under its jurisdiction. FDA officials told us, however, that the agency does not use that information when deciding which countries to visit. As a result, FDA at times conducts inspections in the same countries that USDA has evaluated. For example, USDA and FDA each visited Brazil, Costa Rica, Germany, Hungary, Mexico, and Canada last year. USDA spent almost \$500,000, and FDA spent almost \$5 million, on its foreign country visits in fiscal year 2003. USDA and FDA officials said these agencies do not share information from their overseas visits because their different statutory responsibilities make such information of little advantage. That is, USDA's focus during foreign country visits is to evaluate the meat and poultry inspection systems to determine if they are equivalent to that of the United States, whereas FDA focuses its visits on specific companies that produce food under the agency's jurisdiction.<sup>13</sup>

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### Agencies Maintain Similar Inspection Training Programs

USDA and FDA provide similar training to their inspectors. For example, both agencies train inspectors on sanitation requirements, good manufacturing practices, and HACCP. Agency officials agreed that the training programs have a common foundation but pointed out that there are differences, as each agency applies these principles to the specific foods it regulates. USDA spent \$7.8 million, while FDA spent about \$1.5 million, during fiscal year 2003 to train their food inspection personnel.<sup>14</sup> FDA's comparatively lower training costs reflect a contractual agreement with a private firm that has produced an online curriculum. This curriculum includes over 106 courses that address topics common to both

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<sup>12</sup>FDA has no similar requirement.

<sup>13</sup>According to FDA, in some foreign countries, meat and poultry inspection programs are separate from other food inspections, as they are in the United States.

<sup>14</sup>FDA officials told us that their training expenditures include training that can be applied to products other than food, such as medical devices.

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USDA and FDA—ranging from foodborne pathogens, HACCP requirements, and good manufacturing practices, to courses that are specific to FDA’s regulations and enforcement authorities. Another agency—NMFS—uses 74 of these online courses to train its own seafood inspectors. The benefits NMFS officials cited include accessibility to training materials at times other than when inspectors are “on duty” and no charge to NMFS for the training materials. USDA officials said they are exploring the possibility of entering into an agreement with the company that developed FDA’s online curriculum to allow USDA inspectors access to some of this training. In addition to the costs associated with developing inspector training programs, USDA estimates that it spends an average of about \$900,000 per year on training-related travel, not including other costs related to replacing inspectors in food-processing facilities while they participate in the training. A joint USDA-FDA training program could reduce duplication in developing training materials and in providing instruction, and potentially achieve some savings.

Other federal agencies have consolidated training activities that have a common purpose and similar content. For example, in 1970, the Consolidated Federal Law Enforcement Training Center (the Center) brought together the training programs of 75 federal law enforcement agencies that had maintained separate training programs. Specifically, the Center provides standardized programs for criminal investigators and uniformed police officers across the federal government. While standardizing basic training, the Center also offers specialized courses for individual agencies to address their particular needs. In addition, according to the Center, the interaction with students from other agencies promotes greater understanding of other agencies’ missions and duties, and therefore provides for a more cooperative federal law enforcement system.<sup>15</sup>

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## Agencies Conduct Other Activities That Overlap

We identified overlapping activities in the areas of food safety research and risk assessment, consumer and industry education, and rulemaking.

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<sup>15</sup>GAO, *Federal Law Enforcement Training: Capacity Planning and Management Oversight Need Improvement*, [GAO-03-736](#) (Washington, D.C.: July 24, 2003). In 2003, we reported that the Center had played a vital role in training law enforcement personnel since its inception. The report noted that since the September 11, 2001 attacks, the Center’s overall capacity to provide training was strained and made several recommendations for addressing this issue.

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## Food Safety Research and Risk-Assessment Efforts

USDA and FDA participate in similar food safety research efforts; that is, both agencies collect and analyze food samples for chemical and biological contaminants. During fiscal year 2003, the agencies spent over \$245 million on these types of activities. For example, because of the agencies' split jurisdiction, both USDA and FDA maintain separate laboratory capability to sample and analyze the foods that they regulate for chemical contaminants such as pesticides and dioxins.<sup>16</sup> EPA uses USDA and FDA data to inform EPA's risk assessments on human exposure to pesticides. Specifically, in 2003, FDA analyzed 11,331 food samples for pesticides and chemical contaminants to help estimate the dietary intake of pesticide residues. In 2000, the most recent year for which data are available, USDA's Food Safety and Inspection Service (FSIS) analyzed over 33,000 samples of meat, poultry, and egg products. In addition, USDA's Agricultural Marketing Service's (AMS) Pesticide Data Program samples and tests commodities across the food spectrum to help inform EPA in making decisions on acceptable levels of pesticide residues (tolerances). According to EPA officials, USDA data are their primary source of information. However, FDA provides additional information on a greater range of foods and chemicals that EPA also uses to form its decisions. EPA officials said that the overlap in data collection and analysis adds value because USDA's data comes from a well-controlled survey of food samples taken at the wholesale level, and FDA's data helps fill in the gaps with samples of food at different points in the distribution chain.

USDA and FDA also both conduct risk assessments of foodborne pathogens that can contaminate food products under their respective jurisdictions. For example, in 2000, USDA released a draft risk assessment for *Escherichia coli* (*E. coli*) O157:H7 in ground beef and, FDA released a draft risk assessment for *Vibrio parahaemolyticus* in raw molluscan shellfish. The agencies also conduct joint risk assessments when addressing the same pathogen or the same food product. In the case of eggs, regulatory responsibility shifts as eggs make their way from the farm to the table, with FDA being primarily responsible for the safe production and processing of eggs still in the shell (known as shell eggs), and USDA being responsible for food safety at the processing plants where eggs are broken to produce egg products. In 1996, the agencies began work on a joint risk assessment for salmonella in eggs to evaluate the risk to human health of salmonella in shell eggs and in liquid egg products and to identify

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<sup>16</sup>FDA officials said USDA and FDA look for different levels of dioxin in food products they regulate.

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potential risk reduction strategies. In 1998, USDA and FDA jointly published an advance notice of proposed rulemaking, based on this risk assessment, to identify farm-to-table actions that would decrease the food safety risks associated with eggs. However, the agencies have not issued a joint rule to help eliminate foodborne illnesses caused by salmonella in eggs. In 2004, FDA issued a proposed rule that would require shell egg producers to implement measures to help prevent salmonella from contaminating eggs on the farm. Although USDA released a new draft risk assessment in 2004, the department has not yet issued a proposed rule to help prevent salmonella from contaminating egg products. Both agencies have also committed personnel resources to a World Health Organization effort to conduct a risk assessment of salmonella in eggs and broiler chickens.

## Consumer and Industry Education

USDA, FDA, and EPA conduct education and outreach on food safety—and spent more than \$107 million in fiscal year 2003.<sup>17</sup> In some cases, these agencies' efforts overlap. For example, these agencies create and distribute educational materials to consumers, or host hotlines or other forums that address food safety issues. In some cases, these efforts target the same food safety topic. For example, USDA, FDA, and EPA each develop consumer guidance on chemical food contaminants such as pesticides, dioxin, and mercury. In addition, USDA and FDA each develop similar food safety guidance for (1) consumers on general topics, such as cooking and chilling food, and safe handling practices, such as using a food thermometer and (2) industry, on their HACCP regulations and sanitation and good manufacturing practices. These overlapping efforts, caused in part by the agencies' divisions in jurisdiction, can be confusing to both consumers and industry representatives. For example, USDA officials said they receive calls from consumers and industry representatives to their consumer hotline about FDA-regulated food products. These agencies have made some efforts to reduce overlaps in their consumer education activities. For example, USDA and FDA developed the "Fight Bac" program to educate the public about safe food handling to help reduce foodborne illness. In addition, for the first time in 2004, FDA and EPA issued a joint consumer advisory about mercury in fish and shellfish for women who

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<sup>17</sup>USDA program offices include the Cooperative State Research, Education and Extension Service, Economic Research Service, and the Food Safety and Inspection Service. FDA program offices include the Center for Veterinary Medicine and the Office of Regulatory Affairs. EPA program offices include the Office of Pesticide Programs and the Office of Water.

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might become pregnant, who are pregnant, who are nursing, as well as for young children. However, the joint advisory recommends different consumption levels, depending on whether the fish is commercially caught (regulated by FDA) or recreationally caught (regulated by EPA). Specifically, for fish purchased from a store, the guidance recommends up to 12 ounces per week. However, if the fish is recreationally caught, the guidance recommends that women consume up to 6 ounces per week. EPA said that the consumption guidance differs due to different mercury levels in recreationally and commercially caught fish.

### Rule-Making Activities Vary but Share Some Similarities

As the principal agencies responsible for food safety, both USDA and FDA engage in rule-making and standard-setting activities under their respective statutes. While the rulemakings USDA and FDA undertake vary under those statutes, there are some similarities. For example, USDA and FDA promulgated separate HACCP regulations for industry, but both agencies' regulations require food processors to incorporate certain sanitation processes into their HACCP systems. The HACCP rules are based on the same model, though applied to the different food products each agency regulates.<sup>18</sup> For example, FDA requires seafood-processing facilities to address contaminants that are likely to be found in seafood, such as *Vibrio vulnificus* (a bacteria found in raw seafood, particularly in oysters). USDA requires all meat and poultry processing facilities to address contaminants, such as *E. coli* and salmonella, which are likely to be found in these products. While quantifying the resources dedicated to rule-making activities is difficult for the agencies, the costs are significant. FDA estimates that it spent between \$650,000 and almost \$1 million to issue its seafood HACCP rule in 1995.<sup>19</sup> NMFS officials said they spent \$5 million to support the FDA rule by developing a model seafood surveillance project. USDA was unable to calculate how much it spent to develop its meat and poultry HACCP rule.

In some cases, the agencies collaborate in the early stages of rulemaking. For example, USDA and FDA participated in a joint *Listeria*

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<sup>18</sup>Currently, FDA requires that seafood and juice processing facilities comply with mandatory HACCP regulations. Many HACCP principles are already in place at FDA-regulated low-acid canning facilities. In addition, HACCP is now an option under the pasteurized milk ordinance.

<sup>19</sup>FDA's estimate included research, testing means to verify the standard, legal analysis, economic analysis, policy writing, public comment activities, as well as reviewing the final rule, based on new data and comments received.

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*monocytogenes* (listeria) risk analysis of ready-to-eat foods. However, the agencies will promulgate separate listeria rules for the products under their jurisdiction.

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## Agencies Have Numerous Interagency Agreements to Coordinate Food Safety Activities, but Tracking Mechanisms and Implementation Are Weak

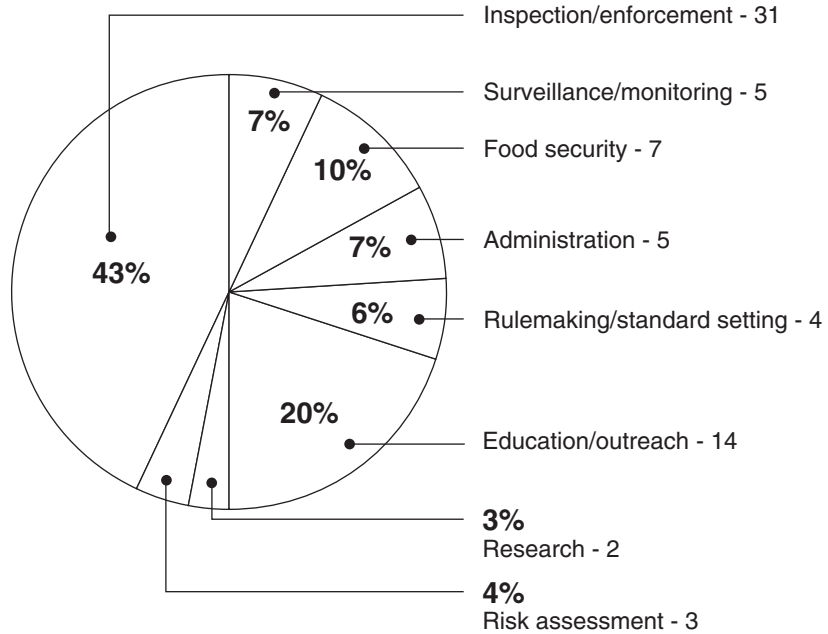
The principal food safety agencies—USDA, FDA, EPA, and NMFS—have entered into 71 interagency agreements to coordinate the full range of their food safety activities and to support their mission to protect the public health. About one-third of the agreements include as objectives, the coordination of activities, reductions in overlaps, and/or leveraging of resources. The agencies’ ability to take full advantage of these agreements is hampered by the absence of adequate mechanisms for tracking them and, in some cases, by ineffective implementation of the provisions of these agreements.

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## Many Interagency Agreements Address Inspection and Enforcement and One-Third Highlight the Need to Reduce Duplication and Overlap

Of the 71 interagency agreements we identified, the largest proportion (43 percent) reflect the agencies agreement to increase cooperation on inspection and enforcement activities. The agencies also spent the largest share of their food safety resources on these activities (as fig. 2 showed). Other agreements address activities such as education/outreach, food security, and monitoring/surveillance related to food safety and quality (as shown in fig. 6). Furthermore, 24 agreements specifically highlight the need to reduce duplication of effort by clarifying responsibilities, reducing overlaps, and/or making efficient and effective use of resources. Appendix III provides additional information about the 71 agreements.

**Figure 6: Food Safety-Related Interagency Agreements by Program Function**



Source: GAO's analysis of USDA, FDA, EPA, and NMFS documents.

In some instances, the agencies entered into multiple agreements to coordinate and ensure the safety of a single type of food. For example, we identified seven agreements that focus on seafood inspection and enforcement activities; signatories to one or more of these agreements include USDA, FDA, NMFS, the Department of Defense, and the Interstate Shellfish Sanitation Conference (ISSC).<sup>20</sup>

In addition to these formal interagency agreements, the agencies cooperate through other mechanisms such as the Foodborne Diseases Active Surveillance Network (also known as FoodNet) that USDA, FDA, and the Centers for Disease Control and Prevention use to help track the incidence of foodborne illness and track the effectiveness of food safety programs in

<sup>20</sup>The ISSC was formed in 1982 by FDA, state regulators, and shellfish industry representatives to develop policies for the safe harvesting, processing, and distribution of fresh and frozen shellfish. FDA must concur with the ISSC's proposed policy changes before they are incorporated into the National Shellfish Sanitation Program's (NSSP) model ordinance.

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reducing foodborne illness. Agency officials also noted that they informally cooperate and collaborate with one another on a regular basis.

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## Controls for Tracking Food Safety Agreements Are Weak

USDA, FDA, EPA, and NMFS do not have adequate mechanisms to track interagency food safety agreements. Consequently, the agencies could not readily identify the agreements that they have entered into, could not determine which agreements are still in effect, and were unable to determine which are still needed. As a result, we could not determine which agreements are currently being used by the agencies. Agency officials did not agree on the number of food safety-related agreements they have entered into, and only 7 of the 71 agreements that we ultimately compiled were identified to us by all signatory agencies. For example, FDA and EPA provided a copy of an agreement they had entered into with USDA about residues in drugs, pesticides, and environmental contaminants in foods; however, USDA officials said the agency is not party to any agreement on residues. Forty-one additional agreements were identified to us by only one of the multiple signatories. In addition, we found three agreements—through our prior work or Internet searches—that none of the agencies had identified to us.

Of the agencies we reviewed, only USDA's Animal and Plant Health Inspection Service maintained a database that allowed it to readily identify all the agreements it was party to. The other agencies did not have such databases. During the course of our review, EPA officials said that, without such tools, they had difficulty identifying the agreements they have entered into. Officials also said they are planning to develop an electronic system to identify and track these agreements. EPA said that, if developed, this system could offer one means of tracking and managing information related to, and contained in, interagency agreements.

The weaknesses in tracking agreements may also affect the agencies' ability to determine whether these agreements are still needed and whether specific provisions are still in effect. First, about one-third of the agreements we identified were created decades ago and may no longer be relevant to current needs. Technological and scientific advances have made some provisions of these agreements obsolete. Second, some agencies that were party to the agreements have ceased to exist because of internal reorganizations; but the agreements have not been modified to reflect such changes, indicating that the agencies may not be actively monitoring the status and relevance of these agreements. For example, a 1978 agreement between USDA and FDA on education programs to assist livestock and



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poultry producers in using animal drugs has not been modified to reflect the fact that USDA's Science and Education Administration no longer exists. Also, we found that some agreements have not been updated to account for changes in a signatory's responsibilities since they were signed. For example, NMFS officials said that the ISSC has taken on some responsibilities that once belonged to NMFS and that the 1985 agreement on shellfish-growing waters signed by FDA, EPA, NMFS, and the U.S. Department of the Interior's Fish and Wildlife Service should be updated to reflect this change.

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### Agencies Are Not Fully Implementing Two Comprehensive Interagency Agreements That Could Eliminate Duplication of Effort and Leverage Resources

Because the agencies spend most of their food safety resources on inspection and enforcement, we evaluated the implementation of two comprehensive inspection and enforcement agreements: one that pertains to DJEs and one that pertains to inspections of fishery products. These agreements were established to make more efficient and effective use of agency resources through improved coordination and information sharing. Although the agencies are exchanging some information as called for in the agreements, they are generally missing opportunities to make more effective and efficient use of their resources, such as leveraging inspection and enforcement resources.

### USDA and FDA Agreement to Exchange Information About Establishments That Are Subject to the Jurisdiction of Both Agencies and to Permit More Efficient Use of Resources

In 1999, USDA and FDA signed an interagency agreement to facilitate the exchange of information between the agencies about food-processing facilities that they both inspect. The agreement stated that the exchange of information will permit more efficient use of both agencies' resources and contribute to improved public health protection. The agreement was to be the first step toward allowing USDA's FSIS inspectors to conduct FDA's inspections at DJEs, according to a former USDA senior food safety official who signed the agreement. The agreement was developed in response to a 1997 report by the President's Food Safety Council,<sup>21</sup> which recommended increased cooperation among agencies. Specifically, the report recommended that USDA and FDA take steps to ensure that the resources and experience of FDA and USDA's FSIS be used as efficiently as possible to avoid duplication of effort and that the agencies consider using FSIS inspectors to conduct FDA inspections at DJEs. The report stated that

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<sup>21</sup>*Food Safety from Farm to Table: A National Food Safety Initiative Report to the President*, May 1997. Food and Drug Administration, U.S. Department of Agriculture, U.S. Environmental Protection Agency, Centers for Disease Control and Prevention. <http://vm.cfsan.fda.gov/~dms/fsreport.html>.

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because FSIS inspectors are already in these plants, they could be used to maximize use of federal resources without loss of inspection coverage for FSIS-regulated foods.

In 2000, USDA and FDA evaluated the agreement's implementation and concluded that the experience had been largely successful because the agencies learned about each other's operations and about ways to cooperate more effectively. However, the evaluation also included recommendations to strengthen, clarify, or otherwise improve the agreement's implementation. Among other things, the evaluation recommended that FDA provide FSIS with access to FDA's inspection database, ensure more frequent updates to the list of jointly regulated facilities, and train inspectors on the provisions of the agreement. The evaluation cited the potential for significant resource savings over time as the agreement is implemented, particularly in personnel, administrative, and travel costs. Since the 2000 evaluation, officials at USDA and FDA said they have not again monitored the agreement's effectiveness, nor have they implemented their own recommendations to realize resource savings.

We found that the agencies are not systematically exchanging information about DJEs, as called for in the agreement. First, the agreement called for USDA and FDA to develop, maintain, and annually update a list of such establishments. We found that although the agencies created such a list in 1999 when the agreement was signed, they had not updated it until 2004, when we brought the matter to their attention. As a result, the agencies had great difficulty identifying the current number of DJEs to which this agreement pertains. For example, during the course of our review, USDA and FDA provided several different lists of jointly regulated establishments. The number of establishments that were listed ranged from 1,152 to 1,867. In December 2004, FDA headquarters officials provided us a list of 1,451 known DJEs, and the agency is verifying approximately 400 establishments that may be added to the list.

Second, the agreement calls for the district offices of each agency to share certain findings with their counterpart district offices and for the agency receiving a finding of noncompliance to track and use that information in its program evaluation, work planning, and consideration of whether action against the facility is warranted. The agreement also calls for the receiving agency to inform the notifying agency of the disposition of the notification, including any actions that it plans or takes, within 30 days. During field visits to three USDA and FDA district offices that, together, are responsible for food safety in 13 states, we found that USDA and FDA field inspection

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personnel are not routinely communicating these findings of mutual concern, such as sanitation problems at facilities they jointly regulate.<sup>22</sup> Nor have USDA and FDA explored the feasibility of developing a system to track and exchange information when each agency finds instances of noncompliance. As a result, work planning by each agency cannot take advantage of the other agency's inspection findings.

Because FDA inspectors visit DJEs less frequently than USDA inspectors, we believe that FDA staff could benefit from the compliance information that USDA inspectors collect.<sup>23</sup> Generally, problems with a facility's manufacturing processes or sanitation procedures affect all products produced at the establishment. As a USDA district official told us, "a rodent doesn't distinguish between FDA-regulated products and USDA-regulated products, so a problem affecting one agency's product is likely to affect the other agency's product."

Third, the agreement calls for the agencies to explore the feasibility of granting each other access to appropriate computer-monitoring systems so 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 past history of compliance with the other agency's regulations. Inspectors told us that compliance information might be helpful when inspecting DJEs so that they could focus attention on past violations.

Fourth, the agreement calls for the agencies to develop and provide appropriate training in the inspectional techniques and processes of each agency to ensure that the contacts for each agency have an appropriate understanding of the working of the other agency. In addition, the 2000 evaluation found that more training was needed, particularly at the field level, to achieve the results of the agreement. Although USDA and FDA held 28 joint training sessions during the first year of the agreement's implementation, no additional training has been provided since then. Because USDA and FDA on-site inspectors are often the first agency staff

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<sup>22</sup>FDA commented that it is the responsibility of district supervisors and district directors to be aware of this agreement and communicate to their local USDA counterparts any cases in which enforcement action was necessary at DJEs. FDA also noted that field personnel could benefit from additional training on the specifics of this agreement.

<sup>23</sup>FDA's goal is to inspect high-risk facilities at least annually and other facilities every 3 to 5 years.

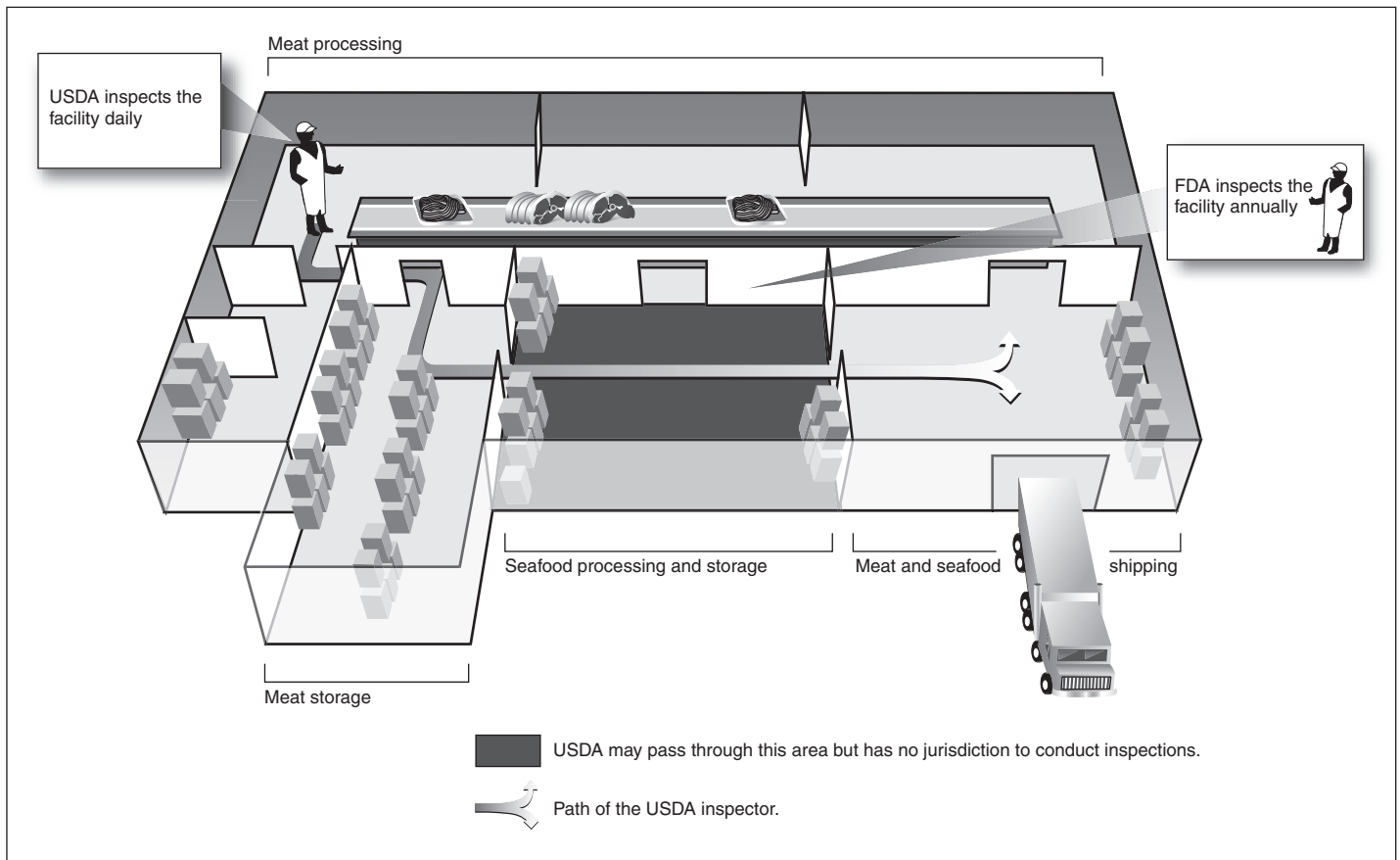
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to become aware of deficiencies at a plant, effective sharing of this type of information depends upon those inspectors being adequately trained.

According to agency officials, the agreement has helped agency coordination and communication, particularly when major public health concerns arise. USDA and FDA headquarters officials identified instances of major enforcement actions resulting from FDA's notification to USDA of problems with products under its jurisdiction. For example, in one case, FDA investigators learned that a sample of chicken salad tested positive for listeria and alerted USDA, resulting in a voluntary recall. In a second case, USDA and FDA cooperated by exchanging information on a severe rodent infestation at a DJE, resulting in the seizure of millions of pounds of USDA- and FDA-regulated product. In addition, USDA and FDA district managers were able to assist each other during the recall of beef and beef products, after the December 2003 discovery of a cow infected with bovine spongiform encephalopathy (BSE, also known as mad cow disease).

However, we found that the stated purpose of the agreement—which is to facilitate an exchange of information permitting more efficient use of both agencies' resources and contributing to improved public health protection—has not been maximized. USDA and FDA are not making better use of each other's inspection resources to reduce overlap and duplication of effort, particularly at establishments that both agencies inspect. Depending on the type and layout of the facility, a USDA inspector may have a more regular presence in an area where FDA-regulated products are maintained. 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. 7). 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 officials at headquarters 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 7: Diagram of a Jointly Regulated Food Processing Facility**



Source: GAO observation of a jointly regulated establishment.

### FDA-NMFS Agreement on Common Responsibilities Regarding Inspection Activities for Fishery Products

A 1974 agreement between FDA and NMFS recognizes the two agencies' related responsibilities for inspecting seafood facilities and standardization activities, and it details actions the agencies can take to enable each agency to discharge its responsibilities as effectively as possible. The agreement states that these actions should minimize FDA inspections in the approximately 275 domestic seafood facilities that NMFS inspects under contract, as long as FDA's inspection requirements are followed. Among other items in the agreement:

- FDA is to (1) request information about NMFS-inspected products when FDA is considering an enforcement action, (2) provide timely

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notification to NMFS of any products seized from NMFS-inspected plants, (3) inform NMFS of FDA industry guidelines and its standards for establishing compliance action levels, and (4) invite NMFS inspectors to observe FDA inspections of companies under contract to NMFS.

- NMFS is to (1) supply FDA headquarters with a list of all NMFS-inspected processing and packing establishments; (2) apply FDA requirements to NMFS-inspected products and establishments and decline to inspect, grade, or certify products that FDA would consider adulterated or misbranded; (3) upon request, provide FDA with information on NMFS-inspected products when FDA is taking or considering compliance action; and (4) cooperate with FDA in investigations of food poisoning, product recalls, and problems concerning food contamination caused by disasters or other phenomena.
- FDA and NMFS may meet periodically and, when appropriate, with industry to promote better communication and understanding of regulations, policy, and statutory responsibilities. If either agency believes that a particular violation is occurring in several seafood-processing plants, it may request a meeting with the other agency to consider investigative steps and, when necessary, mutually agreeable remedial action.

We found that FDA is not using the agreement to minimize its inspections in seafood plants that NMFS has inspected and certified as meeting FDA's safety standards. FDA officials said the agency does not recognize the NMFS inspections as aiding FDA in enforcing pertinent statutes. As a result, FDA is missing opportunities to leverage inspection resources and possibly avoid duplication of effort.

In addition, we found that FDA is not carrying out provisions in the agreement. For example, FDA rarely provides notification of seizure actions it takes against NMFS-inspected plants, as outlined in the agreement. Furthermore, according to a senior NMFS official, NMFS communicates its inspection results to FDA, but FDA does not share its results with NMFS.

FDA officials recently said they do not rely on NMFS' inspection information for two reasons. First, NMFS conducts a fee-for-service inspection, and therefore, FDA officials believe that NMFS could have a

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conflict of interest because, as a nonregulatory body, it is paid for its services by the industry that it inspects. Second, FDA does not know which firms NMFS is inspecting at any given time. FDA officials said the list of firms NMFS inspects changes, depending on market fluctuations that affect each company's need for NMFS' services. Furthermore, FDA officials said that they already have a risk-based system in place to determine which firms to inspect, and at what frequencies, and that NMFS' inspections are not a factor in its determination of risk.

NMFS officials disagreed with FDA's reasons for not using NMFS inspection results. First, they pointed out that NMFS's relationship to industry is similar to USDA's Agricultural Marketing Service, which also conducts fee-for-service grading and certification of poultry, meat, eggs, and other agricultural commodities. Second, NMFS officials said they maintain an up-to-date list of firms that the agency inspects and post this information on its Web site, most recently revised in January 2005.<sup>24</sup> NMFS readily provided us with a list of the firms it was inspecting when we spoke with officials during the course of our review.

Although FDA is not implementing the agreement, the agency 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,<sup>25</sup> the then-Commissioner of Food and Drugs proposed ways that the two agencies could enhance coordination, including commissioning NMFS inspectors to help FDA meet its public health responsibilities. The Commissioner noted 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.

FDA has not used NMFS inspection resources under the terms of the fishery products agreement, nor has the agency used its authority under the Bioterrorism Act to commission NMFS officials. However, FDA used this authority to commission CBP officers to assist FDA at ports of entry. FDA officials said the agency has not yet considered using the act to enter into similar agreements with other federal agencies. NMFS officials said the

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<sup>24</sup>See <http://seafood.nmfs.noaa.gov/ApprovedFacilities.htm>.

<sup>25</sup>NMFS is located within the Department of Commerce's National Oceanic and Atmospheric Administration.

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agency would be willing to enter into such an agreement with FDA, thereby assisting FDA in reaching its goal of conducting annual inspections at all high-risk facilities.

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## Industry and Other Stakeholders Disagree on the Significance of Overlap in the Federal Food Safety System and on How to Improve It

Industry associations, food-processing companies, consumer groups, and academic experts we contacted disagree on the significance of overlapping activities in the federal food safety system. However, most of these stakeholders agree that the laws and regulations governing the system should be modernized so that science and technological advancements can be used to more effectively and efficiently control current and emerging food safety hazards. While we found agreement among the stakeholders about the need for modernization, they differed about whether food safety functions should be consolidated into a single federal agency.

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## Stakeholders Disagree about Overlaps in the Federal Food Safety System

The stakeholders we contacted disagree on whether federal agencies' food safety functions overlap, specifically with regard to inspections. Industry associations that we spoke with, such as the Food Products Association,<sup>26</sup> National Fisheries Institute, American Frozen Food Institute, and Grocery Manufacturers of America, told us that overlaps occur but do not harm the safety of food and therefore are not significant. These overlaps, they noted, occur primarily in dual jurisdiction establishments—those regulated by both USDA and FDA—or facilities inspected by both FDA and NMFS. However, some overlaps occur outside these establishments. For example, although the United Fresh Fruit and Vegetable Association's (UFFVA) member companies are primarily inspected and regulated by FDA, companies that sell fruit and vegetables to the school meals programs are also inspected by USDA. UFFVA officials pointed out that USDA inspects fruits and vegetables to be included in school lunches; and the companies, already subject to FDA inspections, incur additional expenses for these USDA inspections. UFFVA also cited overlaps in USDA's and FDA's sampling and testing for pesticides and microbiological contaminants on fruits and vegetables. Other stakeholders, including the U.S. Tuna Foundation and the American Meat Institute, reported that they do not think the federal agencies' programs overlap because USDA and FDA have

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<sup>26</sup>Prior to 2005, the Food Products Association was known as the National Food Processors Association.



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specific, defined areas of responsibility for their industries. The U.S. Poultry and Egg Association added that the regulatory delineations do not always make sense, citing the split jurisdiction between USDA and FDA over the regulation of eggs. Specifically, FDA regulates an egg farm as a “food factory” within its area of jurisdiction, and USDA regulates plants that process eggs into products such as powdered eggs.

Other stakeholders—generally food companies that are regulated by both USDA and FDA—told us that overlaps can be burdensome. These stakeholders did not see the added value of FDA’s once-a-year (or less) inspections, because USDA inspectors already visit their plants daily. For example, managers at these facilities told us the following:

- At an egg- and potato-processing company, each agency uses different frequencies for monitoring and ensuring food safety, with USDA inspecting the physical plant, usually daily, while FDA’s inspections usually take place annually. According to a senior plant manager, FDA’s inspections place more responsibility for food safety on the company. From the manager’s perspective, the most effective inspection strategy would be to combine elements of both agencies’ inspections into a single inspection program.
- At a facility that produces USDA- and FDA-regulated foods on three different production lines, the facility must maintain different sets of paperwork for each food that the company processes in order to meet USDA and FDA HACCP and sanitation requirements. Since the USDA inspector is at the facility every day, the manager said he does not see any value added by FDA’s inspection because that inspector examines the same areas of the facility—the processing lines and the refrigerated storage area—which are covered by the USDA inspector.
- A facility that cans a variety of soups and bean products experienced contradictory instructions from USDA and FDA during overlapping inspections. USDA inspectors did not want the company to paint its sterilization equipment because they determined that paint chips could contaminate the food. Subsequently, an FDA inspector told the company to paint the same equipment because he determined that it would be easier to identify sanitation problems on lightly painted equipment than on the dark-colored metal. The manager of the facility said the company had to paint and then remove the paint from equipment in order to satisfy both the USDA and FDA inspectors.

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In addition, at a seafood-processing plant that is inspected by both NMFS and FDA, the manager said that when FDA collects product samples for testing, it does not report test results in a timely fashion. According to the manager, NMFS inspections are preferable because the agency is able to provide test results more rapidly than FDA, which, according to the manager, allows the company to know its products are safe before they enter the market.

A few stakeholders also saw value in some of the overlapping activities. For example:

- The American Frozen Food Institute noted that USDA and FDA inspections and their complementary expertise—independent scientific assessment, research, and education—provide value in addressing food safety issues.
- The quality assurance manager at a dual jurisdiction establishment with whom we spoke said he liked having a “second pair of eyes” inspecting the facilities for food safety. The company produces smoked salmon—a high-risk food—and the manager noted that having inspections by FDA and NMFS helps to ensure that products are safe and of high quality.

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### Most Stakeholders Recognize the Need to Modernize the Food Safety System but Differ on What Approach to Take

The majority of stakeholders we contacted said they believed that the federal food safety system needs to be modernized, though they did not agree on what direction this modernization should take. Stakeholders’ views included (1) minor changes to improve coordination among the food safety agencies, (2) statutory changes to make the system more science and risk based, and (3) consolidating federal food safety functions into a single agency.

Some large industry associations (e.g., the Grocery Manufacturers of America, the Food Products Association, the American Frozen Food Institute, the National Fisheries Institute, and the United Fresh Fruit and Vegetable Association) saw the need for only minor changes within the existing regulatory framework to enhance communication and coordination among the existing agencies. Some industry officials said that the current food safety system protects consumers, and they cited decreases in illnesses caused by foodborne bacteria, such as salmonella and listeria. The Grocery Manufacturers of America said that the food safety system must be flexible enough to allow resources to be directed toward identifying and addressing serious food safety problems but that

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this alteration would not require changing the food safety structure. The Grocery Manufacturers of America also reported that the current food safety system could be enhanced, and perhaps made more efficient, through enhanced interagency coordination.

Other stakeholders—including representatives from industry associations, academia, consumer groups, public policy organizations, and individual food companies—believe that the system needs to be modernized through statutory changes to make it more science and risk based. According to the Consumer Federation of America, a science- or risk-based system should consider not only the risk posed by the food but also the history of the plant—whether it has a track record for producing high quality, safe food. Resources for the Future<sup>27</sup> stated that the current food safety laws undermine a successful food safety system. That is, the laws do not build prevention into the farm-to-table continuum and divide responsibility and accountability for food safety among federal agencies. Further, the laws prevent risk-based allocation of resources across the federal food safety agencies. Further, USDA's carcass-by-carcass organoleptic inspections exemplify the outmoded requirements of the current food safety system and cannot identify and control the microbiological hazards associated with meat and poultry products, such as *E. coli* O157:H7. Additionally, such inspections waste resources because new technologies are more efficient and effective. For example, the manager at a jointly regulated canned-goods company told us that daily inspections of meat and poultry products is wasteful and inefficient for most, if not all, heat-processed meat and poultry products, such as canned chicken or pork, since the canning process kills all the bacteria. Some stakeholders, including the Institute for Food Technologists, believe that modernizing the food safety system could be accomplished by rewriting the food safety statutes.

Finally, some of the stakeholders that cited the need for modernization also believe that these changes should be accompanied by consolidation of federal food safety programs into a single agency for the following reasons:

- Consolidation of functions could allow a single food agency to manage the safety of the whole food chain, not just its parts, according to food

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<sup>27</sup>Resources for the Future leads the Food Safety Research Consortium—a multidisciplinary group of academic food safety research institutions—which is funded, in part, by USDA's Cooperative State Research, Education, and Extension Service and was formed to create decision tools needed to build a science- and risk-based food safety system.

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safety experts at the Center for Science in the Public Interest, the Consumer Federation of America, and the University of Illinois.

- Consolidation would eliminate overlap between the agencies, especially at DJEs, according to several individual companies, and could generate substantial savings in terms of administrative efficiency and overall consistency in the application of policy, according to the Food Marketing Institute and food safety experts at Kansas State University and the University of Georgia.
- The legislative changes needed to accomplish consolidation could also be used as the vehicle for modernizing the food safety statutes or establish a scientific basis for distributing food safety resources, according to several individual food companies and food safety experts at the Center for Science at the Public Interest and Resources for the Future.

The stakeholders we contacted also identified a number of roadblocks to changing the system, whether or not they supported such consolidation. First, industry is reluctant to change from a familiar regulatory framework to one that is untested. According to the Food Marketing Institute, food companies tend to prefer the inspection process that is known to them. Second, according to some industry associations, a transition to a single agency could create a period of uncertainty, as limited resources are diverted from the existing programs, and could therefore cause vulnerabilities in the food supply. Third, the transition costs to a single agency would be higher in the short term, according to food safety experts at the University of Illinois and the University of California. Fourth, current agency employees would be concerned that a consolidation would adversely change their working lives and that institutional knowledge would be lost. Finally, some stakeholders, including the Consumer Federation of America, said that some congressional committees may be reluctant to lose jurisdiction over food safety functions.

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## Conclusions

We recognize that current statutory authorities require the food safety agencies to carry out regulatory activities that have resulted in some overlapping or duplicative activities. We have recommended in the past that federal food safety statutes be streamlined and that food safety functions be consolidated into a single agency to ensure the logical and most effective use of government resources and to protect consumers.

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Even within the current statutory framework, the agencies can take practical steps to reduce overlap and duplication and thereby free resources for more effective oversight of food safety. The Congress has recognized this possibility in the Bioterrorism Act by authorizing FDA to commission other agencies' officials to conduct FDA's inspection activities. Other avenues are open to the agencies as well. For example, the two interagency agreements that we examined in detail, could address problems in duplicative inspections if they were more effectively implemented. Other interagency agreements designed to reduce overlap might also prove fruitful. By not effectively implementing these agreements and by not exercising the new authorities under the Bioterrorism Act, the agencies are missing opportunities to make the system more efficient and effective.

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## Recommendations for Executive Action

We are making seven recommendations designed to reduce or eliminate duplication and overlaps, leverage existing resources, and enhance coordination efforts among the principal federal food safety agencies.

We recommend that the Secretary of Agriculture and the Commissioner of the Food and Drug Administration work together to

- ensure the implementation of the interagency agreement that calls for, among other things, sharing inspection- and enforcement-related information at food-processing facilities that are under the jurisdiction of both agencies;
- examine the feasibility of establishing a joint training program for food inspectors; and
- consider the findings of USDA's foreign country equivalency evaluations when determining which countries to visit.

To better use FDA's limited inspection resources and leverage USDA's resources, we recommend that, if appropriate and cost effective, the Commissioner of the Food and Drug Administration, as authorized under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, enter into an agreement to commission USDA inspectors to carry out FDA's inspection responsibilities for food establishments that are under the jurisdiction of both agencies.

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To better use FDA's limited inspection resources and leverage NMFS's resources, we recommend that the Commissioner of the Food and Drug Administration and the Under Secretary of Commerce for Oceans and Atmosphere ensure the implementation of the interagency agreement that calls for FDA to recognize the results of NMFS inspections when determining the frequency of its seafood inspections.

To strengthen management controls and maximize the effectiveness of interagency agreements that are designed to reduce overlap, increase coordination, and leverage resources, we recommend that the Secretary of Agriculture, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, and the Under Secretary of Commerce for Oceans and Atmosphere

- identify and inventory all active interagency food safety-related agreements and
- evaluate the need for these agreements and, where necessary, update the agreements to reflect recent legislative changes, new technological advances, and current needs.

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## Agency Comments and Our Response

We provided USDA, HHS, EPA, and NOAA with a draft of this report for their review and comment. We received written comments on the report and its recommendations from USDA, HHS, and NOAA. EPA provided minor technical comments.

In commenting on a draft of this report, USDA expressed serious reservations about the report, asserting that it oversimplifies food safety regulatory functions within USDA and FDA and that it exaggerates the extent of regulatory overlap. USDA appears to have misinterpreted the focus of this report, and we disagree with USDA's characterization. This report examines overlapping *activities* rather than the *regulatory framework* that allows these activities. Nevertheless, the report contains a clear and accurate acknowledgment that the agencies operate under a statutory framework that gives them different authorities and responsibilities to regulate different segments of the food supply. While we recognize that the agencies operate under different authorities, the activities they perform under these authorities are similar in nature, leading us to question why the federal agencies must continue to spend resources on overlapping, and sometimes duplicative, food safety activities. For example, we disagree with USDA's assertion that the agencies' inspection

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activities are vastly different. As we identify in the report, these inspections have sufficiently common features, including the verification of sanitation procedures and good manufacturing practices at food processing facilities that make them candidates for consolidation within one agency. USDA's comments and our detailed response are contained in appendix V.

In commenting on a draft of this report, HHS raised concerns about our terminology regarding overlapping activities. We disagree with HHS comment that our report's title should substitute the word duplication for overlap. That is, our report distinguishes between "overlap"—which we define as those similar activities being performed by more than one agency and "duplication"—which we define as essentially identical activities performed by more than one agency. Given the definitions we lay out in the report, if we modified the title as HHS suggests, we would risk implying that the agencies are literally duplicating efforts in every instance, even though we are fully aware that, under the current statutory framework, the agencies do not exactly replicate food safety activities. We also disagree with HHS's comment that our report overstates similarities in USDA and FDA inspections because, as our report clearly states, USDA and FDA inspections have similar key elements: sanitation, good manufacturing practices, and HACCP compliance oversight. It also makes it clear that USDA and FDA inspections vary depending on whether the product is a USDA- or FDA-regulated food product. Furthermore, we disagree with HHS's comment that the training programs are vastly different. As our report discusses, FDA's training curriculum includes dozens of courses that address topics common to USDA and FDA. Overall, HHS agreed with three of the report's seven recommendations, including (1) the usefulness of USDA's foreign country evaluations, (2) identifying and inventoring all interagency agreements, and (3) the need to evaluate and update the agreements. HHS disagreed with our recommendation regarding joint training of USDA and FDA food inspectors. HHS took no position on our recommendation for using the Bioterrorism Act authorities. Finally, HHS partially concurred with two other recommendations dealing with the implementation of two interagency agreements. HHS also provided technical comments which we incorporated in our report, as appropriate. HHS's comments and our detailed response are contained in appendix VI.

EPA did not provide official comments, but it provided minor technical comments that we incorporated as appropriate. The technical comments noted that EPA will consider GAO's recommendation for better tracking of interagency agreements when the agency sets priorities for future investments in information technology.

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NOAA provided written comments and agreed with the report's recommendations that pertain to NMFS. NOAA also commented that our report does a fair and thorough job of describing the food safety activities of NMFS. NOAA stated that the positions expressed in GAO's previous work continue to be germane to the issue of coordination with FDA on inspections of seafood.<sup>28</sup> NOAA's comments are contained in appendix VII.

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As agreed with your offices, unless you publicly release the contents of this report earlier, we plan no further distribution until 30 days from the report date. We are sending copies of this report to the Secretary of Agriculture, the Acting Commissioner of the Food and Drug Administration, the Acting Administrator of the Environmental Protection Agency, and the Under Secretary of Commerce for Oceans and Atmosphere. In addition, this report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staffs have any questions concerning this report, I can be reached at (202) 512-3841, or [robinsonr@gao.gov](mailto:robinsonr@gao.gov). Major contributors to this report are included in appendix VIII.



Robert A. Robinson  
Managing Director,  
Natural Resources and Environment

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<sup>28</sup>GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*, [GAO-04-246](#) (Washington, D.C.: Jan. 30, 2004).



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# Scope and Methodology

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To identify overlaps that may exist in the federal food safety system, we collected fiscal year 2003 budget data for food safety-related activities from the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the National Marine Fisheries Service (NMFS).<sup>1</sup> We selected these agencies because they have broad food safety-related inspection and enforcement related responsibilities, the function to which most federal food safety funding is dedicated. We defined overlaps as similar activities being performed by more than one agency, such as training food inspectors. In contrast, we defined duplication as essentially identical activities performed by more than one agency, such as inspecting the same food-processing facility for compliance with sanitation and good manufacturing practices requirements. We used categories of food safety activities contained in the National Academy of Science's 1998 report *Ensuring Safe Food* to group the agencies' food safety activities.<sup>2</sup> These categories include: monitoring/surveillance, inspection/enforcement, education/outreach, research, and risk assessment. We included three additional categories—food security, administration, and rulemaking/standard setting—to capture other relevant activities. We defined the categories of food safety activities into the following program functions:

- **Monitoring/Surveillance**: activities related to the monitoring of foodborne illness or disease, as well as monitoring the agents of illness in the food supply, including the collection of baseline data for contaminants;
- **Inspection/Enforcement**: activities related to ensuring compliance with agency food safety regulations, including premarket application or petition approval;
- **Education/Outreach**: activities related to communicating food safety-related information or guidance to the public, industry, or agencies' other clients;

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<sup>1</sup>Fiscal year 2003 was the most recent year for which data were complete.

<sup>2</sup>National Research Council and Institute of Medicine, *Ensuring Safe Food: From Production to Consumption* (Washington, D.C.: 1998).

- Research: activities related to the study of food safety-related topics, which support agency policy decisions;
- Risk assessment: activities related to evaluation of the likelihood and severity of an adverse event (e.g., illness or death) on the public health as a result of the likelihood of exposure to a particular hazard;
- Food security: activities related to preparing for and responding to deliberate attacks on the food supply;
- Administration: supporting activities that enable the agencies to perform their food safety responsibilities. Examples of administrative activities include: procurement, human resources support, financial management, travel management, and information technology support; and
- Rulemaking/Standard setting: activities related to food safety policy decisions, development of regulations, and administration of regulatory review processes.

Specifically, we obtained actual expenditures and staffing level data in full-time equivalents (FTE) from the following USDA units: Agricultural Marketing Service; Agricultural Research Service; Animal and Plant Health Inspection Service; Cooperative State Research, Education, and Extension Service; Economic Research Service; Grain Inspection, Packers and Stockyards Administration; Food Safety and Inspection Service; and National Agricultural Statistics Service. We also obtained data from the following FDA units: Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, National Center for Toxicological Research, and Office of Regulatory Affairs. EPA's Office of Pesticide Prevention and Office of Water, as well as the NMFS's Seafood Inspection Program and Office of Sustainable Fisheries also provided data. To assess the reliability of the staffing and expenditure data, we questioned knowledgeable agency officials and reviewed existing documentation regarding the data and the systems that produced them. We determined that the data were sufficiently reliable for the purposes of identifying overlaps.

After the agencies provided budget data, we contacted agency budget and program officials to determine what activities were linked to the expenditure and staffing data. We categorized expenditures and staffing and asked agency officials if they considered our categorizations to be appropriate. We adjusted our categorization when agency officials told us it

was inaccurate. In some cases, the agencies' preferred categorization of the same activity varied. For example, FDA considered inspector training as an education/outreach activity, whereas USDA considered it an inspection-related activity. These discrepancies are noted in appendix II. After we categorized the budget and staffing level data, we identified cases in which more than one agency performed similar activities. In some instances, the agencies estimated budget and staffing levels, or they were unable to separate budget data into specific categories. As a result, some agencies did not provide expenditures and staffing data for categories such as administration, food security, and rulemaking. The agencies' officials explained that these expenditures are distributed among more than one of the other categories.

To examine the extent to which federal food safety agencies are using interagency agreements to leverage existing resources to reduce any such overlaps, we requested that agencies provide copies of all active interagency food safety-related agreements, and we selected two agreements to analyze their implementation.<sup>3</sup> We compared the agreements that the agencies provided to determine where there were differences. In the cases where agency signatories provided us an agreement, and one or more agency signatories did not, we followed up with those agencies to reconcile the discrepancies. In some cases, we provided the agreement to an agency to obtain confirmation that it was a signatory to the agreement. We asked the agencies to categorize the agreements according to primary program function. We also independently categorized the agreements using information from their introduction and/or background to ensure consistent categorization across the agencies. If the agencies' categorization differed with ours, we considered their rationale and changed the categorization as appropriate.

We selected two inspection-related interagency agreements for in-depth review because the agencies spend most of their resources on inspection activities; one agreement that pertains to dual jurisdiction establishments (DJE) and one that pertains to inspections of fishery products. In addition, these agreements encompassed a broad range of intended coordination efforts between the agencies involved. We conducted site visits to three

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<sup>3</sup>USDA, EPA, and NMFS supplied agreements in the form of memoranda of agreement, interagency agreement, and memoranda of understanding. We included interagency agreements that, according to FDA do not involve an exchange of people, property, or funds—what the agency refers to as memoranda of understanding.

USDA and FDA field offices to obtain information related to implementation of the agreements. The site visits included USDA district offices in Philadelphia, Pennsylvania and Boulder, Colorado; and FDA district offices in Philadelphia, Pennsylvania; Denver, Colorado; and Seattle, Washington, which are responsible for food safety in a total of 13 states. We met with USDA and FDA district managers, inspectors, and other staff to discuss the agreement's implementation. We also selected two to four DJEs at each location and visited them to discuss implementation of the agreements with plant managers and, in some cases, with USDA or FDA inspectors assigned to these facilities. In some cases, we accompanied inspectors as they conducted inspections of the facilities.

To obtain the views of regulated industry and other stakeholders regarding opportunities to reduce overlap by consolidating federal food safety functions, we contacted a total of 35 stakeholders from food industry associations, food manufacturers, consumer groups, and academic experts using a structured interview format consisting of 22 questions. In selecting associations, organizations, and experts, we included contacts from our previous reports and testimonies and considered recommendations from USDA, FDA, EPA, and NMFS. In selecting which food manufacturers to interview, we used Food Processing's Top 100 Companies to identify the largest food manufacturers. Of those companies, we selected and contacted food manufacturers that have facilities that produce food regulated by both USDA and FDA.

We conducted our review from May 2004 through March 2005 in accordance with generally accepted government auditing standards.

# Food Safety Expenditures and Staffing Levels for Fiscal Year 2003

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We asked agencies within USDA, FDA, EPA, and NMFS to provide all expenditures and staffing levels, in FTEs, related to food safety activities they conducted in fiscal year 2003. Tables 3 and 4 categorize these expenditures and staffing levels according to program function. Though most agencies were able to identify expenditures and staffing levels related to inspection and enforcement, research, risk assessment, education and outreach, and monitoring and surveillance—many were unable to provide expenditures linked to rulemaking and standard setting, food security, and administration. For this reason, table 4 containing this data is included separately. As table 3 shows, inspection and enforcement-related spending accounts for most of these agencies' food safety-related spending in fiscal year 2003.

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**Appendix II**  
**Food Safety Expenditures and Staffing**  
**Levels for Fiscal Year 2003**

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**Appendix II  
Food Safety Expenditures and Staffing  
Levels for Fiscal Year 2003**

**Table 3: Food Safety Expenditures and Staffing Levels by Agency, Fiscal Year 2003**

Dollars in thousands

Program function	USDA								Total
	FSIS	ARS	CSREES	NASS	ERS	APHIS	AMS	GIPSA	
<b>Inspection/ Enforcement</b>									
Expenditures	\$636,841					\$28,220		\$100	\$665,162
Staffing level	8,494					293			8,787
<b>Research</b>									
Expenditures		88,724	18,221	2,473	525				109,943
Staffing level		243	4	11	4.5				263
<b>Risk Assessment</b>									
Expenditures	41,408	6,208	2,516		25		21,908		72,065
Staffing level	294	15	0.5		0.25		39		349
<b>Education/ Outreach</b>									
Expenditures	9,993		8,240		50				18,283
Staffing level	82		2		0.5				85
<b>Surveillance/ Monitoring</b>									
Expenditures	<sup>a</sup>				25	22,438			22,463
Staffing level					0.25	94			94
<b>Total expenditures</b>	<b>\$688,242</b>	<b>\$94,932</b>	<b>\$28,977</b>	<b>\$2,473</b>	<b>\$625</b>	<b>\$50,658</b>	<b>\$21,908</b>	<b>\$100</b>	<b>\$887,916</b>
<b>Total staffing</b>	<b>8,870</b>	<b>258</b>	<b>7</b>	<b>11</b>	<b>6</b>	<b>387</b>	<b>39</b>		<b>9,578</b>

**Appendix II  
Food Safety Expenditures and Staffing  
Levels for Fiscal Year 2003**

FDA				EPA	DOC	Grand total	
CFSAN	CVM	NCTR	ORA	Total	NMFS		
\$4,529 <sup>b</sup>			\$214,297 <sup>c</sup>	<b>\$218,826</b>	\$21,798	\$15,000	<b>\$920,786</b>
27			1,817	<b>1,844</b>	4	155	<b>10,790</b>
33,318 <sup>d</sup>	10,571 <sup>e</sup>	7,000 <sup>f</sup>	4,197 <sup>g</sup>	<b>55,086</b>	10,813		<b>175,842</b>
192	53	48	47	<b>340</b>	49		<b>652</b>
8,553 <sup>h</sup>				<b>8,553</b>	61,785	7,000	<b>149,403</b>
70				<b>70</b>	362	57	<b>781</b>
	810 <sup>i</sup>		59,033 <sup>j</sup>	<b>59,843</b>	29,477		<b>107,603</b>
	11		502	<b>513</b>	116		<b>714</b>
72,456 <sup>k</sup>	17,844 <sup>l</sup>			<b>90,300</b>			<b>112,763</b>
486	85			<b>571</b>			<b>665</b>
<b>\$118,856</b>	<b>\$29,225</b>	<b>\$7,000</b>	<b>\$277,527</b>	<b>\$432,608</b>	<b>\$123,873</b>	<b>\$22,000</b>	<b>\$1,466,397</b>
<b>775</b>	<b>149</b>	<b>48</b>	<b>2,366</b>	<b>3,338</b>	<b>531</b>	<b>212</b>	<b>13,659</b>

Source: GAO analysis of USDA, FDA, EPA, and DOC expenditure and staffing information.

Notes: Other program functions include rulemaking/standard setting, food security, and administration. Because many agencies did not provide expenditure and staffing level data specific to these functions, they are included in table 4 below for the agencies that provided these data separately.

FDA's Office of Financial Management's expenditure tracking is characterized by specific terminology. This terminology is provided below in table notes b through l, with references to data in the table.

FSIS categorized inspector training activities as inspection/enforcement, whereas FDA categorized them as education/outreach.

EPA's budget numbers reflect a greater level of resources than those directly related to food safety since the numbers include other program activities integral to pesticide risk assessment and risk management (e.g., worker protection and environmental assessments).

EPA expenditures and staffing levels include state grants and Headquarters/Regional resources for pesticide program activities in the Office of Pesticide Programs, Office of Enforcement & Compliance Assurance, and Office of Research & Development. Office of Water resources for shellfish protection and water quality criteria are also included.

NMFS inspection/enforcement expenditures are financed solely through revenues generated by user fees.



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**Appendix II**  
**Food Safety Expenditures and Staffing**  
**Levels for Fiscal Year 2003**

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<sup>a</sup>FSIS did not provide expenditures related specifically to surveillance and monitoring.

<sup>b</sup>Post market Inspections.

<sup>c</sup>Post market Inspections; a portion of these expenditures relating to animal drugs and feeds were multiplied by a factor of 0.95 to account for the percent of these activities that are considered food safety related.

<sup>d</sup>Premarket applied research and post market applied research.

<sup>e</sup>Premarket applied research and post market applied research, multiplied by a factor of 0.85 to account for the percent of these activities that are considered food safety related.

<sup>f</sup>Post market applied research; data provided by FDA officials.

<sup>g</sup>Post market applied research.

<sup>h</sup>Post market laboratory analysis (domestic and imports).

<sup>i</sup>Premarket outreach/coordination (domestic).

<sup>j</sup>Premarket outreach/coordination.

<sup>k</sup>Surveillance estimate provided by FDA officials.

<sup>l</sup>Post market outreach/coordination/compliance, subtracting \$950,000 and multiplied by a factor of 0.85 to account for the percent of the activities that are considered food safety related.

**Appendix II  
Food Safety Expenditures and Staffing  
Levels for Fiscal Year 2003**

**Table 4: Other Food Safety Expenditures and Staffing Levels by Agency, Fiscal Year 2003**

Dollars in thousands

<b>Program function</b>	<b>USDA FSIS</b>	<b>USDA APHIS</b>	<b>USDA Total</b>	<b>FDA CFSAN</b>	<b>FDA CVM</b>	<b>FDA Total</b>	<b>EPA Total</b>	<b>Grand total</b>
<b>Rulemaking/ Standard setting</b>								
Expenditures				\$28,448	\$19,322	\$47,770	\$36,840	\$84,610
Staffing Level				176	141	310	241	551
<b>Food security</b>								
Expenditures	1,838	10,072	11,910					11,910
Staffing Level	11		11					11
<b>Administration</b>								
Expenditures	116,027		116,027					116,027
Staffing Level	469		469					469
<b>Total expenditures</b>	<b>\$117,865</b>	<b>\$10,072</b>	<b>\$127,937</b>	<b>\$28,448</b>	<b>\$19,322</b>	<b>\$47,770</b>	<b>\$36,840</b>	<b>\$212,547</b>
<b>Total staffing</b>	<b>480</b>		<b>480</b>	<b>176</b>	<b>141</b>	<b>310</b>	<b>241</b>	<b>1,031</b>

Source: GAO analysis of USDA, FDA, EPA, and DOC expenditure and staffing information.

Notes: FDA CFSAN's rulemaking expenditures are labeled Premarket Review in FDA budget documents. CVM's rulemaking expenditures are labeled Premarket Review, adding \$950,000 and multiplied by a factor of 0.85 to account for the percent of the activities that are considered food safety related.

CFSAN rulemaking expenditures are mainly premarket approval activities; FDA's CVM rulemaking expenditures are composed of pre- and post-market approval activities.

FDA officials estimate that 7 percent of their total expenditures relate to administrative activities.

# Food Safety-Related Interagency Agreements

We solicited all active food safety-related interagency agreements from USDA, FDA, EPA, and NMFS. Table 5 categorizes the 71 agreements by program function. Twenty-four agreements state the need to reduce duplication of effort, reduce or clarify overlaps, or increase the efficient or effective use of resources between agencies. Table 5 also provides the year each agreement became effective and indicates the signatory agencies. The bolded agreements are the two that were analyzed in-depth.

**Table 5: Food Safety-Related Interagency Agreements by Primary Program Function**

Program function (number of agreements)	Title	Date	Agency signatories	Other signatories
Inspection/ Enforcement (31)	Alcohol Labeling Enforcement	1971	FDA	Treasury
	Responsibility of Alcohol Beverages Adulterated under FFDCA	1987	FDA	Bureau of Alcohol, Tobacco, and Firearms
	Inspection, Sampling, & Examination of Imported Dates & Date Material <sup>a</sup>	1985 <sup>b</sup>	FDA    USDA	
	Inspection and Standardization Activities Related to Food Products <sup>a</sup>	1975 <sup>b</sup>	FDA    USDA	
	Inspection, Sampling & Examination of Imported Raisins <sup>a</sup>	1973	FDA    USDA	
	Import of Biological Specimen under the US-USSR Scientific Exchange Agreement	1974	FDA    USDA	National Institutes of Health
	<b>Inspection Program for Fishery Products<sup>a</sup></b>	1974	FDA	NMFS
	Enforcement of Laws Against Illegal Commerce in Molluscan Shellfish <sup>a</sup>	1986	FDA	NMFS
	Inspection and Certification of Fish and Fishery Products	1980		NMFS    Department of Defense
	Inspection of Industrial Fishery Products Intended for Animal Feed Use <sup>a</sup>	1975	FDA    USDA	NMFS
	Inspection of Nonmeat Products for the Child Nutrition Labeling Program	1988 <sup>b</sup>		USDA    NMFS
	To Screen for Chloramphenicol Adulteration of Shrimp for the FDA's ORA	2003	FDA	NMFS
	Improve Sanitation & Quality of Shellfish	1984	FDA	Interstate Shellfish Sanitation Conference

**Appendix III  
Food Safety-Related Interagency  
Agreements**

(Continued From Previous Page)

Program function (number of agreements)	Title	Date	Agency signatories	Other signatories
	Salmonella Inspection & Sampling Coverage of Dry Milk Products Plants <sup>a</sup>	1987 <sup>b</sup>	FDA    USDA	
	Administering and Enforcing the Egg Products Inspection Act	1996 <sup>b</sup>	FDA    USDA	
	Recall & Disposal of Class I and II Recalled Products for Human Consumption	1984	FDA    USDA	
	General War Food Inspection <sup>a</sup>	1983 <sup>b</sup>	FDA    USDA	
	Shipment of Foods, Drugs & Cosmetics <sup>a</sup>	1976	FDA	Interstate Commerce Commission
	Delineate Areas of Jurisdiction of Signatories for Administration of CPS Act <sup>a</sup>	1976	FDA	U.S. Consumer Product Safety Commission
	Sanitary Quality of Milk Products Shipped Interstate	1977	FDA	National Conference of Interstate Milk Shipments
	Inspection & Standardization of Grain, Rice, Pulses & Food Products	1985 <sup>b</sup>	FDA    USDA	
	Exchange of Information on Foods & Cosmetic Recalls and Hazardous Food Situations	1982	FDA	Department of Defense
	Status of Animal Biological Products <sup>a</sup>	1982	FDA    USDA	
	Federal Regulatory Activities Concerning Residues of Environmental Contaminants <sup>a</sup>	1984	FDA    USDA    EPA	
	Testing of Domestic & Imported Peanuts	1997 <sup>b</sup>	FDA    USDA	
	Testing of Imported In-shell Brazil Nuts	1997 <sup>b</sup>	FDA    USDA	
	Testing of Imported In-shell Pistachio	1997 <sup>b</sup>	FDA    USDA	
	<b>Exchange of Information on Dual Jurisdiction Establishments<sup>a</sup></b>	1999 <sup>b</sup>	FDA    USDA	
	Cross-Utilization of Inspection and Grading Personnel (meat) <sup>a</sup>	1992	USDA	NMFS
	Cross-Utilization of Inspection and Grading Personnel (fruit and vegetables) <sup>a</sup>	1993	USDA	NMFS
	To Allow FDA to Commission CBP Officers	2003	FDA	Customs and Border Protection

**Appendix III  
Food Safety-Related Interagency  
Agreements**

*(Continued From Previous Page)*

<b>Program function (number of agreements)</b>	<b>Title</b>	<b>Date</b>	<b>Agency signatories</b>		<b>Other signatories</b>	
Education/ Outreach (14)	Coordination of Industry Education Efforts	1978	FDA	USDA		
	Feeding Programs in Head Start Centers <sup>a</sup>	1989	FDA		Department of Health and Human Services' Administration for Children, Youth, and Families	
	Cooperative Efforts in Food Safety, Nutrition & Veterinary Medicine	1989	FDA	USDA		
	Establish Working Relationship between CFP and FDA	1993	FDA		Conference for Food Protection	
	Foodborne Illness Education Activities of FSIS	1994	FDA	USDA		
	Science-Based Consumer-Oriented Messages to Promote Safe Food	1997	FDA	USDA	Centers for Disease Control and Prevention, Department of Education	
	Cooperative Training and Research	2000	FDA	USDA	University of Puerto Rico	
	FSIS-Antimicrobial Detection Tests	2003	FDA	USDA		
	Interagency Cooperation and Coordination in the Regulatory Oversight of Biotechnological Products	2003	FDA	USDA	EPA	Department of State, U.S. Geological Service
	To Enhance the Cross-Training Capabilities of Both Organizations to Reach Their Audiences <sup>a</sup>	2003		USDA		U.S. Fire Administration
	Establishment of Food Product Evaluation Team for Defense Supply Center	2000		USDA	NMFS	
	Shellfish Safety Assistance Project for the Interstate Shellfish Sanitation Conference	2004 <sup>b</sup>	FDA		NMFS	
	Support Pesticide Applicator Training Activities by the State Cooperative Extension Service	2003 <sup>b</sup>		USDA	EPA	
	USDA/IR-4 Biopesticide Demonstration Grant Program <sup>a</sup>	2004		USDA	EPA	

**Appendix III  
Food Safety-Related Interagency  
Agreements**

(Continued From Previous Page)

<b>Program function (number of agreements)</b>	<b>Title</b>	<b>Date</b>	<b>Agency signatories</b>			<b>Other signatories</b>
Food security (7)	Technical Expertise for Radiological Contamination Testing of Meat, Poultry & Egg Products	2004	FDA	USDA		
	Aberdeen Accept and Analyze High-Risk Samples for Biological Agents <sup>c</sup>			USDA		U.S. Army
	Development of Interagency Emergency Guidelines and Best Practices for Response to Food and Agriculture Incidents	2004	FDA	USDA		Department of Homeland Security, National Association of State Departments of Agriculture
	Develop a Rapid Reverse Transcriptase-Polymerase Chain Reaction (RT/PCR) Test for the Detection and Serotyping of Vesicular Stomatitis Virus (VSV)	2001		USDA		Department of Defense
	To Bring Together Two Workplans regarding the Possible Detection and Identification of Biological Agents <sup>a</sup>	2003		USDA		Department of Defense
	To Comply with the Statutory Obligations of the Bioterrorism Act of 2002	2002		USDA		Centers for Disease Control and Prevention
	Transfer of USDA-APHIS inspectors to DHS <sup>a</sup>	2003		USDA		Department of Homeland Security
Surveillance/Monitoring (5)	Joint Salmonella Enteritidis Risk Reduction Program	1992	FDA	USDA		
	National Antimicrobial Resistance Monitoring Survey (NARMS)	2004	FDA	USDA		Centers for Disease Control and Prevention
	Safe Importation and Biocontainment of Diseases of Livestock and Poultry	2002		USDA		Centers for Disease Control and Prevention
	Mercury in Recreational Finfish of the Gulf of Mexico	2004		EPA	NMFS	
	Shellfish Growing Waters <sup>a</sup>	1985	FDA	EPA	NMFS	U.S. Department of the Interior's Fish and Wildlife Service
Administration (5)	Animal Production and Food Safety <sup>a</sup>	1999	FDA	USDA	EPA	Centers for Disease Control and Prevention, Department of Defense
	Expand Number of PHS Commissioned Corps Officers Detailed to FSIS	2003		USDA		Department of Health and Human Services
	Standardization Document Preparation & Technical Support for Food	1981		USDA	NMFS	
	To Share Information between Pest Management Programs	2004		USDA	EPA	
	To Form the Foodborne Outbreak Response Coordinating Group <sup>a</sup>	1998	FDA	USDA	EPA	Centers for Disease Control and Prevention

**Appendix III  
Food Safety-Related Interagency  
Agreements**

(Continued From Previous Page)

Program function (number of agreements)	Title	Date	Agency signatories		Other signatories
Rulemaking/ Standard setting (4)	To Establish Through Regulations, Standards for the NLAP	1996	FDA	USDA	
	Sanctioning of Food Ingredients and Sources of Radiation	2000	FDA	USDA	
	Sharing Information on Herbicide Tolerant Crops	2000		USDA	EPA
	Collaboration with Respect to the Implementation of the Public Health Pesticides Provisions of FQPA	2000		EPA	Centers for Disease Control and Prevention
Risk assessment (3)	National Advisory Committee on Microbiological Criteria for Foods	2004	FDA <sup>d</sup>	USDA	NMFS
	USDA Pesticide Data Program	1992	FDA	USDA	EPA
	NCHS/CDC IAG-NHANES Dietary Consumption & Human Biomonitoring Data Acquisition & Analysis	2003		EPA	Centers for Disease Control and Prevention
Research (2)	Animal Care & Welfare <sup>a</sup>	1983	FDA	USDA	
	Collaborative Efforts to Make Alternative Pest Management Materials and Techniques Available to Producers	1996 <sup>b</sup>		USDA	EPA

Source: GAO analysis of agreements provided by USDA, FDA, EPA and NMFS or identified by GAO.

<sup>a</sup>The agreement explicitly recognizes the need to reduce duplication of effort, reduce or clarify overlaps, or increase the efficient or effective use of resources between agencies.

<sup>b</sup>Date of the most recent revision or amendment to a previously existing agreement.

<sup>c</sup>The agreement is undated.

<sup>d</sup>FDA is not a signatory to this agreement; however, the agency is a sponsor for the committee.

# Principal Federal Laws Related to Food Safety

As we have noted in this and other reports, the federal framework for food safety is based on a patchwork of numerous laws. Table 6 lists the 30 laws that we have identified as the principal federal laws related to food safety in order of their enactment, along with the agency or agencies that have food safety responsibilities under each law and a brief discussion or example of each law's food safety-related provisions. Included in the table are several laws that primarily deal with health claims or labeling, which we consider to be food-safety related, as well as some laws that are largely amendments of the Federal Food, Drug and Cosmetic Act. This table does not provide an exhaustive list of all food safety-related laws and amendments, nor does it detail all of the food safety provisions for those laws listed.

**Table 6: The 30 Principal Laws Related to Food Safety**

Law	Agency	Food safety provisions
Lacey Act of 1900, ch. 553, 31 Stat. 187 (1900) (codified in part at 16 U.S.C. § 3371)	Department of Commerce (NMFS), USDA	The act makes it a federal crime to import, export, sell, or transport in interstate commerce any plant, fish, or wildlife in violation of state law. The act has been used to prosecute individuals who sell plants, fish, or wildlife for human consumption in violation of state law.
Federal Meat Inspection Act, ch. 2907, 34 Stat. 1256, 1260 (1907) (codified at 21 U.S.C. § 601)	USDA	The act governs the slaughtering of livestock and the processing and distribution of meat products in the United States, authorizing the Secretary of Agriculture to prescribe the rules and regulations of sanitation covering slaughtering, meat canning, salting, packing, rendering, or similar establishments in which cattle, sheep, swine, goats, horses, mules, and other equines are slaughtered and the meat and meat food products thereof are prepared for commerce.
Federal Trade Commission Act, ch. 311, 38 Stat. 717 (1914) (codified at 15 U.S.C. § 41)	FTC	The act prohibits the dissemination of false advertisements for the purpose of inducing the purchase or having an effect upon commerce of foods, drinks, or chewing gum. The act provides for penalties for such false advertisements if the use of the commodity may be injurious to health.
United States Grain Standards Act, ch. 313, 39 Stat. 482 (1916) (codified at 7 U.S.C. § 71)	USDA	The act provides for the inspection, weighing, and grading of grain. Under the act, all corn exported from the United States generally must be tested for aflatoxin contamination.
Import Milk Act of February 15, 1927, ch. 155, 44 Stat. 1101 (1927) (codified at 21 U.S.C. § 141)	FDA	The act prohibits the importation of milk or cream into the United States without a permit and sets standards for when milk and cream shall be considered unfit for import.
Perishable Agricultural Commodities Act, 1930, ch. 436, 46 Stat. 531 (1930) (codified at 7 U.S.C. § 499a)	USDA	The act regulates the sale of perishable agricultural commodities and protects sellers delivering their produce on essentially cash terms.
Federal Alcohol Administration Act, ch. 814, 49 Stat. 977 (1935) (codified at 27 U.S.C. § 201)	Treasury	The act requires that alcoholic beverages for sale or distribution in the United States have a warning label.



**Appendix IV**  
**Principal Federal Laws Related to Food**  
**Safety**

*(Continued From Previous Page)*

<b>Law</b>	<b>Agency</b>	<b>Food safety provisions</b>
Federal Food, Drug and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301)	FDA, EPA	The act and its regulations set forth food and drug labeling requirements, as well as requirements for animal drugs. The act seeks to ensure the purity of the nation's food supply, and accordingly bans "adulterated" and "misbranded" food from interstate commerce. Under the act, EPA regulates the amount of pesticide that may remain on food products.
Federal Seed Act, ch. 615, 53 Stat. 1275 (1939) (codified at 7 U.S.C. § 1551)	USDA, DHS	The act establishes seed labeling requirements, including the requirement for a caution statement such as "Do not use for food or feed or oil purposes" on seeds that have been chemically treated when the amount of chemicals remaining with the seeds is harmful to humans or other vertebrate animals.
Public Health Service Act, ch. 373, 58 Stat. 682 (1944) (codified at 42 U.S.C. § 201)	FDA, CDC	Under the act, CDC engages in public health activities related to food safety and foodborne diseases. FDA is authorized under the act to promulgate regulations to prevent the spread of communicable diseases, including foodborne illnesses.
National School Lunch Act, ch. 281, 60 Stat. 230 (1946) (codified at 42 U.S.C. § 1751)	USDA	The act required the development of a policy and procedures to ensure that schools receive information regarding irradiation technology and any other information necessary to promote food safety in schools.
Agricultural Marketing Act of 1946, ch. 966, 60 Stat. 1087 (1946) (codified at 7 U.S.C. § 1621)	USDA, NMFS	The act promotes a scientific approach to the problems of marketing, transporting and distributing agricultural products and authorizes the Secretary of Agriculture to "inspect, certify, and identify the class, quality, quantity, and condition of agricultural products." Under the act, USDA has, among other things, established meat grading and acceptance services. The act also provides authority for the Seafood Inspection Program, which eventually was transferred to the Department of Commerce.
Federal Insecticide, Fungicide and Rodenticide Act, ch. 125, 61 Stat. 103 (1947) (codified at 7 U.S.C. § 136)	EPA	The act governs pesticide registration and safe use of pesticides.
Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified at 21 U.S.C. § 451)	USDA	The act governs the slaughtering, processing, and distribution of poultry products.
Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958)	FDA	The act amended the Federal Food, Drug and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.
Fair Packaging and Labeling Act, Pub. L. No. 89-755, 80 Stat. 1296 (1966) (codified at 15 U.S.C. § 1451)	FDA, FTC	The act prescribes the placement, form, and contents of a label's statement of the quantity of packaged goods. The act supersedes all local regulation that is less stringent or requires different information.
Egg Products Inspection Act, Pub. L. No. 91-597, 84 Stat. 1620 (1970) (codified at 21 U.S.C. § 1031)	USDA	The act and its regulations set standards for the quality, condition, weight, quantity, and grade of eggs produced for commercial sale.
Safe Drinking Water Act, Pub. L. No. 93-523, § 4, 88 Stat. 1660, 1694 (1974) (codified at 21 U.S.C. § 349)	FDA, EPA	The act, which amended the Federal Food, Drug and Cosmetic Act, and its regulations establish standards for bottled drinking water.
Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. § 2601)	EPA	Under the act, EPA can regulate the use of certain chemical substances in foods that present an unreasonable risk to health. Under the authority granted by the act, EPA's Toxic Substances Control Act Biotechnology Program regulates microorganisms, such as biofertilizers, intended for commercial use that contain or express new combinations of traits.

**Appendix IV**  
**Principal Federal Laws Related to Food**  
**Safety**

*(Continued From Previous Page)*

<b>Law</b>	<b>Agency</b>	<b>Food safety provisions</b>
Infant Formula Act of 1980, Pub. L. No. 96-359, 94 Stat. 1190 (codified at 21 U.S.C. § 350a)	FDA	The act authorizes the Secretary to establish requirements for infant formula for quality factors and good manufacturing practices, including quality control procedures, to assure that an infant formula provides required nutrients and is manufactured in a manner designed to prevent adulteration of the infant formula. The act also authorizes the Secretary to prescribe, by regulation, the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risks to human health.
Federal Anti-Tampering Act, Pub. L. No. 98-127, 97 Stat. 831 (1983) (codified at 18 U.S.C. § 1365)	FDA, USDA	The act prohibits tainting a consumer product with intent to cause serious injury to the business of any person where the consumer product affects interstate or foreign commerce. The act also prohibits providing a materially false or misleading label or container for a consumer product.
Pesticide Monitoring Improvements Act of 1988, Pub. L. No. 100-418, § 4701, 102 Stat. 1107, 1411 (1988) (codified at 21 U.S.C. § 1401)	FDA	The act requires FDA to have in place computerized data management systems to record, summarize, and evaluate the results of its program for monitoring food products for pesticide residues and requires FDA to provide information to EPA.
Sanitary Food Transportation Act of 1990, Pub. L. No. 101-500, 104 Stat. 1213 (1990) (codified at 49 U.S.C. § 5701)	DOT	The act calls for the Department of Transportation to issue regulations prohibiting the transportation of food and food additives in motor or rail vehicles that are used to transport refuse or nonfood products.
Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990)	FDA	The act amended the Federal Food, Drug and Cosmetic Act to prohibit the application of state quality standards to foods moving in interstate commerce and to require labels of food products sold in the United States to display nutritional information.
Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994)	FDA	The act amended the Federal Food, Drug and Cosmetic Act to allow certain health claims for dietary supplements to be made without petitioning the FDA. These include (1) statements asserting a benefit related to a classical nutrient deficiency disease, (2) claims about the role of a nutrient or dietary ingredient with respect to the structure or function of the human body ("structure/function claims"), and (3) declarations of general well-being from consumption of a nutrient or other dietary ingredient. Under the act such claims are permitted if the manufacturer has "substantiation" that the assertion is truthful and nonmisleading, if the label expressly states that FDA has not evaluated the claim, and if FDA is notified within 30 days of the first marketing of the product that bears the claim.
Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996)	EPA, USDA, HHS	The act amended the regulatory scheme under the Federal Insecticide, Fungicide and Rodenticide Act and the Federal Food, Drug and Cosmetic Act to require EPA to reevaluate the safety of pesticide tolerances on a set timetable.
Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997)	FDA	The act amended the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to authorize health and nutrient claims to be made for foods when certain criteria are met.
Animal Health Protection Act, Pub. L. No. 107-171, § 10401, 116 Stat. 134, 494 (2002) (codified at 7 U.S.C. § 8301)	USDA, DHS	The act authorizes the Secretary to prohibit or restrict movements of animals in interstate commerce to prevent the dissemination of any pest or disease of livestock. The act also permits the Secretary to order the destruction or removal of such animals.

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**Appendix IV  
Principal Federal Laws Related to Food  
Safety**

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*(Continued From Previous Page)*

<b>Law</b>	<b>Agency</b>	<b>Food safety provisions</b>
Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002)	USDA, FDA	The act expands APHIS's authorities, including activities to enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists. The act also provides FDA with detention authority, expanded recordkeeping provisions, and authorizes FDA to commission other federal officials to conduct examinations and investigations of FDA-regulated foods at jointly regulated facilities.
Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002)	DHS	The act calls for the securing of critical infrastructure and transfers functions relating to the agricultural import and entry inspection activities under certain laws from the Secretary of Agriculture to the Secretary of the Department of Homeland Security.

Source: GAO analysis of federal laws.

# Comments from the U.S. Department of Agriculture

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



United States Department of Agriculture

Office of the Secretary  
Washington, D.C. 20250

MAR 19 2005

Robert A. Robinson  
Managing Director, Natural Resources and Environment Team  
United States Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Dear Mr. Robinson,

Please find the enclosed United States Department of Agriculture's comments on the Government Accountability Office (GAO) draft report entitled, "FOOD SAFETY: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources."

Sincerely,

A handwritten signature in black ink, appearing to read "Merle D. Pierson".

Merle D. Pierson, Ph. D.  
Acting Under Secretary for Food Safety

An Equal Opportunity Employer

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**U.S. Department of Agriculture (UDSA) Comments on Government  
Accountability Office (GAO) Draft Report  
“FOOD SAFETY: Federal Agencies Should Pursue Opportunities to  
Reduce Overlap and Better Leverage Resources” GAO-05-213**

See comment 1.

The Food Safety and Inspection Service (FSIS) has serious concerns regarding both the interpretations of facts and assumptions contained in this report. The report exaggerates the size and economic impact of regulatory overlaps that exist between FSIS and the Food and Drug Administration (FDA). Its recommendations also rely upon overly simplistic interpretations of food safety authorities, regulations, inspection requirements and training needs; as well as inaccurate characterizations of coordination efforts and agreements between FSIS and FDA.

In terms of food safety authorities, we are concerned that the report overly simplifies the food safety regulatory functions within FSIS and the FDA, and disregards the inherent complexities and differences of our work. The breadth, complexity, and size of the U.S. food production system lends itself to specialized government oversight. As this draft report acknowledges, “The statutory framework underlying the U.S. federal food safety system gives responsibility for specific food commodities to **different** agencies and provides them with **significantly different** authorities and responsibilities.” It is therefore confounding as to why the report continues on to assert in the following sentence that, as a result, “federal agencies are spending resources on similar activities.”

As GAO is aware, FSIS operates under the legal and statutory authorities of the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act. Under the authorities and requirements of these acts, FSIS conducts daily inspection of all meat, poultry, and egg products sold in interstate commerce and re-inspects imported products to ensure that they meet U.S. food safety standards. As a result, FSIS spends the majority of its yearly funding on staffing and training to support these functions. FDA, on the other hand, inspects establishments under its jurisdiction less frequently utilizing an auditing system that relies heavily on investigations. While FSIS and FDA inspection activities may seem similar, they are in reality vastly different due to differences in authorities and responsibilities. The areas of perceived funding and resource overlap noted in the report actually reflect areas of difference.

See comment 2.

In terms of inspection requirements for dual jurisdiction establishments (DJE), GAO states that there is “significant” overlap in inspection authorities. In actuality, DJEs comprise only a very small percentage of the total number of establishments subject to continuous inspection. A significant portion of DJEs are warehouses which, unlike slaughter and processing facilities, do not require a grant of inspection from FSIS. In light of the small number of DJE establishments, and the level of resources dedicated to inspection in these facilities already, the opportunity for cost savings is quite small.

See comment 3.

GAO also references a perceived regulatory overlap when discussing each organization’s Hazard Analysis and Critical Control Point (HACCP) regulations. This draft report leaves the impression that FSIS and FDA have comparable HACCP regulations that

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cover all products they each respectively regulate. While it is true that the two sets of HACCP regulations are quite similar, they diverge in matters that reflect the different work of the two agencies. The report also seems to confuse HACCP general principles with food specific hazards. While HACCP's general principles remain constant, food specific hazards differ greatly by product, thus necessitating differences in provisions and how the rules are applied. USDA's HACCP regulations apply to all meat and poultry products. FDA has two of its inspected commodities (seafood and juices) under mandatory HACCP. While there are commonalities in the USDA and FDA rules, there remain significant differences between FSIS and FDA regulated industries under HACCP that dictate the necessity of distinctly different regulations.

See comment 4.

In discussing inspection requirements for imported products, GAO asserts that "USDA and FDA both inspect shipments of imported food at ports of entry and also visit foreign countries that export food to the United States." This assertion oversimplifies and inaccurately describes the food safety regulatory functions and systems within FSIS and FDA, as well as the inherent differences in food products regulated by FSIS and FDA, and by extension, the complexities of the systems and processes needed to perform this work. In order for meat, poultry and egg products to be eligible for import to the U.S., foreign food safety regulatory systems must employ equivalent sanitary measures that provide the same level of protection against food safety hazards as is achieved domestically under USDA regulations. In addition, only a very small number of USDA certified plants from within those approved foreign countries may export products to the United States.

USDA shares information obtained during its foreign country equivalence determinations with other federal agencies and makes available a wealth of information on the FSIS website including foreign audit reports, export requirements for U.S. producers, import requirements for foreign countries, the equivalence process, port-of-entry procedures, reinspection procedures, and labeling requirements.

See comment 5.

Regarding training, FSIS believes the GAO report is misleading and overly simplistic in its characterizations of the various agencies' training programs. FSIS disagrees that it is feasible to create one unified joint training program between FSIS and FDA covering all food safety verification activities. The draft report cites as a successful model the Federal Law Enforcement Training Center (FLETC). FSIS is familiar with the training efforts at FLETC, and in fact, utilizes training resources provided there. However, in our experience, extensive work must be done to customize the course to meet the training needs of FSIS personnel. In addition, FSIS must supply personnel to conduct FLETC training of FSIS personnel through team teaching to ensure that the knowledge gained from courses transfers to the public health regulatory environment in which FSIS personnel operate. This experience illustrates how an effort that might on the surface appear to consolidate resources in fact requires constant work and resources by both FLETC and FSIS in order for the training to be successful.

Several factors affect the feasibility of conducting joint training activities. Because the authorities and responsibilities at FDA and FSIS differ, the policies, procedures, and the training on inspection and enforcement strategies are by nature quite different. The products regulated by the two agencies are different, and the hazards and public health

risks associated with those products are different. Additionally, there are significant differences in classification of the job series of individuals performing inspection duties. The FSIS inspection workforce includes technical as well as professional job series positions, while FDA positions are predominantly professional series. Moreover, the work environment of the two inspection workforces is different. As a result, the course content and educational strategies to train these two vastly different groups must by nature be significantly different.

In spite of the factors outlined above, FSIS agrees that there is merit in examining the feasibility of conducting joint training activities when workable commonalities can be found and, in fact, has actively sought ways to do just that. FSIS and FDA have recently collaborated to provide joint training activities. Two retail meat and poultry processing teleconferences have been conducted and the two agencies have developed a retail meat and poultry processing training curriculum. Moreover, FSIS and FDA jointly developed and are currently implementing food security awareness training for the workforce and local cooperators.

FSIS believes the implementation of the 1999 MOU has been largely successful. FSIS and FDA significantly increased the effectiveness of communications between the two agencies, heightened awareness of each other's responsibilities and operations, initiated more frequent and more effective cooperative efforts, and altered inspection and investigational priorities as a result of the MOU. Additionally, the FSIS Performance Based Inspection System (PBIS) will be modified to include a field for indicating that an establishment is under dual jurisdiction. This will enable FSIS to generate a real time list of dual jurisdiction establishments. Again, while the areas of overlap are quite small, the MOU assures that the agencies are communicating effectively.

Finally, GAO appears to inaccurately characterize the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). While the Bioterrorism Act gave FDA the authority to commission other federal officials to inspect FDA-regulated foods, implementing such an agreement between FSIS and FDA would require a considerable amount of planning and work. We believe the implementation of such a plan has been oversimplified in the report. In fact, meat and poultry are exempt under this act, and point that GAO has failed to recognize. A comprehensive review would be required of the existing regulatory authorities, training requirements, and reimbursement issues. FSIS and FDA operate under different regulatory structures, and roles and responsibilities would need to be carefully defined.

Nevertheless, to date, FSIS has already developed extensive partnerships with other Federal-level food safety and security agencies, and States to build a strong and vibrant food security infrastructure to protect the public from the threat of intentional and unintentional contamination of the food supply. In light of assessments that showed significant gaps existed between the federal and state governments when it came to coordinating efforts for prevention and the response to any act of intentional contamination, FSIS entered into a cooperative agreement with FDA, the Department of Homeland Security (DHS), and the National Association of State Departments of Agriculture to develop the best practices by which federal assistance can be provided expeditiously and effectively.

See comment 6.

FSIS and FDA also work closely with the White House and DHS to coordinate our food security efforts, including participating in the development and implementation of all Homeland Security Presidential Directives. In order to enhance surveillance and incident response, FSIS has partnered with other food safety agencies such as FDA and our state counterparts to build an integrated laboratory system that would not only monitor the food supply and share data, but also assist in handling samples in the event of an emergency. This integrated system, known as the Food Emergency Response Network, consists of federal and state governmental laboratories responsible for handling the increasing number of samples in the event of an emergency.

FSIS already works very closely with FDA, the Centers for Disease Control and Prevention (CDC), and the Environmental Protection Agency, as well as with State and local health agencies, to share information about illnesses. FSIS, as well as FDA, are participants in PulseNet, a national network of public health laboratories supported by the CDC. PulseNet performs DNA fingerprinting on foodborne bacteria and assists in the detection of foodborne illness outbreaks and traceback to their sources, including detection of a linkage among sporadic cases. PulseNet, combined with epidemiology, has been key in enabling Federal agencies to rapidly detect and control outbreaks of naturally occurring or intentionally introduced foodborne illness.

We also have a greater appreciation for interacting more closely with intelligence and law enforcement communities. In addition to hiring Import Surveillance Liaison Inspectors to work with DHS's Customs and Border Patrol at ports of entry around the nation, we are also building stronger relationships with other intelligence and enforcement agencies, such as the Federal Bureau of Investigation, the Central Intelligence Agency, the Transportation Security Agency, and the Coast Guard.

Additionally, FSIS has made many other strides in protecting food security. After September 11, 2001, FSIS created the Office of Food Security and Emergency Preparedness (OFSEP) to lead all food security activities within the agency. OFSEP works to ensure effective coordination on food security efforts throughout the Government. Working with Federal partners, including FDA, CDC, DHS, USDA's Animal and Plant Health Inspection Service (APHIS), the Department of Defense (DOD), and the Environmental Protection Agency (EPA), and State representatives, OFSEP develops preventive activities and rapid response measures designed to protect the food supply. Through OFSEP's leadership, the Agency has conducted numerous simulation exercises to allow for a more efficient and effective response. FSIS has also made significant enhancements to its Consumer Compliant Monitoring Systems to allow it to serve as a real-time early warning system of a potential attack on the food supply and has expanded its capability to test for threat agents by constructing a biosecurity Level 3 laboratory.

At various times, there has been discussion about consolidating all food safety, inspection, and labeling functions into one Agency with the intention of increasing the effectiveness of the food safety system. In 2002, the White House established a Policy Coordinating Committee (PCC), led by the Domestic Policy Council and the National



Economic Council, to look into the issue of a single food agency. The PCC concluded that the goals of the Administration are better advanced through enhanced interagency coordination rather than through the development of legislation to create a single food safety agency.

We must never lose sight of the fact that improving food safety and public health is the one and only goal. The food safety system can be configured in an endless array of forms, but if food safety and public health are not improved, the system has failed the American public. FSIS and FDA bases their policy decisions on science, so the consolidated food safety agency discussion boils down to one question: will there be a measurable benefit to public health? In other words, would such an effort save lives and reduce foodborne illness rates? As with any new food safety and security effort, we want to make sure that we maintain and continue to improve public health. We must make sure that any reconfiguration to the current food safety system effectively improves food safety and public health. The data from countries that have consolidated their food safety agencies suggests that there is not a change in foodborne illness trends, and in some cases, the illness rates have increased, after the creation of a single food safety agency.

#### **Conclusion**

In summary, the GAO report erroneously interprets the various agencies' food safety authorities, regulations, inspection requirements and training needs. FSIS conducts daily inspection of all meat, poultry, and egg products sold in interstate commerce and re-inspects imported products to ensure that they meet U.S. food safety standards. As a result, FSIS spends the majority of its yearly funding on staffing and training to support these public health functions. FDA inspects establishments under its jurisdiction less frequently. While our food safety systems and processes may seem similar at first glance, the areas of perceived funding and resource overlap noted in the report are actually quite different because of significant differences in authorities and responsibilities. Additionally, the GAO report exaggerates the size and impact of any overlaps that may exist between FDA and FSIS.

The draft report states "federal agencies are spending resources on similar activities," but this statement is flawed. In fact, the statutory framework underlying the U.S. federal food safety system gives responsibility for specific food commodities to different agencies and provides them with significantly different authorities and responsibilities.

Coordination between FSIS and FDA is very strong. Contrary to the impression left by the report, FSIS maintains a strong working relationship with its sister public health agencies. As partners in the U.S. food safety efforts, FSIS and FDA routinely communicate and coordinate with one another to ensure a safe and secure food supply. The draft report highlights several good examples of coordination between FSIS and FDA. These examples demonstrate that our very close cooperation has minimized overlaps and redundancies and has promoted efficiency.

The report overly simplifies the food safety regulatory functions within the FSIS and FDA without regard to the inherent complexities and differences of our work. FSIS

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**Appendix V**  
**Comments from the U.S. Department of**  
**Agriculture**

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believes the existing regulatory framework and operations are working. As a result, the American food supply continues to be among the safest in the world.

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The following are GAO's comments on the U.S. Department of Agriculture's letter dated March 10, 2005.

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## GAO Comments

1. We disagree with USDA's assertion that our report overly simplifies the food safety regulatory functions within USDA and FDA and that it exaggerates the extent of regulatory overlap. USDA has misinterpreted the focus of this report. This report examines overlapping *activities* rather than the *regulatory framework* that allows these activities. Nevertheless, the report contains a clear and accurate acknowledgment that the agencies operate under a statutory framework that gives them different authorities and responsibilities to regulate different segments of the food supply. While we recognize that the agencies operate under different authorities, the activities they perform under these authorities are similar in nature, leading us to question why the federal agencies must continue to spend resources on overlapping, and sometimes duplicative, food safety activities.

We also disagree with USDA's assertion that the agencies activities are vastly different. For example, we find that the agencies' inspection activities to ensure that food manufacturers comply with regulatory requirements are quite similar. As we document in our report, these inspections have sufficiently common features, such as verifying proper sanitation procedures at food processing facilities, that make these inspections activities candidates for consolidation under one agency.

We further disagree with USDA's comment that the report's recommendations rely upon overly simplistic interpretations of food safety authorities, regulations, inspection requirements, and training needs. To the contrary, our recommendations address specific areas where the agencies could improve coordination to better leverage resources. USDA did not comment directly on these recommendations.

2. We believe that USDA mischaracterizes our report in noting that it states that a "significant" overlap in inspection authorities exists. Specifically, our report examines *inspection activities*, not *inspection authorities*, and certainly does not identify "*significant*" overlaps in authorities. In fact, the report clearly states that, because of the agencies' split jurisdiction, they are each responsible for inspecting different food products at jointly regulated facilities. As a result, both

agencies send inspectors into these facilities—USDA on a daily basis and FDA less regularly.

While we agree with USDA that the number of jointly regulated establishments may be a relatively small portion of all regulated food establishments, USDA and FDA had great difficulty identifying the current number of jointly regulated facilities. Consequently, the magnitude of potential savings is difficult to calculate. We continue to believe that, because USDA maintains a daily presence at hundreds of these facilities, FDA could make more effective use of its resources—an average cost of \$4,000 per inspection—if it redirected its inspectors to other facilities for which FDA has sole jurisdiction.

3. Contrary to USDA's assertion, our report does not suggest that USDA (FSIS) and FDA have comparable HACCP regulations. Instead, our report clearly distinguishes between the elements of the agencies' HACCP regulations that are comparable and those that are not. For example, the report acknowledges that, given the agencies' different statutory authorities, both require jointly regulated facilities to maintain separate HACCP plans and states that the contents of these plans differ because the agencies regulate different products. However, as USDA itself notes, the two sets of HACCP regulations (USDA and FDA) are quite similar, and as we point out, they have certain features in common, such as certain sanitation and manufacturing processes. Therefore, we continue to believe that USDA and FDA could consolidate HACCP-based inspections at these jointly regulated facilities. To provide further clarification on what commodities are currently subject to HACCP regulations, we modified our report to indicate, as USDA suggests, that FDA currently requires HACCP plans for seafood and juice products only.
4. We disagree that our report oversimplifies or inaccurately describes federal food safety functions at ports of entry. For example, USDA noted that in order for meat and poultry and egg products to be eligible for import to the United States, foreign food safety regulatory systems must employ equivalent sanitary measures that provide the same level of protection against food safety hazards as is achieved domestically under USDA regulations. We disagree with USDA's comment, because our report clearly and accurately describes the requirement for certification of those countries wishing to export meat and poultry into the United States, including a finding by the Secretary of Agriculture that the countries have equivalent food safety systems. The main point

of our report is that the agencies are not leveraging inspection resources at ports of entry, especially regarding FDA-regulated imported foods that, according to USDA officials, are being stored at USDA-approved inspection facilities. Therefore, we continue to believe that there are opportunities to leverage inspection resources, as we are recommending.

Furthermore, USDA's comment that it shares the results of its overseas equivalency determinations contradicts what USDA and FDA officials told us during the course of our review. However, we note that USDA is now sharing this information. Indeed, FDA commented that it would consider the results of USDA's foreign country equivalency determinations.

5. Any successful consolidation of inspectors' training would of course require work. However, we continue to believe that, as USDA's comments note, there is merit in examining the feasibility of conducting joint training activities when workable commonalities can be found. Our report identifies more than 100 courses in FDA's inspector training curriculum that include topics common to both USDA and FDA.
6. We disagree with USDA's assertion that implementation of the 1999 interagency agreement has been largely successful. Our report highlights several deficiencies, even as it gives the agencies credit for improved communication in times of crisis, such as during major recalls. These deficiencies include agencies' (1) difficulty identifying the establishments to which this agreement pertains, (2) lack of routine communication on inspection findings between agencies' inspection personnel on such findings of mutual concern as sanitation problems at jointly regulated facilities, and (3) lack of a system to track and exchange information when each agency finds instances of noncompliance. Finally, we also found that the agencies' efforts to develop and provide training on each other's inspection techniques and processes did not continue past the first year of the agreement's implementation. As a result, we continue to believe that the stated purpose of the agreement—to facilitate an exchange of information permitting more efficient use of both agencies' resources—has not been maximized.

We further disagree with USDA's comment that our report inaccurately characterizes the Bioterrorism Act. As we state in the report, FDA is

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**Appendix V**  
**Comments from the U.S. Department of**  
**Agriculture**

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authorized under the act to enter into an agreement to commission other agency officials, including USDA officials, to carry out inspections on its behalf—for FDA-regulated foods—at establishments under the jurisdiction of both agencies.

# Comments from the Department of Health and Human Services (FDA)

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAR 11 2005

Mr. Robert A. Robinson  
Managing Director  
Natural Resources & Environment  
U.S. Government Accountability Office  
Washington, DC 20548

Dear Mr. Robinson:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO's) draft report entitled, "Food Safety—Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources" (GAO-05-213). The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson  
Acting Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for U.S. Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

**COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON  
THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT: "FOOD  
SAFETY: FEDERAL AGENCIES SHOULD PURSUE OPPORTUNITIES TO REDUCE  
OVERLAP AND BETTER LEVERAGE RESOURCES" (GAO-05-213)**

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report.

Protecting the food supply is a top priority at HHS's Food and Drug Administration (FDA). FDA conscientiously plans and implements its food safety-related programs to assure a safe and wholesome food supply within its legal authority and financial resources. While FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) share responsibility for food safety, each agency regulates different products and has very different legal authorities, regulations to administer and enforce, and procedures. Regarding concerns about overlap and duplication, it is important to note that in processing establishments, there are no food products that both FDA and USDA regulate. To the extent we have similar responsibilities, we strive to leverage each other's efforts to achieve our common objectives.

Over the years, there has been much discussion about consolidating all food safety, inspection, and labeling functions into one agency with the intention of increasing the effectiveness of the food safety system. In 2002, the Administration looked into food safety issues, including the single food agency issue, and concluded that the goals of the Administration are better advanced through enhanced interagency coordination rather than through the development of legislation to create a single food agency.

The various Federal agencies with food safety authorities are working together effectively. The American food supply continues to be among the safest in the world. Food safety agencies are working more closely together than ever before, especially in the area of food security. For example, FDA, USDA's FSIS and Animal and Plant Health Inspection Service (APHIS), HHS's Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), and the Department of Defense (DOD) are leading the effort to defend the food and agriculture supply under the Department of Homeland Security (DHS) Presidential Directive 9 (HSPD-9) through collective authorities, expertise, and resources. We also coordinate and collaborate with the DHS, which is the overall lead for protecting the food supply from deliberate contamination.

In your draft report, the term, "overlap" is defined as "similar activities being performed by more than one agency," whereas the term "duplication" is defined as "essentially identical activities." The report purports to identify ways to increase efficiency by eliminating *duplicative* effort. As long as more than one agency has the legal authority to secure the food supply generally, they will by necessity generally conduct similar activities, i.e., each one will have to inspect those products over which it has jurisdiction, each one will have to promulgate regulations implementing its statutory authority, etc. We believe, however, that these similarities are superficial. That they exist does not, on its own, contribute to understanding whether and to what extent there is actual duplication of effort among the agencies. The report title should be

See comment 1.



**Appendix VI**  
**Comments from the Department of Health**  
**and Human Services (FDA)**

changed to: “Federal Agencies Should Pursue Opportunities to Reduce Duplication and Better Leverage Resources.”

Throughout the report, use of the term, “overlap” is confusing. While the report defines it at the outset, the term “overlap” connotes sameness, not simply similarity. As a result, the report would be clearer if it used the term “similar,” which is the report’s definition of “overlap” instead of the term “overlap.” In addition, the report would no longer need to define the term “overlap” if that change were made.

In assessing whether or not to consolidate certain functions within a single agency to reduce duplication, the report focuses on what those functions have in common, i.e., similarities, (termed “overlap”) without assessing how they differ.

The similarities cited in the report are often overstated. For example, the report states that USDA and FDA inspections have common features, without specifying the common features or addressing the fact that the inspections conducted by these agencies are far more different than they are similar.

The report states that USDA and FDA provide “similar training,” without mentioning that the training programs, in fact, are vastly different due in large part to the fact that USDA inspectors and FDA investigators have very different academic backgrounds and conduct very different inspections.

FDA disagrees that it is cost effective and of benefit to have a single training program for both FDA and USDA food safety programs. We will continue to collaborate and cooperate on areas of mutual benefit, but these are small in relation to training and preparing our employees to conduct their day-to-day jobs effectively.

See comment 2.

Legal authority and scientific and technical expertise are significantly more important to solving a food safety issue than the organizational component called upon. For example, the Federal food safety and animal health agencies have forged a coordinated effort to prevent, identify, and respond to Bovine Spongiform Encephalopathy (BSE) contamination in the food and animal supply. If all of the current resources were to be housed in one organization, it would not diminish nor eliminate the need for coordination even within that organization.

See comment 3.

To the extent that an establishment processes food products under FDA’s jurisdiction and USDA’s jurisdiction, both agencies have regulatory responsibilities in that facility, referred to as dual jurisdiction establishments in the draft report. Each agency deals within its own area of expertise and jurisdiction at facilities that are common to both agencies. FDA and USDA have signed a Memorandum of Understanding (MOU) that facilitates the sharing of information between the agencies about establishments subject to the jurisdiction of both agencies. FDA and USDA field offices notify their counterpart’s office when significant findings are identified regarding a dual jurisdiction establishment. Overall, this MOU has been successful in enhancing collaboration to improve public health protection.

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**Appendix VI**  
**Comments from the Department of Health**  
**and Human Services (FDA)**

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The GAO draft report makes reference to interagency agreements (IAGs) as a general term. It is important to note the distinct difference between FDA IAGs and MOUs. At FDA, MOUs do not provide for exchanges of funds. Exchanges of funds, personnel, or property are part of IAGs, not MOUs. As written, the GAO draft report is not accurate when referencing many of the MOUs involving FDA as IAGs.

FDA and USDA work together in many ways to ensure the safety of the U.S. food supply. In addition to food security, FDA and USDA's FSIS and APHIS have worked very closely in developing a sound strategy for BSE prevention, control, and response for both public health and animal disease. We recognized early on that we needed to agree on and work under clear jurisdictional authorities at the Federal, as well as State levels. Accordingly, we established a BSE action and response plan that identifies the lead Federal agency to take action depending upon the situation.

The Hazard Analysis Critical Control Point (HACCP) inspection process is a systematic approach to food production and processing that requires the identification of specific hazards associated with a specific food and the process and production system utilized, the means to mitigate such hazards, steps to do so, and documentation that such steps are taken. Throughout the report, there seems to be some confusion about HACCP principles and HACCP plans.

Given the scientific basis upon which HACCP is formulated and the different types of hazards and production and processing techniques that are related *to a specific food commodity*, the expectation is that each HACCP plan is targeted and specific to the facility and food commodity and the respective hazards. Hence, while the HACCP principles are the same, the HACCP plans are different because of the varied hazards that have been shown to cause illness associated with the different food products or processes, or both. It is for this reason that USDA's HACCP rules and FDA's HACCP rules are different because the scientific knowledge of the hazards associated with certain commodities and the technology, processing, and equipment associated with those commodities are different. In our technical comments, we have pointed out where clarification regarding HACCP plans and principles appear to be utilized interchangeably, and should be changed.

Every agency must undertake rulemaking to implement its statutory authority. This is not an activity that can be consolidated unless the underlying authority is consolidated. However, FDA does seek the review and input of USDA and other agencies with food safety authority when promulgating regulations related to food safety.

The GAO draft report includes statements that are opinions expressed by a few current and former Government employees. These individuals clearly are not speaking on behalf of their agency and are expressing their personal opinions, which are not consistent with their agencies' positions. In our technical comments, we have indicated when we believe an item was an opinion and that it should be removed from the report.

See comment 4.

**GAO RECOMMENDATIONS FOR EXECUTIVE ACTION:**

***GAO recommends that the Secretary of Agriculture and the Commissioner of FDA work together to:***

**GAO Recommendation #1:**

***Ensure the implementation of the interagency agreement that calls for, among other things, sharing inspection- and enforcement-related information at those food processing facilities that are under the jurisdiction of both agencies.***

**HHS Comment**

The primary focus of the existing 1999 MOU between FDA and FSIS for dual jurisdiction establishments is to facilitate an exchange of information between the agencies about establishments that are subject to the jurisdiction of both agencies. This exchange of information is to permit more efficient use of both agencies' resources and to contribute to improved public health protection. The primary application for this shared information is for enforcement collaboration when inspections result in unsanitary conditions that cut across the regulatory authority of both agencies. FDA and FSIS coordinate these activities at the local level on a regular basis for those facilities and for those food safety and security activities for which we each have regulatory authority. FDA believes that this MOU has been largely successful in enhancing collaborative activities to improve public health protection.

While only a small percentage, less than 2 percent, of the total food processing or manufacturing facilities in the U.S. are subject to inspection by both FDA and USDA, the notification and sharing of information through this MOU has been productive as it has led to recalls of both FDA- and USDA-regulated products as well as joint enforcement activities by the agencies.

The most recent example is the enforcement action by FDA in conjunction with the U.S. Department of Justice (DoJ), USDA, and the California Department of Health Services, Food and Drug Branch (CFDB) against Fay's Foods, Inc., of North Hollywood, CA. This multi-agency jurisdictional situation resulted in an immediate Class I Recall and a consent decree for permanent injunction against Fay's Foods, Inc., due to continuing *Listeria monocytogenes* contamination of sandwiches and salads and continuing unsanitary production conditions. *Listeria monocytogenes* is a significant pathogenic bacterium capable of causing serious illness and death in immuno-compromised individuals such as cancer patients, neonates, and pregnant mothers. FDA worked collaboratively with the State of California on a State embargo by CFDB based on FDA's findings of widespread *Listeria monocytogenes* contamination of facility and finished products; and worked jointly with USDA findings of products that were under USDA jurisdiction that were considered adulterated.

Additionally, during the course of the GAO study, FDA supplied other examples of where either FDA notified FSIS or FSIS notified FDA, under the MOU, after determining that the conditions found in the facility required enforcement action for all products in the warehouse, regardless of

which agency was regulating the product. In these examples, it is clear that the unsanitary conditions warranted regulatory action and that these unsanitary conditions did not differentiate between food products regulated by FDA or FSIS.

The MOU calls for the local FDA and FSIS offices to meet on an annual basis to share information and called for an evaluation after the first year to confirm that it was implemented. While no further evaluation was required, we believe that this annual information sharing of local FDA and FSIS offices has generally occurred and is evident based on the annual changes in number of dual jurisdiction firms, as well as the joint enforcement actions taken over the past years. FDA believes that this MOU has been largely successful in enhancing collaborative activities to improve public health protection. FDA and FSIS significantly increased the effectiveness of communications between the two agencies, heightened awareness of each other's responsibilities and operations, and initiated more frequent and more effective cooperative efforts. HHS recognizes that there are additional actions that may be taken to further strengthen and enhance collaborative efforts with FSIS. The signing of the MOU was meant to be only one step in building a stronger food safety public health infrastructure. Therefore, FDA and FSIS agreed to conduct some additional joint training to further the implementation of this MOU.

**GAO Recommendation #2:**

***Examine the feasibility of establishing a joint training program for food inspectors.***

**HHS Comment**

HHS agrees that USDA and FDA must collaborate in developing training from which both agencies can benefit. However the report implies that FDA and USDA are not collaborating, which is incorrect. We have collaborated and will continue to do so. A few examples are:

- As recently as February 2005, FDA posted and presently hosts a web-based training course on food security. FDA and USDA developed this course jointly. The target audience is FDA staff, USDA staff, State/tribal/local regulators, and the regulated industry.
- Over the years FDA and USDA have collaborated on numerous satellite downlinks that benefited the staff of both agencies. Examples of this collaboration include the conduct of two retail meat and poultry processing teleconferences, Personal Safety Training for Field Personnel, Multi-Agency BSE Import Safety Net, FDA/FSIS Memorandum of Understanding: An Overview, Food Microbiological Control, Foodborne Illness Investigations, Traceback of Fresh Produce and Other Commodities, Communication Skills for Regulators, and Plain Language 2000: It's the Write Idea.
- The training director of FSIS and the training director of FDA's Office of Regulatory Affairs regularly meet to discuss best practices and opportunities to collaborate.
- USDA and FDA training staffs regularly support each other. For example, in the fall of 2004 FDA staff trained school lunch officials on HACCP process. The training was held at the FDA training facility.

**Appendix VI**  
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**and Human Services (FDA)**

- FDA shared a best practice by briefing USDA executives, including the previous FSIS Administrator, on FDA's Cooperative Research and Development Agreement (CRADA) with a private learning firm to develop and deliver web-based training.
- FDA and USDA have collaborated on training related to epidemiology, tissue residue, retail food, and laboratory science.

HHS agrees that FDA and USDA should continue to identify additional opportunities to collaborate on training issues when workable commonalities can be found. An example would be to have a joint downlink(s) on the FDA/USDA MOU. Also, if USDA does develop a business relationship with FDA's CRADA partner, existing FDA web courses could be shared with USDA and future courses could be developed collaboratively.

HHS disagrees with the recommendation of a unified joint training program between FDA and USDA. The two agencies enforce different laws using different procedures. Our staffs are different—having different backgrounds and experiences. The foods regulated by the two agencies are different. In order for training to be effective, it must be focused on the day-to-day needs of the students, providing both theory and practical application and expectations. By suggesting a unified program, the report suggests that HACCP is the same for all products and should be taught jointly. While the seven principles of HACCP are the same, the practical application of HACCP is different for each food. Therefore the practical application of HACCP taught to FDA staff is and must be different than what is taught to USDA staff.

HHS further disagrees with the unified joint training program because such a unified approach would result in duplication and inefficiency to FDA. FDA would still have to maintain a training program and training facilities to train the same investigators in their other work related to human and veterinary drugs, medical devices, and blood products.

**GAO Recommendation #3:**

***Consider the findings of USDA's foreign country equivalency evaluations when determining which countries to visit.***

**HHS Comment**

FDA's enforcement program considers many factors in identifying domestic and foreign facilities for inspection, including risk-based product priority, compliance history, current production, product technology changes, emerging food safety issues and data, or information provided by others. Accordingly, FDA will also consider USDA's foreign country equivalency evaluations for facilities and Government authorities that manufacture and assure safety of FDA-regulated products.

**GAO Recommendation #4:**

***To better use FDA's limited inspection resources and leverage USDA's resources, we recommend that, if appropriate and cost effective, the Commissioner of Food and Drug Administration, as authorized under the Public Health Security and Bioterrorism***

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**Appendix VI**  
**Comments from the Department of Health**  
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*Preparedness and Response Act of 2002, enter into an agreement to commission USDA inspectors to carry out FDA's inspection responsibilities for those food establishments that are under the jurisdiction of both agencies.*

**HHS Comment**

Section 314 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides FDA with the authority to commission other Federal officials to conduct inspections. This section amends Section 702 of the Federal Food, Drug, and Cosmetic (FD&C) Act to authorize the Secretary of HHS to commission other Federal employees to conduct examinations and inspections. It requires an MOU between the Secretary and the head of the other Federal agency. The MOU must address adequate training of officers and employees of such other department or agency to conduct such examinations and inspections. It also must address reimbursement for examinations and inspections conducted under this authority. It is restricted to facilities or other locations that are jointly regulated by the Secretary and the other department or agency. Because of the reimbursement and training requirements, FDA wants to point out that the commissioning of other Federal agencies may not be resource neutral, as GAO assumes, and will not necessarily result in a net savings for FDA.

This section also requires the Secretary and the head of the other Federal department or agency to submit a report to Congress each fiscal year that provides the number of employees that carried out one or more activities, the number of additional articles that were inspected or examined, and the number of additional examinations or investigations that were carried out pursuant to the memorandum.

The agencies have looked at the issue of commissioning FSIS personnel preliminarily. One issue that will need to be addressed is the different legal authority each agency has for the foods it regulates. The Federal Meat Inspection Act and the Poultry Products Inspection Act require that food products be approved for sale, i.e., stamped by USDA inspectors. The FD&C Act does not require premarket approval, in general, for FDA-regulated food products. These different statutory mandates might create some issues that will have to be examined further.

There are other issues to address, including the differences in core qualifications for each agency's inspectorate. We found that the FSIS personnel with scientific education comparable to FDA's Consumer Safety Officer/Investigator were not the in-plant inspectors, but were the area circuit supervisors and/or FSIS Compliance Officers. These FSIS personnel are not in the facilities on a continuous operating basis but rather are present in the facilities on a periodic basis to provide oversight or compliance review. Additionally, the qualified FSIS personnel would need to receive training on the FD&C Act, evidence development, policy and procedures, documentation, and reporting.

Additionally, there are only a relatively small percentage of the total food establishments in the U.S. that are subject to inspection by both FDA and USDA. Some of these dual jurisdiction establishments are also covered by States under existing contracts with FDA.

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**Appendix VI  
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and Human Services (FDA)**

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All of these factors and others would need to be considered in a formal manner if the agencies were to enter into an agreement to commission USDA inspectors to carry out FDA's inspection responsibilities. The agencies will continue to look at all appropriate leveraging opportunities that enhance our public health responsibilities in an efficient manner.

**GAO Recommendation #5:**

*To better use FDA's limited inspection resources and leverage NMFS's resources, we recommend that the Commissioner of the Food and Drug Administration and the Under Secretary of Commerce for Oceans and Atmosphere ensure the implementation of the interagency agreement that calls for FDA to recognize the results of NMFS inspections when determining the frequency of its seafood inspections.*

**HHS Comment**

An MOU between the U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA), NMFS and FDA was signed in 1974 regarding inspection programs for fishery products. We recognize the report's concerns that agreements created decades ago may no longer be relevant to current needs, that some provisions of these agreements may be obsolete and that some agreements do not reflect changes in a signatory's roles and responsibilities since they were signed. FDA intends to assess the NMFS MOU in light of these concerns, as well as in light of the conflict of interest concerns expressed in the report.

**GAO Recommendation #6:**

*To strengthen management controls and maximize the effectiveness of interagency agreements designed to reduce overlap, increase coordination, and leverage resources, we recommend that the Secretary of Agriculture, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, and the Under Secretary of Commerce for Oceans and Atmosphere:*

*Identify and inventory all active interagency food safety-related agreements.*

**HHS Comment**

FDA has identified and inventoried all MOUs with various agencies, including all active food safety related agreements.

**GAO Recommendation #7:**

**Evaluate the need for these agreements and, where necessary, update the agreements to reflect recent legislative changes, new technological advances, and current needs.**

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**Appendix VI  
Comments from the Department of Health  
and Human Services (FDA)**

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**HHS Comment**

As the draft report points out, these interagency agreements were developed, some more than 30 years ago, to exchange information that was of mutual benefit to the agencies. FDA will review all active food safety agreements and updates will be made, as necessary.



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The following are GAO's comments on the U.S. Department of Health and Human Services' (HHS) letter, dated March 11, 2005.

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## GAO Comments

1. We disagree with HHS's comment that our report's title should substitute the word duplication for overlap. Given the definitions we lay out in the report, if we modified the title as HHS suggests, we would risk implying that the agencies are undertaking many duplicative efforts, even though we are fully aware that under the current statutory framework the agencies do not exactly replicate food safety activities. That is, our report distinguishes between "overlap"—which we define as those similar activities being performed by more than one agency and "duplication"—which we define as essentially identical activities performed by more than one agency.

We also disagree with HHS's comment that our report overstates similarities in USDA and FDA inspections. First, our report clearly states that USDA and FDA inspections have common key elements: sanitation, good manufacturing practices, and HACCP compliance oversight. Second, the report makes it clear that USDA and FDA inspections vary, depending on whether the product is a USDA- or FDA-regulated food product.

Furthermore, we disagree with HHS's comment that the training programs are vastly different. As our report discusses, FDA's training curriculum includes dozens of courses that address topics common to USDA and FDA. Despite HHS's disagreement with our recommendation that the agencies examine the feasibility of establishing a joint training program for food inspectors, we continue to believe that such an examination has merit. In its comments, USDA agreed that there is merit in examining the feasibility of conducting joint training activities when commonalities can be found.

2. We agree with HHS's comment that, if a single agency were to be responsible for the safety of all food products, different organization units within that agency may need to coordinate their activities. However, we believe that some economies of scale would be derived from combining overlapping activities, including those that our report highlights. For example, with a single food safety agency, the federal government would not need to have two separate food inspection workforces or two separate training programs.

3. We acknowledge that some elements of the 1999 interagency agreement on dual jurisdiction establishments have been implemented and that the agreement has enhanced coordination. However, we continue to believe that the agreement could be better implemented. We further disagree that the report does not identify the distinct difference between FDA interagency agreements and memoranda of understanding. We acknowledge that, as used in our report, the term interagency agreement refers generally to memoranda of understanding, memoranda of agreement, and interagency agreements identified by USDA, FDA, EPA, and NMFS. The report includes a footnote to indicate that FDA makes a distinction, which the other agencies do not, between interagency agreements and memoranda of understanding. The footnote explains that, according to FDA, FDA memoranda of understanding do not provide for exchanges of funds. FDA refers to agreements that involve exchanges of funds, personnel, or property as interagency agreements. We did not consider this type of agreement in our analysis.
4. We understand the differences between HACCP principles and plans. Our report acknowledges that while HACCP principles are the same for both FDA and USDA, the HACCP plans are different as they address different risks associated with different products (i.e., seafood, juice, meat, or poultry). Our report's identification of HACCP requirements as another area of overlap between the two agencies refers to the fact that both agencies have issued HACCP regulations that are based on a similar HACCP model. We have modified our report to indicate that, short of consolidating all inspection functions, consolidating inspections of the similar elements in the agencies' HACCP plans would reduce overlap. We further note that USDA's HACCP rule applies to both meat and poultry products, although these products present different hazards. Thus, we believe it is possible to issue broad regulations based on common principles that can then be applied to specific products. We have made minor modifications in the report to avoid confusion regarding HACCP principles and HACCP plans and to indicate that different risks are associated with different food products and, therefore, require different HACCP plans.

# Comments from the U.S. Department of Commerce (NOAA)



**UNITED STATES DEPARTMENT OF COMMERCE**  
The Under Secretary of Commerce  
for Oceans and Atmosphere  
Washington, D.C. 20230

MAR 11 2004

Mr. Robert A. Robinson  
Director, Natural Resources  
and Environment  
United States Government Accountability Office  
Washington, D.C. 20548

Dear Mr. Robinson:

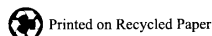
Thank you for the opportunity to review and comment on the Government Accountability Office's draft report entitled *Food Safety: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources* (GAO-05-213). Enclosed is the National Oceanic and Atmospheric Administration's comments to this draft report.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Lautenbacher, Jr.", written in a cursive style.

Conrad C. Lautenbacher, Jr.  
Vice Admiral, U.S. Navy (Ret.)  
Under Secretary of Commerce for  
Oceans and Atmosphere

Enclosure



THE ADMINISTRATOR



**NOAA Comments on the Draft GAO Report Entitled  
“Food Safety: Federal Agencies Should Pursue Opportunities  
to Reduce Overlap and Better Leverage Resources”  
(GAO-05-213/March 2005)**

**General Comments**

The draft report regarding overlap in food safety activities among federal agencies does a fair and thorough job, in general, of describing the major activities of the National Oceanic and Atmospheric Administration’s (NOAA) National Marine Fisheries Service (NMFS) relative to food safety.

**Recommended Changes for Factual/Technical Information**

*Page 11, Table 1, row beginning with Department of Commerce:*

In addition to the “Voluntary, fee-for-service examinations of seafood for safety and quality,” NMFS 1) conducts research, including risk analysis, on levels of contaminants found in target species of fishery products; and 2) analyzes species impacted by oil spills, including species that may be harvested for human consumption.

*Page 37, first paragraph, last sentence:*

“NMFS officials told us that the agency would be willing to enter into such an agreement with FDA, thereby assisting FDA in reaching its goal of conducting annual inspections at all high-risk facilities.”

NOAA agrees with this statement and believes the positions expressed in a previous GAO report entitled “Food Safety: FDA’s Imported Seafood Safety Program Shows Some Progress, But Further Improvements Are Needed” (GAO-04-246/January 2004) continue to be germane to this issue. The following statements have been extracted from pages 24 to 25 of the referenced report:

**NOAA’s Seafood Inspection  
Personnel and Laboratories  
Could Augment FDA’s  
Regulatory Program**

NOAA officials said that they could assist FDA by providing various Services to augment FDA’s regulatory program for imported seafood. These services include

- foreign firm inspections,
- HACCP training,
- domestic importer inspections,
- port-of-entry inspection and product sampling, and
- assistance in developing and verifying equivalence or other types of agreements with seafood exporting countries.

**Appendix VII  
Comments from the U.S. Department of  
Commerce (NOAA)**

NOAA officials also said that they could conduct some domestic seafood inspection services that FDA currently conducts, which would allow FDA to refocus some of its resources on imported seafood. For example, NOAA inspectors could certify domestic seafood products shipped to the European Union and other countries, which is a service that NOAA provided in the past on a fee-for-service basis. Also, FDA and NOAA could agree to recognize NOAA's current inspections of approximately 240 domestic processing firms and authorize NOAA to inspect other domestic firms for compliance with HACCP. NOAA officials estimate that they could provide FDA with up to 22 full-time-equivalent field inspectors as well as additional technical support staff in its headquarters office.

In addition, NOAA and FDA officials are now negotiating the terms of an agreement to use two NOAA laboratories to screen imported shrimp samples for the antibiotic chloramphenicol. FDA is taking this action to increase its testing capacity in response to the detection of the drug in imported shrimp by food safety authorities in Europe, Canada, and some U.S. states. Chloramphenicol is banned for use in food-producing animals because there is no known safe level for human ingestion of this substance. If the negotiations succeed, FDA would increase its screening capacity by 400 samples per year.

Although the central focus of the current draft report is food safety, NOAA believes a better integration of the resources and expertise among federal agencies could further assist FDA in improving the frequency of inspections, which is now estimated to be three to five years for facilities other than high-risk foods (see footnote 17, page 32). Based on NOAA's experience, adverse consequences (e.g., deterioration of hygienic practices and economic fraud such as product substitution) become more probable as the frequency of oversight is lessened.

*Page 46, first paragraph after bullets, third sentence:*

This sentence should be revised to read: "EPA's Office of Pesticide Prevention and Office of Water, as well as the NMFS' Seafood Inspection Program and Office of Sustainable Fisheries also provided data."

*Page 49, Table 3, column heading "DOC"; row "Risk Assessment; Staffing Level":*

The staffing level associated with the \$7 million expenditure should be "57". This change will then require the "Total Staffing" figure at the top of page 50 under the DOC column to be changed from "155" to "212".

**Editorial Comments**

*Page 13, Figure 1:*

Change "NFMS" to "NMFS" in the title.

*Page 33, line 5:*

Insert "of" before "millions of pounds..."

**NOAA Response to GAO Recommendations**

**Recommendation:** “To better use FDA’s limited inspection resources and leverage NMFS’ resources, we recommend that the Commissioner of the Food and Drug Administration and the Under Secretary of Commerce for Oceans and Atmosphere ensure the implementation of the interagency agreement that calls for FDA to recognize the results of NMFS inspections when determining the frequency of its seafood inspections.”

**NOAA Response:** NOAA agrees with this recommendation. NOAA will work with the appropriate components of FDA to answer any questions they may have to allow them to move expeditiously toward implementation of this recommendation.

**Recommendation:** “To strengthen management controls and maximize the effectiveness of interagency agreements designed to reduce overlap, increase coordination, and leverage resources, we recommend that the Secretary of Agriculture, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, and the Under Secretary of Commerce for Oceans and Atmosphere

- identify and inventory all active interagency food safety-related agreements; and
- evaluate the need for these agreements and, where necessary, update the agreements to reflect recent legislative changes, new technological advances, and current needs.”

**NOAA Response:** NOAA agrees with this recommendation and will establish an inventory of active interagency food safety-related agreements where NOAA is a signatory. In addition, NOAA will contact the applicable agency or agencies associated with food-safety related agreements whenever NOAA believes they should be revised.

# GAO Contacts and Staff Acknowledgments

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## GAO Contacts

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## Staff Acknowledgments

In addition to those named above Lawrence J. Dyckman, Katheryn Hubbell, Jane Kim, Sara Margraf, Carol Herrnstadt Shulman, Michele Fejfar, Amy Webbink, and Katherine Raheb made key contributions to this report.

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