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QUESTION: WHAT IS MORE SCRAMBLED THAN AN EGG? ANSWER: THE FEDERAL FOOD INSPECTION SYSTEM

HEARING

BEFORE THE

SUBCOMMITTEE ON THE FEDERAL WORKFORCE AND AGENCY ORGANIZATION

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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CONTENTS

	Page
Hearing held on May 17, 2005	1
Statement of:	
Robinson, Robert A., Managing Director, Natural Resources and Environment, U.S. Government Accountability Office; Robert E. Brackett, Ph.D., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration; Merle Pierson, Ph.D., Acting Undersecretary for Food Safety, U.S. Department of Agriculture; Jim Jones, Director of Pesticide Programs, U.S. Environmental Protection Agency; and Richard V. Cano, Acting Director, Seafood Inspection Program, National Marine Fisheries Service	3
Brackett, Robert E.	36
Cano, Richard V.	87
Jones, Jim	79
Pierson, Merle	63
Robinson, Robert A.	3
Letters, statements, etc., submitted for the record by:	
Brackett, Robert E., Ph.D., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, prepared statement of	39
Cano, Richard V., Acting Director, Seafood Inspection Program, National Marine Fisheries Service, prepared statement of	89
DeLauro, Hon. Rosa L., a Representative in Congress from the State of Connecticut, prepared statement of	58
Jones, Jim, Director of Pesticide Programs, U.S. Environmental Protection Agency, prepared statement of	81
Pierson, Merle, Ph.D., Acting Undersecretary for Food Safety, U.S. Department of Agriculture, prepared statement of	65
Robinson, Robert A., Managing Director, Natural Resources and Environment, U.S. Government Accountability Office, prepared statement of	7

QUESTION: WHAT IS MORE SCRAMBLED THAN AN EGG? ANSWER: THE FEDERAL FOOD INSPECTION SYSTEM

TUESDAY, MAY 17, 2005

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON FEDERAL WORKFORCE AND AGENCY ORGANIZATION,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:07 p.m., in room 2154, Rayburn House Office Building, Hon. Jon C. Porter (chairman of the subcommittee) presiding.

Present: Representatives Porter, Norton, Cummings, and Van Hollen.

Staff present: Ron Martinson, staff director; B. Chad Bungard, deputy staff director/chief counsel; Chris Barkley and Shannon Meade, professional staff members; Reid Voss, legislative assistant/clerk; Patrick Jennings, detail from OPM serving as senior counsel; Mark Stephenson and Tania Shand, minority professional staff members; Earley Green, minority chief clerk; and Teresa Coufal, minority assistant clerk.

Mr. PORTER. Thank you, everyone, for being here. I appreciate your being with us this afternoon.

We are actually going to start the meeting until we get a quorum, and then we will recess and get into the markup, which really should be shortly. But for the element of time and for those that are here, for the balance of the meeting, I'm going to start the issue regarding Federal food inspection, and then we will recess as soon as we have the quorum and go into the markup.

So with that, again, thank you for being here and good afternoon. We're going to start by answering the question, what is more scrambled than an egg? The answer is the Federal Food Inspection System.

I'd like to let everyone know again, for the record, that we will move into the markup, but this hearing is just about the basic commonsense in finding ways to achieve efficiency and economy for taxpayers.

As chairman of the subcommittee, I will continue to look for ways to organize the government in a more effective manner and to do so in an expedited fashion, such as reconstituting Fast Track Authority for agency reorganization proposals.

We have chosen to examine the food inspection process today only because of the seemingly nonsensical organizational structure

of the inspection process itself. For example, if Congress were to set up an organizational structure today, I hardly believe that we would have the USDA inspect manufacturers of spaghetti with meat sauce, pepperoni pizza, open face meat and poultry sandwiches, corn dogs and beef broth daily and require the FDA to inspect manufacturers of spaghetti without meet sauce, cheese pizzas, close faced, which are traditional meat and poultry sandwiches, bagel dogs and chicken broth once every 5 years.

We also would not require school lunches to be inspected twice, once by the USDA and once by the FDA. It is almost too hard to believe, but that's the organizational structure that we have today in the current food inspection system. I'm sure there was a method to this madness at one point in time, but we have to be more efficient and find a more effective way to organize the inspection process.

At the hearing this subcommittee held last March, it looked into why the food inspection process has become what may seem like an organizational nightmare. It was uncovered that 10 agencies are now responsible for executing more than 30 laws directing how the Federal Government inspects food. Moreover, the inspection process has become an intricate web of governmental agencies with responsibilities that often overlap one another, as I just cited a few moments ago. So the question then becomes, who is to blame for this? Well, actually, the blame for this organizational problem does not lie primarily with the past organizations, Republicans or Democrats, or with the food industry that has to live with this system. And as a matter of fact, many folks in the food industry would prefer we leave it the way it is. The blame lies primarily with Congress, which has haphazardly passed the laws making the system what it is today throughout the years. It has been a Band-Aided system.

Though the organizational problems with the system are deep-seated. It does not let off the hook the agencies charged with inspecting food for improving upon the job that they're doing. I am deeply concerned with the findings uncovered by the Government Accountability Office, which are contained in the report I will release today, entitled, Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage of Resources.

The report focuses on the problem of overlap and duplications between the various food inspection agencies. GAO concentrated its investigation on the four agencies with the most food inspection responsibilities, the USDA, the FDA, EPA and National Marine Fisheries Service. As a result of the hearing, GAO has made a number of recommendations for the agency to better operate within the current operation structure. The subcommittee will be examining those recommendations today.

One of the more troubling findings in the report, though, reveals that simply between the four agencies represented here today there are 71—yes, 71 memorandum of understanding to keep the agencies coordinating with one another. Of these 71 agreements, GAO recovered that only in seven cases did all signatory agencies know that they were a party to the agreement. This means that in 64 of 71 agreements, one or more agencies were completely unaware that it was responsible for coordinating with another agency on a

certain matter. This kind of example does not speak to safety of food. I want to make that clear. We're not here to talk about safety of food, although in the long run, it does have an impact. But we understood that we have one of the best and safest food systems in the world, we are just trying to make it more efficient. Rather, it highlights the need that the Federal Government is using the tax dollars taken from the American people as wisely and efficiently as possible. Anything less than a lean and well organized food inspection process is unacceptable.

Regardless of the organizational ideas offered today, I would emphasize at the outset that everyone in this room is in agreement that we want our food supply to be safe, so that's not the issue.

I thank our witnesses for being here, and I look forward to the discussion. Again, we are waiting for a quorum, so what I would like to do is ask all those on the panel to please stand, and I'll swear them in at this time.

On the first panel today, we're going to hear from Robert Robinson. Mr. Robinson is the Managing Director of Natural Resources and Environment, Government Accountability Office. And we're going to hear from Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration.

Welcome.

Then we'll hear from Dr. Merle Pierson, Acting Undersecretary for Food Safety at the U.S. Department Of Agriculture. And then we will be hearing from Mr. Jim Jones, Director of Pesticide Programs at the U.S. Environmental Protection Agency. And finally, we will hear from Richard Cano, Acting Director of the Seafood Inspection Program at the National Marine Fisheries Service.

OK. What I'd like to do is let the record reflect the following.

[Witnesses sworn.]

Mr. PORTER. Thank you very much. Would you please be seated.

Mr. Robinson, welcome. Thank you for joining us today, you will be recognized for 5 minutes.

STATEMENTS OF ROBERT A. ROBINSON, MANAGING DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; ROBERT E. BRACKETT, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION; MERLE PIERSON, PH.D., ACTING UNDERSECRETARY FOR FOOD SAFETY, U.S. DEPARTMENT OF AGRICULTURE; JIM JONES, DIRECTOR OF PESTICIDE PROGRAMS, U.S. ENVIRONMENTAL PROTECTION AGENCY; AND RICHARD V. CANO, ACTING DIRECTOR, SEAFOOD INSPECTION PROGRAM, NATIONAL MARINE FISHERIES SERVICE

STATEMENT OF ROBERT A. ROBINSON

Mr. ROBINSON. Thank you, Mr. Chairman.

Thank you for holding this hearing and giving us the opportunity to express our views about the Federal food safety's food inspection structure.

As you can see in our appendix to our statement, we have been weighing on this and related topics for quite some time. We first

called for fundamental restructuring of the system in 1992 when my hair color was decidedly different than it is today. In the more than a decade since then, some important progress has been made in making our food safety system more science based.

Of particular note, the agencies have begun requiring companies to adopt the HACCP system to try to prevent contamination before it occurs, rather than simply dealing with it after it has been detected. HACCP shifted a significant share of responsibility for ensuring safe food from government to industry, and there are clear signs the industry has responded. However, the same structural problems and inefficiencies present in 1992 remain today. And in the intervening years, a number of trends have emerged that make the case for restructuring even more compelling today.

First, as the Comptroller General pointed out in his 2003 testimony before this subcommittee, our Nation is facing increasingly serious long-term fiscal challenges. We are on an unsustainable fiscal path that, without a change in course, could have future revenues unable to cover much more than interest on the debt just a few decades from now. If we ever could, we probably have reached a point where we can no longer afford a government weighed down by duplicative and overlapping missions and functions.

Second, the chorus of voices calling for change is growing. While a number of industry associations we contacted in assembling our report continue to believe that the structural problems are not significant, many other stakeholders are coming to realize that the current structure doesn't meet the commonsense test. In fact, a number of food companies subjected to dual regulation by USDA and FDA told us that the overlaps can be burdensome as they deal with two sets of HACCP requirements and two sets of inspection approaches. In some cases, they even told us of conflicting direction being provided by different inspectors from different agencies.

Likewise, the Institute of Medicine, the Consumer Federation of America and the National Commission on the Public Service have now also supported a move to a more consolidated structure.

Third, several other countries have moved to a single food safety agency to increase efficiency, to eliminate conflicts of interest and improve the safety of their food supply. As we reported in February, officials in each of the seven developed countries we reviewed believe the overall effect of consolidation has been or is expected to be positive. For example, as the first exhibit to your left shows, the government of Denmark consolidated major food safety functions that were performed by three separate entities, numerous municipalities into a single agency, the Danish Veterinary and Food Administration. As the second exhibit shows, Canada also consolidated food inspection functions from food agencies into a single Canadian food inspection agency, while placing public health policy and standard setting with Health Canada.

Finally, as we pointed out in the report you're releasing today, the overlap and duplication consequences of our current organizational structure are becoming more apparent. Because the key agencies still have jurisdiction over different segments of the food supply, USDA and FDA both conduct overlapping and even duplicative inspections at more than 1,450 domestic food processing facilities that produce multi-ingredient foods or different types of

food. In our view, this represents an inefficient use of increasingly scarce government resources. For example, as shown in the third exhibit, a facility that the GAO team visited that produces both meat and seafood products and therefore comes under the jurisdiction of both USDA and FDA, the USDA inspector is there on a daily basis. And because of the physical plant layout, the inspector must walk through an area containing FDA-regulated seafood. However, because FDA regulates seafood, the USDA inspector does not monitor or inspect that section of the plant.

As the final exhibit shows, most Federal food safety expenditures involve inspection or enforcement activities. Oddly enough, though, USDA spends about 75 percent of these inspection dollars, even though it is responsible for regulating about 20 percent of the food supply. Conversely, FDA regulates about 80 percent of the food supply, but spends only about 25 percent of these dollars.

FDA and the seafood inspection program run by the National Marine Fisheries Service also conduct somewhat overlapping inspections at about 275 domestic seafood facilities. The NMFS program is a volunteer fee-for-service that is not mandated by legislation. However, FDA does not take full account whether NMFS has already inspected a facility when devising its inspection plans.

USDA and FDA also both inspect imported foods at U.S. ports of entry, and the agencies also visit foreign countries to perform equivalence exams, but they do so under significantly different authorities. Thus, in 2004, USDA conducted equivalence reviews in 34 countries that supply meat and poultry products to the United States. FDA also sent separate teams to conduct inspections in 6 of these same 34 countries.

Finally, USDA and FDA spend millions of dollars each year developing and delivering food inspection training that could easily be unified.

Testifying to the cumbersome structure in an effort to reduce duplication of effort, among other objectives, Federal agencies have developed at least 71 interagency agreements. Unfortunately, the agencies are having difficulty trying to make these agreements work because they don't have adequate mechanisms for tracking them; in many cases, couldn't identify that they existed. In other cases, they simply have not been able to implement them effectively on a day-to-day basis.

Mr. Chairman, at the end of the day, we continue to hold the view that we first expressed more than a decade ago, the Federal Food Safety Inspection System is fragmented and based on outdated laws that reduce its effectiveness and efficiency.

The millions of foodborne illnesses and thousands of hospitalizations in foodborne disease-related deaths tell us we can be more effective. The duplicative inspections, overlapping training and uneven information-sharing among agencies tell us we can be more efficient. The experiences of seven developed countries that moved forward and consolidated their previously fragmented operations tell us that better operations are possible.

And finally, the Nation's growing fiscal imbalance tells us that there is growing urgency to address inefficiencies whenever we find them. With that, let me pause, and I would be anxious to answer questions when the time comes.

[The prepared statement of Mr. Robinson follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on the Federal Workforce and Agency Organization, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 2:00 p.m. EDT
Tuesday, May 17, 2005

OVERSEEING THE U.S. FOOD SUPPLY

Steps Should be Taken to Reduce Overlapping Inspections and Related Activities

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

GAO-05-549T

May 17, 2005

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Highlights

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

OVERSEEING THE U.S. FOOD SUPPLY

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

Why GAO Did This Study

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

What GAO Recommends

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

What GAO Found

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

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

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

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

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

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

Mr. Chairman and Members of the Subcommittee:

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

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

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

[2]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).

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

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

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

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

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

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

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

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

Background

The safety and quality of the U.S. food supply is governed by a highly complex system stemming from 30 principal laws related to food safety that are administered by 15 agencies. In addition, dozens of interagency agreements are intended to address a wide range of food safety-related activities. The federal system is supplemented by the states, which have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products. USDA and FDA, within the Department of Health and Human Services, have most of the regulatory responsibilities for ensuring the safety of the nation's food supply and account for most federal food safety spending. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, USDA is responsible for the safety of meat, poultry, and certain egg products. FDA, under the Federal Food, Drug and Cosmetic Act, and the Public Health Service Act, regulates all other foods, including whole (or shell) eggs, seafood, milk, grain products, and fruits and vegetables.[6] Appendix 1 summarizes the agencies' food safety responsibilities.

The existing statutes also give the agencies different regulatory and enforcement authorities. For example, food products under FDA's jurisdiction may be marketed without the agency's prior approval. On the other hand, food products under USDA's jurisdiction must generally be inspected and approved as meeting federal standards before being sold to

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

the public. Under current law, UDSA inspectors maintain continuous inspection at slaughter facilities and examine each slaughtered meat and poultry carcass. They also visit each processing facility at least once during each operating day. For foods under FDA's jurisdiction, however, federal law does not mandate the frequency of inspections (which FDA typically conducts every 1 to 5 years). Although recent legislative changes have strengthened FDA's enforcement authorities, the division of inspection authorities and other food safety responsibilities has not changed.

As we have reported, USDA traditionally has had more comprehensive enforcement authority than FDA; however, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 granted FDA additional enforcement authorities that are similar to USDA's.[7] For example, FDA now requires all food processors to register with the agency so that they can be inspected. FDA also has the authority to temporarily detain food products when it has credible evidence that the products present a threat of serious adverse health consequences. Moreover, FDA requires that entities such as the manufacturers, processors, and receivers of imported foods keep records so that FDA can identify the immediate previous source and the immediate subsequent recipients of food. This record-keeping authority is designed to help FDA track foods in the event of future health emergencies, such as terrorism-related contamination. In addition, FDA now requires advance notice of imported food shipments under its jurisdiction. Despite these additional authorities, important differences remain between the agencies' inspection and enforcement authorities. For example, the Federal Meat Inspection Act and the Poultry Products Inspection Act require that meat and poultry products be inspected and approved for sale (i.e., stamped by USDA inspectors). The Federal Food, Drug and Cosmetic Act does not require premarket approval, in general, for FDA-regulated food products.

Finally, following the events of September 11, 2001, in addition to their established food safety and quality responsibilities, the federal agencies began to address the potential for deliberate contamination of agriculture and food products. In 2001, by executive order, the President added the food industry to the list of critical infrastructure sectors that need protection from possible terrorist attack. As a result of this order, the Homeland Security Act of 2002 establishing the Department of Homeland

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

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

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

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

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

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

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

Table 1: Examples of Similar Food Safety Activities

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

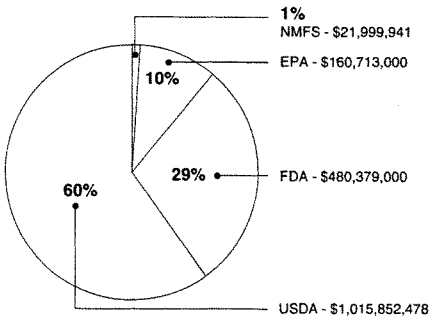
Source: GAO analysis of documents obtained from, and discussions with, USDA, FDA, EPA, and NMFS officials.

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

[b]NMFS participated in developing FDA's seafood HACCP rule.

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

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



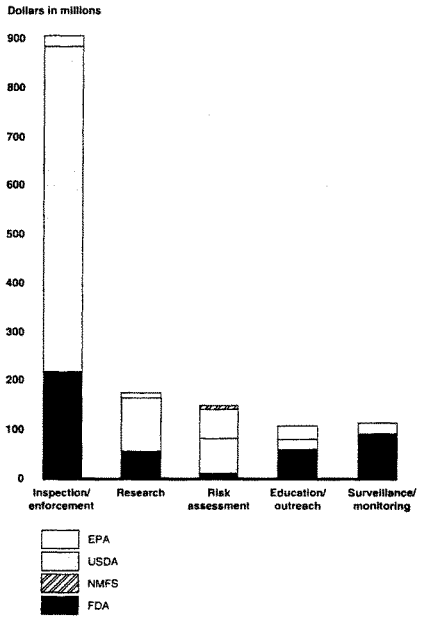
Source: GAO analysis of data obtained from, and discussions with, USDA, FDA, EPA, and NMFS officials.

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

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

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

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



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

Federal Food Safety Agencies Conduct Overlapping Activities

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

USDA and FDA Inspections of Jointly Regulated Facilities Overlap

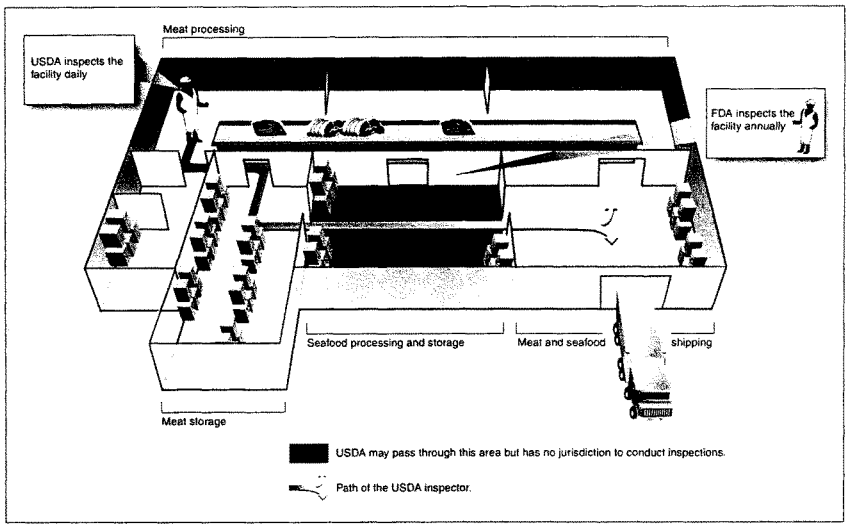
USDA and FDA conduct overlapping, and even duplicative, inspections at more than 1,400 domestic facilities that produce foods such as canned goods and frozen entrees. Both agencies inspect these facilities because each has statutory responsibility for the safety of different foods or food ingredients.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

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

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

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

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



Source: GAO observation of a jointly regulated establishment.

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

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

FDA and NMFS Inspections of Domestic Seafood Processors Overlap

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

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

[11]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.

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

USDA and FDA Both Inspect Imported Food

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

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

USDA and FDA Have Similar Training Programs for Food Inspectors

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

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

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

Interagency Agreements Are Not Reducing Overlaps

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

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

- USDA and FDA are not fully implementing an agreement to exchange information about jointly regulated facilities in order to permit more efficient use of both their resources and contribute to improved public health protection. Under this agreement, the agencies are to share inspection information, but FDA does not routinely consider compliance information from USDA when deciding how to target its inspection resources. Also, the agreement calls for the agencies to explore the feasibility of granting each other access to appropriate computer-monitoring systems so that each agency can track inspection findings. However, the agencies maintain separate databases and the inspectors with whom we spoke continue to be largely unaware of a facility's history of compliance with the other agency's regulations. Inspectors told us that compliance information might be helpful when inspecting jointly regulated facilities so they could focus on past violations.

- An agreement between FDA and NMFS recognizes the agencies' related responsibilities at seafood-processing establishments. The agreement details actions the agencies can take to enable each to discharge its responsibilities as effectively as possible, minimizing FDA inspections at these facilities. However, we found that FDA is not using information from

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

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

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

- *Industry Associations*: Representatives of industry associations do not see the need to consolidate food safety-related functions, but they see the need for minor changes within the existing regulatory framework to enhance communication and coordination among the existing agencies.

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

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

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

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

Other Countries Have Modified Laws and Consolidated Food Safety Functions

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

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

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

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

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

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

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

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

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

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

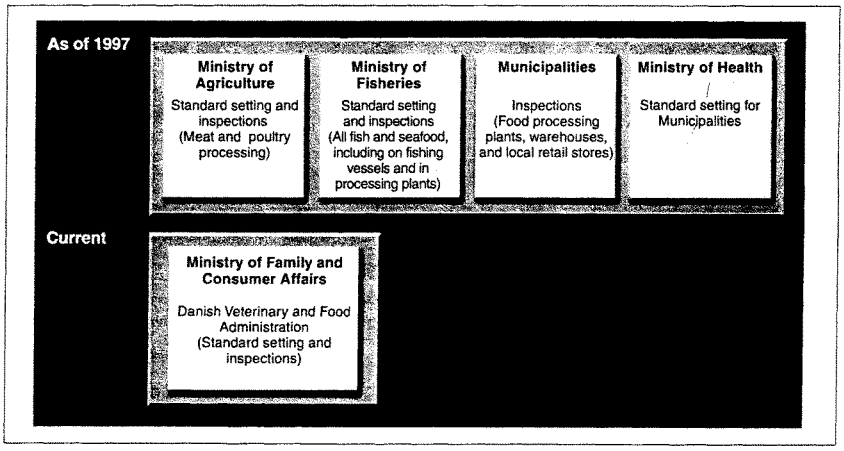
None of the countries has conducted an analysis to compare the effectiveness and efficiency of its consolidated food safety system with that of the previous system. However, government officials in these countries as well as other stakeholders consistently stated that consolidation of their systems has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

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

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

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

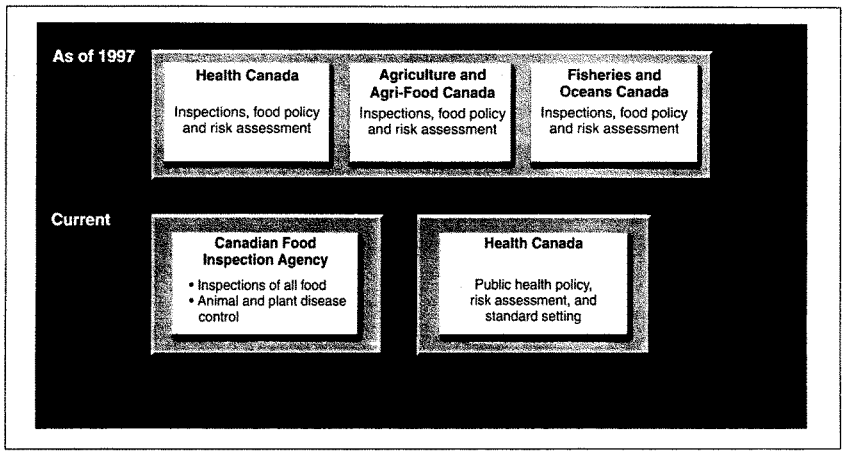
Figure 4: Consolidation of Food Safety Entities in Denmark



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

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

Figure 5: Consolidation of Food Safety Entities in Canada



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

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

Conclusions

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

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

Contacts and Staff Acknowledgements

For further information about this testimony, please contact Robert A. Robinson, Managing Director, Natural Resources and Environment, (202) 512-3841. Maria Cristina Gobin, Terrance N. Horner, Jr., Gary Brown, Katheryn Hubbell, Carol Herrnstadt Shulman, and Katherine Raheb made key contributions to this statement.

Appendix I: Federal Agencies with Food Safety Responsibilities

Table 2: Federal Agencies' Food Safety Responsibilities

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

Source: GAO.

[a]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.

[b]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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Mr. PORTER. Thank you, Mr. Robinson.

I would like to take this time now to recess our hearing on the food inspection system and open our hearing regarding the markup on H.R. 994, H.R. 1283 and H.R. 1765.

[Recess.]

Mr. PORTER. We will go back to the other hearing, and bring it back into session, and that's the Federal Food Inspection System.

Thank you, Mr. Robinson, again for your testimony.

And I would now like to ask Robert Brackett, again, Director of Center for Food Safety and Applied Nutrition, Food and Drug Administration, you are recognized for 5 minutes.

STATEMENT OF ROBERT E. BRACKETT, PH.D.

Mr. BRACKETT. Thank you. And good afternoon, Chairman Porter and members of the subcommittee.

I am Robert E. Brackett, Ph.D, Director of the Center for Food Safety and Applied Nutrition at the FDA, which is part of the Department of Health and Human Services.

Thank you for this opportunity to discuss the role that the HHS plays in the Federal Food Safety System. As has been stated, ensuring the safety of the food supply continues to be a top priority for HHS and the administration, and so I am pleased to be here today with my colleagues from USDA, EPA and the National Marine Fisheries Service.

Your letter of invitation mentioned that this hearing will examine the need for reorganizing Federal food safety activities. The current system of interagency coordination is helping to improve the safety of the food supply and will continue to look for new ways to further this coordination. The American food supply continues to be among the safest in the world, and the current Federal Food Safety System is working well.

Just last month, the Centers for Disease Control Prevention, in collaboration with FDA and USDA, released a report with preliminary surveillance data that showed important declines in 2004 in foodborne infections due to common pathogens. This report shows that we are achieving significant public health outcomes in the effort to reduce the incidence of foodborne illness to the lowest level possible.

FDA is the Federal agency that regulates everything we eat except for meat, poultry and egg products, which are regulated by our partners at USDA. FDA's responsibility also extends to life-food animals and animal feed.

You asked about our role in the food inspection system. In fact, FDA has many roles. For example, FDA conducts investigations into foodborne illness outbreaks, along with CDC and our Federal and State partners. And FDA conducts inspections of food manufacturing facilities. We utilize a risk-based approach and expect high-risk facilities with greater frequency than low-risk facilities. We have many contract and partnership agreements with States to assist us with the domestic inspection activities. In addition, FDA works closely with States and local officials on inspections at the retail level.

For foreign producers, FDA conducts a limited number of compliance inspections of high-risk food facilities, such as firms that man-

ufacture low-acid can foods or infant formula. FDA also works through the international organization such as Codex Alimentarius to establish international standards. Through this mechanism, we extend science-based inspection of standards worldwide.

To manage the ever-increasing volume of imported food shipments, we also utilize risk-management strategies. Through the use of an electronic screening system, FDA is able to concentrate its inspection resources on high-risk shipments while allowing the low-risk shipments to proceed into commerce. FDA personnel conduct examinations and collect and analyze samples as necessary to determine compliance with FDA's food safety requirements.

You asked FDA to respond to a recent report by GAO about the use of Federal food safety resources. And we certainly share GAO's interest in finding ways to make FDA more efficient. However, we do not believe the report provides an accurate assessment of how to achieve this. We do not agree with GAO's characterization of what constitutes overlap. In processing establishments, there are no food products that both FDA and USDA regulate. Each agency inspects those products over which it has jurisdiction. The FDA and USDA inspectors have different educational backgrounds, have received different training and have responsibility for different food products and industries.

GAO's report cites the inspection of dual jurisdiction establishments, so-called DJEs, as a primary example of overlapping and efficiency. DJEs are facilities that are regulated by both FDA and USDA because the establishment produces food products that fall under each agency's jurisdiction. We do not agree with GAO's emphasis on inspection of these facilities as a way to save resources and achieve efficiencies. DJEs comprise less than 2 percent of the total food processing or manufacturing facilities in the United States, and further, the report did not seem to take into account the fact that more than half of the 1,451 dual jurisdiction facilities are low-risk facilities, such as warehouses, that do not require a high inspection frequency. Thus, the opportunity for achieving efficiencies through leveraging of inspection resources for these facilities is quite small.

As noted in the report, FDA and USDA's Food Safety and Inspection Service have signed a memorandum of understanding to facilitate the sharing of information about DJEs. This MOU has been successful in enhancing collaborative activities to improve public health protection. To further strengthen this MOU, we have agreed to conduct some additional joint training. We are also following up on GAO's report recommendations to inventory all active interagency agreements and to evaluate and update them as necessary.

I would like now to provide some other examples of successful collaborations with our food safety partners. HHS, USDA, EPA and other agencies are working with the Department of Homeland Security to achieve the objectives of homeland security Presidential Directive No.'s 7, 8, and 9, which identify critical infrastructures, improve response planning, and establish a national policy to defend the agriculture and food systems against terrorist attacks, major disasters and other emergencies.

DHS serves as the coordinator of the food and agriculture sector, with the FDA and HHS as the lead for the food sector, and the

Homeland Security Office and USDA as the lead for the agricultural sector. Today, FDA and FSIS are also announcing a joint proposal to establish a set of general principles for evaluating existing and proposed food standards. General food standards are used to ensure that products sold under particular names have the characteristics expected by consumers. Adherence to the proposed principles will result in more modern standards that will better promote honesty and fair dealing, and will allow for technological advances for food processing. Such technological advances mean enhanced manufacturing efficiency and reduced costs, which could benefit consumers through lower prices and increased product diversity in the marketplace.

In conclusion, FDA is working closely with its Federal food safety partners and others to protect the food supply from deliberate and accidental contamination. And as a result of this effective collaboration, the Federal Food Safety System is stronger than ever before.

Thank you, Mr. Chairman. I would be pleased to respond to any questions.

[The prepared statement of Mr. Brackett follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

STATEMENT OF

ROBERT E. BRACKETT, PH.D.

DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON FEDERAL WORKFORCE AND AGENCY ORGANIZATION

UNITED STATES HOUSE OF REPRESENTATIVES

MAY 17, 2005

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon, Chairman Porter and Members of the Subcommittee. I am Robert E. Brackett, Ph.D., Director of the Center for Food Safety and Applied Nutrition (CFSAN) in the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for this opportunity to discuss the Federal food safety system and to provide testimony on behalf of HHS. Ensuring the safety of the food supply continues to be a top priority for HHS and the Administration. I am pleased to be here today with my colleagues from the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the National Marine Fisheries Service (NMFS) in the Department of Commerce (DOC).

In your letter of invitation, you asked FDA to respond to the recent report by the Government Accountability Office (GAO) entitled "Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources." I would like to take this opportunity to assure you that FDA is committed to using our resources as effectively as possible. Both FDA and our colleagues at USDA work cooperatively to leverage each other's resources when appropriate. However, we recognize that one can always do more and welcome your suggestions. Although HHS does not agree with the GAO report's overall assessment, we do agree with some of its recommendations and are implementing them.

Your letter of invitation mentioned that this hearing will also examine the need for reorganizing. The current system of interagency coordination is helping improve the safety of the food supply, and we will continue to look for ways to further this coordination.

The American food supply continues to be among the safest in the world. The current Federal food safety system is working well, and food safety agencies are working more closely together than ever before. Just last month, the Centers for Disease Control and Prevention (CDC) in HHS, in collaboration with FDA and USDA, released a report with preliminary surveillance data that show important declines in foodborne infections due to common pathogens in 2004 when compared against baseline data for the period 1996 through 1998. We will continue to strive to reduce the incidence of foodborne illness to the lowest level possible. This report shows that FDA's and USDA's efforts are working, and we are making progress.

Reductions in foodborne infections are a result of numerous measures taken by FDA, USDA, and others. For example, in the fall of 2003, HHS and USDA released the "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Food." This assessment identified clear measures that industry, retailers, and consumers can take to dramatically reduce the risk of illness from this foodborne pathogen. HHS also released the *Listeria* Action Plan that identified additional measures to reduce the risk of listeriosis.

In October 2004, FDA released the Produce Action Plan, which will aid in reducing the incidence of foodborne illness attributed to the consumption of produce. In 2001, FDA issued

its Juice Hazard Analysis and Critical Control Point (HACCP) regulation, which provided control measures to prevent, reduce, or eliminate hazards from fruit and vegetable juice and juice products. This regulation was promulgated in response to a number of foodborne illness outbreaks associated with these products. After raw sprouts were associated with several outbreaks, FDA issued guidance documents in 1999 for the sprout industry. The guidance documents contain steps that the sprout industry can take to reduce microbial hazards common to sprout production to ensure that sprouts are not a cause of foodborne illness. These are just a few examples of the many activities that have contributed to a decline in the incidence of foodborne illness.

In my testimony today, I will first describe HHS' food safety and defense responsibilities. Then, I will discuss some of the issues raised in the GAO report. I will also describe a few of our many cooperative activities with USDA and our other partners.

HHS' FOOD SAFETY AND DEFENSE RESPONSIBILITIES

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. FDA is the Federal agency that regulates everything we eat except for meat, poultry, and certain egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. FDA is also responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as veterinary drugs are safe and effective, and that cosmetics are safe. In addition, FDA is responsible for assuring that the health consequences of foods and

medicines are accurately and honestly represented to the public, so that they can be used as effectively as possible to protect and improve the public health.

FDA has many roles in the food inspection system. For example, FDA conducts investigations into foodborne illness outbreaks along with CDC and our Federal and state partners. FDA utilizes a risk-based approach for inspections of food manufacturing facilities, inspecting high-risk facilities with greater frequency than low-risk facilities. We have 39 contract and 37 partnership agreements with states to assist with these domestic inspection activities. In addition, FDA works closely with state and local food safety officials on food safety inspections at the retail level. For foreign producers, FDA conducts a limited number of compliance inspections, with the permission of the foreign country, of high-risk food facilities, such as firms that manufacture low-acid canned foods or infant formula. FDA also works through international organizations such as Codex Alimentarius to establish international standards. Through this mechanism, we extend technical assistance and science-based inspectional standards worldwide.

To manage the ever-increasing volume of imported food shipments, we also utilize risk-management strategies in the review of foods that are being imported or offered for import into the United States. Working with information submitted to Customs and Border Protection (CBP) in the Department of Homeland Security (DHS), FDA screens shipments electronically to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. This electronic screening allows FDA to concentrate its resources on high-risk shipments while allowing low-risk shipments to proceed

into commerce. FDA personnel conduct examinations and collect and analyze samples as necessary to determine compliance with FDA food safety requirements. For any products found to be in violation of the Federal Food, Drug, and Cosmetic Act, we take appropriate enforcement action, working closely with CBP.

By way of background, while FDA has the lead responsibility within HHS for ensuring the safety of food products, CDC in HHS has an important complementary and non-regulatory public health role. As the lead Federal agency for conducting disease surveillance, CDC monitors the occurrence of illness in the U.S. attributable to the entire food supply. The disease surveillance systems coordinated by CDC provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness. In addition, these systems can be used to indicate new or changing patterns of foodborne illness. Because CDC also detects and investigates outbreaks of foodborne illness through its networks, CDC is able to alert FDA and USDA about implicated food products associated with foodborne illness and works closely with the agencies to take protective public health action. In keeping with its agency mission, CDC also identifies, evaluates, and provides expert scientific opinion on the effectiveness of foodborne disease prevention strategies.

FDA contributes financially and scientifically to the Foodborne Diseases Active Surveillance Network (FoodNet), the principal foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative activity of CDC, FDA, the Food Safety and Inspection Service (FSIS) of USDA, and ten EIP sites (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee, and New Mexico). Through

this active surveillance system, these sites actively seek out information on foodborne illnesses identified by clinical laboratories, collect information from patients about their illnesses, and conduct investigations to determine which foods are linked to specific pathogens. This surveillance system provides important information about changes over time in the burden of foodborne diseases. For example, the CDC foodborne illness report I mentioned earlier, which shows a decline in the incidence of foodborne illness, used data from FoodNet. These data help public health and food safety agencies evaluate the effectiveness of current food safety initiatives and develop and plan future food safety activities to prevent and reduce emerging foodborne illnesses.

In addition, just as FDA works with state and local food safety counterparts, CDC works extensively with state and local health departments to build their epidemiology, laboratory, and environmental health expertise in foodborne disease surveillance and outbreak response. All of these collaborations draw on and apply the unique expertise within HHS to address significant and emerging challenges to our food supply.

GAO'S REPORT

Although we certainly share GAO's interest in finding ways for FDA to make FDA more efficient, we do not believe the report provides an accurate assessment of how to achieve this with food inspection and training activities. For example, we do not agree with GAO's characterization of what constitutes "overlap." 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. As each agency has separate statutory authority to regulate different food products, naturally we engage in activities that, on the surface, appear similar. For example, each agency inspects those products over which it has jurisdiction and promulgates regulations to implement its statutory authority. We believe, however, that these similarities are broad and superficial and that the GAO report sweeps too broadly when it characterizes our similar activities as "overlap." In fact, we believe the inspections conducted by these agencies are far more different than they are similar. FDA and USDA inspectors have different educational backgrounds, have received different training, and have responsibility for different food products and industries. These differences are due to the different legal authorities and the different scientific knowledge necessary to understand and regulate different food products and different processing techniques. All of this makes each agency's inspections different.

GAO's report cites the inspection of dual jurisdiction establishments (DJEs) as a primary example of overlap and inefficiency. DJEs are facilities that are regulated by both FDA and USDA because the establishment processes some food products that fall under FDA's jurisdiction and other food products that fall under USDA's jurisdiction. First, let us be clear on the scope of GAO's focus. DJEs comprise less than two percent of the total food processing or manufacturing facilities in the U.S. This is a very small percentage of food facilities and, in many cases, these are facilities at which FDA has assessed the risks to be low. At DJEs, each agency is responsible for products and processes within its own area of expertise and jurisdiction. We do not agree with GAO's characterization of these inspections as examples of overlap. We also do not agree with GAO's emphasis on DJE inspections as a significant way to save resources and achieve efficiencies. The report did not seem to take into account the fact

that many of these facilities are low-risk facilities such as warehouses or other establishments that do not require a high inspection frequency by either agency. Of the 1,451 DJEs, more than a third (539) are warehouses, which are considered low-risk. Of the 772 food manufacturers, FDA considers 284 of these to be low-risk. The remaining DJEs include 140 other types of establishments such as retailers, importers, packers, and labelers. We believe the report's findings are flawed. The report did not take into account the fact that more than half of the DJEs are low-risk facilities that, under FDA's risk-based strategy, do not require frequent inspections; thus, the opportunity for achieving efficiencies through the leveraging of resources is quite small.

As noted in the report, FDA and USDA's FSIS have signed a Memorandum of Understanding (MOU) to facilitate the sharing 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 find 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. We believe this MOU has been quite productive and has been successful in enhancing collaborative activities to improve public health protection. For example, the sharing of information through this MOU has led to a number of recalls of both FDA- and USDA-regulated products and has led to joint enforcement activities by the agencies.

An example of a joint enforcement action that occurred as a result of the MOU involved a large warehouse in Illinois. In March of this year, the U.S. Attorney's Office charged the company and a former company executive with two felony counts of improperly storing USDA-regulated meat and poultry products and one misdemeanor count of improperly storing FDA-regulated food products. This action began with a joint FDA/USDA inspection after USDA reported, pursuant to the MOU, extensive rodent infestation in the perishable meat and produce section, as well as the dry goods section. FDA pursued the prosecution in conjunction with the local FSIS district office and the U.S. Attorney's Office of the Northern District of Illinois. During the course of the GAO study, FDA supplied other examples in which FDA and FSIS notified each other 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.

The MOU calls for the local FDA and FSIS offices to meet on an annual basis to share information. It also called for an evaluation after the first year to confirm that it was implemented. Although no further evaluation was required under the agreement, we believe that this annual information-sharing of local FDA and FSIS offices has generally occurred. This is evident based on the annual changes in the number of dual jurisdiction firms, as well as the joint enforcement actions taken over the past years. Through this MOU, FDA and FSIS have 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. We recognize that there are additional actions that may be taken to further strengthen and enhance our collaboration with FSIS. Therefore, FDA and

FSIS have agreed to conduct some additional joint training to further the implementation of this MOU. In addition, we are following up on the GAO report's recommendations to identify and inventory all active interagency agreements and to evaluate and update them as necessary. With regard to training, the GAO report recommends that FDA and USDA examine the feasibility of establishing a joint training program for food inspectors. HHS agrees that USDA and FDA should collaborate in developing training where 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.

For example, as recently as February 2005, FDA posted and presently hosts a web-based training course on food defense. FDA and USDA's FSIS and Agricultural Marketing Service jointly developed this food defense awareness training program to help reduce the risk of an attack on the food supply. The training is intended for individuals who play an important role in defending our nation's food from attack: federal, state, local, and tribal regulators; school food authorities; and nutrition assistance program operators and administrators. Representatives from the food industry and individuals essential in responding to an attack on the food supply, such as law enforcement, public health, and homeland security officials, are also encouraged to participate. The program is available free of charge in three formats: via FDA's website, via face-to-face training courses offered across the country, and via a CD-ROM for limited distribution.

Over the years, FDA and USDA have collaborated on numerous satellite downlinks that have benefited the staff of both agencies. These joint downlinks have covered such topics as retail

meat and poultry processing; personal safety training for field personnel; multi-agency import controls to prevent bovine spongiform encephalopathy (BSE); the FDA/FSIS MOU; food microbiological control; foodborne illness investigations; traceback of fresh produce and other commodities; and communication skills. FDA and USDA have also collaborated on training related to epidemiology, tissue residue, retail food safety, and laboratory science.

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. Further, USDA and FDA training staffs regularly provide support for each other. For example, in the fall of 2004, FDA staff trained school lunch officials on the HACCP process. The training was held at FDA's training facility.

We agree that FDA and USDA should continue to identify additional opportunities to collaborate on training issues when sufficient commonalities can be found. However, we do not agree with GAO's recommendation to pursue the establishment of a joint training program for FDA investigators and USDA inspectors. The two agencies enforce different laws and regulations using different procedures. The foods regulated by the two agencies are different. In addition, our staffs have different educational backgrounds as well as experience. By suggesting a unified program, the report suggests that, for example, HACCP is the same for all products and should be taught jointly. Although the seven principles of HACCP are the same, the practical application of HACCP is significantly different for each food. Therefore, the practical application of HACCP that is taught to FDA staff is different than what is taught to USDA staff.

However, as we have described above, FDA and USDA regularly collaborate on joint training programs when appropriate.

COLLABORATIVE ACTIVITIES

I have described above a few examples of collaboration between FDA and USDA on inspections, enforcement, and training. I would now like to provide a few additional examples of other successful collaborations with our food safety and food defense partners.

The Secretary of DHS is responsible for coordinating the overall national effort to enhance the protection of the critical infrastructure and key resources of the nation, including food and agriculture defense. The White House has issued Homeland Security Presidential Directives HSPD-7, -8, and –9, which identify critical infrastructures, improve response planning, and establish a national policy to defend the agriculture and food systems against terrorist attacks, major disasters, and other emergencies. The USDA Secretary, the HHS Secretary, and the EPA Administrator exercise key responsibilities as sector-specific agencies. DHS serves as the coordinator of the Food and Agriculture Sector with FDA in HHS as the lead for the food sector and the Homeland Security Office in USDA as the lead for the agriculture sector. This collaborative effort combines expertise from several Federal agencies (FDA, USDA, EPA, Department of Defense [DoD], DOC, Department of the Interior, and the Department of Justice) as well as that of state and local officials (representing agriculture, public health, and veterinary services), and the private sector (more than 100 trade associations and individual firms participate). As part of the HSPD-7 National Infrastructure Protection Plan (NIPP)

development, FDA and USDA have drafted sector-specific plans, which will be finalized after obtaining additional input from states and the private sector. Using these plans as components, DHS has formulated the Interim NIPP for all sectors. The Interim NIPP is now being reviewed by sector members who are obtaining input from industry and state and local government participants. With the close working relationship of FDA and USDA and the other government and industry collaborators, the Food and Agriculture Sector activities to protect critical infrastructure have set the organizational and operational standard for 13 of the critical infrastructure sectors. DHS has applauded the Food and Agriculture Sector's organizational structure, consensus building, and the steps it has taken to improve food defense.

In April 2003, FDA began using the CARVER+Shock analytical tool to perform vulnerability assessments to identify what a party, intent on doing damage, could do based on their capability, intent, and past history. The CARVER+Shock methodology was developed under Homeland Security Council leadership by FDA, USDA, and DoD with coordination by DHS, the Central Intelligence Agency, and the Federal Bureau of Investigation. FDA's approach has been to seek voluntary, mutually-beneficial partnerships with various segments of the food industry. We have completed such cooperative assessments with two segments of the regulated industry that involve bottled water and dairy products. FDA is in the process of collaborating and providing technical assistance in assessments to a number of other food product industries using this tool. FDA also has collaborated with USDA to provide assistance to the USDA Food and Nutrition Service on the use of this analytical tool on specific commodities in the school lunch program.

A critical component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a broad array of biological, chemical, and radiological agents. HHS has worked in close collaboration with USDA's FSIS to establish the Food Emergency Response Network (FERN). FERN will increase our laboratory surge capacity through a nationwide network of Federal and state laboratories capable of testing the safety of thousands of food samples, thereby enhancing the nation's ability to respond swiftly to a terrorist attack.

FDA is also collaborating with CDC, USDA, EPA and many other Federal agencies to create a Memorandum of Agreement for an Integrated Consortium of Laboratory Networks (ICLN). The ICLN will be an integrated system of laboratory networks to provide for early detection and effective consequence management of acts of terrorism and other events involving a variety of agents and more than one section or segment of the nation (i.e., humans, animals, plants, food, the environment). ICLN will include FERN for food-related information and assistance. It will use other networks to address the other segments.

FDA has long been actively involved nationally and internationally in efforts to understand and prevent the spread of BSE. To address these concerns, FDA collaborates extensively with USDA's Animal and Plant Health Inspection Service (APHIS) and FSIS, CBP, EPA, the U.S. Department of State, our HHS colleagues at CDC and the National Institutes of Health, other Federal agencies, state and local jurisdictions, affected industries and consumer groups, and the World Trade Organization. Both FDA and USDA closely coordinated the Federal government's actions in response to the finding of a BSE-positive cow in the state of Washington in December

2003. This coordinated response was successful in quickly containing adulterated food and feed products and limiting food safety concerns in the general public.

On July 14, 2004, FDA published an Interim Final Rule, which became effective immediately, that banned the use of specified risk materials (SRMs) and other prohibited cattle materials in all FDA-regulated foods and cosmetics. Prohibited cattle materials include SRMs from cattle 30 months of age and older, small intestine of all cattle, materials from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef. These are the cattle materials at highest risk of containing the BSE agent. FDA's regulation parallels USDA's Interim Final Rule for meats and meat products. The agencies cooperated in the development of these documents and continue to cooperate to maintain a harmonized U.S. food safety policy for BSE.

Both the FDA regulation covering foods and cosmetics and the USDA regulation covering meat and meat products augment the preventive measures already in place to reduce or eliminate the threat of BSE in the U.S. and in the U.S. food supply. These measures include FDA's 1997 regulation that prohibits, with some exceptions, the use of protein derived from mammalian tissues in feed for cattle and other ruminant animals. This is the basis of FDA's efforts to prevent the spread of BSE in U.S. cattle. The import controls imposed by FDA and APHIS in USDA are other preventive measures.

Most of the examples above have focused on our collaborations with USDA. I would also like to describe some of our collaborations with the two other agencies represented on the panel today, DOC and EPA. For example, FDA, NMFS, and USDA jointly sponsor the National

Advisory Committee on Microbiological Standards for Foods. NMFS, FDA, and the International Atomic Energy Commission are cooperating on a study to develop an alternative method for the detection of paralytic shellfish poisoning. To address the issue of contaminants, including methylmercury, in seafood, FDA is working closely with the National Oceanic and Atmospheric Administration on a study being conducted by the National Academy of Sciences entitled "Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks." The outcome of this study will provide useful information for the development of public health policy on contaminants in seafood. In addition, NMFS and FDA jointly support the executive office of the Interstate Shellfish Sanitation Conference, the standards-setting body for a Federal/state cooperative program to ensure the safety of raw molluscan shellfish. To validate a risk assessment on *Vibrio parahaemolyticus,* FDA and NMFS have been jointly funding a study on the levels of this organism in raw molluscan shellfish at the retail level.

For several decades, EPA and FDA have collaborated on food safety and other public health issues. For example, in the regulation of pesticides, EPA sets tolerances, and FDA monitors the food supply for illegal pesticide residues and takes enforcement action. Similar collaboration occurs for bottled water contaminants. Recently, FDA and EPA collaborated on a joint consumer advisory on methylmercury in fish and shellfish. It provides advice for reducing the exposure to high levels of mercury in women who may become pregnant, pregnant women, nursing mothers, and young children. FDA and EPA are also working closely together on the issue of perchlorate. EPA has developed a risk assessment, and FDA is providing data on the levels and occurrence in food.

CONCLUSION

In conclusion, FDA is working closely with its Federal food safety partners and others to protect the food supply from deliberate and accidental contamination. As a result of this effective collaboration, the Federal food safety system is working well. The recent FoodNet data show that the preventive measures being implemented by FDA, USDA, and others are achieving significant public health outcomes in the effort to reduce the incidence of foodborne illness.

Thank you for this opportunity to discuss HHS' role in the Federal food safety system. I would be pleased to respond to any questions.

Mr. PORTER. Thank you, Mr. Brackett. Before we move on, I would like to ask unanimous consent to submit testimony from Congresswoman Rosa L. DeLauro. Any objections? Thank you.

[The prepared statement of Hon. Rosa L. DeLauro follows:]

TESTIMONY

By
Congresswoman Rosa L. DeLauro

Before
Subcommittee on the Federal Workforce and Agency Organization
Committee on Government Reform

Oversight Hearing on "Question: What is More Scrambled Than an Egg? Answer: The Federal Food Inspection System"
Tuesday, May 17, 2005

Good afternoon Mr. Chairman, Members of the Subcommittee. Thank you for giving me the opportunity to offer some comments today on this important subject, our food safety system. I commend you for holding this hearing and drawing attention to this critical issue.

This is an issue on which I have been working for several years, and I recently introduced H.R. 1507, The Safe Food Act of 2005. H.R. 1507 creates a Food Safety Administration and consolidates within it the agencies that will testify before you today, as well as the Center for Veterinary Medicine (CVM) in the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture.

The national food safety system started almost one hundred years ago within one Cabinet Department, but since then statutes creating new authorities for food safety have dispersed these agencies across our government – and I should add down to the states and local governments for inspection and enforcement.

The food safety system of the United States is very complex and disjointed, and the American people suffer from the lack of coordination. The agencies that combat foodborne illness must be better coordinated in order to lower the incidence of hospitalizations and death. We know that the Centers for Disease Control (CDC) at the Department of Health and Human Resources (HHS) has estimated that about 70 million Americans have an episode of foodborne illness each year, hundreds of thousands are hospitalized and about 5,000 die.

This year for the first time, it is predicted that the United States will be a net importer of food after many years of contributing food exports to our balance of payments. And yet we know that these foods are not produced under the same conditions and regulations that we have here in the United States. And they are not regulated and inspected effectively by our government on entry, in part because of lack of resources, lack of coordination and in the case of FDA lack of appropriate authority.

I am encouraged that the subcommittee is facilitating communication and coordination among the agencies. These actions may contribute in a small way to enhanced food safety.

- I am disappointed that FDA has declined to use the authority to commission USDA inspectors to inspect and report back to FDA about the conditions in the almost 1500 dual jurisdiction plants. FDA does authorize and pay for a substantial number of state inspection authorities to help them with their work in various states, so they must be aware of how to perform this important co-inspection duty.

- As stated above, the level of imported food shipments is rising exponentially and we must find ways to enhance the inspection of these products, both by better use of resources and by granting new authority and oversight to the agencies.

Mr. Chairman, I believe that these small coordination efforts are stopgap at best. In April, with the support of the Ladies Home Journal and many consumer groups, I introduced H.R. 1507, The Safe Food Act of 2005, bringing together in a new agency nine key elements of the U.S. food safety system into one Food Safety Administration.

I did this because I strongly believe that we must create a food safety system that will be efficient for the next hundred years. Senator Durbin introduced a similar bill in the Senate.

The new agency would be responsible for administering a national food safety program to protect public health. The Administrator would ensure that the food industry has effective programs in place to make food as safe as possible. The bill would make the food industry responsible for preventing and minimizing food safety hazards related to their products. The national food safety program would consist of:

- A system of registration and regular inspection of slaughterhouses, food processing, storage and distribution facilities prior to delivery for retail sale;
- Inspection and oversight of process control systems in food establishments based on science and public health considerations;
- Science-based standards for substances that may contaminate food and for safety and sanitation in the processing and handling of food;
- A sampling program to ensure that food industry procedures are effective and that food meets established safety standards;
- Implementation of procedures and requirements to ensure the safety and security of imported foods;
- Coordination with other federal agencies and state governments;
- A national surveillance system in cooperation with the Centers for Disease Control and Prevention (CDC);
- Basic and applied research to combat and understand all manner of pathogenic diseases, including those that are zoonotic, as well as chemical and other

contamination problems that can cause public health problems being carried by our foods.

- Public education.

Preventative Process Controls to Reduce Adulteration of Food

The implementation of science-based process controls is critical to ensuring that food is kept free of contamination throughout the production process. The bill would require all food establishments to implement appropriate measures to control and reduce the levels of harmful contaminants in food and meet performance standards for harmful pathogens. The bill allows the existing Hazard Analysis of Critical Control Points (HACCP) program, a prevention-based food safety system, to remain, but does not limit the Administrator to relying solely on this program.

Firms that prepare processed or ready-to-eat products would be required to use reasonably available technology to eliminate contaminants. Food products prepared for final processing outside the food plant would be labeled with instructions for handling and preparing the food in a manner that will destroy contaminants that may be on or in the product.

Regulations under this section would establish: preventative processing controls; standards for sanitation; performance standards for contaminants; record keeping to monitor compliance; and sampling to ensure that process controls are effective.

Performance Standards for Contaminants in Food

The Administrator would expand current food safety efforts to control contaminants by establishing and enforcing performance standards for the reduction of contaminants in raw meat, poultry, meat and poultry products and other high-risk foods. After enactment, the Administrator would identify contaminants and foods that contribute significantly to the risk of foodborne illness and would establish performance standards to protect against those contaminants. Performance standards would ensure the lowest level or incidence of contamination that is reasonably achievable using the best available processing technology, interventions and practices.

Once standards are established, the Food Safety Administration would implement a sampling program to determine compliance of food firms. If a firm does not meet the standard, the Administrator may detain, seize, or condemn the food; order a recall; increase inspections; withdraw the mark of inspection or registration from the establishment; or take other appropriate action.

Inspection of Domestic Food Establishments

The bill would streamline food safety inspections to ensure that inspections are based on risk. The inspection system would ensure food establishments are operating in

a sanitary manner, are in compliance with performance standards, and maintains required records.

The frequency of inspections and related requirements would be determined by the type of food handled and the type of processing to which the food is subjected.

- *Category 1 Establishments:* These firms routinely slaughter animals and would be subject to ante mortem, postmortem and continuous inspection on each slaughter line.
- *Category 2:* These firms process raw meat, poultry, seafood, and other high-risk products and their processing does not include a step to destroy contaminants. These firms would be inspected at least daily.
- *Category 3:* These firms process meat, poultry, seafood and other high-risk products but processing does include a step to destroy contaminants. These firms would be inspected at least monthly.
- *Category 4:* These firms process all other categories of food products and would be inspected at least quarterly.
- *Category 5:* These firms store or transport food products for retail sale and would be inspected at least annually.

The Administrator could establish a different inspection schedule as necessary to use resources more effectively and may propose to increase or decrease inspection based on performance.

State and Federal Cooperation

The Safe Food Act would provide for better coordination among federal, state and local governments to help them fulfill their food safety mandates. It would provide for federal assistance to the states, including advisory, technical, educational and financial assistance. The Administrator would also be able to use state and local agencies to enforce the national food safety program and build on databases currently underway in the states.

Imports

The bill would improve the safety of imported foods by instructing the Food Safety Administration to evaluate and certify a country's food safety program to ensure that it meets the same level of safety as that of the United States. The Administrator also would have the authority to certify foreign firms whose food safety practices meet U.S. standards. In addition, the Administrator would inspect food that is imported into the country to ensure that it is safe for consumption.

USDA has much of this authority now but has not used it to the fullest extent possible. Currently, FDA only has the authority to evaluate foreign food safety systems or inspect foreign plants on a comparable scale with the evaluation and inspection it performs domestically. Since FDA is only able to inspect a little more than one percent

of domestic firms annually, due to its limited resources, it has done little in the arena of inspections overseas.

Mr. Chairman, I am serving as co-chair of the Congressional Food Safety Caucus in the 109th Congress as I did in the 108th. I know all of us understand that our food safety system must keep the American people safe and healthy and make our products for export completely acceptable to our customers overseas, and our imported foods subject to excellent oversight. Doing less is a disservice to our farmers and producers as well as to all our citizens. It is too important to leave to stop gap measures.

Thank you for allowing me to share my views with you today.

Mr. PORTER. Next, Dr. Pierson, welcome, Acting Undersecretary for Food Safety, U.S. Department of Agriculture, you are recognized for 5 minutes.

STATEMENT OF MERLE PIERSON, PH.D.

Mr. PIERSON. Good afternoon, Mr. Chairman, and members of the subcommittee. I appreciate the opportunity to speak about the important issue of protecting the Nation's food supply.

I'm Dr. Merle Pierson, Acting Undersecretary for Food Safety at the U.S. Department of Agriculture.

The mission of the agency under the Food Safety Inspection Service is to ensure that meat, poultry and egg products prepared for use assembling food are safe, secure, wholesome and accurately labeled. FSIS is charged with administering and enforcing the Federal Meat, Poultry and Egg Products Inspection Acts.

Ensuring the safety of meat, poultry and egg products requires a strong infrastructure. FSIS has a work force of over 7,600 inspection personnel in approximately 6,000 federally inspected meat, poultry and egg product plants, import establishments every day. These public health inspection personnel verify each year that 43.6 billion pounds of red meat, 49.2 billion pounds of poultry, and 33.7 billion pounds of liquid egg products, as well as 4.2 billion pounds of imported products comply with the agency's regulatory requirements.

Our efforts are paying off, as seen by the decline in foodborne illness over the last 7 years. Last month, the Centers for Disease Control and Prevention reported continued reductions in foodborne illnesses in 2004 from E. Coli 157:H7, Listeria monocytogenes, Camplyobacter, Yersinia, and Salmonella.

The CDC contributes the changes in the incidents of these infections in part to the control measures implemented by government and industry leaders, enhanced food safety education efforts and increased attention by consumer groups and the media. Through close cooperation, communication and coordination, Federal agencies and others do work effectively together to ensure a safe and secure food supply. As a partner in the U.S. food safety effort, Food Safety Inspection Service strives to maintain a strong working relationship with its sister public health agencies.

We appreciate the GAO's efforts in producing their March 2005 report on what they call overlaps in the Federal Food Safety System. However, I am concerned with any assessment that oversimplifies the food safety regulatory functions of FSIS and FDA, as well as others. And it is not clear on the inherent complexities and differences in our work. It is important to recognize that while FSIS and FDA inspection activities may seem similar in some cases, there are essential differences due to their authorities and responsibilities.

I want to point out that considering what GAO describes as jurisdictional overlap between FSIS and FDA, particularly with regard to dual jurisdiction establishments, the amount of food products and number of establishments that fall within these dual jurisdiction establishments is small compared to what the two agencies regulate independently.

Another topic the GAO report dealt with, the joint training: Both FSIS and FDA HAPCC and sanitation is important aspects of the regulations, and there are certain similarities in hazards and their controls. However, in the broader context, specific food safety hazards and sanitary approaches differ greatly by product, thus necessitating differences in provisions in how the rules are applied.

FSIS's HACCP regulations apply to all meat and poultry products. FDA has two of its inspected commodities, seafood and juices, under mandatory HACCP.

FSIS has experienced considerable change over the past few years with the adoption of a HACCP-based regulatory system, an implementation of policies that have worked to provide a significant reduction in foodborne illness. It is essential that the agency's resources be effectively directed toward those areas of greatest risk and not be diverted to efforts that have little potential for improving public health.

We look forward to working with Congress, GAO and our food safety partners to continue the best we can to make our Nation's food supply the safest in the world. Thank you.

[The prepared statement of Mr. Pierson follows:]

For release only by the House Committee on Government Reform

FOOD SAFETY AND INSPECTION SERVICE

Submitted for the Record

Statement of Dr. Merle Pierson, Acting Under Secretary for Food Safety Before the Subcommittee on the Federal Workforce and Agency Organization

Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to speak with you about the important issue of protecting the nation's food supply. I am Dr. Merle Pierson, Acting Under Secretary for Food Safety at the U.S. Department of Agriculture (USDA). I am pleased to be here today with Dr. Robert Brackett, from the Department of Health and Human Services'(HHS) Food and Drug Administration (FDA); Susan Hazen from the Environmental Protection Agency (EPA); and Richard V. Cano from the National Marine Fisheries Service (NMFS).

I applaud your interest in the safety and security of the U.S. food supply and look forward to a full discussion on the issues you are raising today. In USDA's view, the question of whether the various Federal agencies with food safety authorities are working together effectively to address food safety and security can be answered with a resounding, "Yes." The American food supply continues to be the safest in the world, and we are always striving to make it safer.

In my testimony, I will first address some of the issues raised in the March 2005 GAO report on overlap in the Federal food safety regulatory system and the concerns I have about that report. Then I will discuss FSIS' statutory authorities, the components of an effective food safety and

security system, the success of U.S. food safety and security efforts, and our cooperative efforts with our Federal, State and local partners.

The GAO Report

We appreciate the GAO's efforts in producing their March 2005 report on jurisdictional overlaps in the Federal food safety system. We all share a commitment to ensuring that the American food supply remains safe and secure.

FSIS would be concerned with any assessment that oversimplifies the food safety regulatory functions of FSIS and FDA, or is not clear on the inherent complexities and differences of our work. The breadth, complexity and size of the U.S. food production system lend itself to specialized government oversight. It is important to recognize that while FSIS and FDA inspection activities may seem similar, they are in reality vastly diverse due to differences in authorities and responsibilities.

While it is true that both FSIS and FDA have HACCP as a founding principle for food safety and public health, and it is also true that HACCP's general principles remain constant, food specific hazards differ greatly by product, thus necessitating differences in provisions and how the rules are applied. FSIS' HACCP regulations apply to meat and poultry products. FDA has two of its inspected commodities (seafood and juices) under mandatory HACCP. While there are commonalities in the FSIS and FDA rules, there remain significant differences between the two agencies' regulated industries under HACCP that dictate the necessity of distinctly different regulations.

Because the authorities and responsibilities at FDA and FSIS differ, the policies, procedures, and the training on inspection and enforcement strategies are also quite different. The products regulated by the two agencies are different, and many of 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. 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.

There are two important points that we must keep in mind when considering jurisdictional overlap between FSIS and FDA, particularly with regard to dual jurisdiction establishments (DJEs). First, the amount of food product, which falls within the overlap, is miniscule compared to the overall amount of product that the two agencies regulate independently. Correspondingly, the number of DJEs is also small, relative to the total number of establishments the agencies inspect. And second, any meat, poultry or egg product that falls within the jurisdictional overlap has already been inspected and passed by the USDA. Because of these key factors, the small amount of products in question pose a very low-risk to human health.

Finally, I am concerned that the Public Health Security and Bioterrorism Preparedness and Response Act (BT ACT) of 2002 is not completely understood. For example, meat, poultry and egg products that are within USDA's exclusive jurisdiction are not subject to the BT Act's

requirement that prior notice be given for imported food. In addition, while this Act gave FDA the authority to commission other Federal officials to inspect FDA-regulated foods, implementing an agreement between FSIS and FDA based on this Act would require a considerable amount of planning and work without any guarantee of improving public health. Since FSIS and FDA operate under different regulatory structures, roles and responsibilities would need to be carefully defined.

FSIS Statutory Authority

Since 1884, the regulatory structure of what is now the Food Safety and Inspection Service (FSIS) and its predecessor agencies has been designed to protect public health by preventing and containing any threats to the U.S. food supply. The Agency's mission is to ensure that meat, poultry, and egg products prepared for use as human food are safe, secure, wholesome, and accurately labeled. FSIS is charged with administering and enforcing the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), and the regulations that implement these laws. Under the authority of these Acts, FSIS provides continuous inspection of meat, poultry, and egg products prepared for distribution in commerce and re-inspects imported products, to ensure that they meet U.S. food safety standards. FSIS has jurisdiction over products that generate more than $94 billion in farm cash receipts. This is an enormous responsibility and one the Agency takes very seriously.

Ensuring the safety of meat, poultry, and egg products requires a strong infrastructure. To accomplish this task, FSIS has a workforce of over 7,600 inspection and public health veterinary personnel stationed in approximately 6,000 federally inspected meat, poultry, and egg product

plants and import establishments every day. These public health inspection and veterinary personnel verify that the processing of 43.6 billion pounds of red meat, 49.2 billion pounds of poultry, and 3.7 billion pounds of liquid egg products comply with the Agency's statutory requirements. In addition, 4.2 billion pounds of imported meat, poultry, and processed egg products were presented for entry into the United States from 27 of 33 countries eligible to export to this nation in FY 2004. Overall, FSIS' responsibility covers a very large amount of product produced not only here in the United States, but throughout the world.

In addition to the inspection of products defined above, FSIS has many additional public health regulatory responsibilities. For example, the Agency sets policy requirements for meat and poultry label requirements and for slaughter and processing activities, such as plant sanitation and cooking of ready to eat products that the industry must meet. FSIS tests for microbiological, chemical, and other types of contamination and conducts epidemiological investigations, in cooperation with the CDC, based on reports of foodborne health hazards and disease outbreaks. In addition, the Agency conducts enforcement activities to address situations where unsafe, unwholesome, or inaccurately labeled products have been produced or marketed. FSIS also conducts Food Safety Education activities.

FSIS is also responsible for assuring that U.S. imported meat, poultry and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. While foreign food regulatory systems need not be identical to the U.S. system, they must employ equivalent sanitary measures that provide the same level of protection against food hazards as is achieved domestically. To ensure the continued safety of imported products after initial equivalence is determined, FSIS

maintains a comprehensive system of import inspection and controls, which includes audits of a foreign country's inspection system and port-of-entry reinspection. At import establishments, FSIS import inspectors ensure that each shipment of meat and poultry products is properly certified, examine each lot for general condition and labeling, and conduct re-inspection based on the agency's risk-based systems approach to sampling. In addition, FSIS annually reviews inspection systems in all foreign countries eligible to export meat and poultry to the United States, to ensure that their inspection systems are equivalent to those of the United States.

FSIS is also responsible for assessing whether State inspection programs that regulate meat and poultry products are at least equal to the Federal program. The 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Act established the "at least equal" standard. Products produced under the State programs may be distributed only within the State in which they were produced. FSIS assumes responsibility for inspection if a State chooses to end its inspection program or cannot maintain the equivalent standard.

Additionally, the 1967 Wholesome Meat Act extended FSIS jurisdiction over meat and meat products beyond the plant, granting authority to regulate transporters, renderers and cold storage warehouses. As a result of this action, FSIS also has responsibility to ensure, during all points of distribution, that meat and meat food products are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS uses program investigators throughout the chain of distribution to detect and detain potentially hazardous foods in commerce to prevent their consumption and to investigate violations of law. Every year, on average, FSIS program investigators conduct approximately 11,000 compliance reviews, detain approximately 13

million pounds of suspected products and issue more than 1300 letters of warning. As a result, FSIS, on average, suspends operations at more than 100 plants and refers approximately 30 cases for criminal prosecution to the Department of Justice annually.

FSIS' Role in the Food Safety and Security System

FSIS' Inspection System and Food Safety Successes

Our inspection system for meat and poultry is based on what we believe to be the most scientifically advanced process for food safety worldwide – the Pathogen Reduction/Hazard Analysis and Critical Control Points system (HACCP). HACCP is a preventive system that was implemented by the industry to put controls in place in their process in the most critical steps in their operation for purposes of food safety.

FSIS believes – and both GAO and the National Academy of Sciences agree – that a critical component of an effective public health food safety and security system is the use of a verifiable inspection system that is both risk-based and science-based. A risk-based system is rooted in the premise that the most effective and efficient method of allocating resources is to base them on the assessment of greatest risks and hazards. The implementation of the Pathogen Reduction/HACCP regulations as well as a series of subsequent regulations and work force initiatives by FSIS have been both science and risk-based.

FSIS currently operates under a science-based system. Science allows for policy decisions to be continually updated based on technological advances and emerging threats. Science-based decision-making is objective and preventive in nature, and thus offers the best foundation for the

development of policies that will improve public health, both in the short term and the long term. Threats to public health – both intentional and unintentional – need to be understood and addressed within the context of the best available research and risk analysis. With input from the scientific community, FSIS can develop practical policies that allow the industry to implement new technologies as food safety interventions.

Our efforts are clearly on the right track, as evidenced by the decline in foodborne illness over the last seven years. This spring, the HHS' Centers for Disease Control and Prevention (CDC) reported continued reductions in foodborne illnesses from 1996 through 2004 stemming from *E. coli* O157, *Listeria monocytogenes*, *Campylobacter*, and *Yersinia*. Compared to the 1996-98 baseline illnesses caused by *E. coli* O157 decreased by 42%; *Listeria monocytogenes* dropped by 40%; *Campylobacter* fell 31%; and caused by *Yersinia* decreased by 45%. Overall, *Salmonella* illnesses have fallen by eight percent compared to the 1996-98 baseline.

The dramatic, multi-year reductions in illnesses from *E. coli* O157 mean the United States is now, in 2005, beating the Healthy People 2010 goal of one case per 100,000 persons, according to the CDC. This is six years early, and a remarkable national achievement. We are also very close to meeting the Healthy People 2010 goal set for illnesses from *Listeria monocytogenes* and *Campylobacter*.

This year's report indicates that reductions in foodborne illness reported in 2003 were not an isolated event and that sustained progress is being made toward reducing illness from very dangerous foodborne pathogens. The CDC attributes the changes in the incidence of these

infections in part to the control measures implemented by government and industry leaders, enhanced food-safety education efforts, and increased attention by consumer groups and the media.

Earlier this year, FSIS released data showing a 43.3% drop in the percentage of *E. coli* O157:H7 positive ground beef regulatory samples collected in 2004 compared with the previous year. Between 2000 and 2004, the percentage of positive *E. coli* O157:H7 samples in FSIS' regulatory sampling has declined by more than 80%. These reductions have been made possible in large part to FSIS' risk-and science-based approach to combat *E. coli* O157:H7 during the slaughter and processing stages.

Food Security

FSIS' century worth of experience has allowed the Agency to develop the expertise to protect the U.S. meat, poultry, and egg products supply wherever and whenever food security threats arise. However, FSIS does not carry out these efforts alone. FSIS works closely with the White House Homeland Security Council, the Department of Homeland Security (DHS), HHS-FDA, the USDA Homeland Security Staff, and other Federal, State and local partners to develop and carry out strategies to protect the food supply from an intentional attack.

In addition, the President's Homeland Security Presidential Directive 9 has led to stronger working relationships among food regulatory agencies. This Directive, coordinated by DHS, addresses the need for interagency cooperation and communication to address food defense

issues by establishing joint leadership as the goal to secure the Nation's agriculture production and food supply from terrorist attacks, major disasters, and other emergencies.

To facilitate stronger interagency cooperation, information sharing is needed. This is why FSIS continues to build relationships with the intelligence and law enforcement communities, such as the Federal Bureau of Investigation, the Central Intelligence Agency and local law enforcement agencies. FSIS is providing information to these communities on food security concerns for intelligence collection and participating in information-sharing conferences sponsored by these agencies. Utilizing active intelligence will allow us to direct our financial, laboratory and human resources more efficiently, as well as inspection, in-distribution and outreach activities.

To further improve Federal and State government coordination to prevent and respond to any act of intentional contamination, FSIS entered into a cooperative agreement with HHS/FDA, DHS, and the National Association of State Departments of Agriculture to develop guidelines and procedures for State and local first responders and Federal food regulatory agencies. This interagency response plan will facilitate cooperation with State and local emergency efforts when responding to incidents involving the food supply. Following the development of these best practices, FSIS and its partners will test them through exercises and make improvements as necessary.

Another example of coordination with our partners is building a strong nationwide laboratory network that could quickly identify the presence, or absence of, a particular threat agent in a food commodity. To enhance this surveillance, FSIS has partnered with other food safety agencies

such as the FDA and its 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 is known as the Food Emergency Response Network (FERN). The goal is to establish 100 FERN laboratories, creating a network of Federal, State and local laboratories that could be called upon to handle the numerous samples that would be required to be tested in the event of a terrorist attack on the food supply. Such a system, in addition to providing an umbrella of protection for the food supply, would also help us identify and remove contaminated product from the marketplace quickly should an attack occur.

To further enhance food security, FSIS recently developed model food security plans as a valuable resource that can help plant operators identify preventive steps to minimize food security risks. FSIS strongly encourages all establishments to develop plans to fit their particular needs. The model plans are designed for meat and poultry slaughter facilities, meat and poultry processing plants, egg processing plants and import facilities. The materials are available on the FSIS web site (www.fsis.usda.gov) and are intended to be used with other FSIS food security resources, such as food security guidelines and food security checklists that were developed over the past three years. To assist the industry, especially small and very small establishments in developing food security plans, FSIS will conduct a series of training workshops throughout the nation in May, June and July 2005.

Recognizing employee training as another critical component of the government's food security efforts, FSIS is working with FDA, USDA's Food and Nutrition Service and Agricultural Marketing Service and related State and local regulatory personnel to provide joint training on

food security for field personnel from these agencies. This training is offered not only in 12 classroom sessions nationwide but also through CD-Rom and the Internet. It focuses on the vulnerabilities in the food supply and provides information on what government personnel should do in the event they identify an incident.

Coordination and Cooperation with Our Food Safety Partners

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 single food agency issue. 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 agency.

We believe that cooperation, communication, and coordination are absolutely essential to ensure a safe and secure food supply. As a partner in the U.S. food safety effort, FSIS strives to maintain a strong working relationship with its sister public health agencies. I have already mentioned several situations in which FSIS partners with other Federal, State and local agencies to improve public health. I'll also discuss another example in which FSIS has partnered with another important public health agency to bolster our public health mission with the best available experts.

FSIS entered into a working relationship with the HHS U.S. Public Health Service (PHS) and the HHS Office of the Surgeon General. Two years ago, FSIS signed a Memorandum of Agreement with the Surgeon General and the PHS that allows expanded numbers of PHS Commissioned

Corps Officers to be detailed to the Agency. Not only do these officers help FSIS respond to foodborne disease outbreaks and assist in preventing foodborne illness, but they assist in the Agency's homeland security efforts as well.

The projects I have described above are highlights in the ongoing, sustained effort FSIS has undertaken to work in coordination with our food safety partners both here at home and around the world. We will continue to explore additional opportunities that will allow us to better protect the public health and better serve the American taxpayer.

Conclusion

FSIS is always willing to improve and change its systems to better meet a purpose and a goal. For example, FSIS has experienced considerable change over the past few years with the adoption of a HACCP based regulatory system and implementation of policies that have worked to provide a significant reduction in foodborne illness. It is essential that the agency's resources continue to be effectively directed towards those areas of greatest risk and not be diverted to efforts that have little potential for improving public health. Any such decisions must be based on science, and can be boiled down to one question: will there be a measurable benefit to public health? In other words, would any changes to the current food safety infrastructure save lives and reduce foodborne illness rates? Most importantly, we must ask ourselves is the public better served by FSIS, FDA and other agencies continuing to work closely together to better utilize resources and positively impact public health? Once again, our answer is a resounding, "yes".

We are proud of our accomplishments over the past few years and need to continue the progress that we and our partners here today – FDA, EPA, and NMFS – have made thus far. The strides made in protecting our food supply from intentional contamination, reduction in foodborne illnesses, as well as sustained reductions in the amount of pathogens on product samples collected and analyzed by FSIS, clearly indicate that our existing infrastructure and science-based policies are working and working well. We are committed to apply the best available science and management practices to continually seek to improve on our goal of protecting public health.

We appreciate the opportunity to discuss our food safety and security program and our continued efforts in this area. We are all here today because we want to protect public health by ensuring that the food on American tables is safe and secure. We look forward to working with Congress, GAO and our food safety partners to continue to keeping our nation's food supply the safest in the world.

Mr. PORTER. Thank you, Doctor, I appreciate it.

Thank you, Doctor.

Now we will hear from Jim Jones, Director of Pesticide Programs, U.S. Environmental Protection Agency. You are recognized for 5 minutes.

STATEMENT OF JIM JONES

Mr. JONES. Good afternoon, Mr. Chairman, and members of the committee. My name is Jim Jones, and I serve as the Director of the Office of Pesticide Programs at the U.S. Environmental Protection Agency. I appreciate the opportunity to discuss EPA's role in food safety and how we coordinate with other Federal agencies on this important topic.

EPA's main food safety responsibility is to regulate pesticides, including setting health-based standards for pesticides use in food production, and ensuring our decisions promote the protection of public health and the environment. The EPA protects public health through the registration or licensing of pesticides prior to their marketing and use in the United States under the authority of the Federal Insecticide, Fungicide and Rodenticide Act, as well as setting and reevaluating tolerances or legal maximum residue levels under the Federal Food, Drug and Cosmetic Act. This requires use of a scientifically sound risk assessment process to consider the potential risks of pesticide use not only to human health, but to the environment as well.

Registration tolerances will be granted only if EPA determines that there is a reasonable certainty of no harm from exposure to the pesticide residues in food and the use of the pesticide will not pose an unreasonable risk to human health or the environment.

In addition to pesticides, EPA also works closely with FDA on the development and publication of National Fish Advisories for fish and shellfish. While EPA is responsible for establishing pesticide tolerances during the registration process, FDA and USDA's Food Safety Inspection Service enforce these tolerances. If pesticide residues on food or feed exceed the tolerance, or if no tolerance exists for such pesticide residues, the food or feed would be subject to regulatory action.

EPA actively cooperates and collaborates with FDA and FSIS regarding tolerance levels for pesticide residues on both domestically produced and imported foods. Some of the data EPA uses when establishing tolerances are generated through interagency agreements with USDA, FDA and the Centers for Disease Control and Prevention. These agreements provide valuable information related to food consumption patterns, pesticide use and expected levels of pesticide residues once food products actually reach the consumer.

The Agency is also partner to a number of agreements in areas such as training for agricultural workers, providing alternatives to the use of pesticides and coordinating work on pesticide residues.

As mentioned by Dr. Brackett, EPA is collaborating with other food safety agencies, including FDA and USDA and the Department of Homeland Security on a number of initiatives to protect the Nation's food supply from natural, unintended or malicious threats.

In closing, EPA is committed to continuing to work with our Federal partners, including FDA, USDA and others, to ensure that the United States maintains its well-earned reputation for protecting the safety of our Nation's food supply.

Mr. PORTER. Thank you, Mr. Jones. We appreciate that.

[The prepared statement of Mr. Jones follows:]

STATEMENT OF
JIM JONES
DIRECTOR OF PESTICIDE PROGRAMS
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON THE FEDERAL WORKFORCE AND AGENCY ORGANIZATION

MAY 17, 2005

Introduction

Good afternoon, Mr. Chairman and members of the subcommittee. My name is Jim Jones and I serve as the Director of the Office of Pesticide Programs at the U.S. Environmental Protection Agency. I appreciate the opportunity to discuss EPA's role in food safety, and how we coordinate with other federal agencies on this important topic. I am pleased to be here today with my colleagues from FDA and USDA

EPA enjoys a strong working relationship with its federal partners in assuring food safety and security for the American public. As a consequence of the collective efforts of FDA, USDA, and EPA, the U.S. enjoys one of the safest, most abundant, and most affordable food supplies in the world. EPA's main food safety responsibility is to regulate pesticides, including setting health-based standards for pesticides used in food production, and ensuring our decisions promote the protection of public health and the environment.

Overview of Pesticide Registration and Food Safety

EPA protects public health through the registration, or licensing, of pesticides prior to their marketing and use in the U.S. under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as well as setting and reevaluating tolerances (legal maximum residue levels) under the Federal Food, Drug and Cosmetic Act. This requires the use of a scientifically sound risk assessment process to consider the potential risks of pesticide use not only to human health, but to the environment as well. Registration and tolerance setting decisions are based on an extensive assessment of the pesticide's potential risks. Registration and tolerances will be granted only if EPA determines that there is a reasonable certainty of no harm from exposure to the pesticide residues in food and that use of a pesticide will not otherwise pose an unreasonable risk to human health or the environment.

EPA has a highly regarded program for ensuring pesticide and food safety and making regulatory decisions. Our reputation and credibility rests on our world-renowned expertise in pesticide risk assessment, as well as the ability to systematically require and evaluate an extensive amount of health and safety data to protect against potential risks. The Agency has regulations establishing a rigorous battery of tests necessary to support the registration of a pesticide. A typical agricultural pesticide used in food production must undergo over 100 different tests (which can cost in excess of $12 million) to characterize its potential to harm humans, wildlife, and plants, and to evaluate its fate and movement in the environment. In addition, the Agency gives particular attention to the potential effects of pesticides in the diets of

infants and children, who can be more sensitive, and people who may be exposed to pesticides through their occupation, such as farm workers.

A pesticide risk assessment considers several factors in addition to human health. EPA also reviews studies that show how a pesticide will react in the environment, including how long it remains after application and whether it could reach ground or surface water. The Agency considers a pesticide's potential effects on wildlife, fish, and plants in general, in addition to the possibility that its use might specifically harm endangered species, and implements measures through the pesticide label to ensure the product can be used safety.

Tolerance Setting

Where a pesticide may be used on food or feed, EPA is responsible for setting tolerances, or maximum allowable residue levels. As with the general risk assessment, the process of setting tolerances is based on rigorous data. The data required to establish a tolerance include extensive food residue chemistry data and short- and long-term feeding studies in animals. The goal of EPA's review is to protect against possible health effects, including aggregating exposure to a pesticide, including dietary, residential, and drinking water sources, and whether such exposures represents an acceptable level of risk. This risk determination must not only be made for an individual pesticide, but for the cumulative effect of groups of pesticides which share a common mechanism of toxicity. Before establishing a tolerance, the Agency must reach a conclusion that under the proposed use conditions there is a reasonable certainty that no harm will result from

exposure to pesticide levels remaining on food, and that infants and children are provided an extra margin of protection as provided by the Food Quality Protection Act (FQPA).

While EPA is responsible for establishing pesticide tolerances during the pesticide registration process, FDA and USDA's Food Safety and Inspection Service (FSIS) enforce these tolerances. If pesticide residues on food or feed exceed the tolerance, or if no tolerance exists for such pesticide residues, the food or feed would be considered adulterated and would be subject to regulatory action. EPA actively cooperates and collaborates with FDA and FSIS regarding tolerance levels for pesticide residues on both domestically produced and imported foods.

EPA also establishes tolerances for imported commodities for pesticide uses that are not registered domestically. EPA has devoted significant resources to working internationally on the harmonization of pesticide data and tolerance levels. Through this work, the Agency has reached work sharing agreements with several countries, encouraging efficiencies and facilitating trade.

As part of its ongoing work to ensure that all pesticides meet current public health and environmental standards, EPA's is reevaluating older pesticides so that they meet the safety standards called for under the FQPA. This law requires EPA to reassess the maximum pesticide residue levels allowed in food (tolerances), with particular consideration of protecting subpopulations which may be more susceptible to the adverse effects of pesticides, such as children, evaluating cumulative and aggregate risks, and promoting ample stakeholder input in our decisions. At the end of fiscal year 2004, the Agency had completed 7,093 tolerance

reassessments, and is currently working hard to complete tolerance reassessment by August 3, 2006.

Interagency Agreements

Some of the data EPA uses when establishing tolerances are generated through interagency agreements with USDA, FDA, and the Centers for Disease Control and Prevention. These agreements provide valuable information related to food consumption patterns, pesticide use, and expected levels of pesticide residues once food products actually reach the consumer. The Agency is also partner to a number of agreements in areas such as training for agricultural workers, providing alternatives to the use of pesticides, and coordinating work on pesticide residues. In addition, EPA is collaborating with other food safety agencies, including FDA and USDA, and the Department of Homeland Security on a number of initiatives to protect the nation's food supply from natural, unintended, or malicious threats.

In addition to our formal interagency agreements, EPA has established strong working relationships with its regulatory partners. The Agency has participated in numerous workshops and work groups, and encourages agencies such as USDA and FDA to participate on pesticide advisory groups. In the past, EPA and USDA have co-chaired public advisory groups related to food safety. The Agency enjoys strong partnerships with other federal agencies, with each contributing based on its particular strengths and existing relationships.

In addition to pesticides, EPA also works closely with FDA on the development and publication of national fish advisories for fish and shellfish. These advisories provide important information to consumers on healthy seafood consumption, and steps they can take to limit exposure to possible contaminants found in seafood. Currently, we are continuing to closely coordinate with FDA on activities that involve contaminants in fish tissue, with a focus to better ensure safe and beneficial seafood consumption.

Conclusion

EPA is responsible for evaluating the risks of pesticides, and establishing tolerance levels which are used to ensure the safety of the food supply. Given our unique and successful role in conducting and refining pesticide risk assessments, EPA is uniquely qualified to continue the important work of strengthening the safety of the food supply. EPA looks forward to continuing to work with its regulatory partners, including FDA and USDA, to ensure that the U.S. maintains its well earned reputation for protecting the safety of our nation's food supply.

I appreciate the opportunity to testify before your Committee, and would be glad to answer any questions you might have.

Mr. PORTER. Next we have Richard Cano, Acting Director of Seafood Inspection Program, National Marine Fisheries Services. You are recognized for 5 minutes. Thank you for being here.

STATEMENT OF RICHARD V. CANO

Mr. CANO. Mr. Chairman and members of the committee, thank you for inviting me to speak on the GAO report, Oversight of Food Safety Activities. I am Richard Cano, Acting Director of the Seafood Inspection Program of the National Oceanographic and Atmospheric Administration [NOAA]. My testimony today will provide a brief description of the Seafood Inspection Program and comment on the GAO report.

NOAA oversees the fishery management in the United States. Through the delegated authority of both the Agricultural Marketing Act of 1946 and the Fish and Wildlife Act of 1956, NOAA provides voluntary seafood inspection programs on a fee-for-service basis.

The NOAA Seafood Inspection Program offers a variety of professional inspection services, including vessel and plant sanitation, product inspection, laboratory analysis, training and consultation. These activities ensure that products from firms participating in the NOAA Seafood Inspection Program comply with all applicable Federal regulations.

Our inspections, both in the United States and in other countries, examine facility conditions, personnel practices and safety and effectiveness of protocols. To ensure safe and properly labeled products, our evaluation considers both the risks associated with the product and the manufacturing process. We inspect products directly at the facility and by taking random samples from warehouses.

NOAA also certifies products by periodically monitoring written industry control systems to ensure facilities are meeting their responsibilities. For example, we use Hazard Analysis Critical Control Point [HACCP], techniques that focus on hazard identification, problem prevention and corrective actions taken by industry to produce complying products.

By identifying and monitoring control points in the process, our HACCP-based program helps ensure that requirements such as proper labeling and quality attributes are met, in addition to safety.

In 1974, NOAA signed a memorandum of understanding with the Food and Drug Administration and the Department of Health and Human Services recognizing our agencies' related responsibilities. This agreement is designed to outline a working relationship in the public interest to enable each agency to discharge as effectively as possible its responsibilities related to the inspection and standardization activities for fishery products. In general, this agreement outlines requirements regarding adulterated and misbranded products, how best to maximize resources, and the need for effective communication between the agencies.

The most notable accomplishment under this agreement has been in the area of training. NOAA's inspection staff has benefited from FDA's willingness to provide access to their online training modules. Since January 2003, NOAA personnel have completed ap-

proximately 9,100, a combined employee total, of the FDA online courses.

In addition, most NOAA workshops on sensory evaluation of fishery products are jointly instructed by both NOAA and FDA personnel, and NOAA provides an instructor to assist FDA in retail training courses. However, both the FDA and NOAA believe this agreement, which is now more than 30 years old, needs to be assessed in the light of changing roles and responsibilities, and we have been in discussions with FDA on this. Both industry and other agencies use the NOAA Seafood Inspection Program to ensure that fishery products procured and distributed comply with regulatory requirements, purchasing specifications and consumer expectations.

As the GAO report outlined, several agencies are involved in food safety oversight. In general, we believe the report does a fair and thorough job of describing the major food safety activities at NOAA.

As the GAO report outlines, in fiscal year 2003, of the $1.7 billion spent on food safety-related activities, NOAA spent just under $22 million, only approximately 1 percent of the total expenditure.

The GAO report made several recommendations, and I will focus on those directly relevant to NOAA. As I mentioned earlier, the FDA and NOAA have an interagency agreement. We agree with the GAO recommendation for FDA and NOAA to ensure the implementation of this agreement, and we will continue to work with the appropriate components of FDA in order to do this.

In addition, the report recommends that the leaders of each of the agencies discussed in the report identify and inventory all active interagency food safety-related agreements, evaluate the need for these agreements and, where necessary, update the agreements to reflect recent legislative changes, technological advances and current needs. We agree with this recommendation and will establish an inventory of active, interagency, food-related agreements on which NOAA is a signatory.

In addition, NOAA will contact the applicable agencies associated with food safety-related agreements whenever NOAA believes an agreement should be revised.

Mr. Chairman, members of the committee, thank you for inviting me here to speak about our Seafood Inspection Program and the recommendations in the GAO report. I will be happy to answer any questions you may have.

Mr. PORTER. Thank you, Mr. Cano. I appreciate that.

[The prepared statement of Mr. Cano follows:]

Testimony of Richard V. Cano
Acting Director
Seafood Inspection Program
National Marine Fisheries Service
National Oceanic and Atmospheric Administration
U.S. Department of Commerce

Oversight Hearing on the Federal Food Inspection Programs
Subcommittee on the Federal Workforce and Agency Organization
Committee on Government Reform
U.S. House of Representatives
May 17, 2005

Mr. Chairman and members of the Committee, thank you for inviting me to speak on the Government Accountability Office (GAO) report, *Oversight of Food Safety Activities*. I am Richard Cano, Acting Director of the Seafood Inspection Program at the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA). My testimony today will provide a brief description of the Seafood Inspection Program and comment on the GAO report (GAO-05-213).

Seafood Inspection Program
NOAA oversees fisheries management in the United States. Through the delegated authority of both the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621-1627), and the Fish and Wildlife Act of 1956, NOAA provides a voluntary seafood inspection program on a fee-for-service basis. The NOAA Seafood Inspection Program offers a variety of professional inspection services, including vessel and plant sanitation, product inspection, laboratory analysis, training, and consulting. These activities ensure that products from firms participating in the NOAA Seafood Inspection Program comply with all applicable Federal regulations.

Our inspections, both in the United States and in other countries, examine facility conditions, personnel practices, and the safety and effectiveness of protocols. To ensure safe and properly labeled products, our evaluation considers both the risks associated with the product and the manufacturing process. We inspect products directly at the facility and by taking random samples from the warehouse. NOAA also certifies products by periodically monitoring written industry control systems to ensure facilities are meeting their responsibilities. For example, we use Hazard Analysis Critical Control Point (HACCP) techniques that focus on hazard identification, problem prevention, and corrective actions taken by industry to produce complying products. By identifying and monitoring control points in the process, our HACCP-based program helps ensure that requirements such as proper labeling and quality attributes are met.

In 1974, NOAA signed a memorandum of understanding (MOU) with the Food and Drug Administration (FDA) of the Department of Health and Human Services recognizing our agencies' related responsibilities. This agreement is designed to outline a working relationship

in the public interest to enable "each agency to discharge as effectively as possible, its responsibilities related to the inspection and standardization activities for fishery products." In general, this agreement outlines requirements regarding adulterated or misbranded products, how best to maximize resources, and the need for effective communication between the agencies.

The most notable accomplishment under this agreement has been in the area of training. NOAA Inspection staff has benefited from FDA's willingness to provide access to their online training modules. Since January 2003, NOAA personnel have completed approximately 8,900 (combined employee total) of the FDA online courses. In addition, most NOAA workshops on sensory evaluation of fishery products are jointly instructed by both NOAA and FDA personnel, and NOAA provides an instructor to assist FDA in its retail training courses. However, both the FDA and NOAA believe this agreement, which is now more than 30 years old, needs to be assessed in light of changing roles and responsibilities, and we have been in discussions with the FDA on this.

NOAA is involved with several other food safety projects including a National Academies of Science study entitled, "Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks." This study will provide useful information for the development of public health policy on contaminants in seafood. We also work with other federal agencies on many projects beyond what I outlined above. For example, we jointly sponsor the National Advisory Committee on Microbiological Standards for Foods with the USDA and the FDA. In addition, NOAA and FDA both support the executive office of the Interstate Shellfish Sanitation Conference, which is the standards-setting body for a Federal/state cooperative program to ensure the safety of raw molluscan shellfish.

Both industry and other agencies use the NOAA Seafood Inspection Program to ensure that fishery products comply with regulatory requirements (both domestic and foreign), purchasing specifications, and consumer expectations.

GAO Report: *Oversight of Food Safety Activities*
As the GAO report outlined, several agencies are involved in food safety oversight. In general, we believe the report does a fair and thorough job of describing the major food safety activities at NOAA.

As the GAO report outlines, in FY 2003, of the $1.7 billion spent on food safety–related activities, NOAA spent just under $22 million—only approximately 1 percent of the total expenditure.

The GAO report made several recommendations, and I will focus on those directly relevant to NOAA. As I mentioned earlier, the FDA and NOAA have an interagency agreement. We agree with the GAO recommendation for FDA and NOAA to ensure the implementation of this agreement and we will continue to work with the appropriate components of the FDA in order to do this.

In addition, the report recommends that the leaders of each of the agencies discussed in the report identify and inventory all active interagency food safety–related agreements; evaluate the

need for these agreements; and, where necessary, update the agreements to reflect recent legislative changes, technological advances, and current needs. We agree with this recommendation and will establish an inventory of active interagency food safety–related agreements on which NOAA is a signatory. In addition, NOAA will contact the applicable agencies associated with food safety–related agreements whenever NOAA believes an agreement should be revised.

Conclusion

Mr. Chairman and members of the Committee, thank you for inviting me here today to speak about our Seafood Inspection Program and the recommendations in the GAO report. I would be happy to answer any questions you have.

Mr. PORTER. I would like to start by asking a question to all of you and would like a response.

In the GAO's report, they identified over 71 memoranda of understanding, MOUs, between the four agencies present today. Unbelievably, in only seven cases do all agencies party to an agreement identify that they were a part of such an MOU. This means in 64 of 71 cases, one or more agencies had no idea they were part of an agreement.

How would you explain this?

We will start with Mr. Brackett.

Mr. BRACKETT. Thank you, Mr. Chairman.

Many of these MOUs actually were written for specific issues at the time. Many of them were also written at the local level. These were meant to be operational, and in some cases where the issue in the past may no longer be applicable, but they were never taken off the books, consequently, what FDA is doing is actually doing the inventory as was suggested by GAO, looking through our MOUs, revising them if necessary, sunsetting those that don't apply, and perhaps leaving those alone that are working well.

Mr. PIERSON. We also look at the MOUs in a similar fashion to which Dr. Brackett has just commented on.

These have evolved over the years. If you notice, some of these go back into the 1970's and 1980's and the like. We certainly agree that they do deserve review. FSIS certainly is willing to take a look at those MOUs that apply to them and see whether or not we should revise them or sunset them or whatever is appropriate for the MOUs.

MOUs have served a very, very important purpose for us in many cases, and I just think of one now, for instance, with the Public Health Service. We have an MOU with them relative to members of the Public Health Service to become part of our Food Safety Inspection Service, and we have a number of physicians and veterinarians who are uniformed and work for us. For example, our administrator of our Office of Public Health Science is a physician from the Public Health Service, and he is over there in part because of this MOU that was created.

So they do serve a very useful purpose, but, yes, historically the ones that are there need to be reviewed, and we will be doing that. Thank you.

Mr. JONES. I would agree with my colleagues on some of the reasons why these MOUs have not been tracked as aggressively as they should have been. Many of them at the Agency, the EPA, are over 30 years old. We have now identified a tracking system to make sure we have in front of us all the existing MOUs, and we will be going back to look at them for their relevance. Some of them may be sunsetted and some of them, updated.

Mr. CANO. As I mentioned, we are intending to establish an inventory and to followup on any of the MOUs that NOAA is a signatory to and that appear to need revision.

Mr. ROBINSON. Mr. Chairman, could I just make a quick summary comment?

Based on my 32 years of experience doing this kind of work, any system that requires, at least—and I emphasize, at least—71 interagency agreements to function is a system built for problems. Peo-

ple retire. Agreements that are made on the ground are based on human relations. Those things change over time. Pretty soon, as we discovered in this particular case, folks drift away and agreements are forgotten or not aggressively implemented.

The whole system that begs for this volume of interagency agreement is a system that is severely handicapped, in our opinion.

Mr. PORTER. It seems to me that these MOUs were the basis for cooperation, supposed cooperation.

I know, Mr. Brackett, you mentioned they were for local operational purposes. Can you expand upon that a little more?

Mr. BRACKETT. Sure, Mr. Chairman.

Many of these had very specific purposes. In one that we have, for instance, with the Food Safety and Inspection Service, it was specifically designed for information sharing, particularly at the district level. That one actually called for a reassessment after 1 year, which was done. It was not reassessed after that because the MOU didn't request that. But that particular operational MOU has continued on, and it has been one of the more successful operational MOUs we have had, as sort of evidenced by many of the joint enforcement actions it has prompted.

Mr. PORTER. Thank you.

Mr. Marchant, do you have any questions?

Mr. MARCHANT. Thank you, Mr. Chairman.

The administration has put forth a proposal for results commissions which would examine sectors of the government in need of reform and issued recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment.

What is each of your opinions on promoting such a fast track reorganization legislation to solve these problems we are talking about today?

Mr. BRACKETT. Thank you, Mr. Marchant.

I am not in a position really to state with any authority what reorganization proposals the administration would contemplate, referring to commissions for consideration, but I am certain the administration is not currently contemplating a commission that would consider reorganization of the food safety agencies at this point.

Mr. MARCHANT. Mr. Pierson.

Mr. PIERSON. Yes. Certainly we are supportive of any effort where we can better address public health. That is our baseline, is effectively addressing public health. However, without knowing all the details, etc., of what is proposed and what will finally transpire, it is very, very difficult to comment specifically on that.

But I might say that the White House has established a Policy Coordinating Committee, led by the Domestic Policy Council and the National Economic Council, to look into the issue of a single food safety agency. I believe this was in 2002. The Policy Coordinating Committee did conclude 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; and that is the current position of this administration.

We feel that we have worked very effectively together, and I think the outcomes, as seen, for example, by CDC, speak very loudly to the success of effectively addressing food safety and assuring public health.

Mr. MARCHANT. Mr. Jones.

Mr. JONES. Yes. Similar to my colleagues, I don't feel like I am in a position to speak directly to the question related to the results commission.

Mr. CANO. Similarly, I am not prepared to comment on that.

Mr. MARCHANT. You have recommended that all agencies coordinate better when evaluating the food inspection system in foreign countries. How do you think that this can be done in the most effective and useful way for all the agencies?

Mr. ROBINSON. Well, Mr. Marchant, I think we come back to where we have been for quite some time, that a consolidated enterprise is the best way to proceed. A single food safety agency that is independent, free of inherent conflicts of interest, able to move resources about, to ensure two delegations from two different agencies are in the same country in the same year, evaluating essentially the same kinds of things, is the way to go.

Again, systems built on trying to make interagency agreements function are suboptimal by their definition, in our opinion.

Mr. MARCHANT. Can you tell me, are the agencies self-funded? Do the companies that you inspect the food of pay the fees that fund the agencies?

Mr. ROBINSON. I will let the administration witnesses speak for their own agencies, but in general, this is about—at least in the last year we had complete data, about $1.7 billion in appropriated funds were applied here. NIMS essentially operates their enterprise on a fee-for-service basis, so they don't receive a great deal of appropriated funds to conduct their activities. They are done on a fee-for-service basis.

The rest of the agencies operate with appropriated funds, with the exception of FSIS line inspectors; when they go into overtime mode, the companies pay for the overtime. But the regular tours of duty are paid for out of appropriated funds.

Mr. MARCHANT. Thank you.

Mr. PORTER. Actually, I have a question for Dr. Pierson and Dr. Brackett regarding the cheese pizzas. You think it makes the most economically and efficient sense to require the USDA to inspect pepperoni pizzas and require the FDA to inspect cheese pizzas?

Actually, both of you.

Mr. PIERSON. Certainly. This example has been used time and time again as something where there appear to be very serious, very large problems, discrepancies, etc.

Let me point out, like Dr. Brackett pointed out, first of all, that these dual-jurisdiction establishments amount to a very, very low percentage of volume and numbers of establishments that we are dealing with. The vast bulk of our inspection system deals strictly with meat, poultry and egg products, not dual-jurisdiction establishments.

Our inspectors are required to be present daily by statute. They are in these operations daily, where you would find meat and poultry-topped products. We do have—through our MOU, we feel the

flexibility that if FSIS sees or perceives something that is out of line, we can contact our colleagues at FDA and inform them of a situation that is out of line or not appropriate or meeting what we feel would be, potentially, regulatory requirements.

Certainly this type of thing should be given consideration. For example, the meat and poultry that goes on the pizzas has already been federally inspected and passed, and we feel that these sorts of products are, to us, low-risk products.

Mr. PORTER. Thank you.

Mr. BRACKETT. Mr. Chairman, as Dr. Pierson said, many of these sorts of confusing products are very small in comparison to the rest of the food that we regulate, but nevertheless, they have evolved over the years for numerous reasons, and sometimes they may confuse some people.

We have discussed with our partners at FSIS, and will continue to discuss, ways that we can clarify the jurisdiction; and at some point in the future we would hope that we could also provide this to the public for input also to see if we can clarify better.

Mr. PORTER. It seems to me this has been a problem for a decade or more.

I guess, to followup on your answer, or partial answer, to my question, I have outlined five or six, maybe seven different areas of duplication. Why haven't you done something about that? Why haven't you taken the initiative to correct and create a more efficient program and more economical program for the American people? Is it something not important, so you allow it to continue, or am I missing something here?

Mr. PIERSON. First of all, we are very concerned about the resources and how we effectively apply those resources. We feel that we do a pretty good job of that in, again, effectively applying one to better provide protection, public health protection.

There are management issues that we do in fact continually address. There are just a number of issues that we do constantly sort out of how we can better coordinate, cooperate in terms of our effectivenesses and efficiencies.

I disagree with GAO's previous reports that there is this matrix that has been evolving. And certainly we do not have the instantaneous solution, but we are giving these, I think, due consideration.

Mr. BRACKETT. Well, Mr. Chairman, the first thing I would like to point out is, again, there are no foods that are inspected duplicatively by both FSIS and USDA. We inspect those ingredients or those foods for which we have statutory authority, and that is the reason that is set up that way.

But, nevertheless, there are a number of foods, such as those that you have mentioned, where the jurisdiction may not be as clear to the outside. But, nevertheless, one or the other of us is inspecting those, is making sure that they are safe; and of course, in our minds, what is of foremost importance is public health.

Mr. PORTER. I appreciate that everyone in this room believes everything is for the health of the American people. I think that it is important to state it again, and I appreciate hearing it. But, again, for over a decade we have been seeing some distinctions between the two different agencies, but yet you have not taken steps to correct some of these areas.

With the state of the budget—and I would expect, I think I heard it today, some of you need additional funds for operations; and if I haven't heard it today, I hear it most every day from different Federal agencies, that they are underfunded.

Yet, FDA does closed-face meat sandwiches, USDA does open-face meat sandwiches. FDA does the frozen pizza, and USDA does the pepperoni. FDA does hot dogs on a roll and the USDA does hot dogs on a pastry dough. FDA does beef soup and USDA does chicken soup. FDA does chicken broth, but USDA does beef broth.

It is very difficult for me to tell my constituents that we are running these agencies in an efficient manner.

I appreciate you have done things this way and—for whatever reason, but the reason we are here today is you haven't taken steps to correct some of these problems.

I guess, Dr. Brackett, I want to ask you one more question and then move on. Do you think there is room for improvement in the organizational structure?

Mr. BRACKETT. Well, in each agency, I think we continually look at the organizational structure to find out the best and most efficient way to use our resources that we have. So I think there is always room for improvement, and I think we are always looking for ways to improve what we do.

Mr. PORTER. What would you suggest for organizational reforms as we move into the future? You are the expert. We are Members of Congress and, of course, trying to take all the information we can and come up with some possible solutions.

What would you suggest needs to be done to help improve the efficiency and performance of your agency?

Mr. BRACKETT. Well, I think the main thing is that the two agencies, regardless of the structure, are built upon what we consider to be very strong food safety systems. That is the reason for our being, and anything that would change the structure would have to be looked at to see if it affected that. That would include such things as maybe a Farm to Table approach. The organization has to address that. It has to address the proper amount of outreach to the consumers, as well as to the regulated industry and the amount of research needed to back up science-based decisions, which are based on risk assessments.

It would also include the proper funding, surveillance and reporting back, so that we knew that what we were doing is efficient. Any kind of organizational change would have to be looked at with that in mind, and also so that we would still be in harmony with our legislative directives.

Mr. PORTER. Dr. Pierson.

Mr. PIERSON. Yes, we can, and we have created organizational charts of new vintages and looked at them and said, oh, we will do better under this structure and that structure. I know when I first came in the under secretary's office, one of the first thing we did was to do some reorganization at FSIS.

One can do that. But I think the fundamental, important concept here is, regardless of whether or not you are in FSIS, FDA, EPA or combinations thereof, you have to have cooperation and communication and coordination, and, to me, that is the key to moving forward.

One of the examples that I think is very appropriate is the cooperation, coordination and communication that occurred in addressing the BSE situation here in the United States. Through cooperative efforts of a number of agencies, we were able to provide consumers with immediate assurance of the safety of our beef supply and to coordinate very, very tireless efforts to reopen markets. We are very hopeful that is going to happen. But it required a tremendous amount of coordination between agencies within USDA, with FDA and many others—the State Department, USTR, etc.

So it is that coordination, I think, that is just so key and so essential. If we act as stovepipes regardless of our structure, we are not going to get ahead. We have to work together.

Mr. ROBINSON. Mr. Chairman, may I weigh in?

Mr. PORTER. Yes, but I want to comment first.

I appreciate your comments, but unfortunately, I don't think you answered the question. I would agree that we need more cooperation, and there is no question we need more coordination. But what specific organizational reforms do you think are needed? Again, yes, we need more coordination and more cooperation.

But beyond those good political terms, what do you suggest specifically be done, Doctor?

Mr. PIERSON. Well, I think at this point for me to sit here and provide some type of structure without working with my colleagues and others at USDA and the like, you know, without having that coordinated effort to give you a distinct answer in terms of representing USDA, I think that would be inappropriate for me.

Mr. PORTER. Isn't that your job? I am sorry, isn't this your responsibility?

Mr. PIERSON. Yes. Well, I am Acting Under Secretary for Food Safety in USDA, correct.

Mr. PORTER. So your answer today is cooperation and coordination?

Mr. PIERSON. I think that is done very effectively. If we talk about any type of restructuring, I think it has to be through a collaborative effort to come out with a plan; and for me, right now, to lay out a plan, I think I would have a lot of people that I would be having to have further discussions with. I think it is quite appropriate for me to work with others in moving forward, if we were to discuss such things.

Mr. PORTER. Thank you, Doctor.

Mr. Robinson.

Mr. ROBINSON. I was going to weigh in relative to the BSE issue. We have done work on BSE, and I think it speaks to this exact point you are raising here, that we pointed out situations in our work where FDA, who had identified potentially contaminated feed and didn't inform USDA of those events and potentially—fortunately, it didn't turn out—potentially put the system at risk. FDA's own acting counsel, I think, has referred to the structure between FDA and USDA as hampering Federal abilities to deal with this issue.

I also want to come back to your opening statement that the problems here are unfortunately rooted in statute. The various systems are directed largely by statute, and the statutes direct that USDA has to have an inspector at every plant looking at every car-

cass, carcass by carcass by carcass. Those resources can't be shifted to other higher priority areas.

We now know that the food safety threats are seafood first, fruits and vegetables second, eggs third, and meat and poultry fourth. The resources by statute are heavily directed toward the fourth priority and not priorities one through three. That is not something that the agencies can do a heck of a lot about. They are directed by statutes to do certain things the way they are doing them now.

Mr. PORTER. Mr. Robinson, I partially agree, but partially disagree. Yes, it is directed by statute, but I would hope that the agencies wouldn't expect all the statutes to come out of this body. I would expect that in their role and responsibilities, they would bring forward ideas and suggestions, because if they don't, then we are going to pass legislation that may well be another Band-Aid.

I guess I agree with you, but we should take it a step further. These are the experts, and we would hope in the future that they would bring forward their own, and possibly they have before my tenure. But I think your point is well taken.

Mr. ROBINSON. We recommended they do just that. Obviously, I think you are hearing today there is no likelihood of that occurring any time soon.

Mr. PORTER. I won't repeat that, but I will concur. I think that is part of the problem.

What I would like to do is say thank you to the panel for being here, for your testimony. There may well be followup questions.

I also ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record, and that any answers provided by the witnesses also be included in the record. Without objection, so ordered.

I also ask unanimous consent that all exhibits, documents and the materials referred to by the Members and witnesses may be included in the hearing record and that all Members be permitted to revise and extend their remarks. Without objection, so ordered.

Again, I want to say, thank you all. I appreciate that we have one of the best systems in the world. We are here today just trying to make it a little bit better.

Thank you all for being here, and the meeting is adjourned.

[Whereupon, at 3:20 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

Questions for the Record

"Question: What's More Scrambled Than an Egg?
Answer: The Federal Food Inspection System"
Subcommittee on the Federal Workforce and Agency Organization
Chairman Jon C. Porter
June 3, 2005

GOVERNMENT ACCOUNTABILITY OFFICE

- **Consolidate Training Programs:** GAO has recommended that food safety agencies consolidate all training programs as is done for Federal law enforcement personnel. Please explain how you think this can and should be done.
    - How do you respond to those who say that this is not practical? That each agency has its own specific concerns that would make such a plan impractical?

- **Fast Track Legislation:** The Administration has put forth a proposal in the fiscal year 2006 budget for "Results Commissions," which would examine sectors of the Government in need of reform and issue recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment. What is your opinion of promoting such "fast-track reorganization" legislation as a means to improve efficiency within the food inspection process?

- **Bioterrorism Act:** FDA has suggested that granting USDA officials authority to inspect FDA-regulated foods and facilities would not be practical because of prohibitively high costs. What do you estimate would be the cost of implementing this authority?
    - Would the costs for implementation be prohibitively high, in your estimate?

ALL ADMINISTRATION WITNESSES

- Do you think that Memoranda of Understanding are often an effective means for avoiding duplication of effort and reducing overlap? If so, please provide specific examples supporting your answer.

- Outside of the recommendations made by the Government Accountability Office in its report, what specific organizational reforms are needed throughout the Federal food inspection system?

- **Fast Track Legislation:** The Administration has put forth a proposal in the fiscal year 2006 budget for "Results Commissions," which would examine sectors of the Government in need of reform and issue recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment. What is your opinion of promoting such "fast-track reorganization" legislation as a means to improve efficiency within the food inspection process?

- Is it your position that the status quo is fine and that your respective agency is opposed to any kind of consolidation that could potentially improve economic efficiency, without sacrificing the safety of the food supply, within the food inspection process?

- If you are open to improving the economic efficiency of the process, without sacrificing the safety of the Nation's food, would your particular agency be willing to sit down with the other agency to try and come up with a joint solution on how best to such efficiency through consolidation? (Please answer even if you are not open to improving the economic efficiency of the food inspection process.)

- If no, why not. If yes, when will the first meeting take place and what officials will be attending this meeting?

USDA

- It is my understanding that in 2004 USDA and FDA both visited the following countries: Brazil, Costa Rica, Germany, Hungary, Mexico and Canada. If the Congress saw fit to authorize USDA to do inspections for FDA under the Bioterrorism Act, does it not seem plausible that USDA and FDA could share inspections of foreign systems?

- **Bioterrorism Act:** As you know the FDA was given authority to cross-deputize USDA employees to perform its inspections at dual-jurisdiction establishments. Do you think that it would be possible for USDA to perform all or some of the inspections currently done by FDA in locations where both inspectors have jurisdiction?

  - If no, then is it your opinion that Congress was wrong to give this broad authority to FDA and should repeal it?

- According to the GAO, both USDA and FDA inspect almost 1,500 "dual jurisdiction establishments." Notwithstanding current law, do you think that it is essential to have both USDA and FDA inspectors visit each of these establishments?

  - In your opinion, would it be impossible for the inspectors of one agency to perform the inspection duties of another agency?

FDA

- **Bioterrorism Act:** GAO reports that, according to the Bioterrorism Act, FDA has the authority to commission inspectors of another agency to inspect facilities that fall under its jurisdiction—most likely this would involve the USDA. Is this an option that FDA is currently pursuing?

  - GAO has reported that FDA and USDA share responsibilities at 1,451 "dual jurisdiction" facilities. Is it your impression that USDA inspectors are capable of handling additional FDA responsibilities?

  - It is my understanding that the reason in the past why FDA has not pursued this option is because of concerns that the costs of doing so would be prohibitively high. Has FDA done a complete cost analysis of any associated costs or savings that could result from such collaboration? If so, what was the result? If not, why has this not been done?

- GAO reports that a 1974 agreement between NMFS and FDA is in place currently to reduce overlap in inspections done by both agencies—is this true?
    - How would you assess the current working relationship between FDA and NMFS when it comes to eliminating duplicative inspections?
    - What more could be done to work together in this area?
    - Why has more coordination failed to occur in the past?
- **Overlap:** It is my understanding that both the FDA and the National Marine Fisheries Service perform inspections at 275 of the same seafood facilities. GAO reports that FDA does not recognize the work done by NMFS, thus essentially repeating an inspection. Is it FDA's position that NMFS does not perform legitimate inspections, such that its information would not be useful to FDA?
    - GAO has recommended that FDA and NMFS coordinate so that there are fewer duplicative inspections at each jointly inspected facility. Do you plan on doing this? If so, how? If not, please explain in detail why not.

NMFS

- GAO reports that FDA will not recognize the inspections done by NMFS because of an apparent "conflict of interest" that arises from the fee-for-service nature of your inspections. How would you respond to the claim that your inspections are not as legitimate as those done by the FDA?
- GAO reports that a 1974 agreement between NMFS and FDA is in place currently to reduce overlap in inspections done by both agencies—is this true?
    - How would you assess the current working relationship between FDA and NMFS when it comes to eliminating duplicative inspections?
    - What more could be done to work together in this area?
    - Why has more coordination failed to occur in the past?

EPA

- According to GAO, EPA is not the only Federal agency that participates in research aimed at understanding chemical and biological agents. How does EPA distinguish itself from the other agencies in its areas of responsibility?
- Regarding EPA's role in establishing tolerances for pesticides in food, what is the value of USDA, FDA, and EPA collecting samples of food and analyzing them for the presence of pesticides?
    - Would it not be more effective to combine these efforts and still maintain the value of the information? If not, please explain.

Questions for the Record
"Question: What's More Scrambled Than an Egg?
Answer: The Federal Food Inspection System"
Subcommittee on the Federal Workforce and Agency Organization
Chairman Jon C. Porter

Government Accountability Office (GAO)

1. **Consolidate Training Programs:** GAO has recommended that food safety agencies consolidate all training programs as is done for Federal law enforcement personnel. Please explain how you think this can and should be done. How do you respond to those who say that this is not practical? That each agency has its own specific concerns that would make such a plan impractical?

GAO Response: We believe that a joint training program for food inspectors represents a practical, common sense solution to one portion of the overlap and duplication plaguing our food safety system, as recommended in our report *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, GAO-05-213, March 30, 2005. Our comparison of the curricula for both agencies' food inspection training programs shows that they are similar in several respects. These training similarities stem from the agencies' regulations, which require that food-processing facilities comply with similar sanitation standards, good manufacturing practices, and Hazard Analysis and Critical Control Point (HACCP) standards. USDA and FDA inspectors are trained on how to check on food processors' employee hygiene programs, pest control, and the cleanliness of food contact surfaces. Similarly, both agencies' training programs include instruction on how to review a food manufacturer's HACCP plan and how to determine if the facility has taken corrective action for any shortcomings.

Regarding how this joint training could be achieved, during our work on oversight of food safety activities, we noted that the Federal Law Enforcement Training Center has consolidated all law enforcement training under one center. This does not mean that all trainees take every course that is offered. Similarly, USDA's Animal and Plant Health Inspection Services' Professional Development Center offers agriculture training to both USDA and DHS inspectors involved in inspecting agricultural products coming into the United States. The curriculum has common elements as well as subject-specific courses that trainees participate in depending on their specific job responsibilities.

Regarding comments about the impracticality of consolidating USDA and FDA food inspection training because each agency has its own specific concerns, we recognize that specialized training will continue to be needed to address the agencies' different statutory authorities and food products as long as existing laws give them responsibility for different segments of the food supply. This should not make it impractical to consolidate training programs that have many common

elements while maintaining the necessary training on agency-specific inspection and enforcement authorities. In commenting on our report, both USDA and FDA stated that there are significant differences in authorities and responsibilities of each agency and, hence, the training on inspection and enforcement must be different. On the other hand, USDA saw some merit in examining the feasibility of conducting joint training when commonalities exist –the core of our conclusion and recommendation—and pointed out that USDA's Food Safety and Inspection Service and FDA have jointly developed and are currently implementing food security awareness training. This example points to the feasibility of conducting joint training even as the agencies continue to operate under different authorities and responsibilities for different segments of the food supply.

2. **Fast Track Legislation:** The Administration has put forth a proposal in the fiscal year 2006 budget for "Results Commissions," which would examine sectors of the Government in need of reform and issue recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment. What is your opinion of promoting such "fast-track reorganization" legislation as a means to improve efficiency within the food inspection process?

GAO Response: As you point out, the President's fiscal year 2006 budget proposes the establishment of "Results Commissions" that would improve program performance and increase efficiency by reviewing Administration proposals to consolidate or streamline programs that cross departmental or congressional committee jurisdictional lines. Experts that serve on the Commission would review proposals before the President submits them to Congress for expedited consideration.

This proposal mirrors the 2003 recommendation made by GAO in the Comptroller General Walker's testimony.[1] The Comptroller General noted that while some expedited congressional consideration may well be appropriate for specific issues, the Congress has an important role to play in government reform initiatives, especially from an authorization and oversight perspective. The Comptroller General suggested that the President and the Congress may wish to consider establishing processes (e.g., a commission) that provide for the involvement of key players and a means to help reach consensus on any specific restructuring proposals that would be submitted for consideration by the Congress.

[1]GAO, *Executive Reorganization Authority: Balancing Executive and Congressional Roles in Shaping the Federal Government's Structure*, GAO-03-624T (Washington, D.C.: April 3, 2003).

The Comptroller General's testimony included several caveats:

- Only the Congress can decide whether it wishes to limit its powers and role in government reorganizations.
- The key issue is how to make changes and reforms and what the respective roles of the Congress and the executive branch should be.
- In certain circumstances, the Congress may deem it appropriate to limit its role in government reorganizations. However, care should be taken regarding the nature, timing, and scope of any changes.
- A distinction needs to be made between policy choices and operational choices, and a balance must be struck between the need for due deliberation and the need for action.

Consistent with the Comptroller General's recommendation, it is GAO's opinion that such legislation could provide a means to improve efficiency within the food inspection process.

3. **Bioterrorism Act:** FDA has suggested that granting USDA officials the authority to inspect FDA-regulated foods and facilities would not be practical because of prohibitively high costs. What do you estimate would be the cost of implementing this authority? Would the costs for implementation be prohibitively high, in your estimate?

GAO Response: We recommended in our report on oversight of food safety activities that the FDA Commissioner enter into such an agreement with USDA if appropriate and cost effective. We did not estimate these costs because, in general, it is the agencies' task to develop such estimates, although GAO is willing to review their results if requested.

From the information available to us, however, we believe that using USDA inspection resources at dual jurisdiction establishments is feasible and would not be prohibitively costly. First, USDA already maintains a daily presence at dual jurisdiction establishments that manufacture and handle food, so the additional costs would not likely be substantial. As a result of USDA's presence, FDA would not incur the travel costs associated with inspecting these establishments.

Second, according to the USDA officials with whom we spoke, USDA's inspection force is increasingly capable, in terms of scientific background, of handling the inspections that FDA conducts. Third, FDA could continue to handle any specialized enforcement actions that resulted from the USDA inspectors' findings. In short, the USDA inspectors would serve as FDA's "eyes," alerting their supervisory USDA Consumer Safety Officers when lack of compliance is noted. If necessary, referrals could be made to FDA's Consumer Safety Officers. Such an arrangement would free FDA inspection resources, allowing the agency to focus on higher-risk establishments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG - 4 2005

The Honorable Jon Porter
Chairman
Subcommittee on the Federal Workforce and Agency Organization
Committee on Government Reform
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to the questions you submitted for the record of the May 17, 2005, hearing regarding the Federal food inspection process. Our responses to the questions are enclosed.

The Food and Drug Administration appreciated the opportunity to testify before the subcommittee at this hearing. We look forward to continuing to work with you and your staff on issues related to the Federal food safety system.

Sincerely,

Patrick Ronan

Patrick Ronan
Associate Commissioner
for Legislation

Enclosure

FOOD AND DRUG ADMINISTRATION RESPONSES TO QUESTIONS SUBMITTED FOR THE RECORD BY CHAIRMAN JON PORTER

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON THE FEDERAL WORKFORCE AND AGENCY ORGANIZATION

ALL ADMINISTRATION WITNESSES

- **Do you think that Memoranda of Understanding are often an effective means for avoiding duplication of effort and reducing overlap? If so, please provide specific examples supporting your answer.**

Memoranda of Understanding (MOU) are useful tools to help agencies coordinate efforts to improve public health protection. MOUs are developed for a variety of reasons that include: to facilitate sharing of information, to enhance interaction between agencies, and to respond to a specific public health problem that may arise related to a commodity.

The Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA) have an MOU to facilitate the sharing of information between agencies about the establishments that are subject to the jurisdictions 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. This shared information helps agencies coordinate enforcement efforts when inspections find 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.

This MOU has been very effective in enhancing collaborative activities to improve public health protection. The sharing of information through this MOU has led to a number of recalls of both FDA- and USDA-regulated products and has led to joint enforcement activities. For example, an FDA/USDA collaborative effort found unsanitary conditions at an Illinois cold storage warehouse during an inspection. This joint effort resulted in the seizure of approximately 22 million pounds of food products along with the successful prosecution of several top warehouse executives. Another example involves a cooperative association that distributes food to more than 250 independent grocers across the Midwest. This association was recently fined $1 million for storing meat, poultry and other food products in a warehouse with a serious mouse infestation. The fine was a direct result of a joint FDA/USDA investigation.

FDA and the National Marine Fisheries Service (NMFS) have an MOU to enhance interactions between the agencies. The purpose of this MOU is to ensure that the actions taken by one agency are consistent with the activities of the other. This MOU is more than thirty years old, and the agencies are in the process of updating its contents.

MOUs are also developed when specific problems arise in a commodity. For example, in 1997, in response to concerns about aflatoxin levels in various products, FDA and USDA's Agriculture Marketing Service (AMS) entered into three MOUs related to aflatoxin testing in peanuts, brazil nuts, and pistachios. For the nut products, testing is voluntary, and at the request of the importer, AMS tests the nuts for aflatoxins. AMS notifies FDA of analytical results so FDA can detain violative product.

The MOUs described above are just a few examples of MOUs that have been successful by enhancing coordination between agencies. MOUs continue to be an efficient means to help agencies work together more effectively to protect the food supply.

- **Outside of the recommendations made by the Government Accountability Office in its report, what specific organizational reforms are needed throughout the Federal food inspection system?**

The Administration has examined the Federal food safety system and has not identified the need for reorganization. The existing Federal food safety system is working effectively to protect public health. The Federal food safety agencies work closely together and leverage each other's resources when appropriate. For example, we utilize MOUs to exchange inspection information to permit more efficient use of each agency's resources and to contribute to improved public health protection. In addition, we have utilized new authority in the Public Health Security and Bioterrorism Preparedness Act of 2002 (Bioterrorism Act) to commission Customs and Border Protection (CBP) officers to conduct examinations on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff in enforcement of the Bioterrorism Act's prior notice requirements for imported food shipments.

- **Fast Track Legislation: The Administration has put forth a proposal in the fiscal year 2006 budget for "Results Commissions," which would examine sectors of the Government in need of reform and issue recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment. What is your opinion of promoting such "fast-track reorganization" legislation as a means to improve efficiency within the food inspection process?**

The Administration is not currently contemplating that the Commissions would consider reorganization of the Federal food safety agencies.

- **Is it your position that the status quo is fine and that your respective agency is opposed to any kind of consolidation that could potentially improve economic efficiency, without sacrificing the safety of the food supply, within the food inspection process?**

- **If you are open to improving the economic efficiency of the process, without sacrificing the safety of the Nation's food, would your particular agency be willing to sit down with the other agency to try and come up with a joint solution**

on how best to such efficiency through consolidation? (Please answer even if you are not open to improving the economic efficiency of the food inspection process.)

- **If no, why not. If yes, when will the first meeting take place and what officials will be attending this meeting?**

FDA is constantly looking for new opportunities to enhance economic efficiency of its food safety and inspection programs. We believe that this is best achieved within the existing food safety and inspection framework, working cooperatively with other Federal, state, and international food safety and defense agencies. 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 to protect public health.

The food safety agencies collaborate at many different levels to ensure food safety and, wherever possible, economic efficiency. The agencies use several mechanisms that enable sharing of information and expertise to enhance food safety and defense. These mechanisms include MOUs, interagency working groups, research meetings, international fora such as G-8, and U.S./Mexico/Canada border initiatives.

NMFS and FDA recently collaborated in the closure of federal waters along the New England coast to minimize consumer exposure to hazardous marine toxins and are working together to determine when it is safe to reopen waters for harvesting seafood. Research conducted by USDA's Agricultural Research Service helps support FDA's preventive control, inspection, and compliance programs. These are just a couple of examples of how food safety agencies cooperate to ensure food safety and achieve economic efficiencies.

FDA

- **Bioterrorism Act: GAO reports that, according to the Bioterrorism Act, FDA has the authority to commission inspectors of another agency to inspect facilities that fall under its jurisdiction—most likely this would involve the USDA. Is this an option that FDA is currently pursuing?**

Yes. As we mentioned in our response to an earlier question, the Bioterrorism Act authorizes the Secretary of Health and Human Services to commission other Federal officers and employees to conduct examinations and investigations. Pursuant to this new authority, FDA and CBP have signed a Memorandum of Understanding to commission CBP officers to conduct examinations and investigations pursuant to information obtained through the prior notice requirements. These examinations and investigations may be carried out on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff at ports that

do have an FDA presence. This collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade. In accordance with this new authority, FDA has already commissioned over 8,150 CBP officers. The Agency will continue to explore use of this authority with other agencies as a tool to further improve efficiencies.

- **GAO has reported that FDA and USDA share responsibilities at 1,451 "dual jurisdiction" facilities. Is it your impression that USDA inspectors are capable of handling additional FDA responsibilities?**

FDA and USDA inspectors have different educational backgrounds, have received different training, and have responsibility for different food products and industries. These differences are due to the different legal authorities and the different scientific knowledge necessary to understand and regulate different food products and different processing techniques. The core qualifications for the agencies' inspection personnel are different. For example, FDA has educational requirements in the science field for its Consumer Safety Officers/Investigators.

By way of background, dual jurisdiction establishments (DJEs) are facilities that are regulated by both FDA and USDA because the establishment processes some food products that fall under FDA's jurisdiction and other food products that fall under USDA's jurisdiction. At DJEs, each agency is responsible for products and processes within its own area of expertise and jurisdiction. DJEs comprise less than two percent of the total food processing or manufacturing facilities in the United States. This is a very small percentage of food facilities, and, in many cases, these are facilities at which FDA has assessed the risks to be low. Thus, the opportunity for achieving efficiencies through the leveraging of resources at DJEs is quite small.

- **It is my understanding that the reason in the past why FDA has not pursued this option is because of concerns that the costs of doing so would be prohibitively high. Has FDA done a complete cost analysis of any associated costs or savings that could result from such collaboration? If so, what was the result? If not, why has this not been done?**

Section 314 of the Bioterrorism Act, which provides commissioning authority, requires an MOU between the Secretary of Health and Human Services and the head of the other Federal agency. The MOU must address training of the officers and employees of the other agency to conduct the examinations and investigations. The MOU must also address reimbursement. FDA and FSIS have looked preliminarily at the issue of utilizing FSIS personnel to achieve economic efficiencies at dual jurisdiction facilities. This preliminary review looked at costs associated with the necessary training and reimbursement, oversight of such a program, availability of comparable personnel, and the inventory of firms. FDA has not pursued this further as such collaboration would not appear to be cost-effective, especially in view of the small inventory of dual jurisdiction manufacturing facilities.

- **GAO reports that a 1974 agreement between NMFS and FDA is in place currently to reduce overlap in inspections done by both agencies—is this true?**
    - **How would you assess the current working relationship between FDA and NMFS when it comes to eliminating duplicative inspections?**
    - **What more could be done to work together in this area?**
    - **Why has more coordination failed to occur in the past?**

The FDA and the National Marine Fisheries Service (NMFS) signed an MOU in 1974. The primary goal of the MOU is to "...enable each agency to discharge as effectively as possible, its responsibilities related to inspection..." The MOU does not call for FDA or NMFS to avoid coverage of firms covered by the other agency. Rather, it provides for the manner in which the two agencies will interact so that actions taken by one agency do not adversely affect the activities of the other. For example, it calls for agencies to: 1) inform the other when it takes an adverse action against a firm subject to the other's inspectional activities; and 2) to apply FDA regulatory requirements.

FDA and NMFS have recently begun a review of the MOU. The purpose of the MOU discussion is to refine the mechanisms through which the agencies interact, in an effort to maximize the benefit derived by both agencies.

- **Overlap: It is my understanding that both the FDA and the National Marine Fisheries Service perform inspections at 275 of the same seafood facilities. GAO reports that FDA does not recognize the work done by NMFS, thus essentially repeating an inspection. Is it FDA's position that NMFS does not perform legitimate inspections, such that its information would not be useful to FDA?**
    - **GAO has recommended that FDA and NMFS coordinate so that there are fewer duplicative inspections at each jointly inspected facility. Do you plan on doing this? If so, how? If not, please explain in detail why not.**

FDA does not question the legitimacy of NMFS inspections for their intended purpose. FDA and NMFS inspections are performed for different reasons and cannot simply be replaced by the other as they accomplish different purposes. FDA conducts inspections as part of its mandate to ensure compliance with statutory requirements and the provisions of Agency regulations. These inspections are regulatory in nature. NMFS performs its inspections to satisfy a prospective customer of a fishery product that its conditions of purchase have been met by the producer of the goods. These inspections are trade-facilitating in nature. The manner in which an inspection is performed to accomplish the former, and the controls placed on persons entrusted to act in that capacity, are necessarily different than to accomplish the latter. NMFS inspections do perform a useful and necessary function.

However, we are working with NMFS to address certain concerns. For example, because

NMFS is serving the regulated firm in a fee-for-service contract, this transaction and the inspection output are subject to possible conflict of interest concerns, or the appearance of a conflict of interest, if used as the government's independent assessment and assurance of product safety. Specifically, under certain conditions (e.g., remote areas) a firm may choose to discontinue inspection service in response to adverse inspection results, possibly jeopardizing the employment of the inspector and possibly compromising or creating the appearance of comprising the integrity of the inspection process. This potential conflict does not exist in a regulatory agency funded by general revenue.

NMFS contracts with firms to conduct a variety of inspectional activities. Only a portion of those are in-depth facility inspections, similar to FDA inspections. Those kinds of inspections cover about 240 firms, just over 5% of FDA's inventory of US seafood firms. Moreover, not all parts of these plants or products produced in these plants are always inspected, depending on the contract with the plant. FDA would need to inspect the parts of the facilities not covered by the NMFS contracts, minimizing the benefit derived from the NMFS inspections.

The products contracted for coverage by NMFS are not necessarily consistent with the products that are highest in priority for coverage under FDA's risk-based approach.

Additionally, in order to use NMFS inspections in lieu of FDA conducting its own inspections, FDA would need to train NMFS inspectors in FDA policy and procedures. FDA would also need to audit the performance of NMFS inspectors to ensure consistency. Training and audit efforts may not be cost effective, given the small number of firms involved in the NMFS program.

Lastly, because of the contractual arrangement between NMFS and the firm, NMFS treats information received from the firm as confidential. This limits the information NMFS would be able to share with FDA.

Questions for the Record
"Question: What's More Scrambled Than an Egg?
Answer: The Federal Food Inspection System"
Subcommittee on the Federal Workforce and Agency Organization
Chairman Jon C. Porter
June 3, 2005

ALL ADMINISTRATION WITNESSES

- Do you think that Memoranda of Understanding are often an effective means for avoiding duplication of effort and reducing overlap? If so, please provide specific examples supporting your answer.

  Response: Yes, Memoranda of Understanding (MOU) and Memoranda of Agreement (MOA) are effective means for improved efficiency and coordination between Federal, State and local authorities. The Food Safety and Inspection Service (FSIS) uses MOUs extensively within the U.S. Department of Agriculture (USDA), as well as externally with our sister food safety agencies. For example, the MOU that FSIS signed with the National Association of State Departments of Agriculture (NASDA), the Department of Health and Human Services' Food and Drug Administration (FDA) and the Department of Homeland Security (DHS) last year is helping to advance the goals of Homeland Security Presidential Directives 8 and 9, which encourage the enhancement of response and recovery procedures through improved cooperation of Federal, State and local governments and instruct Federal agencies to develop a national emergency preparedness plan.

  Since 1999, FSIS and FDA have had a MOU to exchange information on an on-going basis about establishments that fall under the jurisdiction of both agencies. The cooperation stemming from this MOU, along with assistance from other public health partners, was instrumental in the prosecution and conviction of a Chicago-based company and its president on five counts related to unsanitary conditions at its cold storage warehouse.

- Outside of the recommendations made by the Government Accountability Office in its report, what specific organizational reforms are needed throughout the Federal food inspection system?

  Response: The ultimate goal for Federal food safety programs must be to improve food safety and public health. USDA is fully committed to continuing to work with DHS, FDA and other Federal and State partners to ensure the safety and security of the food supply and protect public health. For instance, FSIS has

partnered with FDA and other food safety agencies to develop the Food Emergency Response Network (FERN) to integrate the nation's laboratory infrastructure for the detection and identification of threat agents in food at the local, State and Federal levels. The strides made in protecting our food supply from intentional contamination, reducing foodborne illnesses, as well as continuing to reduce the amount of pathogens on product samples collected and analyzed by FSIS, clearly indicate that our existing infrastructure and science-based policies are working to protect public health. The Federal agencies with food safety authorities are working together effectively to address food safety and security and the American food supply continues to be among the safest in the world.

- **Fast Track Legislation:** The Administration has put forth a proposal in the fiscal year 2006 budget for "Results Commissions," which would examine sectors of the Government in need of reform and issue recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment. What is your opinion of promoting such "fast-track reorganization" legislation as a means to improve efficiency within the food inspection process?

  Response: I am not in a position to state with any authority what reorganization proposals the Administration would contemplate referring to Commissions for consideration. I am not aware that the Administration is currently contemplating that the Commissions consider reorganization of Federal food safety authorities.

- Is it your position that the status quo is fine and that your respective agency is opposed to any kind of consolidation that could potentially improve economic efficiency, without sacrificing the safety of the food supply, within the food inspection process?

  Response: The most important question is whether the various Federal agencies with food safety authorities are working together effectively to address food safety and security. The American food supply continues to be among the safest in the world. We are proud of our accomplishments over the past five years and need to continue the progress that we and our Federal, State and local food safety partners have made. The strides made in protecting our food supply from intentional contamination, reducing foodborne illnesses, as well as reducing the amount of pathogens on product samples collected and analyzed by FSIS, clearly indicate that our existing infrastructure and science-based policies are working to protect public health. We are committed to apply the best available science and management practices to continually seek to improve on our goal of protecting public health. If we determine ways to further strengthen our system, we will move forward accordingly.

- If you are open to improving the economic efficiency of the process, without sacrificing the safety of the Nation's food, would your particular agency be willing to sit down with the other agency to try and come up with a joint solution on how best to such efficiency through consolidation? (Please answer even if you are not open to improving the economic efficiency of the food inspection process.)

  Response: FSIS continually works to strengthen the coordination between FSIS and other Federal, State and local food safety agencies in order to adopt the most cost-effective policies for protecting public health.

- If no, why not. If yes, when will the first meeting take place and what officials will be attending this meeting?

  Response: We have ongoing meetings to coordinate activities and policies with other relevant agencies. For example, in the area of homeland security, FSIS currently conducts food security awareness training with local cooperators, such as State and local inspectors, in a cooperative effort with other Federal agencies including USDA's Food and Nutrition Service and Agriculture Marketing Service, as well as FDA.

USDA

- It is my understanding that in 2004 USDA and FDA both visited the following countries: Brazil, Costa Rica, Germany, Hungary, Mexico and Canada. If the Congress saw fit to authorize USDA to do inspections for FDA under the Bioterrorism Act, does it not seem plausible that USDA and FDA could share inspections of foreign systems?

  Response: USDA currently shares information obtained during foreign country equivalency determinations with other Federal agencies and makes available a wealth of information on the FSIS Web site, 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.

- **Bioterrorism Act:** As you know the FDA was given authority to cross-deputize USDA employees to perform its inspections at dual-jurisdiction establishments. Do you think that it would be possible for USDA to perform all or some of the inspections currently done by FDA in locations where both inspectors have jurisdiction?

Response: I am concerned that the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 is not completely understood. While this Act gave FDA the authority to commission other Federal officials to inspect FDA-regulated foods, implementing an agreement between FSIS and FDA based on this Act would require a considerable amount of planning and work without any guarantee of improving public health. Before entering into an MOU pursuant to the Act, FSIS and FDA would need to conduct a comprehensive review of regulatory authorities, training requirements and reimbursement issues. Since FSIS and FDA operate under different regulatory structures, the roles, responsibilities and authorities of both agencies would need to be carefully defined.

- If no, then is it your opinion that Congress was wrong to give this broad authority to FDA and should repeal it?

  Response: FDA's authority to commission other Federal officials to inspect FDA-regulated foods would be critical in a food security emergency.

- According to the GAO, both USDA and FDA inspect almost 1,500 "dual jurisdiction establishments." Notwithstanding current law, do you think that it is essential to have both USDA and FDA inspectors visit each of these establishments?

  Response: While there are commonalities in the FSIS and FDA regulations, there remain significant differences between the two agencies' regulated industries under the Hazard Analysis and Critical Control Point system (HACCP) that dictate the necessity of distinct regulations. There are two important points to keep in mind when considering the perceived jurisdictional overlap between FSIS and FDA, particularly with regard to dual jurisdiction establishments (DJEs). First, the amount of food product, which falls within the overlap, is miniscule compared to the overall amount of product that the two agencies regulate independently. Correspondingly, the number of DJEs is also small, relative to the total number of establishments the agencies inspect. And second, any meat, poultry or egg product that falls within the jurisdictional overlap has already been inspected and passed by the USDA.

  In addition, it is important to note that under FSIS' MOU with FDA regarding DJEs, if the FSIS inspection program personnel that are in such establishments daily observe adulterated product that is under FDA's jurisdiction, the FSIS inspectors immediately notify FDA.

  - In your opinion, would it be impossible for the inspectors of one agency to perform the inspection duties of another agency?

Response: Because the authorities, the products regulated and the responsibilities of FDA and FSIS differ, the policies, procedures, and the training on inspection and enforcement strategies are also quite different. Since the products regulated by the two agencies are different, many of 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. 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.

U.S. Environmental Protection Agency
Responses to the Questions for the Record
Subcommittee on the Federal Workforce and Agency Organization
Committee on Government Reform
May 17, 2005 Hearing on Food Safety
Chairman Jon C. Porter

ALL ADMINISTRATION WITNESSES

Do you think that Memoranda of Understanding are often an effective means for avoiding duplication of effort and reducing overlap? If so, please provide specific examples supporting your answer.

Memoranda of Understanding (MOUs) can be an effective way to reduce duplication of effort and overlap between agencies. EPA actively participates in several MOUs designed to reduce duplication of effort and overlap in ensuring a safe food supply. For example, a 1984 MOU between EPA, USDA, and FDA helps to coordinate Federal Regulatory Activities Concerning Residues of Environmental Contaminants. 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. Further, a 1992 MOU between the same three agencies promotes information sharing and collaboration for USDA's Pesticide Data Program.

Outside of the recommendations made by the Government Accountability Office in its report, what specific organizational reforms are needed throughout the Federal food inspection system?

Since EPA is not the lead agency for food inspection activities, we defer to USDA and FDA on this issue.

Fast Track Legislation: The Administration has put forth a proposal in the fiscal year 2006 budget for "Results Commissions," which would examine sectors of the Government in need of reform and issue recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment. What is your opinion of promoting such "fast-track reorganization" legislation as a means to improve efficiency within the food inspection process?

EPA is not the lead agency for food inspection activities, we defer to USDA and FDA on this issue.

Is it your position that the status quo is fine and that your respective agency is opposed to any kind of consolidation that could potentially improve economic efficiency, without sacrificing the safety of the food supply, within the food

inspection process? *If you are open to improving the economic efficiency of the process, without sacrificing the safety of the Nation's food, would your particular agency be willing to sit down with the other agency to try and come up with a joint solution on how best to such efficiency through consolidation? (Please answer even if you are not open to improving the economic efficiency of the food inspection process.) If no, why not. If yes, when will the first meeting take place and what officials will be attending this meeting?*

EPA works with our partner agencies to advance the food safety goals of the Administration. The Agency is committed to making sure that there is thorough interagency coordination.

EPA WITNESS

According to GAO, EPA is not the only Federal agency that participates in research aimed at understanding chemical and biological agents. How does EPA distinguish itself from other agencies in it areas of responsibility?

The Environmental Protection Agency (EPA) has been given specific responsibilities in the areas of water security, decontamination, and emergency response that are separate and distinct from the responsibilities of other federal agencies. EPA research is specifically related to EPA's mission responsibilities, and is coordinated and leveraged to ensure that the limited resources are being spent to deal with the most significant needs. EPA's expertise with hazardous materials, chemical and radiological site remediation, and water quality improvement is considered a critical national resource required to address potentially catastrophic environmental damage caused by terrorists.

EPA faces new and unique challenges in the matters dealing with chemical and biological warfare agents. Scientific and risk management research activities for these kinds of agents have historically been associated with the Department of Defense (DOD) and work has been limited to military operations. EPA now must address impacts of these same agents on non-military populations and in non-military environments. EPA's activities includes the development of risk assessment methodologies, understanding the behavior of agents in non-battlefield situations (e.g., water supply systems, urban areas, residential communities, parks and sports venues, etc.), development of monitoring strategies, planning and undertaking decontamination research, and the development of laboratory protocols and methods to identify and confirm the extent of agent contamination and decontamination.

In order to efficiently address all these research issues, EPA has, from the inception of its homeland security research program, established an approach in which it teams with others to identify domestic research gaps and to leverage their experience. DOD and EPA, for example, are engaged in numerous efforts, sharing research facilities and scientific expertise, to address a wide range of critical issues, such as decontamination of public water systems, agent detection methods, fate and transport studies, and laboratory methods development. We conduct joint program reviews

with elements of DOD and DHS. We co-fund some research with DHS and DOD. We seek guidance and share research information with a clientele that includes, among others, emergency responders, municipal water providers, and professional organizations responsible for structural ventilation systems. EPA research plans have also been reviewed by the National Academy of Sciences and the Department of Homeland Security, and will be reviewed by the EPA Science Advisory Board. These reviews are undertaken to assure that EPA homeland security science is sound and relevant, that it avoids unnecessary duplication, and that the appropriate emphasis is being placed on the most critical research gaps. This approach leverages the limited assets available to address critical needs.

Below is a summary of the Homeland Security Presidential Directives which guide Homeland Security research initiatives:

- **Homeland Security Presidential Directive - 5: Management of Domestic Incidents**. This directive is intended to enhance the ability of the United States to manage domestic incidents by establishing a single, comprehensive, national, incident management system. The EPA is the lead agency in responding to incidents involving hazardous materials. Research in this area includes how chemical and biological agents may be quickly and reliably detected and sampled and how to determine their appropriate clean-up levels in the environment. This research is closely coordinated with numerous federal partners. Much of it involves finding and reviewing existing data generated by the military and determining how it can be applied domestically.

- **Homeland Security Presidential Directive - 9: Defense of United States Agriculture and Food**. This directive establishes a national policy to defend the agricultural and food systems against terrorist attacks, major disasters, and other emergencies. This directs the EPA to work interactively with other federal agencies to assure the nation's water resources are protected. This includes such things as detection and monitoring systems and the development of timely and effective decontamination methods. Drinking water research has always been a primary responsibility of the EPA. Current research is closely coordinated with the Department of Homeland Security and includes such topics as drinking water system contaminate modeling and detection.

- **Homeland Security Presidential Directive-10: National Policy for Biodefense**. This directive establishes a comprehensive approach to counter weapons of mass destruction threats in all their dimensions. It assigns the EPA to be the lead agency for decontamination. Research in this area includes identifying and validating analytical methods for uncommon environmental contaminants. Research also includes decontamination and disposal approaches for large volumes of materials contaminated with extremely hazardous materials. This research is being done in conjunction with and collaboration with multiple federal agencies including the Department of Defense, the Centers for Disease Control, the Department of Homeland Security, and the Federal Bureau of Investigation.

Regarding EPA's role in establishing tolerances for pesticides in food, what is the value of USDA, FDA, and EPA collecting samples of food and analyzing them for the presence of pesticides? *Would it not be more effective to combine these efforts and still maintain the value of the information? If not, please explain.*

EPA, USDA, and FDA implement unique programs that each contribute to the collection and analysis of data related to pesticides on food commodities.

EPA requires that pesticide registrants submit pesticide residue data to support their registration applications. This information also supports the establishment of a pesticide tolerance for each individual food commodity for which the pesticide is registered. The studies measure residues when pesticides are applied at maximum application rates and using the highest frequency of applications allowed. The purpose of these studies is to enable Agency scientists to determine the maximum amount of pesticide which could be contained in a food commodity at the time of harvest, given maximum application under use directions. This forms the basis for establishing tolerances, or Maximum Residue Levels (MRLs), for each pesticide on each food commodity. The MRL is developed to ensure that pesticide residues are within acceptable levels if farmers follow label use directions (e.g., do not exceed application rates or violate pre-harvest intervals).

FDA monitors food crop commodities, such as vegetables and fruits, in commerce for pesticide tolerance enforcement. Therefore, the FDA's pesticide residue sampling program analyzes commodities for pesticide residues to carry out their enforcement roles and responsibilities, and to ensure that residues on food commodities in the channels of trade are within legal limits. Generally, actual residue levels in food will be significantly lower than tolerance levels established by EPA.

USDA monitors other food commodities, such as livestock, poultry, dairy, and eggs, in the same way that FDA monitors the food commodities within their realm of responsibility (e.g., fruits and vegetables).

Further, USDA conducts the Pesticide Data Program (PDP) which is a national pesticide residue database program. Through cooperation with state agriculture departments and other Federal agencies, PDP manages the collection, analysis, data entry, and reporting of pesticide residues on agricultural commodities, with an emphasis on those commodities highly consumed by infants and children. The goal of the PDP is to develop statistically valid data on actual residues in food commodities. EPA uses PDP data to prepare realistic pesticide dietary exposure assessments for use in the Agency's risk assessment process.

In summary, the FDA and USDA pesticide residue monitoring studies produce data that is more characteristic of actual dietary exposure than EPA-required studies. This information is used routinely by EPA in our human health risk assessments to ensure

pesticide tolerances are based on the best available information. Each agency's data collection and analysis of data from pesticide residue monitoring programs is unique and important to EPA's decisions on pesticides. Based on a record of successful collaboration between the food safety agencies in gathering information on pesticide residues in food, EPA believes that the existing responsibilities and coordination are providing valuable information that helps ensure a safe food supply.

Questions for the Record from the Honorable Chairman Porter
Committee on Government Reform
Subcommittee on the Federal Workforce and Agency Organization
Oversight Hearing on the Federal Food Inspection Programs
May 17, 2005

QUESTIONS TO BE ANSWERED BY ALL ADMINISTRATION WITNESSES

1. Question: Do you think that Memoranda of Understanding are often an effective means for avoiding duplication of effort and reducing overlap? If so, please provide specific examples supporting your answer.

Answer: The National Oceanic and Atmospheric Administration (NOAA) believes Memoranda of Understanding (MOUs) are important in providing the framework to allow for and encourage greater interaction between agencies, including avoiding duplication of effort and reducing overlap. For example, NOAA, FDA, and the Department of Agriculture (USDA) Animal Plant Health Inspection Service have a long history of constructive interaction to address inspection and certification issues for industrial fishery products intended for use as animal feed. Cross-utilization agreements between NOAA and USDA allow NOAA cross-licensed USDA inspectors to inspect and certify fishery products where and when it would be neither efficient nor cost-effective for NOAA to locate personnel. In addition, NOAA and USDA provide inspection personnel to assist the Department of Defense in reviewing the acceptability of food products purchased for troops.

Following are examples of agency interaction between the Food and Drug Administration (FDA) and NOAA that result in a more efficient and effective use of Federal resources:

- Research related to the public health implications of mercury in seafoods.
- Histamine research, both on the U.S. mainland and in Hawaii.
- Development of proper validation procedures to ensure that post-harvest treatment of oysters containing marine pathogens is effective.
- Fishery species identification for domestic or imported products to combat economic fraud in the marketplace.
- Participation—along with the Environmental Protection Agency, the Center for Disease Control, and 23 coastal states—in the Interstate Shellfish Sanitation Conference, which helps ensure the safety of molluscan shellfish through the proper functioning of state and Federal control programs.

2. Question: Outside of the recommendations made by the Government Accountability Office in its report, what specific organizational reforms are needed throughout the Federal food inspection system?

Answer: The Administration believes that enhanced interagency coordination is sufficient to address food safety issues effectively and efficiently. NOAA will continue to work with other Federal agencies to achieve the Administration's goals.

3. Question: Fast Track Legislation: The Administration has put forth a proposal in the fiscal year 2006 budget for "Results Commissions," which would examine sectors of the Government in need of reform and issue recommendations for reorganization. Under the proposal, Congress would vote the recommendation up or down without amendment. What is your opinion of promoting such "fast-track reorganization" legislation as a means to improve efficiency within the food inspection process?

Answer: NOAA is not familiar with the proposal to establish Results Commissions and is therefore unable to respond to this question.

4. Question: Is it your position that the status quo is fine and that your respective agency is opposed to any kind of consolidation that could potentially improve economic efficiency, without sacrificing the safety of the food supply, within the food inspection process?

Answer: NOAA supports the Administration's position that issues related to maintaining the safety of the food supply can best be addressed through enhanced interagency coordination rather than a major reorganization (e.g., creating a single food agency). This position does not seek to preserve the status quo, as evidenced by numerous recent initiatives. For example, interagency cooperation and coordination was enhanced during actions taken under Homeland Security Presidential Directive 9, "Defense of United States Agriculture and Food." Following the September 11 terrorist attacks, an unprecedented partnership between Federal agencies and state and local leadership, the private sector, and the academic community implemented measures to strengthen the security of our nation's food supply, taking specific steps toward the strategic goals of awareness, prevention, protection, response, and recovery.

5. Question: If you are open to improving the economic efficiency of the process, without sacrificing the safety of the Nation's food, would your particular agency be willing to sit down with the other agency to try and come up with a joint solution on how best to such efficiency through consolidation? (Please answer even if you are not open to improving the economic efficiency of the food inspection process.) If no, why not. If yes, when will the first meeting take place and what officials will be attending this meeting?

Answer: As noted in the answer to the previous question, NOAA has acted and will expand its efforts to enhance the cooperation, coordination, effectiveness, and efficiency of the agencies to ensure the safety of the nation's food supply. In addition to the actions taken under HSPD-9 and HSPD-7 ("Critical Infrastructure Identification, Prioritization, and Protection," which focuses on protection of food and agriculture), the Administration is also examining the Federal Health Architecture (including processes involved with food safety) to better understand the current actions being taken by the agencies involved and then to identify how functions may be improved to enhance efficiency. NMFS and FDA held a meeting on June 3, 2005, to discuss elements that could be incorporated into a revised interagency MOU. The Assistant Administrator for Fisheries and the Director of the Seafood Inspection Program also look

forward to meeting with leadership at FDA in the near future to discuss solutions to improving efficiency.

QUESTIONS TO BE ANSWERED BY NMFS

1. Question: GAO reports that FDA will not recognize the inspections done by NMFS because of an apparent "conflict of interest" that arises from the fee-for-service nature of your inspections. How would you respond to the claim that your inspections are not as legitimate as those done by the FDA?

Answer: NOAA does not believe there is a conflict of interest in the operations of its Seafood Inspection Program, or that a problem exists with the legitimacy or integrity of its inspections. We have an ongoing relationship with FDA, and we will continue to work with appropriate components of FDA to answer any questions they may have and to share the expertise of NOAA Seafood Inspection Program personnel. I would like to quote from a letter from the Commissioner of the Food and Drug Administration to the Under Secretary of Commerce for Oceans and Atmosphere, in which the Commissioner proposes FDA credentialing for NMFS inspectors:

> "Another option I recommend we pursue is commissioning NMFS inspectors. Under FDA's commissioning authority, your inspectors could be granted FDA credentials, which would help FDA in meeting its public health responsibilities. Initially, we were uncertain whether commissioning would be possible. Now, however, we have the authority to proceed, if you agree. Further, it may be possible to use NMFS inspectors when it is more cost-effective to reimburse your inspectors, who may already be 'onsite,' than having an FDA inspector travel to a distant location."

2. Question: GAO reports that a 1974 agreement between NMFS and FDA is in place currently to reduce overlap in inspections done by both agencies—is this true?

- **How would you assess the current working relationship between FDA and NMFS when it comes to eliminating duplicative inspections?**
- **What more could be done to work together in this area?**
- **Why has more coordination failed to occur in the past?**

Answer: Yes, the agreement (published in the *Federal Register* on January 17, 1975) is an MOU between FDA and NMFS, "Relative to Inspection Programs for Fishery Products." Both FDA and NMFS recognize this MOU is more than 30 years old and needs revision to reflect changes in the capabilities, authorities, and increased potential for interaction. The agencies held a meeting on June 3, 2005, to discuss elements that could be incorporated into a revised MOU. During this meeting, NMFS provided FDA with a proposed draft revision of the MOU. We look forward to reviewing the FDA comments so that we may quickly continue our combined actions toward implementing a fully functional MOU to benefit trade and consumers.

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