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A SYSTEM RUED: INSPECTING FOOD

HEARING

BEFORE THE

SUBCOMMITTEE ON CIVIL SERVICE
AND AGENCY ORGANIZATION

OF THE

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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A SYSTEM RUED: INSPECTING FOOD

TUESDAY, MARCH 30, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CIVIL SERVICE AND AGENCY ORGANIZATION,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 3 p.m., in room 2203, Rayburn House Office Building, Hon. Jo Ann Davis of Virginia (chairwoman of the subcommittee) presiding.

Present: Representatives Jo Ann Davis of Virginia, Davis of Illinois, Norton, Deal, Blackburn, Murphy, and Van Hollen.

Staff present: Ron Martinson, staff director; B. Chad Bungard, deputy staff director and chief counsel; Shannon Meade, professional staff member; Reid Voss, clerk; John Landers, OPM detailee; Michelle Ash, minority senior legislative counsel; Tania Shand, minority professional staff member; and Teresa Coufal, minority assistant clerk.

Ms. DAVIS OF VIRGINIA. We're going to go ahead and start, and there will be a few more Members joining us in a few moments.

The Subcommittee on Civil Service and Agency Organization will come to order.

Two years ago, the Federal Government saw its largest reorganization since the end of World War II with the creation of the Homeland Security Department, which involved the merger of 22 existing agencies and 180,000 employees into one mammoth Cabinet department. Today, this subcommittee begins its examination of how the rest of the Government is structured, and whether the existing structures need reorganization on a much smaller scale.

We begin this process by focusing on one aspect of the Federal Government that touches our daily life, which is how the Government inspects food. Right now, there are more than a dozen Federal agencies that enforce more than 35 food safety laws, creating such illogical situations as the Food and Drug Administration having responsibility for inspecting closed faced meat sandwiches, while the U.S. Department of Agriculture is in charge of inspection open faced meat sandwiches. Or if you prefer, the FDA is in charge of cheese pizzas, while the USDA has jurisdiction over pepperoni pizza.

And here is one more. The FDA inspects both beef soup and chicken broth, but USDA inspects chicken soup and beef broth. In case you didn't get that, it's reversed. As the old saying goes, you can't make this stuff up.

This situation did not happen overnight, but it's a result of piecemeal legislative solutions crafted over the years. It is a good example of why, every once in a while, Congress needs to take a step back and look at the whole picture to see if there is some rearranging that should take place.

In this instance, one possible solution that some have raised is to consolidate all the food inspection programs under a single agency. We're going to hear testimony today on that subject, as well as the other organizational issues facing food inspection programs. Regardless of the organizational ideas offered here today, I want to emphasize at the outset that everyone in this room is in agreement that we want our food supply to be safe. So that is not an issue.

I thank our witnesses and I look forward to the discussion.

We've been joined now by Ms. Holmes Norton and I'm going to recognize you. Do you have an opening statement?

[The prepared statement of Hon. Jo Ann Davis follows:]

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Chairwoman Jo Ann Davis
Subcommittee on Civil Service and Agency Organization

"A System Rued: Inspecting Food"
Opening Statement
March 30, 2004

Two years ago, the federal government saw its largest re-organization since the end of World War II with the creation of the Homeland Security Department, which involved the merger of 22 existing agencies and 180,000 employees into one mammoth Cabinet department.

Today, this Subcommittee begins its examination of how the rest of the government is structured, and whether the existing structure needs re-organization on a much smaller scale. We begin this process by focusing on one aspect of the federal government that touches our everyday life – how the government inspects food.

Right now, there are more than a dozen federal agencies that enforce more than 35 food safety laws - creating such illogical situations as the Food and Drug Administration having responsibility for inspecting closed-face meat sandwiches, while the U.S. Department of Agriculture is in charge of inspecting open-face meat sandwiches. Or, if you prefer, the FDA is in charge of cheese pizzas while the USDA has jurisdiction over pepperoni pizzas. And here's one more: FDA inspects both beef soup and chicken broth – but USDA inspects chicken soup and beef broth.

As the old saying goes, you can't make this stuff up.

This situation did not happen overnight, but is the result of piecemeal legislative solutions crafted over the years. It is a good example of why, every once in a while, Congress needs to take a step back and look at the whole picture, to see if there is some re-arranging that should take place. In this instance, one possible solution that some have raised is to consolidate all the food inspection programs under a single agency. We are going to hear testimony today on that subject, as well as the other organizational issues facing food inspection programs.

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 is not an issue.

I thank our witnesses for being here, and I look forward to the discussion.

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Ms. NORTON. Thank you very much, Madam Chairwoman. I want to especially thank you for calling this hearing on a subject of vital importance to the American people, especially in recent years and months. Some of us thought that mad cow would never make its way, for example, to the United States, some of us thought it was only a matter of time. I grew up thinking that the food supply of the United States was impenetrable. We have learned differently.

We have just finished a major reorganization, one of the largest reorganizations since World War II, of the Homeland Security agency. I'm on the Homeland Security Committee, I was on the two main committees that considered most of the legislation that resulted in the Department.

As much as it is apparent that this set of blocks doesn't make much sense, about the easiest thing to do, we've learned, is to say that what it takes to cure a problem is simply reorganize it. I happen to be a big fan of reorganization, because I believe in rational structures. When I headed a Federal agency, one of the first things we did was to reorganize the agency, reconfigure it to better do its job and I do believe that it worked.

But we are still very much in a learning mode when it comes to the Department of Homeland Security, huge disruptions and disquiet has resulted in some parts of the agency that we learn are far worse off than they were before, such as processing of immigration claims. Perhaps there are other parts that are better.

I do hope before we jump in again with both feet that we learn from that experience, I certainly hope that we learn from the experience that employees have had, where we have disrupted the way in which employees relate to the agencies from which they came, thrown out many of their Civil Service and collective bargaining rights all in the name of reorganization. It does seem to me one can reorganize without that kind of penalty and disruption.

Finally, let me say that because of the melange we see of agencies with different jurisdictions when it comes to our food supply, of course, is the way in which Congress does business. The way in which we do business is of course endemic to a democratic society. When a crisis arises, and when a problem arises, we say let's fix that problem. And what you have if you will forgive the analogy is some real sausage there. We just pack it in wherever we can seem to fit, and nobody sits down and says, now, let's do this in some rational way, even if we reorganize our food, our approach to food safety, we're likely to continue to do that.

I would only caution, Madam Chairwoman, that we take a deep breath, learn from what is happening to the Homeland Security Department before we jump right back in with another whole, big reorganization with all that entails for employees and management alike.

Thank you, Madam Chairwoman.

Ms. DAVIS OF VIRGINIA. Thank you, Ms. Norton. We've been joined by our ranking member, Mr. Danny Davis. I'll yield to you for an opening statement.

Mr. DANNY DAVIS. Thank you very much, Madam Chairwoman, and let me apologize for being late. I was having difficulty pulling myself away from a very interesting discussion of the effectiveness

of drug treatment at another hearing. So I thank you for your indulgence.

Madam Chairwoman, experts and Members of Congress have long complained that there are jurisdictional overlaps within the executive branch. As a result, some important Federal missions slip through the cracks. Some complaints, however, go as far back as World War I, when calls for efficiency and economy in Government led to efforts to strengthen the President's management ability.

In 1932, for the purposes of reducing expenditures and increasing efficiency in Government, the President was given statutory authorization to issue Executive orders proposing reorganization within the executive branch. A reorganization order became effective within 60 days, unless either the House of Congress adopted a resolution of disapproval. Modification of the President's reorganization plan authority was made necessary in 1983, when the Supreme Court in the Chattah case effectively invalidated Congress' continued reliance upon a concurrent resolution to disapprove of a proposed plan.

Currently in the absence of reorganization plan authority, the President may propose executive branch reorganization through the normal legislative process. Calls to reorganize the Federal Government have more recently come from the National Commission on the Public Service. The Commission, also known as the Volcker Commission, released a report in January 2003 that included the recommendation that the Federal Government be reorganized into a limited number of mission related executive departments.

The Federal Government's structure for regulating for structure is a prime example of Federal agency mission and program overlap. Twelve different agencies administer as many as 35 laws that make up the Federal food safety system. Two agencies account for most Federal food safety spending and regulatory responsibilities, the Food Safety and Inspection Service within the U.S. Department of Agriculture and the Food and Drug Administration within the Department of Health and Human Services.

I look forward to hearing testimony from today's witnesses on how the Federal food safety system should be reorganized and who

should have the authority to effect the reorganization. So I thank you very much, Madam Chairwoman, and yield back the balance of my time and look forward to hearing from the witnesses.

Thank you again.

[The prepared statement of Hon. Danny K. Davis follows:]

STATEMENT OF THE HONORABLE DANNY K. DAVIS
AT THE SUBCOMMITTEE ON CIVIL SERVICE
AND AGENCY ORGANIZATION
HEARING ON

A SYSTEM RUED: INSPECTING FOOD

March 29, 2004

Chairwoman Davis, experts and members of Congress have long complained that there are jurisdictional overlaps within the executive branch, and, as a result, some important federal missions slip through the cracks. Such complaints, however, go as far back as World War I, when calls for efficiency and economy in government led to efforts to strengthen the President's management ability.

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I look forward to hearing testimony from today's witnesses on how the federal food safety system should be reorganized and who should have the authority to affect the reorganization.

Thank you

Ms. DAVIS OF VIRGINIA. Thank you, Mr. Davis.

Are there any further opening statements?

[No response.]

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

I ask unanimous consent that the statement of the Grocery Manufacturers Association be included in the record. And without objection, it is so ordered.

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

On the first panel, we're going to hear from Mr. Lawrence Dyckman, Director of National Resources and Environment at the General Accounting Office. Second, we will hear from Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. And finally, we will hear testimony from Dr. Merle Pierson, from the U.S. Department of Agriculture.

It is standard practice for this committee to administer the oath to all witnesses. If all the witnesses on both the first and second panel will please stand, I will administer the oath to you at one time. Anyone who is going to be testifying.

If you'll please raise your right hands.

[Witnesses sworn.]

Ms. DAVIS OF VIRGINIA. Let the record reflect that the witnesses have answered in the affirmative.

And if the first panel would come forward and please be seated.

We will begin with you, Mr. Dyckman, Director of National Resources and Environment at the General Accounting Office. And we do have your complete statement in the record, so if you'd like to summarize for 5 minutes, we would certainly appreciate it.

STATEMENTS OF LAWRENCE J. DYCKMAN, DIRECTOR, NATIONAL RESOURCES AND ENVIRONMENT, U.S. GENERAL ACCOUNTING OFFICE; ROBERT E. BRACKETT, DIRECTOR, CENTER FOR FOOd SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION; AND MERLE PIERSON, DEPUTY UNDER SECRETARY FOR FOOD SAFETY, U.S. DEPARTMENT OF AGRICULTURE

Mr. DYCKMAN. Thank you, Madam Chairwoman. Good afternoon, Members.

I'm pleased to be here today to discuss the subcommittee's interest in streamlining the Federal Government. Today I will highlight our considerable body of work on the Federal food safety system and whether its current design provides sufficient protection for consumers while ensuring logical and effective Government resources.

In his September 2003 testimony before this subcommittee, the Controller General stressed the importance of beginning to take

steps to achieve fundamental reorganization of the Federal Government into a limited number of mission related executive departments. His testimony pointed out that redundant, unfocused, uncoordinated programs waste scarce resources, confuse and frustrate program customers and limit overall program effectiveness.

As we've heard in the opening statement, our food supply is governed by a highly complex system, more than 30 laws administered by 12 area agencies and various departments. Now, the system is not a product of strategic design but rather, it emerged piecemeal over many decades, and as was indicated, typically in response to particular health threats or economic crisis. The result, in our opinion, is a fragmented legal and organizational structure that gives responsibility for food commodities to different agencies and the real problem is, it provides them with significantly different authorities and responsibilities.

As we heard in the opening statements, two principal food safety agencies involved are FDA and USDA, but many others are involved. And we have a flip chart which shows the ever popular frozen pizza example. If you look at the chart, and you have it before you, multiple agencies regulate both the ingredients and the processing of the pies. And to complicate matters, it was mentioned that non-meat pizzas fall under one agency, FDA, while pizzas with meat toppings fall under USDA. As a result, some manufacturers, those with meat toppings, get inspected on a daily basis while others are inspected much less frequently.

The fact that the frequency of inspection is not based on risk is really a very important but troubling distinction between the two agencies' enabling legislation. USDA by law must maintain continuous inspection at slaughter facilities and visit each processing plant at least once a day while FDA generally visits plants under its jurisdiction once every several years.

Another problem with the food safety system is that Federal resources are allocated on the basis of statutory requirements and not based on risk. If you look at the pie charts there, you'll see that USDA and FDA, their funds are not proportionate to the amount of food produced in terms of the food that they regulate. It's not proportionate to the level of consumption of these foods by the American consumers or even more importantly, the frequency of food-borne illnesses associated with these products. While USDA regulate about 21 percent of the consumer food supply, its expenditures are about 50 percent more than FDA's.

Our past work has chronicled these problems with the current food safety system, but I'd like to go into, and my full statement goes into more detail, but I'd like to touch on some highlights of some additional problems. Let's talk about egg safety, the overlapping responsibilities there. FDA regulates whole eggs, which are eggs in shells. USDA regulates egg products, which are liquid eggs or freeze-dried egg products, mostly used for manufacturing. However, over 10 years has passed since the Government is aware that salmonella contamination from eggs poses a significant health risk, we still don't have a comprehensive Federal egg safety program.

Another example, with regard to health benefits that certain food products claim. Our work shows that consumers face risks because current Federal laws and agencies do not consistently ensure that

these products are safe. Also, health benefits may be treated differently by different agencies. There are three agencies involved with health claims, we have USDA, FDA and the Federal Trade Commission. This leads consumers to face a confusing array of decisions on health claims of certain products, and particularly on the health claims of dietary supplements.

Now, the same fragmented structure in this inconsistent approach unfortunately is being used to ensure the safety of imported foods, which is an increasing part of the national diet. USDA must determine that foreign suppliers of meat and poultry products have food safety systems that are basically comparable to ours. We refer to that as equivalency agreements.

While FDA, not having that authority, doesn't have similar requirements, and therefore it depends largely on port of entry inspections, which we have pointed out are not as effective.

Let's look at livestock regulation. We've heard about the one case that we had in Washington on BSE, and the Canadian case. That's another example where you have USDA regulating the animal and the meat it produces, but FDA regulates the safety of the feed fed to the livestock. We believe this can compromise our ability to protect our citizens from animal diseases.

Finally, potentially an even more serious issue is that the current food safety system is further challenged by the realization that American farms and ranches and our processed foods are in fact vulnerable to potential attack and deliberate contamination. As we recently reported to the Senate Committee on Governmental Affairs, bioterrorist attacks could be directed to many different targets in the farm to table continuum. This includes crops, livestock, food products, processing foods, transportation, storage facilities and even food and agricultural research laboratories.

While both FDA and USDA have taken steps to protect our food supply from terrorist attack, we have to realize for the most part it's this antiquated system that we're talking about that we must depend on to prevent and respond to any such attacks.

In conclusion, given the risk posed by the existing and the new threats that I spoke about, be they inadvertent or deliberate, we believe we can no longer afford these inconsistent, overlapping programs and this patchwork approach to food safety. It's time to ask whether a system that has developed piecemeal over many decades can efficiently and effectively respond to today's challenges. That's why we believe that creating a single food safety agency to administer a uniform risk-based inspection system is the most effective way to prevent and protect the Nation's food supply.

Madam Chairwoman, I would be happy to answer any questions after the panel is completed.

[The prepared statement of Mr. Dyckman follows:]

United States General Accounting Office

GAO

Testimony

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

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

FEDERAL FOOD SAFETY AND SECURITY SYSTEM

Fundamental Restructuring Is Needed to Address Fragmentation and Overlap

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

GAO-04-588T

March 30, 2004

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Highlights

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

FEDERAL FOOD SAFETY AND SECURITY SYSTEM

Fundamental Restructuring Is Needed to Address Fragmentation and Overlap

Why GAO Did This Study

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

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

What GAO Recommends

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

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

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

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

What GAO Found

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

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

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

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

Madam Chairwoman and Members of the Subcommittee:

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

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

While the food supply is generally safe, each year tens of millions of Americans become ill and thousands die from eating unsafe food. The federal government spends about $1.3 billion annually[1] to ensure the safety of domestic and imported foods, and estimates that the costs associated with foodborne illnesses are about $7 billion, including medical costs and

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

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

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

Background

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

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

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

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

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

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

Fragmented System Hampers the Efficiency and Effectiveness of Food Safety Efforts

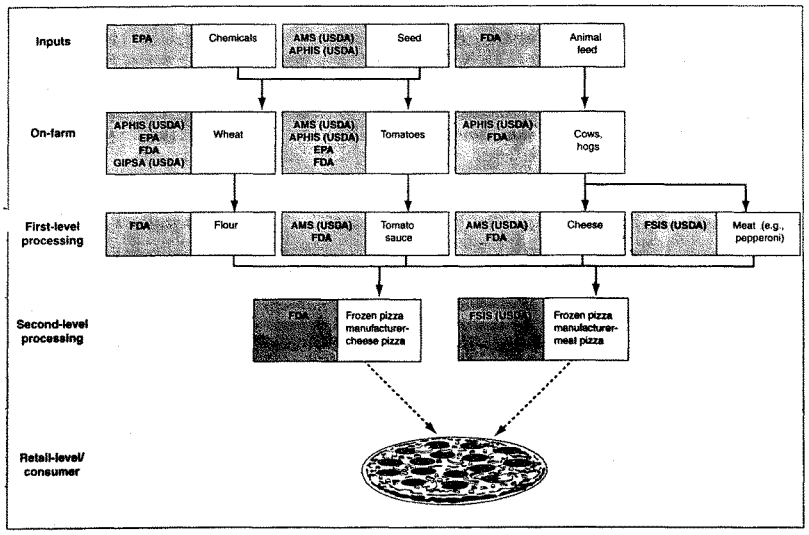
As we have stated in numerous reports and testimonies, the fragmented federal food safety system is not the product of strategic design.[3] Rather, it emerged piecemeal, over many decades, typically in response to particular health threats or economic crises. In short, what authorities agencies have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

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

[3]Appendix III lists relevant GAO reports and testimonies.

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

Figure 1: Federal Agencies Responsible for Ensuring Safe Pizza



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

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

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

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

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

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

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

- **Federal agencies' different authorities to oversee imported foods also result in inconsistent efforts to ensure safety**. A significant amount of the food we consume is imported; yet, as we have testified in the past, the same fragmented structure and inconsistent regulatory approach is being used to ensure the safety of imported foods. For example, more than three-quarters of the seafood Americans consume is imported from an estimated 13,000 foreign suppliers in about 160 different countries.[4] As we have reported, however, FDA's system for ensuring the safety of imported seafood does not sufficiently protect consumers. For example, the agency inspected about 100 of roughly 13,000 foreign firms in 2002 and tested slightly over 1 percent of imported seafood products. In January 2004, we reported that despite some improvements, FDA is still able to inspect only a small proportion of U.S. seafood importers and visit few seafood firms overseas yearly. As we have previously recommended, a better alternative would be to strengthen FDA's ability to ensure the safety of imported foods by requiring that all food eligible for importation to the United States be produced under equivalent food safety systems. USDA has such authority. In fact, USDA is legally required to review certifications made by other countries that their meat and poultry food safety systems ensure compliance with U.S. standards and USDA must also conduct on-site inspections before those products can be exported to the United States. At this time, 37 countries are approved to export meat and poultry products to the United States.

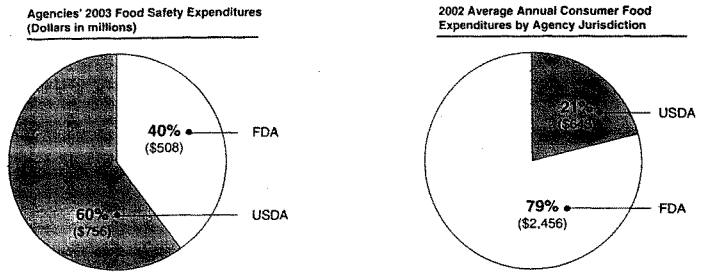
- **Frequency of inspections is not based on risk.** Under current law, USDA inspectors maintain continuous inspection at slaughter facilities and examine each slaughtered meat and poultry carcass. They also visit each processing plant at least once during each operating day. For foods under FDA jurisdiction, however, federal law does not mandate the frequency of inspections. The differences in inspection frequencies are, at times, quite arbitrary, as in the case of jointly regulated food products. For example, as we testified in 2001, federal responsibilities for regulating the production and processing of a packaged ham and cheese sandwich

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

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

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

Figure 2: Comparison of Agencies' Food Safety Expenditures Versus Consumers' Annual Food Expenditures[5]

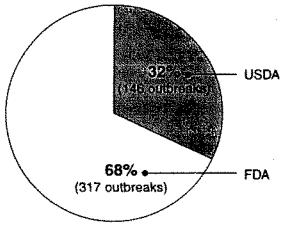


Sources: (left to right): GAO analysis of USDA and FDA data; GAO analysis of Bureau of Labor Statistics data.

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

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

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

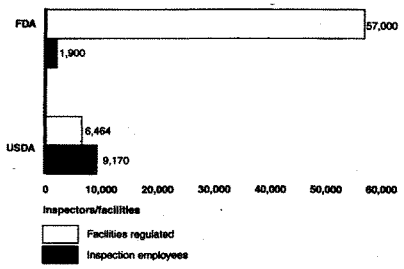


Source: GAO analysis of CDC data.

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

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

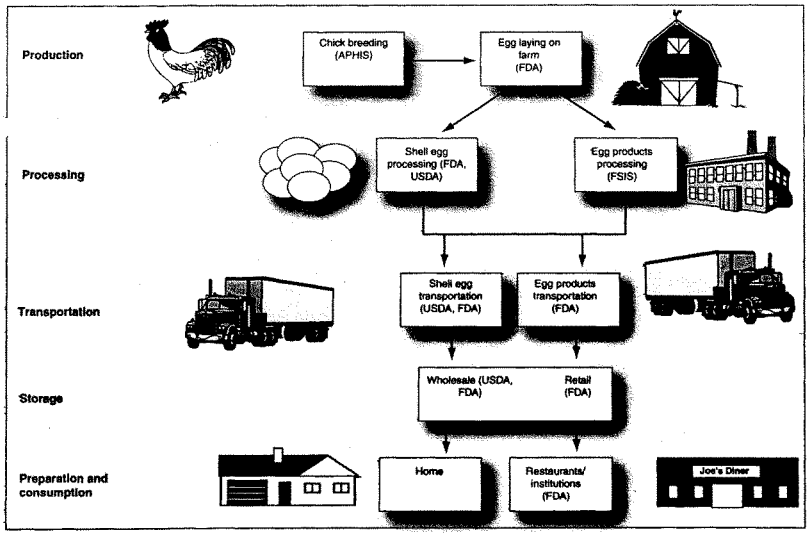
Figure 4: FDA and USDA Fiscal Year 2003 Inspection Resources Versus Facilities Regulated by Each Agency



Source: GAO analysis of FDA and USDA data.

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

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



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

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

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

- **Claims of health benefits for foods may be treated inconsistently by different federal agencies.** Overlaps also exist in the area of health benefit claims associated with certain foods and dietary supplements. FDA, USDA, and the Federal Trade Commission (FTC) share responsibility for determining what types of health benefit claims are allowed on product labels and in advertisements. The varying statutory requirements among the agencies can lead to inconsistencies in labeling and advertisements. As a result, the use of certain health benefit claims on a product might be denied by one agency but allowed by another. For example, the FTC may allow a health claim in an advertisement as long as it meets the requirements of the Federal Trade Commission Act, even if FDA has not approved it for use on a label. Similarly, USDA reviews requests to use health claims on a case-by-case basis, regardless of whether or not FDA has approved them. Thus, consumers face a confusing array of claims, which may lead them to make inappropriate dietary choices.

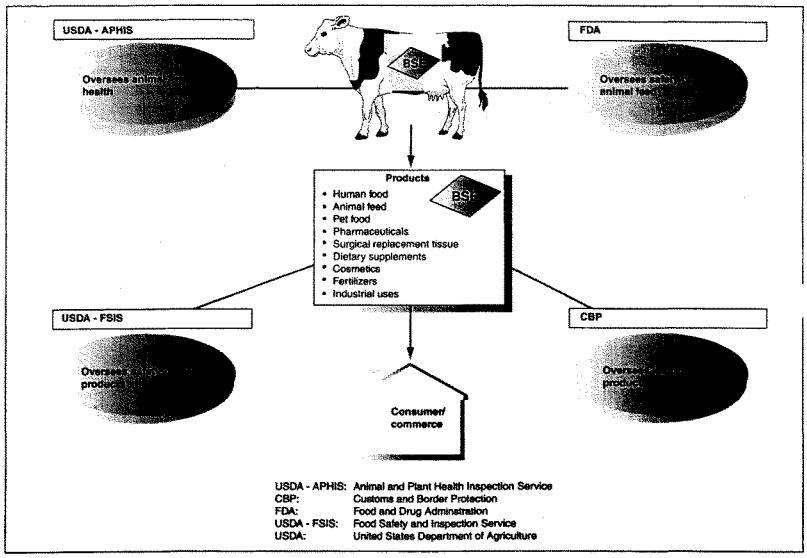
- **Multiple agencies must respond when serious food safety challenges emerge.** Inconsistent food safety authorities result in the need for multiple agencies to respond to emerging food safety challenges. This was illustrated recently with regard to ensuring that animal feed is free of diseases, such as bovine spongiform encephalopathy (BSE), or mad cow disease. A fatal human variant of the disease is linked to eating beef from cattle infected with BSE. As we reported in 2002, four federal agencies are responsible for overseeing the many imported and domestic products that

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

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

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

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



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

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

animal found in Washington state, FSIS conducted a recall of meat distributed in markets in six states. Both USDA and FDA have reported that meat from the cow was not used in FDA-regulated foods. However, had the meat been used, for example, in canned soups that contained less than 2 percent meat, FDA—not FSIS—would have been responsible for working with companies to recall those foods. (As app. II shows, the agencies' oversight responsibilities for food products vary depending on the amount of beef or poultry content.) Neither FDA nor USDA has authority under existing food safety laws to require a company to recall food products.[6] Both agencies work informally with companies to encourage them to initiate a recall, but our ongoing work shows that each agency has different approaches and procedures. This can be confusing to food processors involved in a recall. Overlapping responsibilities in responding to mad cow disease highlight the challenges that government and industry face when responding to the need to remove contaminated food products from the market. As part of work currently underway, we are looking at USDA and FDA food recalls—including USDA's oversight of the BSE-related recall and FDA's oversight of the feed ban. We are also monitoring both USDA's and FDA's BSE-response activities.

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

[6]FDA, however, does have legislative authority to require recalls that involve infant formula.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusions

In conclusion, given the risks posed by new threats to the food supply, be they inadvertent or deliberate, we can no longer afford inefficient, inconsistent, and overlapping programs and operations in the food safety system. It is time to ask whether a system that developed in a piecemeal fashion in response to specific problems as they arose over the course of several decades can efficiently and effectively respond to today's challenges. We believe that creating a single food safety agency to administer a uniform, risk-based inspection system is the most effective way for the federal government to resolve long-standing problems, address emerging food safety issues, and better ensure the safety of the nation's food supply. This integration can create synergy and economies of scale,

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

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

The National Academies and the President's Council on Food Safety have reported that comprehensive, uniform, and risk-based food safety legislation is needed to provide the foundation for a consolidated food safety system. We recognize that consolidating federal responsibilities for food safety into a single agency or department is a complex process. Numerous details, of course, would have to be worked out. However, it is essential that the fundamental decision to create more uniform standards and a single food safety agency to uphold them is made and the process for resolving outstanding technical issues is initiated.

Matters for Congressional Consideration

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

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

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

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

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

Contacts and Staff Acknowledgments

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

Appendix I: Federal Agencies' Food Safety Responsibilities

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

Source: GAO.

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

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

Source: GAO.

Appendix III: Related GAO Products

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

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

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

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

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

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

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Ms. DAVIS OF VIRGINIA. Thank you, Mr. Dyckman. Now we'll hear from Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. Dr. Brackett, you're recognized for 5 minutes, and again, we have your full statement for the record, so if you can summarize, that would be great.

Mr. BRACKETT. Thank you and good afternoon, Chairwoman Davis and members of the committee. I am Dr. Bob Brackett, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration within the Department of Health and Human Services. And I am pleased to be here today with my colleague from USDA, Dr. Merle Pierson, as well as Mr. Dyckman, to discuss the Federal food safety system. And I do want to thank you for the opportunity to provide testimony on behalf of Health and Human Services.

The subcommittee has expressed interest in the potential benefits of consolidating a number of food safety functions into a single food agency. Over the years, there has been much discussion about this. In fact, in 2002, the White House looked into this issue and concluded that the goals of the administration are better advanced through enhanced interagency coordination rather than through development of legislation to create a single food agency.

Is the interagency food coordination working? Yes, the American food supply continues to be among the safest in the world, and food safety agencies are working more closely than ever before. Of course, we continue to face many challenges. We face the traditional challenge of reducing the incidence of food-borne illness due to unintentional contamination and in addition, we now face a heightened challenge of protecting food from deliberate contamination.

To address these issues, the Department of Health and Human Services has been implementing the most fundamental enhancements in our food safety and food defense activities in many years. FDA is the Federal agency that regulates about 80 percent of the Nation's food, 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. Our sister public health agency in HHS, the Centers for Disease Control and Prevention, plays a very important and complementary role through its surveillance of illness associated with the entire food supply. Food supply and food defense continue to be top priorities for this administration.

In our food safety and defense efforts, FDA has many partners, Federal and State agencies, academia, and of course industry. We're working closely with our Federal partners, such as USDA, the Department of Homeland Security, the Homeland Security Council at the White House, and the Department of State as well as with law enforcement and intelligence gathering agencies.

I want to emphasize the close working relationship with Food Safety and Inspection Service and the Animal and Health Plant Inspection Services at USDA, Customs and Border Protection at the Department of Homeland Security, and with our sister public health agencies, CDC and the National Institutes of Health. Specific examples of cooperative activities included within HHS and

USDA and the Environmental Protection Agency and other agencies that are working with DHS, Department of Homeland Security, to achieve the objectives of Homeland Security Presidential Directive No. 9, or HSPD–9, which has established a national policy to defend the agriculture and food system against terrorist attacks, major disasters and emergencies.

A second example is that FDA, CDC and USDA work together on Healthy People 2010 to identify the most significant preventable threats to health and to establish national goals to reduce these threats. FDA, CDC and the Food Safety Inspection Service work together on food code to provide a model ordinance to local, State and Federal Governmental bodies and tribal nations to ensure that the food provided by retail food establishments and institutions such as nursing homes is not a vector of communicable diseases.

To increase laboratory search capacity, FDA has worked with CDC and FSIS to expand laboratory response network by establishing the Food Emergency Response Network to include a substantial number of new laboratories capable of analyzing foods for agents of concern. These are just a few of the many cooperative activities that we participate together on.

Last July, former FDA Commissioner Mark McClelland issued a report to Health and Human Services Secretary Tommy Thompson entitled, "Ensuring the Safety and Security of the Nation's Food Supply." The report outlines a comprehensive 10 point program to protect the safety and security, now referred to as defense, of our food supply. I'll briefly describe three of the program areas.

A key component of the FDA's strategic plan is to assure a high quality professional work force. So we're trying to create a stronger FDA. FDA has created many new human resource policies to attract and keep high caliber employees.

A second point involves imports. Thanks to a bipartisan congressional support, a fiscal year 2002 supplemental appropriation enabled FDA to hire over 800 employees, 635 of these were hired principally to address food safety and food defense issues, primarily at the borders. With these additional field employees, we've expanded FDA's presence at ports of entry, increased surveillance of imported foods, increased domestic inspections and enhanced our laboratory analysis capacity. In addition, we're using risk management strategies to achieve the greatest food protection for our limited resources.

The Bioterrorism Act provided the Secretary of Health and Human Services with new authorities to protect the Nation's food supply against the threat of intentional contamination and other food related emergencies. These new authorities will improve our ability to act quickly in responding to a threatened or actual terrorist attack as well as other food related emergencies. FDA has been working hard to implement this law effectively and efficiently.

In conclusion, the Department of Health and Human Services is making tremendous progress in its ability to ensure the safety and defense of the Nation's food supply. And due to the enhancements being made by FDA, CDC and other agencies and due to the close coordination between the Federal food safety, public health, law enforcement and intelligence gathering agencies, the U.S. food safety and defense system is stronger than ever before.

Thank you for this opportunity to discuss Health and Human Services food safety and defense activities, and I would be pleased to respond to any questions after the panel.

[The prepared statement of Dr. 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 CIVIL SERVICE AND AGENCY ORGANIZATION

UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 30, 2004

FOR RELEASE ONLY UPON DELIVERY

Introduction

Good afternoon, Chairwoman Davis 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 U.S. Department of Health and Human Services (HHS or the Department). 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 colleague from the U.S. Department of Agriculture (USDA), Dr. Merle Pierson.

The Subcommittee has expressed interest in the potential benefits of a single food agency. 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 White House 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.

In my view, the important question is whether the various Federal agencies with food safety authorities are working together effectively. The answer to that question is yes. The existing system is working. The American food supply continues to be among the safest in the world. Food safety agencies are working more closely together than ever before.

Of course, we all face many challenges. We face the traditional challenge of reducing the incidence of foodborne illness from unintentional contamination. In addition, we now face a heightened challenge of protecting food from deliberate contamination. To address these challenges, HHS has been implementing the most fundamental enhancements in our food safety and food defense activities in many years. For example, the new authorities in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) provide significant new tools for protecting the nation's food supply. In addition, the President recently issued Homeland Security Presidential Directive 9 (HSPD-9) which establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. With the U.S. Department of Homeland Security (DHS) as the coordinating lead, HSPD-9 promotes interagency cooperation and leadership to protect critical infrastructure and key resources. HHS, USDA, the Environmental Protection Agency (EPA), and other appropriate agencies are working with DHS in this national effort.

In my testimony today, I will describe HHS' food safety and security responsibilities and our many cooperative activities with USDA and our other partners. I will also discuss FDA's ten-point plan for ensuring the safety and security of the nation's food supply.

HHS' Food Safety and Security Responsibilities and Collaborative Efforts

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 80

percent of the nation's food supply–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.

By way of background, while FDA has the lead responsibility within HHS for ensuring the safety of food products, the Centers for Disease Control and Prevention (CDC) within 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 offers expert scientific opinion on the effectiveness of foodborne disease prevention strategies.

FDA contributes 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. These data help public health and food safety agencies evaluate the effectiveness of current food safety initiatives and develop future food safety activities. FDA provides monetary support and technical expertise to the program.

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.

FDA has a myriad of cooperative and collaborative activities with USDA that assist in ensuring public health and the safety of our nation's food supply. We have signed several Memoranda of Understanding (MOU) with FSIS that encompass dual jurisdiction establishments, food additive

petitions, and the detailing of Public Health Service Commissioned Corp Officers from HHS to FSIS - just to name a few examples. These MOU have been quite productive. For example, the sharing of information through the MOU regarding dual jurisdiction establishments has led to numerous recalls of both FDA- and USDA-regulated products.

FDA works very closely with USDA on common research activities. FDA meets quarterly with the National Program Leaders from USDA's Agricultural Research Service (ARS) to discuss FDA's food safety research needs that ARS has the expertise and/or program time to undertake. FDA also meets regularly with the National Program Leaders of USDA's Cooperative State Research Education and Extension Service (CSREES) to identify the Agency's research needs for consideration in their various granting programs.

FDA, CDC, and USDA also work together on Healthy People 2010 – the prevention agenda for the nation. Healthy People 2010 is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats. FDA and FSIS co-lead the Healthy People 2010 Food Safety Focus Area, which includes goals and objectives for improving food safety, as measured by decreasing foodborne illness and allergic reactions to foods, improving food preparation practices in retail establishments and by consumers, and preventing an increase in antimicrobial resistance in foodborne pathogens.

FDA, CDC, and FSIS also work jointly on the Food Code to provide a model ordinance to local, state, and Federal governmental bodies and tribal nations to ensure that the food provided by retail food establishments and institutions, such as nursing homes and child care centers, is not a vector of communicable diseases. The Food Code is updated every two years and provides practical, science-based guidance to assist in mitigating risk factors known to cause foodborne illness.

Another example of our cooperative food safety efforts is the Partnership for Food Safety Education, a public-private partnership established to educate the public about safe food handling to help reduce foodborne illness. FDA and FSIS were founding members along with CDC, USDA's CSREES, consumer groups and industry. This cooperative effort yielded the Fight BAC!® campaign that was launched in 1998 and to date has reached millions of consumers. The four key food safety messages within the Fight BAC!® campaign are: Clean, Separate, Cook, and Chill. Thousands of teachers, dietitians, public health officials, and extension agents across the U.S. use Fight BAC!® materials every year.

From an international perspective, the Codex Alimentarius Commission (Codex) is a further example of our collaborative efforts. Codex was created in 1962 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. Codex is the major international mechanism for encouraging fair international trade in food while promoting the health and economic interests of consumers. In the U.S., Codex activities are coordinated by officials from USDA, FDA, and the Environmental Protection Agency

(EPA). FDA exercises leadership in Codex committees to promote development of science-based international food safety and labeling standards that provide a level of consumer protection and label information consistent with that provided by corresponding U.S. regulations and laws.

FDA has long been actively involved nationally and internationally in efforts to understand and prevent the spread of Bovine Spongiform Encephalopathy (BSE). To address these concerns, FDA collaborates extensively with USDA's Animal and Plant Health Inspection Service (APHIS) and FSIS, Customs and Border Protection (CBP), EPA, the U.S. Department of State (DOS), our HHS colleagues at CDC and the National Institutes of Health (NIH), other Federal agencies, state and local jurisdictions, with affected industries and consumer groups, and the World Trade Organization. Specific examples of the cooperative efforts FDA has undertaken with CBP and USDA to restrict the spread of BSE include:

- Instituting a multi-tiered approach by FDA, CBP, and APHIS to ensure that BSE infected material is not introduced into the domestic human or veterinary food supply. At each stage in the import process (manifest, entry, and release) the appropriate agency reviews the data submitted and cross checks results with the other agencies.
- Establishing a seamless coordinated system for import review to safeguard against BSE. CBP agricultural inspection officers review vessel and truck manifests to determine if ruminant material is present and, if so, whether the appropriate USDA permits have been obtained. Non-permitted material is denied entry. When the importer files the customs entry, CBP's Automated Commercial System (ACS) screens the entry against the

Harmonized Tariff Schedule (HTS) classifications selected by APHIS which may contain products of ruminant origin or which may contain ruminant materials and which originate from a BSE country. CBP refers any such entries to USDA for further review and possible denial of entry. CBP's ACS electronically transmits data for FDA-regulated products to the Agency's Operational and Administrative System for Import Support (OASIS) for entry admissibility review. As part of this review, OASIS electronically screens the FDA product code supplied by the entry filer against lists of products known to contain ruminant material and BSE countries. Suspect products are referred to USDA for further action. If the product has already been released by CBP, USDA may request that CBP order the redelivery of the product to CBP custody for return to the port and storage in a bonded warehouse.

Collaborative activities such as these enabled implementation of a multi-layered system of firewalls to reduce the U.S. consumer's risk of exposure to the BSE infectious agent, including development and testing of Agency contingency response plans that were initiated immediately upon discovery of the first case of a BSE-positive cow within the U.S. This collaboration also has enabled the Agency to further strengthen safeguards for FDA-regulated products.

FDA and FSIS are also working on a joint proposed rule to develop general principles for reviewing and revising food standards regulations. FDA also collaborates with USDA on a variety of food security issues that will be discussed in the remaining portion of this testimony.

Ten-Point Plan for Ensuring the Safety and Security of the Nation's Food Supply

On July 23, 2003, former FDA Commissioner Mark B. McClellan issued a report to HHS Secretary Tommy G. Thompson entitled, "Ensuring the Safety and Security of the Nation's Food Supply." The report outlines a comprehensive ten-point program for safety and security, now referred to as defense, of our food supply. The ten-point program is based on four overall principles:

- Food defense and food safety are integrated goals. By building upon the Nation's core food safety/public health systems and expertise, FDA is enhancing food defense and improving food safety in the process.
- The food safety and defense system is comprehensive, addressing the full range of assessment, prevention, and response needs throughout the food production and distribution chain.
- The food safety and defense system is built on a solid foundation of a national partnership with other entities involved in food safety and food defense that fully integrates the assets of state, local and tribal governments, other Federal agencies, and the private sector.
- Americans must have confidence that the government is taking all reasonable steps to protect the food supply and is providing Americans with timely and relevant information about threats.

Consistent with these principles, the Agency is employing the following overall strategies:

- Awareness: develop increased awareness among Federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge;
- Prevention: develop capacity to identify a specific threat or attack on the food supply;
- Preparedness: develop effective protection strategies to "shield" the food supply from terrorist threats;
- Response: develop capacity for a rapid, coordinated response to a foodborne terrorist attack; and
- Recovery: develop capacity for a rapid, coordinated recovery from a foodborne terrorist attack.

In these efforts, FDA has many partners – Federal and state agencies, academia, and industry. We are working closely with our Federal partners such as USDA, DHS, the Homeland Security Council (HSC) at the White House, DOS, and the U.S. Trade Representative, as well as with law enforcement and intelligence-gathering agencies. I also want to emphasize our close working relationships with our sister public health agencies, CDC and NIH, and FSIS, our counterpart agency responsible for meat, poultry, and certain egg products, and with CBP, our partner at the border. Some of our other Federal partners include APHIS, USDA's Foreign Agriculture Service, USDA's Agricultural Research Service, USDA's Food and Nutrition Service, Department of the Army Veterinary Services Activity, U.S. Air Force, Department of Commerce's (DOC) National Oceanic and Atmospheric Administration, the Environmental

Protection Agency (EPA), the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), the Federal Bureau of Investigation, and the Central Intelligence Agency (CIA).

Now, I would like to describe the program areas in the ten-point plan.

1. Stronger FDA

Thanks to bipartisan Congressional support, a Fiscal Year 2002 supplemental appropriation included counterterrorism funds for FDA. This enabled FDA to hire over 800 employees, 655 of whom were hired by FDA's Office of Regulatory Affairs (ORA) as additional field personnel. Of the 655 field personnel, 635 were hired principally to address food safety and food defense issues, primarily at the border. These staff have all been hired, trained, and deployed. Three hundred support consumer safety investigations at 90 U.S. ports of entry, 100 support laboratory analyses on imported products, 33 are for criminal investigations of import activities, and the remaining personnel support domestic efforts.

As I mentioned earlier, in addition to ensuring the safety and security of the food supply, FDA is responsible for the safety of cosmetics and the safety and efficacy of human and veterinary drugs, human biologicals, medical devices and radiological products. FDA's field staff is responsible for conducting operations in these multiple product areas in both the domestic and import arenas, and their time is not completely obligated in only one specific product area. While the 635 field staff primarily conducts food work, they also conduct work in these other important product areas when needed. Should a single food agency be created, there may be a

request to reallocate these 635 field personnel to the newly formed agency. Such a reallocation would measurably diminish FDA's ability and efficiency to potentially address issues involving the safety and efficacy of the other FDA-regulated commodities. This could potentially increase the vulnerability of the population to the exposure of unsafe or ineffective products.

The continuous threat of terrorism requires FDA to remain persistent in its effort to recruit and retain a competent, trained workforce if we are to maintain a high level of readiness. A key component of FDA's strategic plan is to assure a high-quality professional workforce. Capable personnel with the appropriate expertise are critical for the success of FDA and for the Agency's ability to maintain a high level of public trust in its activities. FDA's responsibilities require a very special workforce, one that can keep up with rapid changes in the industries that it regulates and one that is capable of developing and implementing effective and innovative public health measures. Our workforce includes a solid cadre of experienced physicians, toxicologists, chemists, microbiologists, statisticians, mathematicians, biologists, pharmacologists, veterinarians, and other highly qualified and dedicated professionals.

FDA continues to find innovative ways to educate and train our staff and further develop the necessary scientific, technical, and investigational skills to integrate food safety and food defense activities. FDA has not only mobilized the new staff but also has redirected and trained current investigators and scientists to ensure that the Agency has the necessary expertise to respond to an event that could threaten the safety and security of the food supply. FDA has hired or re-trained scientific experts in biological, chemical, and radiological agent research, detection

methodology, and preventive technologies. It has also acquired substantial knowledge of biological, chemical, and radiological agents.

2. Imports

The volume of imported food shipments has been rising steadily in recent years, and this trend is likely to continue. In Fiscal Year 2003, FDA had the challenge of assuring the safety and security of approximately 6 million line entries of imported food. We anticipate 7.1 million line entries of imported food this fiscal year. To manage this ever-increasing volume, we are using risk management strategies to achieve the greatest food protection with our limited resources. We are working to increase the information gathered throughout the life cycle of imported products -- from raw materials to foreign processing to shipping to the U.S. consumer – to create a risk profile of imported products that will allow us to focus our resources on products that present the greatest risk.

While we cannot physically inspect every shipment, it is important to note that every shipment that contains FDA-regulated products that is entered for consumption or warehouse storage through CBP's ACS is electronically reviewed by FDA's OASIS 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 limited inspection resources on high-risk shipments while allowing low-risk shipments to proceed into commerce.

With the new prior notice requirement, specific information mandated by the Bioterrorism Act must be submitted to FDA before the imported food arrives in the United States. This not only allows the electronic system to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the United States, but it will also allow for FDA staff review of prior notices for those products flagged by the systems as presenting the most significant risk. FDA worked very closely with CBP in developing this screening system.

In addition, FDA has been actively working with the analysts at CBP's National Targeting Center to utilize their Automated Targeting System as an additional tool to enhance the Agency's ability to focus attention on those imported foods that may pose a serious threat to public health. We anticipate that the use of FDA's and CBP's screening systems will enable both agencies to effectively target shipments posing the greatest risk in order to further focus our border inspection efforts. FDA worked very closely with CBP in developing this screening system.

We have also increased surveillance. With the additional field employees that we mentioned earlier, we have expanded FDA's presence at ports of entry, increased surveillance of imported foods, increased domestic inspections, and enhanced our laboratory analysis capacity. More specifically, within the last two years, we have more than doubled the number of ports that have an FDA presence from 40 to 90 ports. We have increased by more than six-fold the number of food examinations at the border. This past fiscal year, we surpassed our

goal of 48,000 import examinations, conducting 78,569 food import examinations compared to 12,000 just two years ago. This increase was so significant due, in large part, to increased surveillance of imported food products during Operation Liberty Shield when the nation was at a heightened security alert status. The President's FY 2005 budget proposal requests $7 million for increased FDA inspections of domestic and imported food to reduce the risk of contaminated products entering the U.S. market.

3. Implementation of the Bioterrorism Act

Title III of the Bioterrorism Act provided the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA is responsible for implementing these food safety and food defense provisions. This landmark legislation represents the most fundamental enhancement to our food safety and food defense authorities in many years. These new authorities will help improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies.

The Agency has been working hard to implement this law effectively and efficiently. On October 10, 2003, we published two interim final regulations to implement Section 305, Registration of Food Facilities, and Section 307, Prior Notice of Imported Food Shipments. In accordance with the Bioterrorism Act, these two regulations became effective on December 12, 2003. We have also published proposed regulations to implement Section 303, Administrative Detention, and Section 306, Maintenance and Inspection of Records for Foods. We intend to

finalize the regulations on these two provisions in the near future. Section 303 gives FDA new authority to detain any article of food for which there is credible evidence that it poses a threat of serious adverse health consequences or death. When finalized, the recordkeeping regulation will help FDA track and contain foods that pose a threat of serious adverse health consequences or death from accidental or deliberate contamination of food.

The interim final rule on registration requires domestic and foreign facilities that manufacture or process, pack, or hold food for human or animal consumption in the U.S. to register with FDA. FDA will have, for the first time, a roster of foreign and domestic food facilities. In the event of a potential or actual terrorist incident or an outbreak of foodborne illness, the registration information will help FDA to quickly identify and locate the facilities that may be affected. FDA expects up to 420,000 facilities to register under this requirement.

FDA's electronic registration system became operational on October 16, 2003. The system is available 24 hours a day, seven days a week, to anyone with access to the Internet. We are also providing technical assistance to persons who need help with the registration process. Facilities are strongly encouraged to use the electronic system to register. As of March 24, 2004, 194,889 facilities have registered. This includes 94,716 domestic and 100,173 foreign facilities.

The interim final regulation on prior notice requires the submission to FDA of prior notice of food, including animal feed that is imported or offered for import into the U.S. This advance information enables FDA, working closely with CBP, to more effectively target inspections at

the border to ensure the safety of imported foods before they move into the U.S. CBP represents the Administration's attempt to build a single lead border authority, which was part of the rationale for establishing DHS. FDA has been receiving about 25,000 notifications about incoming shipments each day since the regulation became effective on December 12, 2003. The timeframes for submitting prior notice are the least amount of time that FDA needs to meet our statutory responsibility to receive, review, and respond to the prior notice submission. They take into account different modes of transportation. The regulations allow two hours for arrival by land by road, four hours for arrival by air or land by rail, and eight hours for arrival by water. The staggered prior notice submission timeframes will allow FDA reviewers to direct additional resources to shipments with shorter transport times and to defer review of shipments with longer transport times.

HHS and DHS co-signed the regulations. FDA and CBP worked collaboratively to ensure the new regulations promote a coordinated strategy for border protection. Thanks to this collaboration, prior notice may be submitted by using CBP's ACS or by using FDA's Prior Notice System Interface. FDA and CBP are committed to the joint implementation of a plan for increasing integration and assessing the coordination of the prior notice timeframes that will: (1) achieve the goal of a uniform, integrated system; (2) build on current operational procedures; and (3) implement the law with minimal disruption to current entry practices. Although the interim final rules became effective December 12, 2003, FDA and CBP intend to generally exercise enforcement discretion for several months following implementation. During this time, FDA and CBP intend to focus on educating our stakeholders about the requirements of the rules.

Pursuant to the commissioning authority provided in Section 314 of the Bioterrorism Act, FDA and CBP have signed an MOU to commission CBP employees to conduct investigations and examinations on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff in the enforcement of FDA's prior notice requirements. In accordance with this new authority, FDA has already commissioned over 7,500 CBP employees. The Agency will continue to explore use of this authority with other agencies as a tool to further improve efficiencies.

4. Industry Guidance and Preventive Measures

FDA has issued guidance on the security measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. We have issued such guidance, "Security Preventive Measures Guidance Documents," for food producers, processors, and transporters; for importers and filers; for retail food stores and food service establishments; and for cosmetic processors and transporters. In addition, we have issued specific security guidance for the milk industry. During domestic inspections and import examinations, FDA's field personnel continue to distribute and discuss these guidance documents with firms that have not previously received them.

5. Vulnerability and Threat Assessments

As part of our efforts to anticipate threats to the food supply, we have conducted extensive scientific vulnerability assessments of different categories of food, determining the most

serious risks of intentional contamination with different biological or chemical agents during various stages of food production and distribution. FDA's initial assessment utilized an analytical framework called Operational Risk Management (ORM) that considers both the severity of the public health impact and the likelihood of such an event taking place. This framework was provided to us by the U.S. Air Force. FDA has incorporated threat information received from the intelligence community.

To validate our findings, FDA contracted with the Institute of Food Technologists to conduct an in-depth review of ORM and provide a critique of its application to food security. This review validated FDA's vulnerability assessment and provided additional information on the public health consequences of a range of scenarios involving various products, agents, and processes.

FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment." The assessment also affirmed the findings of FDA's ORM assessment. In addition, it provided another decision-making tool for performing risk assessments. Further, the Battelle assessment made a number of recommendations that addressed research needs, the need for enhanced laboratory capability and capacity, and the need for enhanced partnerships between Federal, state, and local governments to ensure food security. FDA is addressing each of these recommendations.

FDA is continuing to update and refine these assessments regarding the vulnerability of FDA-regulated foods to intentional contamination from biological, chemical, and radiological agents. These refinements use processes adapted from techniques developed by the U.S. Department of Defense (DOD) for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments will be used to develop technology interventions and countermeasures, identify research needs, and provide guidance to the private sector. Through an HSC interagency working group, FDA, FSIS, APHIS, and the Food and Nutrition Service worked together on their assessment efforts, utilizing DOD assessment techniques, to ensure that each agency was using the same approach to assess its vulnerabilities.

6. Operation Liberty Shield

In March 2003, the Federal government launched Operation Liberty Shield to increase security and readiness at a time of elevated risk for terrorist attack. Operation Liberty Shield was a comprehensive national plan to increase protections for America's citizens and infrastructure while maintaining the free flow of goods and people across our border with minimal disruption to our economy and way of life. FDA's efforts during Operation Liberty Shield were targeted towards increasing the Agency's surveillance activities in the food and cosmetic areas in an effort to enhance defense of these products. This targeted approach was based on the vulnerability assessments described above and included domestic inspections and import examinations, sample collections of targeted commodities, and import reconciliation examinations. Domestic and import reconciliation examinations were conducted to ensure that: 1) the targeted food/cosmetic was what it purported to be; 2) there were no unexplained

differences in the quantity of products ordered and what was subsequently received; 3) there were no visible signs of tampering or counterfeiting; and 4) sampled products were not adulterated with contaminants of concern. During each and every domestic inspection or import examination, FDA personnel handed out and discussed FDA's "Security Preventive Measures Guidance Documents."

7. Emergency Preparedness and Response

FDA has established an Office of Crisis Management (OCM) to coordinate the preparedness and emergency response activities within FDA and with our Federal, state, and local counterparts. Over the past three years, FDA has participated in and conducted multiple emergency response activities including exercises coordinated with other Federal and state agencies. For example, FDA and USDA's FSIS have focused on strengthening our working relationships through joint testing of several response plans in an exercise environment. FDA has also reviewed food security and rapid response and recovery procedures with industry groups and trade associations.

In May 2003, FDA participated in the government-wide TOPOFF2 counterterrorism exercise led by the DHS and the Department of Justice. This was a national, full-scale, fully functional exercise intended to simulate two separate terrorist attacks -- detonation of a "dirty bomb" in Seattle and aerosol release of plague in Chicago -- that had implications for food products (e.g., the possibility of food contamination by radiation). The ensuing response involved participation from 17 Federal departments and agencies, the state governments of Washington and Illinois, the

local governments of the affected cities, and the Canadian Government. FDA's response was coordinated from our Emergency Operations Center (EOC)on an around-the-clock basis throughout the exercise, working together with all of FDA's Centers.

From September 8 – 10, 2003, FDA participated in Exercise Global Mercury. Global Mercury involved the G-7 countries plus Mexico and was designed to test international communications during a public health emergency in the international community. Coordination of HHS participation was done through the Secretary's Command Center. Other U.S. players in the exercise were CDC and DOS.

On October 7, 2003, FDA hosted the first trilateral food terrorism tabletop exercise via videoconference with Mexico and Canada. The exercise was conducted from FDA's OCM/EOC. Participants included FDA's CFSAN, ORA, Office of International Programs, Southwest Import District, New York District, Mexico's Federal Commission for Health Risk Protection (COFEPRIS), Health Canada, and the Canadian Food Inspection Agency. The objectives of the exercise were to elicit discussion of emergency preparedness and response activities, to ensure that all players have a common understanding of the communications plans and systems that could be utilized in response to an international terrorism event, and to use videoconferencing to practice international response communications. The players were pleased with the opportunity to participate in the exercise and found it to be a valuable learning experience. At the Trilateral Meeting on October 29, 2003, in Baltimore, Maryland, a discussion was held on the lessons learned including the challenges related to notification,

sharing of data including classified information, and sharing of intelligence information between and among the three countries. Another trilateral exercise will be conducted this year.

FDA and USDA have also closely coordinated our BSE efforts both prior to and following the identification of the BSE positive cow in Washington State. During late 2001 and 2002, FDA in conjunction with USDA, conducted a series of three exercises to test our BSE response plans. These exercises served us well in establishing the lines of communication and coordination needed to respond to the finding of the BSE positive cow in December 2003. Once notified of the finding, FDA and USDA were in close communication at multiple levels. At a headquarters staff level, USDA hosted daily interagency calls with APHIS, FSIS, FDA, DOD and CDC to share information. FDA personnel were sent to the USDA/APHIS emergency operations center to assist that operation. Local communication occurred in Washington State between the FDA district office in Seattle and the local USDA incident command center. Many of the inspections of facilities in Washington were conducted as joint inspections with FDA, USDA, and state inspectors all participating. FDA worked closely with USDA on the disposal of rendered product produced from the index cow. Numerous other policy level meetings and teleconferences occurred between FDA and USDA senior officials.

Finally, FDA's OCM/EOC will coordinate FDA participation in other interagency exercises planned for this year and will conduct two additional exercises to test updated response plans for chemical/biological and radiological emergencies.

The President's FY 2005 budget proposal requests an additional $3 million to upgrade the agency's crisis management capacity for a rapid and coordinated response to a threat to the food supply.

8. Laboratory Enhancements

An additional step in enhancing our response capability is to improve our laboratory capacity. A critical component of controlling threats from deliberate food-borne 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. To increase surge capacity, FDA has worked in close collaboration with CDC and USDA/FSIS to augment the Laboratory Response Network by establishing the Food Emergency Response Network (FERN) to include a substantial number of laboratories capable of analyzing foods for agents of concern. We are seeking to expand our capacity through agreements with other Federal and state laboratories. As of last week, 30 laboratories representing 23 states have submitted laboratory qualification checklists for membership in FERN. The President's FY 2005 budget proposal requests $35 million for FDA to enhance FERN. The President's budget proposal also requests funding for USDA to enhance FERN. Once completed, FERN will encompass 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 swiftly respond to a terrorist attack.

We also are expanding Federal, state, and local involvement in our Electronic Laboratory Exchange Network (eLEXNET) by increasing the number of laboratories around the country that

participate in this electronic data system. eLEXNET is a seamless, integrated, web-based data exchange system for food testing information that allows multiple agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET is funded by FDA and supported by USDA and DOD. It enables health officials to assess risks and analyze trends, and it provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. At present, there are 108 laboratories representing 49 states that are part of the eLEXNET system with 62 laboratories actively submitting data. We are continuing to increase the number of participating laboratories.

Moreover, during the U.S./Canada/Mexico Trilateral Cooperation Meeting held in Baltimore, Maryland, at the end of October, the three governments agreed to establish a pilot to use eLEXNET to share food sample data among the three countries' laboratories. FDA and the Office of the Assistant Secretary for Public Health and Emergency Preparedness in HHS have begun working with Mexico and Canada to establish an integrated secure network between U.S., Mexican, and Canadian food testing laboratories. One of the major goals of the project is to create an early warning notification system to identify potentially hazardous foods and more quickly contain their distribution to prevent consumption.

In addition, FDA's ORA has signed an Interagency Agreement with the U.S. Department of the Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to enhance our ability to provide timely and efficient analyses of imported food. The mobile laboratories are expected to be ready for deployment this year.

9. Research

To prioritize research needs and avoid duplication, FDA coordinates with its sister agencies within HHS, such as CDC and NIH, and with other Federal partners such as USDA, DHS, DOD, and the Department of Energy. Within FDA, we have embarked on an ambitious research agenda throughout the Agency to address potential terrorist threats. To enhance food defense, FDA has significantly redirected existing research staff to ensure that appropriate resources are focused on priority food safety and defense issues. For example, research sponsored by FDA's CFSAN is aimed at developing the tools essential for testing a broad array of food products for a multiple number of biological and chemical agents. We are actively working with our partners in government, industry, and academia to develop such methods. In addition, research conducted at FDA's National Center for Toxicological Research is providing rapid detection techniques and risk assessment models for biological pathogens. FDA's work with AOAC International, an association of analytical chemists, on validating analytical methods for the detection of biological, chemical, and radiological agents in foods is considered the "gold standard" against which other validations programs are judged. Likewise, FDA's research on microbial genomics and analytical chemistry is widely recognized for its importance to other Federal agencies charged with forensic investigations of terrorism events.

In compliance with Section 302 of the Bioterrorism Act, on October 16, 2003, we submitted a report to Congress, "Testing for Rapid Detection of Adulteration of Food," about the research that is underway. FDA has commenced more than 90 different research projects to develop tests and sampling methodologies to increase the detection of adulteration of food. A number of the

research projects are designed specifically to develop tests suitable for inspections of foods at ports of entry. For example, commercially available test kits are currently being analyzed for a variety of food matrices to evaluate their suitability for use in the field at ports of entry.

The President's FY 2005 budget proposal requests $15 million to fund additional research on prevention technologies, methods development and determination of the infectious dose for potential terrorism agents when ingested with food, and identification of agent characteristics within specified foods. Developing these strategies will shield the food supply from potential attacks and enable rapid response if needed.

10. Interagency and International Communication and Collaboration

Food safety and food defense require effective and enhanced coordination across many government agencies at the Federal, state, and local level. FDA's activities in public health security are coordinated through the HHS Secretary's Command Center. This relationship facilitates communication between all HHS Operating Divisions, the Department, and other Federal agencies and departments, including DHS. FDA has also worked closely with the Interagency Food Working Group of the White House HSC on three initiatives – development of a national network of food laboratories, identification of vulnerabilities and subsequent mitigation tactics for commodities of concern, and the development of a national incident management system. Additional Federal agencies participating in these efforts are USDA, CDC, DOD, EPA, and CIA.

FDA conducts regularly scheduled interagency conference calls with representatives from USDA's APHIS and FSIS, CDC, EPA, DOD, DOC, TTB, and CBP. On February 4, 2003, FDA, in conjunction with the National Association of State Departments of Agriculture, the Association of State and Territorial Health Officials, USDA, and CDC, sponsored a one-day executive level meeting with the Secretaries of State departments of agriculture and State departments of health titled "Homeland Security – Protecting Agriculture, the Food Supply and Public Health – the Role of the States." FDA is also working closely with Canada and Mexico in an effort to assess and strengthen our public health and food security systems and infrastructures at our mutual borders.

In addition, ORA's Office of Criminal Investigations (OCI) maintains professional relationships with domestic and foreign law enforcement agencies to receive and act on any information regarding product tampering. OCI is FDA's liaison with the intelligence community (CIA, National Security Agency, and others). OCI agents serve on several interagency committees including the FBI's Joint Terrorism Task Forces, the U.S. Attorney's Office Anti-Terrorism Task Forces, and DHS' Bureau of Immigration and Customs Enforcement Task Forces around the country. OCI has a specialized staff with the capability and background to analyze information from law enforcement and intelligence community sources to assist in terrorism-related threat assessments pertaining to FDA-regulated products.

Many of the activities described above will help achieve the goals established in HSPD-9, which I mentioned earlier. HSPD-9 has five major objectives:

- Identifying and prioritizing sector-critical infrastructure and key resources for establishing protection requirements;
- Developing awareness and early warning capabilities to recognize threats;
- Mitigating vulnerabilities at critical production and processing nodes;
- Enhancing screening procedures for domestic and imported products; and
- Enhancing response and recovery procedures.

HHS, USDA, EPA, and other appropriate agencies are working with DHS to achieve these objectives.

Conclusion

In conclusion, FDA is making tremendous progress in our ability to ensure the safety and defense of the nation's food supply. Due to the enhancements being made by FDA and other agencies and due to the close coordination between the Federal food safety, public health, law enforcement, and intelligence-gathering agencies, the U.S.'s food safety and defense system is stronger than ever before.

Thank you for this opportunity to discuss HHS' food safety and defense activities. I would be pleased to respond to any questions.

Ms. DAVIS OF VIRGINIA. Thank you, Dr. Brackett. Finally, we'll hear from Mr. Merle Pierson, with the USDA. Dr. Pierson, again, your statement is in the record, if you would summarize in 5 minutes.

Mr. PIERSON. Madam Chairwoman, I appreciate the opportunity to speak to you about the important issue of protecting the Nation's food supply. I'm Dr. Merle Pierson, Deputy Under Secretary for Food Safety at USDA.

Although I served in this capacity for only the past 2 years, my entire career, including 32 years at Virginia Tech, has been devoted to food safety and public health. First, let me offer a brief overview of the work and responsibilities of the Food Safety Inspection Service [FSIS]. FSIS operates under the legal and statutory authorities of the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act. Under these authorities, FSIS inspects all meat, poultry and egg products sold in interstate commerce and reinspects imported products to ensure that they meet U.S. food safety standards.

Ensuring the safety of meat, poultry and egg products requires a strong, well integrated infrastructure. In order to accomplish this, FSIS has a work force of approximately 10,000 employees, which includes 7,600 inspection personnel stationed in over 6,000 federally inspected meat, poultry and egg products plants every single day these plants are in operation. FSIS jurisdiction encompasses over 45 percent of all foods produced by U.S. agriculture. The FSIS work force verifies the processing of 43.6 billion pounds of red meat, 49.2 billion pounds of poultry, 3.7 pounds of liquid egg products, certifies that these meet strict statutory requirements.

In addition, 3.8 billion pounds of imported meat, poultry and processed egg products were presented for entry into the United States from 28 of the 33 countries eligible to export in 2003. I welcome the discussion on the creation of a single food safety agency. As you and members of the subcommittee are aware, any food safety and security system must be able to meet current and future food safety and security challenges. In addition, I strongly believe that any effective food safety and security system must be rooted in public health and science.

FSIS believes and the GAO and National Academy of Sciences has agreed that a critical component of the food safety system is a verifiable food safety inspection system that is both risk based and science based. A risk based system allocates resources based on the greatest risks or hazards, while a science based system takes these risks and hazards into account to develop science based programs and policies.

Thanks in part to the efforts by FSIS to follow the scientific approach in administering its food safety programs, the American public remains confident of the safety of the U.S. food supply. Additionally, our efforts are paying off, as seen by the decline in foodborne illness over the past 6 years. FSIS routinely communicates and coordinates with its sister public health agencies. Cooperation, communication and coordination are absolutely essential to effectively address public health issues.

I'd like to point out a few of the many examples exemplified in these successful partnerships. FSIS works closely with the White

House Homeland Security Council, the Department of Homeland Security and the Department of Health and Human Services, the USDA Homeland Security staff and other Federal, State and local partners to develop and carry out strategies to protect the food supply from potential attack.

In December 2003 there was the discovery of a single case of BSE in Washington State. This provides an excellent example of the strong communication ties between USDA and its Federal and State food safety partners. The Federal Government's swift response to the BSE diagnosis played a vital role in maintaining high consumer confidence.

Since 1999, FSIS and FDA have had an MOU to exchange information on an ongoing basis about establishments that fall under both jurisdictions. Another example is the Codex Alimentarious Commission, which is a joint WHO-FAO international standard setting body for food safety. The USDA Under Secretary for Food Safety has responsibility for leadership of Codex with the U.S. Government and the Codex office is managed through FSIS. Codex is an excellent example of wide reaching coordination of food safety activities throughout the U.S. Government.

In considering a single food safety agency, Congress must analyze the efficacy of the single food safety agency models in the countries that have adopted such paradigms, while being mindful of the ultimate goal, improving food safety and public health. FSIS bases its policy decisions on science, so the single food safety agency discussion boils down to the question, will there be a measurable benefit to public health.

As with any new food safety and security effort, we want to make sure we maintain and continue improving on any progress that we have made to improve public health. We must also consider the costs associated with any major overhaul to the U.S. food safety inspection system. In addition, Congress would need to determine how current statutory authorities would be merged into a single food safety agency. The acts under which the food safety inspection service operates are different than the Federal Food, Drug and Cosmetic Act administered by the Food and Drug Administration. Under the acts FSIS administers, it must find a product not adulterated before the product can enter commerce. This is because inherent in these acts is a finding by Congress that the risks presented by meat, poultry and egg products are such that trained inspectors must affirm that these products are safe before they can enter commerce and be distributed to consumers.

We are proud of our accomplishments, particularly the declines in food-borne illnesses over the past few years, and we must maintain and improve on the progress that FSIS, FDA, and our food safety partners have made thus far. Thank you for the opportunity to provide these overview comments on our food safety and security programs. We look forward to working with Congress to continue to keep the Nation's food supply safe and secure and strengthen public health. I certainly welcome any other questions or comments. 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, Deputy Under Secretary for Food Safety Before the Subcommittee on Civil Service and Agency Organization

Madame Chairwoman 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, Deputy Under Secretary for Food Safety at the U.S. Department of Agriculture (USDA). I also am pleased to be here today with Dr. Robert Brackett, my colleague from the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN), whom I've had numerous opportunities to work with on issues of mutual concern. I would also like to thank the General Accounting Office (GAO) for its efforts to provide a better understanding of our nation's current food safety system and structure. GAO's research has provided valuable information and has helped facilitate open discussions about our current system.

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. 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 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.

In my testimony, I will discuss components of an effective food safety and security system, USDA Food Safety and Inspection Service's (FSIS) role in the U.S. food safety and security system, the success of U.S. food safety and security efforts, and our cooperative efforts with our food safety partners. Because we understand and recognize the rationale of some stakeholders who believe that the existing food safety system is confusing, I will also raise important issues that should be considered before making changes to our Nation's current food safety and security system. However, in our view, the most important question is whether the various Federal agencies with food safety authorities are working together effectively to address food safety and security. I believe the existing system is working. The American food supply continues to be among the safest in the world.

Building a Risk- and Science-Based Food Safety and Security System

Any food safety and security system must be able to meet current and future food safety and security challenges. In addition, I strongly believe that any effective food safety and security system must be rooted in public health and security.

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 based on the premise that the most effective and efficient method of allocating resources is to base them on

the assessment of greatest risks/hazards. A science-based system builds upon a risk-based system, by ensuring that the risks/hazards are taken into account to develop science-based programs and policies. A verifiable inspection system based upon these two premises provides assurance that the system is meeting its public health goals.

FSIS' Role in the Food Safety and Security System

FSIS has a long, proud history of protecting public health, dating back to 1906. FSIS' 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. FSIS has jurisdiction over products that generate more than $120 billion in sales, which represents one-third of all consumer spending on food. This is an enormous responsibility and one we take very seriously.

Ensuring the safety of meat, poultry, and egg products requires a strong infrastructure. To accomplish this task, FSIS has a large workforce of approximately 10,000 employees, mostly stationed in the field on the front lines and dedicated to rigorous inspection. In fiscal year (FY) 2003, over 7,600 inspection personnel were stationed in about 6,000 federally inspected meat, poultry, and egg products plants every day that they were in operation, verifying 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 complied with statutory requirements. In addition to domestic products, 3.8 billion pounds of imported meat, poultry, and processed egg products were

presented for entry into the U.S. from 28 of 33 countries eligible to export to the United States in FY 2003. Assuring that these products are safe and wholesome is a serious responsibility.

On the international front, FSIS actively participates in the development of international food safety standards through the Codex Alimentarius Commission. As the highest ranking food safety official in the United States, the Under Secretary for Food Safety at the USDA leads the U.S. Codex Office. The U.S. Codex Office is located within the Food Safety and Inspection Service.

FSIS' Inspection System

FSIS currently operates under a science-based system. Science allows for policy decisions to be continually updated based on technological advances and to respond to emerging threats. Science-based decision-making is objective and preventive in nature, and thus, it offers the best foundation for the development of policies that will achieve the desired result of improving 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.

Thanks in part to the efforts by FSIS to follow this scientific approach in administering its food safety programs, the American public remains confident in the safety of the U.S. food supply. Our efforts are paying off, as seen by the decline in foodborne illness over the last six years. The Centers for Disease Control and Prevention (CDC) attributes these results in part to the

implementation of the Hazard Analysis Critical Control Point (HACCP) system in all meat and poultry plants in the United States.

In addition, FSIS has seen a dramatic decline in pathogen levels in regulatory samples. Late last year, the agency released data that showed a 25 percent drop in the percentage of positive *Listeria monocytogenes* samples from the previous year, and a 70 percent decline compared with years prior to the implementation of the HACCP program. In June 2003, to further reduce the incidence of *Listeria monocytogenes*, we issued regulations for establishments producing ready-to-eat products.

Our measures to prevent *E. coli* O157:H7 contamination of ground beef have yielded similar results. In September 2002, based on evidence that *E. coli* O157:H7 is a hazard reasonably likely to occur at all stages of handling raw beef products, FSIS issued a directive requiring all establishments that produce raw beef products to reassess their HACCP plans. Last year, FSIS' scientifically trained personnel conducted the first-ever comprehensive audits of more than 1,000 beef establishments' HACCP plans. A majority of those plants made major improvements based on their reassessments, and, as a result, we are seeing a substantial drop in the percentage of ground beef samples that are positive for *E. coli* O157:H7. In 2003, of the ground beef samples collected and analyzed for *E. coli* O157:H7, only 0.30 percent tested positive, compared to 0.78 percent in 2002 – a 62 percent reduction. This is a definite and dramatic improvement, and the strongest signal that science can drive down the threat from pathogens.

However, the emergence of previously unrecognized pathogens, as well as new trends in food distribution and consumption, highlights our need for new strategies to reduce the health risks associated with pathogenic microorganisms in meat, poultry and egg products. To improve the application of risk analysis to regulatory and enforcement activities, FSIS is exploring the development of a real-time measure of how well an establishment controls the biological, chemical, and physical hazards inherent in its operations. Such a predictive model would help the agency make better resource allocations across the country's approximately 6,000 meat and poultry establishments to maximize food safety and public health protection.

FSIS Authorities

FSIS currently operates under appropriate legal and statutory authorities – namely the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). Under the authority of these Acts, FSIS provides continuous inspection of all 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 many regulatory responsibilities in addition to these inspection activities. The Agency sets requirements for meat and poultry labels and for certain slaughter and processing activities, such as plant sanitation and thermal processing, 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.

Meat, poultry, and egg products imported into the United States must be produced under processes equivalent to those applied to U.S. domestic establishments to ensure that they attain the same level of wholesomeness and safety and are accurately labeled. To ensure the safety of imported products, FSIS maintains a comprehensive system of import inspection and controls, which includes audits of a country's foreign inspection system and port-of-entry reinspection. FSIS reinspects imported meat and poultry products entering the United States to verify that a country's inspection system is working. 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 reinspection 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 they are equivalent to those under U.S. laws. During foreign reviews conducted in FY 2003, FSIS audited 340 plants and delisted 25 of those plants after finding that their individual system of inspection and controls was ineffective.

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, cold storage warehouses, and animal-food manufacturers. 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 suspends operations at more than 100 plants and refers approximately 30 cases for criminal prosecution to the Department of Justice annually.

Food Security

While the events of September 11, 2001, brought the issue of the vulnerability of our food supply to the forefront, FSIS' food biosecurity efforts did not start on September 12, 2001. FSIS' century worth of experience in dealing with food emergencies has allowed the agency to develop the expertise to protect the U.S. meat, poultry, and egg products supply wherever and whenever emergencies or new threats arise. However, FSIS cannot carry out these efforts alone. Instead, FSIS works closely with the White House Homeland Security Council, the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS), 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.

As a result of partnering with our Federal, State, and local food safety partners, the agency has strengthened existing efforts to prevent, detect, and respond to food-related emergencies resulting from acts of terrorism. For example, FSIS, along with HHS-FDA and industry partners, is working with DHS to establish a new food information sharing and analysis activity for the food sector. This public/private partnership will aid in the protection of the critical food infrastructure by centralizing the information about threats, incidents, and vulnerabilities.

In addition, the President's recently signed Homeland Security Presidential Directive 9 has been in development since late 2003 and has served as a source of interagency cooperation resulting in even stronger working relationships among food regulatory agencies. The new Directive recognizes and 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. This new Presidential Directive, coordinated by DHS, promotes interagency leadership by establishing a national policy on agriculture and food defense. The goal of this Directive is to harness the collective problem solving and resource amplification of a multiagency effort to better protect the Nation's food supply.

To further refine the nation's ability to respond to an attack on the food supply, FSIS also works with its food safety and law enforcement partners to conduct food security exercises. These exercises give agency employees the opportunity to simulate their actions in response to a threat on the food supply and have allowed the agency to recognize and correct vulnerabilities in its

Homeland Security response plans. In addition, FSIS has conducted its own vulnerability assessments of regulated domestic and imported products. The assessments identify potentially vulnerable products and processes, likely threat agents, and points along the production/consumption continuum where attack is most likely to occur. Using this information, the agency will focus its resources on the points of greatest vulnerability.

FSIS also works with its partners to protect the food supply through our import reinspection activities. To further strengthen our import inspection program, we established a new position called the import surveillance liaison inspector, using funds provided in the FY 2001 Homeland Security Supplemental Appropriations Act. These inspectors augment the current activities of traditional FSIS import inspectors at locations across the country. The import surveillance liaison inspectors conduct a broader range of surveillance activities, and they coordinate with other agencies, such as the Animal and Plant Health Inspection Service (APHIS), HHS-FDA, and the U.S. Customs and Border Protection within the DHS. Currently, 20 of these new inspectors are on board, and we anticipate more will be added as the need arises.

Another example of coordination with our partners is the Food Emergency Response Network (FERN) initiative. A nationwide laboratory system with sufficient capacity to meet the needs of anticipated emergencies is integral to any bioterror surveillance and monitoring system. FERN consists of Federal and State governmental laboratories which are responsible for protecting citizens and the food supply from intentional acts of biological, chemical, and radiological terrorism. Currently, over 60 laboratories, including public health and veterinary diagnostic laboratories, representing 27 States and five Federal agencies, have agreed to participate in

FERN. The goal is to establish 100 FERN laboratories, creating a network of Federal, State and local laboratories that FSIS could call upon to handle the numerous samples that would be required to be tested in the event of a terrorist attack on the meat, poultry, or egg supply.

Because everyone has a stake in a safe and secure food supply, FSIS has worked closely with HHS-FDA and other public health agencies to provide food security guidelines to businesses engaged in the production and distribution of food products during transportation, distribution, and storage. These guidelines provide safety measures to prevent physical, chemical, or microbiological contamination of food products during transportation and storage, including measures that deal specifically with the prevention of intentional contamination due to criminal or terrorist acts. This publication is just one in a series of food security guidelines issued by FSIS that includes *FSIS Security Guidelines for Food Processors* and *Food Safety and Food Security: What Consumers Need to Know,* as part of the agency's continuing effort to protect public health by preventing and responding to contamination of the food supply throughout the farm-to-table continuum.

Coordination and Cooperation with Our Food Safety Partners

FSIS routinely communicates and coordinates with other government entities to ensure a safe and secure food supply. With authority over meat, poultry, and egg products, FSIS plays an integral role in ensuring the safety of America's 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. Cooperation, communication, and coordination are absolutely essential to effectively address public health issues. I'd like to discuss just a few of the many examples of situations in

which FSIS has successfully partnered with other public health agencies to solve food safety issues and crises.

BSE Coordination

The December 2003 discovery of a single case of Bovine Spongiform Encephalopathy (BSE) in Washington State provides an excellent example of the strong communication ties and the cooperation between USDA and its Federal and State food safety partners. The Federal government's swift and substantial reaction to the BSE diagnosis played a vital role in maintaining high consumer confidence. FSIS and its sister agencies moved effectively and forcefully upon the discovery of a BSE case in this country, further strengthening already formidable BSE preventive measures. Being a part of the continuous briefings, planning meetings, international trade discussions, and all the other events surrounding this situation has helped ensure that the Federal government has been speaking with one voice on this issue and that food safety and security remain a central component of our actions. FSIS has worked closely with APHIS and other mission areas in USDA, FDA, State and local governments, industry, and consumers to ensure our BSE prevention and response measures are fully effective in the United States.

MOU with FDA

Since 1999, FSIS and FDA have had a Memorandum of Understanding (MOU) to exchange information on an on-going basis about establishments that fall under both jurisdictions. FSIS will continue to collaborate and partner with FDA and other agencies who share public health and food safety responsibilities. The Bioterrorism Act of 2001 (P.L. 107-188) further enhanced

this cooperation by authorizing FDA to commission FSIS employees to conduct inspection at dual jurisdiction facilities.

Public Health Service Commissioned Corps Officers

In addition to its partnerships with the White House and Federal agencies, FSIS has entered into a working relationship with the U.S. Public Health Service (PHS) and the Office of the Surgeon General. In April 2003, 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 will these officers help FSIS respond to foodborne disease outbreaks and assist in preventing foodborne illness, but they will assist in the agency's homeland security efforts as well. By working together, we will be able to better enhance public health.

Coordinated Research Efforts

Even within USDA, coordination and cooperation among agencies is vital. Because ensuring public health depends on sound scientific research, USDA's Agricultural Research Service (ARS) plays a critical role in assisting FSIS to achieve its public health and food safety goals. The research ARS conducts helps us to assess public health problems and to develop policies to reduce the risk of foodborne illness. For example, ARS' studies on the prevalence of *E. coli* O157:H7 were very helpful to us before we issued our *E. coli* O157:H7 policy initiatives last September. As another example, ARS' research studies are helping us to improve HACCP. By determining where contamination is likely to occur, we can then craft interventions that are effective in reducing contamination.

Northeast *Listeria* Outbreak

An example of the progress in coordinating efforts was an unprecedented investigation conducted with the CDC and State and local public health agencies on the Northeastern listeriosis outbreak that occurred in 2002. FSIS dispatched seven teams that also included State officials on September 25, 2002, to affected Northeastern States and used information provided by CDC to help target the collection of product samples. FSIS collected more than 400 samples of product and the environment for analysis in the course of the investigation. When it was first suspected that a turkey product caused the outbreak, FSIS took immediate, focused steps to identify plants that could potentially be the source of the contaminated product. Functioning as a true public health agency, FSIS spent an enormous amount of time and resources investigating this outbreak, including creating a team of more than 50 laboratory scientists, regional epidemiologists, Consumer Safety Officers, program investigators, compliance officers, field personnel, and headquarters management to work closely with CDC and State and local public health officials to locate the source. This investigation marked the first time that CDC staff participated as part of an FSIS food safety assessment team at an inspected establishment. CDC has publicly commended FSIS for its successful public health role in addressing this outbreak.

Training Partnerships

In 2001, USDA initiated a partnership with the Federal Law Enforcement Training Center (FLETC) in New Mexico to develop and provide training programs for FSIS employees. This training includes specialized safety courses specially designed for FSIS and an Instructor Verbal Judo Course designed to instruct them how to teach other employees how to better handle stressful situations they may encounter as part of their jobs. Most recently, an Assistant U.S.

Attorney and FLETC teamed up to provide training to 24 FSIS program investigators and managers on Federal judicial proceedings. The three-week course also included Leadership Training and Ethics for Law Enforcement Officers, sessions in Criminal and Civil Law and Advanced Investigative Methods and Techniques.

FSIS has also initiated a comprehensive two-year training and education effort designed to ensure that every FSIS employee fully understands their role in preventing or responding to an attack on the food supply. The Law Enforcement Academic Research Network (LEARN), which conducts the training, has stated that because it is being provided to such a broad base of our employees, this training effort is unparalleled in the Federal sector.

FSIS has a contract with Texas A&M University to train up to 150 Consumer Safety Officers. The four-week class covers scientific design of food safety systems, microbiology, utilizing scientific information, and report writing. The students receive three college credits from Texas A&M University.

USDA Partnerships

In addition to our partnerships with sister public-health agencies who have a stake in food safety and security, FSIS also works in coordination with other agencies within USDA. As a key component of the Department of Agriculture, the Food Safety mission area is able to ensure that food safety remains a priority during discussions of food nutrition, animal and plant health, marketing, research, and foreign trade programs under the purview of USDA.

Issues to Consider Before Altering the Current U.S. Food Safety System

In considering a single food safety agency, Congress must analyze the efficacy of the single food agency models in the countries that have adopted such paradigms, keeping in mind that the ultimate goal is to improve food safety and public health. We can re-configure the food safety system in an endless array of forms, but if food safety and public health is not improved, we have failed.

FSIS bases its policy decision on science, so the single food agency discussion boils down to one question: will there be a measurable benefit to public health? In other words, would such an effort save lives and reduce foodborne illness rates? As with any new food safety and security effort, we want to make sure that we maintain and continue improving on any progress that we have made to improve public health. We must make sure that any disruption to the current food safety system effectively improves food safety and public health. The data from countries that have consolidated their food safety agencies suggests that there is not a change in foodborne illness trends, and in some cases, the illness rates have increased, after the creation of a single food safety agency. As a scientist and a public health regulator, I strongly believe that our actions must have a positive impact on public health.

We must also consider the costs associated with any major overhaul to the U.S. food safety inspection system. As I am sure you are aware, consolidating multiple agencies is a monumental task, as can be seen in the examples of the recent creation of the Department of Homeland Security, as well as the creation of the Environmental Protection Agency in 1970. It is important to determine what the financial and human costs associated with a single U.S. food safety agency

would be, and to determine if this cost will best leverage funding for food safety. In addition, the effect such an effort may have on staffing numbers should also be considered.

Conclusion

We are proud of our accomplishments, particularly the declines in foodborne illnesses over the past few years, and must maintain and improve upon the progress that FSIS, FDA, and our food safety partners have made thus far. However, there is always more that can be done. As our food safety and security system continues to evolve, we must evolve with it. Our commitment to taking food safety and security to the next level is plain to see in the vision paper we released in 2003 titled *"Enhancing Public Health: Strategies for the Future."* This document is helping FSIS adapt to the changing needs of food safety and security and helping us ensure that our food safety and security system is capable of responding to and preventing foodborne illness and food hazards through the most effective means possible.

In conclusion, there are many outstanding questions to be addressed when considering fundamental changes (strikethrough: that may be needed) to the U.S. food safety system. FSIS is keenly aware of the sensitivity surrounding this issue, and particularly the viewpoint that the various agencies involved in food safety may cause confusion. We are also extremely concerned about not reversing the progress made in improving food safety and security thus far. FSIS is certainly investigating these issues and believes that before Congress decides to move further with any such initiative, these outstanding questions need to be seriously considered, researched, and answered.

Thank you for the opportunity to discuss our food safety and security program and our continued efforts in this area. We look forward to working with Congress to continue to keep the nation's food supply safe and secure and strengthen public health.

Ms. DAVIS OF VIRGINIA. Thank you, Dr. Pierson. I thank all three of you.

We are going to move now to the question and answer period, but I will say that we may very well be interrupted for a series of, I believe three votes. We may have to ask for your indulgence, to wait for us until we get back.

I will yield now to my ranking member, Danny Davis, for questions.

Mr. DANNY DAVIS. Thank you very much, Madam Chairwoman, and I want to thank the witnesses.

Mr. Dyckman, GAO has widely reported and talked about the high number of Federal employees that can be expected to retire over the next few years. What impact would these retirements have on our ability to protect the Nation's food services and to your knowledge, are the agencies, the U.S. Department of Agriculture and Food and Drug Administration, taking steps to address this probability?

Mr. DYCKMAN. Mr. Davis, we have not looked specifically at human resource management issues in the inspection service at USDA or at FDA. But it is my understanding that like other agencies, they face aging work forces and the stress of trying to train their employees, to keep their skill levels up, and to transition to a new work force. But we haven't specifically looked at the impact of the aging work force on the food safety agencies.

Mr. DANNY DAVIS. Drs. Brackett and Pierson both in their testimony talked about in 2002, the administration established a policy coordinating committee to look into the possibility of creating a single food agency, and it concluded that the goals of the administration are better advanced through enhanced agency coordination, rather than creating a single agency. Do you agree or not agree?

Mr. DYCKMAN. With all due respect, I can understand to some extent why the administration would do that. It is difficult to bring about change. Unfortunately, it usually takes a crisis in the food safety system. It might unfortunately take a health crisis, a larger outbreak of mad cow disease or foot and mouth disease or something of that nature.

Obviously, you can improve the effectiveness of any system where you have multiple operatives of you have improved coordination. But I think the question really should be, why do we have to rely on coordination just because we have players there? Why can't we reshuffle the deck and have a smaller deck, so we don't have to rely on one agency talking to another agency? The issue of coordination obviously is important. Over the years we have done some work that has questioned in some cases the effectiveness of coordination.

But I'm not here today to criticize FDA or USDA. I think I'm here today to talk about, does it make sense to have a single food safety agency. If we had to do it from scratch, if we just started today and we had to do it from scratch, would we create the existing organizational structure or would we create one agency.

Obviously, the short answer to your question is, I can understand how the administration would like to improve coordination and not embark on a new reorganizational structure. But I think for the long term and for the American people, it really pays to have one

agency look at food safety, for a lot of the reasons I outlined in my testimony.

Mr. DANNY DAVIS. Dr. Pierson, Dr. Brackett, why do you think that there appears to be so much resistance to, I mean, we know that agencies kind of grow up and take on roles and responsibilities that are perhaps a little different than if we were to start something from scratch or have the opportunity to just kind of say, we're going to create X to take care of these needs, and so no one, do you have any ideas about why there seems to be the reluctance to let something go and start something new?

Mr. PIERSON. As I stated in my opening comments, the baseline is protecting public health. That should be our main concern and consideration. We are certainly open and willing to have consideration, discussion, opportunities looked at in terms of how can we do what we're doing better, and again to enhance public health. So I don't think it's something that we're closed minded about it, but we're open to discussion and to further doing the best job we can possibly do. I think we're totally devoted to doing that.

I might also further state as an example, there was a tremendous undertaking in creating the Department of Homeland Security, and the President and Congress should be applauded for that just absolutely major undertaking and doing something very, very well and very successfully. In doing so, we still, in USDA and other agencies have to work in a collaborative way. And we do very, very actively work in a collaborative way to address our issues and to cooperate to assure that the security of the American public is protected from potential threats.

So the point I'm making is, if one creates a so-called single food safety agency, you still have to have collaboration and cooperation with other partners, other States, other governments, so on and so forth, in order to make that effective.

Mr. DANNY DAVIS. Thank you.

Mr. BRACKETT. Congressman Davis, I would like to also emphasize that the current structure results from the statutes that we must operate under. So even with the single food agency model, you would still end up having two systems, one governing meats, poultry and eggs, the others all the other foods. So again, the coordination, the communication between these different groups that would oversee those sorts of foods would still be critical, and as critical as they are right now.

Mr. DYCKMAN. Could I just add, I should have probably added that it's not our intent to just simply create a single food safety agency. And I agree with Dr. Brackett that doing that by itself wouldn't accomplish that much. What we're really talking about is looking at the underlying legislation, coming up with a single food safety model legislation that covers all food based on science or risk.

The other thing, and then, and you can even do that before you reorganize, and maybe you might find that it's not necessary to reorganize, you could just have a level playing field on the regulatory authorities of the agencies.

But I do want to add something interesting. In our full testimony we have a chart which shows that, we interviewed senior, very senior, and one of them will testify, former executives that worked at

USDA, even the former Secretary of Agriculture. It's funny, when you leave the position, frequently your ideology and your views on the subject change. I believe that on page 18 of our full statement, we indicate how these positions have changed. Most of the former executives that we spoke to do favor a consolidation.

Mr. DANNY DAVIS. Thank you very much, Madam Chairwoman.

Ms. DAVIS OF VIRGINIA. Thank you, Mr. Davis. We still have about 13 minutes. Mr. Deal, do you have questions you'd like to ask?

Mr. DEAL. Thank you, Madam Chairwoman.

Thank you, gentlemen, for being here. I think it's interesting to note, as you indicate in your surveys of these officials, they all agree on consolidation. We have the two heads of the two primary agencies here, and obviously there's always going to be the feeling and desire to protect what you already do, because you feel you're doing it well. And I notice your recommendation is not specific as to where that consolidation should occur.

Is it inappropriate for me to ask you, Mr. Dyckman, whether or not you have a preference from the GAO perspective as to what agency, if any, and I notice that only two of the ones you interviewed said an independent agency should be created for that purposes, which is a minority position. I think most of us who are interested in downsizing Government would say we don't need to create another agency.

Where would you think it would be most logically placed?

Mr. DYCKMAN. That's obviously an interesting question, one that I've given a lot of thought to. I've testified on this issue before and I've been asked this before. I hope I'm consistent in my answer.

First let me start off by saying there are advantages and disadvantages with creating it either in USDA or FDA. Our first preference would be an independent agency, but I recognize that creating another agency in this budgetary crisis that we find ourselves might be very difficult.

So if you don't create an independent agency, the issue is which of the two existing agencies. USDA has, in my opinion, more expertise, has more resources and possibly one could argue more experience. They do, however, have a downside. They promote agriculture. And one can perceive a possible conflict of interest. And I'm not suggesting that there is a real conflict of interest, but one can perceive that.

On the other hand, FDA, with a much smaller staff, one could argue that it is a health agency, and that's really what food safety should be about. So I could see transferring assets from one agency to another. The long answer is that I would lean, if I personally had to choose, toward putting it in FDA because it is a health agency and because it has, I think, more scientific knowledge and it is not a promotion agency, as agriculture is. But obviously that is a congressional decision.

Mr. DEAL. I would just make one further observation. One thing that all of your interviewees agree with is that there needs to be legislative reform, and I agree with that.

Mr. DYCKMAN. That is correct.

Mr. DEAL. I have some specifics that may be more appropriate in the next panel we'll get a chance to discuss some of those specif-

ics. Because quite frankly, what we have done with the legislative language in many cases is create a conflict between the agency that's required to certify food safety, we put barriers to their efforts to certify because of legislative language.

The organic industry is one that comes to mind right off the top, because we are on the one hand allowing it to be touted as safer than everything else, yet they are excluded from many of the inspection provisions that are required of others that produce main line products that are not labeled with a label that is giving the impression to the public at least is safer than other products. That I think is primarily a legislative problem that needs to be addressed.

I realize we have votes going on. Thank you, Madam Chairwoman.

Ms. DAVIS OF VIRGINIA. Thank you, Mr. Deal.

If you all will be patient with us, we have three votes. Hopefully we'll be back here around 4:15. But we will start the minute that I get back in here.

Thank you. With that, the hearing is recessed.

[Recess.]

Ms. DAVIS OF VIRGINIA. Gentlemen, thank you so very much for your patience.

Let me ask a few questions. Mr. Dyckman, let me ask you, would the consolidation of the food inspection activities result in any savings for the taxpayers?

Mr. DYCKMAN. In the short term, probably no. There probably will be startup costs. In the longer term, or the mid-term, particularly again if we could have one uniform risk-based legislative authority to cover food safety, I think we would be able to reduce some inspections on foods that are not as high risk. Because inspections, particularly some of the USDA inspections, are fairly expensive on a product by product basis. So we might be able to free up some of that inspection power and make it available for higher risk things, or to some extent, reduce expenditures.

But there are also other savings that can be achieved. You have regional office structures in two agencies, and some of them, I think on average are within 10 miles of one another. You have regulatory writing, you have enforcement, you have attorneys. I think there would be an economy of scale if you would combine.

We haven't done specific work to look at some of the savings. And as you know, Madam Chairwoman, we are continuing our review to look at some of these issues. Plus we're also doing a review for the Senate Agriculture Committee to look at the experiences of some of the other nations that have consolidated their agencies to see if they have tangible benefits, whether it's cost savings or reductions in illnesses or pathogen reductions.

So it's an appropriate question to ask. Right now I can't assure you that there will be cost savings. I believe I can assure you that there will be more effective regulation and you'll have a lot more latitude to spend the existing dollars that we spend. But I'm hopeful that there will be eventually cost savings.

Ms. DAVIS OF VIRGINIA. If we went the route of the legislation to make it more consistent as opposed to consolidating and making one agency, would there be a savings then?

Mr. DYCKMAN. There should be some savings, again, particularly in the inspection, reduction of inspections. If inspections were purely based on risk, and not on legislative requirements, there should be some. But obviously there are more opportunities if you can combine functions.

Ms. DAVIS OF VIRGINIA. Let me go to you, Dr. Pierson. Based on something that you said on there being a cost to reorganization, some believe that the status quo is acceptable in this system because there is communication between the various agencies with food safety responsibilities. But wouldn't the system be better served if you spent more time and resources on enforcement as opposed to communication?

Mr. PIERSON. No. 1, certainly we again are very open to consideration of a regulatory authority on how we carry out our responsibilities. Whether or not there would be specific cost savings relative to——

Ms. DAVIS OF VIRGINIA. I'm not even talking cost savings now, I'm talking, wouldn't we be better served if one or more agencies, depending on whether you want legislative or into one agency, wouldn't we be better served, the public, if we were concentrating on enforcement instead of worrying about FDA communicating with USDA?

Mr. PIERSON. Within our area of responsibility, of course, our main focus is in fact enforcement. And yes, there are certain areas where we do in fact have to specifically collaborate. I think these collaborations in fact, even though you might be under one structure, would still have to occur. You still have the boxes and lines and arrows to different areas, segments, etc.

So it would depend on how all this would set up. There would still have to be collaboration between these areas. We have that within our own structure within FSIS. Different specific areas have to communicate with those other areas and collaborate with them, our policy labeling staff relative to field operations, and other examples where we have to have that continuing interaction. But our overall goal of course would be to focus on the major resources. That's where our major resources are, is in the inspection side of our agency.

Ms. DAVIS OF VIRGINIA. I guess the one thing that concerns me on the whole issue of communication, and I think you guys are probably doing a very good job of that, please don't misunderstand me, I'm not attacking USDA or FDA. I'm just trying to make some sense out of where I know Congress has gotten us, not by any fault of yours. It's by piecemeal legislation.

But it's been said that when everyone's in charge, no one's in charge. I guess that's my concern, if we were to have some problem or something and there's no one official who's in charge of all the food inspection, responsibility gets scattered around to so many different agencies. How do you deal with that? How do you handle that? And that can be to any of you.

Mr. PIERSON. I think that we, through the collaboration that does in fact occur that responsibility is quite well relied on, and there are many examples. Dr. Lester Crawford, Acting Commissioner of FDA, we work with him very closely. We know who has responsibilities for different areas. Very specifically, the BSE issue that

occurred, I think we all very well realized our area's responsibility. It was really, I think an excellent example of a seamless interaction to address what was a major issue and to make sure that we maintain consumer confidence relative to the safety of this food supply.

But that effort took interaction between Animal Plant Health Inspection Service, Food Safety Inspection Service, the Center for Veterinary Medicine. So it was multiple mission areas. I think it worked in, as I said, a seamless operation where we really understood those divisions of responsibilities.

Ms. DAVIS OF VIRGINIA. I may come back with some other questions, but I want to get to our other Members here. Forgive me, but someone testified and said one of you was responsible for the dairy and so forth, but the other is responsible for the grain. How do you then reconcile what I said in my opening statement, one does chicken soup and beef broth and the other does chicken broth and beef soup? That doesn't fall in line with anything I heard. Where's the area of responsibility there? I guess I'm not even sure of the clear lines of responsibility, so I'm not sure how you all can keep it straight.

But I want to go on to the other Members now. Mr. Deal, were you finished before we left?

Mr. DEAL. Yes, but if you have second go-around, I'd like to ask one quick question.

Ms. DAVIS OF VIRGINIA. OK. Mr. Murphy.

Mr. MURPHY. Thank you, Madam Chairwoman. I'm really confused. Because your statement just about one does beef soup, another one does beef broth, and one does chicken broth, the other one does chicken soup, one does frozen cheese pizza——

Ms. DAVIS OF VIRGINIA. You didn't even get it right.

Mr. MURPHY. No, I didn't. [Laughter.]

The other one does frozen pizza manufacturing, meat pizza. Is there a difference between the level of job training requirements, education, anything between those who inspect cheese pizzas and those who inspect pepperoni or sausage pizza?

I didn't think so. When we talk about, how about beef broth and beef soup? Why do we have to have two different groups inspecting those?

Mr. PIERSON. I think in part some of this is something that has evolved over the years, quite frankly.

Mr. MURPHY. I'm a psychologist, and we always say, one of the definitions of insanity is doing the same thing over and over again, expecting different results. This seems to fit in that category.

Mr. PIERSON. Yes.

Mr. MURPHY. Let me go to a statement that you made, Dr. Brackett. You said, should a single food agency be created, there may be a request to reallocate 635 field personnel to newly formed agencies. Such reallocation would measurably diminish FDA's ability and efficiency to potentially address issues involving the safety and efficacy. Why would we have to reallocate 635 people, if they're needed?

Mr. BRACKETT. Congressman, I think the main reason why that would be necessary is actually, again, and a lot of this goes to the risk based, if you have a uniform inspection across all different

commodities, you would be taking from areas to put them in another one, as opposed to doing it with a risk based system where you are focusing specifically on those areas that are the highest risk.

Mr. MURPHY. But I don't understand why merging this into one agency would prevent you from making the kind of adjustments necessary to do it right. I don't think that's part of the discussion here, is everybody do the same thing one way. But I would think the discussion is still to allow enough flexibility so that you could do the job.

Mr. BRACKETT. It would be. And again, this goes back to my earlier statement about with the assumption that if you have the current statutory structure, you have all the meat, poultry and egg products with continuous inspection mandated as opposed to the FDA's laws, which require a risk based approach which is not continuous. So you still have those commodities outside of meat, poultry and egg products that do not have the requirement for a continuous inspection, together with those inspectors who must be in the meat, poultry and egg plants under——

Mr. MURPHY. Why can't you make that adjustment? Why can't we design it so—I think with some of these issues here, unless there's really an entirely different graduate degree required to inspect one thing versus another, can't there be some overlap and cross training of skills, someone could check a couple things at the same time, beef broth, beef soup, chicken and the eggs?

Mr. BRACKETT. Congressman, there are also cases where this is being done now. A good example might be a plant that produces a cheese pizza and a meat pepperoni pizza, in which we have an MOU with the FDA so that their inspectors are looking at everything. If they happen to see something related to the cheese pizzas, they have the authority to call us, we come in there, so they are eyes and ears——

Mr. MURPHY. Call you into what?

Mr. BRACKETT. To act upon the observations that they have made.

Mr. MURPHY. But they don't have the authority to take other actions, they can't simply say, there's something wrong with the cheese here?

Mr. BRACKETT. Or perhaps that it was produced under unsanitary conditions. But now with the new Bioterrorism Act, that will allow us to actually give them that authority, and we are looking into that possibility of doing that.

Mr. MURPHY. So they wouldn't have to call in another layer of bureaucracy. Yes, Mr. Dyckman.

Mr. DYCKMAN. Again, I want to emphasize that we're not calling for reorganization or consolidation first, without looking at the basic underlying statutes. I think your assumptions are correct, that it would make no sense to just reorganize with the same statutory legislation requirements, because that would tie up the flexibility that you would gain by a reorganization. So I think what we're talking about is looking at the enabling legislation, coming up with a uniform food safety piece of legislation, and then considering how best to reorganize.

Mr. MURPHY. Do we know what the level of administrative costs are of having these multiple agencies?

Mr. DYCKMAN. We have issued a report, it's several years old, that documents the costs of each agency. What we have not done is try to estimate what would be saved by consolidation. That's a little more difficult.

I might add that one of the countries that we will be looking at that did consolidate, they originally estimated, I think, a 7 percent initial startup cost, but they hope to save 13 percent in the midterm. So those are the types of things we will look at when we look at the foreign country experiences, so we might have some additional information on other countries' experiences with this issue.

Mr. MURPHY. That would be helpful. Thank you.

Ms. DAVIS OF VIRGINIA. If the gentleman would yield to me for just 1 second, let me just be clear on the cheese and meat pizzas. I think you said it depends, sometimes there's overlap if they did both at the factory. Do I take it to mean that you inspect it at the manufacturer, and if that's the case, I wouldn't think DiGiorno has a cheese manufacturing plant and a meat manufacturing plant, do they?

Mr. BRACKETT. No, they don't.

Ms. DAVIS OF VIRGINIA. Don't most of the frozen pizzas, don't they do them all in one place?

Mr. BRACKETT. Yes, Madam Chairwoman, they do that. But what I'm saying is those products that have a certain level of meat, that is, such as pepperoni pizzas, must be produced under continuous inspection. That is not the case with the cheese pizzas, which are under FDA authority.

The other point that I omitted to say about the FDA inspectors is they often do have multiple responsibilities, that they also may do drugs, devices, other FDA regulated products, in which case they would have to have significantly more education.

Ms. DAVIS OF VIRGINIA. I think you make the argument yourself for having one set of inspections. Because it bothers me a little bit that the cheese wouldn't be inspected very often but the meat is. You can do something to cheese as well as you could to meat, right?

Mr. BRACKETT. You could do something, and if it's intentional, that's a different story. But one of the reasons that we look at it this way, too, is risk based inspection. Cheese pizzas are typically not considered one of the higher risk foods, so it would not necessarily get the same scrutiny that another high risk product will. Whereas in the case of USDA, and I'll let Dr. Pierson talk, their product, they don't have a choice, it must be done under continuous inspection.

Mr. MURPHY. I feel better already.

Ms. DAVIS OF VIRGINIA. I'm glad you do, Mr. Murphy, because I don't.

Mr. MURPHY. I actually don't feel better.

Ms. DAVIS OF VIRGINIA. I thought you were being a little facetious over there.

Mr. MURPHY. I did get sick off a cheese pizza once.

Mr. PIERSON. That's correct, for meat and poultry topped pizzas, the type of thing that Bob is talking about, they would come under our authority, that's our statutory authority for inspection on that

particular case when our inspector has to be there at least one time during the shift, during the day at those operations. Slaughter operations, our inspectors have to be there continuously. So there's differences on that. But it's a presence each day in those operations.

Ms. DAVIS OF VIRGINIA. I've gone way over my time, but Mr. Dyckman's dying to say something.

Mr. DYCKMAN. Yes, I really don't want to pick on the frozen pizza industry, I love pizza.

Ms. DAVIS OF VIRGINIA. It's the easiest one to talk about.

Mr. DYCKMAN. Right. But I think their most substantive issues in terms of the whole issue of whether meat has continuous inspection or should it have continuous inspection or not. But another issue, you asked about overlap and duplication in general. Let me give you an example. Both USDA and FDA did risk assessments because of bioterrorism and the like. And they did them independently. Both agencies issued guidelines to the industries that they regulate in terms of how to protect for security issues. And they did those independently.

And those are the types of issues that I think we're also talking about in terms of a scale of efficiency that would be appropriate and would be achievable if you had one agency.

Ms. DAVIS OF VIRGINIA. I started something here. Dr. Brackett.

Mr. BRACKETT. Thank you, Madam Chairwoman. The point I'd like to make, or correction for the record, which is that the vulnerability assessments at USDA and FDA were done collaboratively, sitting down together, going through the whole thing. The guidance documents were done separately, because again of our constituencies and our knowledge of the particular commodities. So USDA had one set for meat and poultry and FDA had some for our commodities. But that was mainly a means of communicating to our regulated constituency.

Ms. DAVIS OF VIRGINIA. Thank you. Mr. Van Hollen, I will yield to you for questions.

Mr. VAN HOLLEN. Thank you, I'll just wait to hear the next round of testimony.

Ms. DAVIS OF VIRGINIA. Mr. Davis, do you have any other questions?

Mr. DANNY DAVIS. Well, I do indeed, thank you, Madam Chairwoman.

Dr. Pierson, I know that Mr. Glickman, former Secretary of Agriculture, is going to testify on the next panel that due to a lack of resources, products in FDA's regulatory system do not undergo as thorough an inspection process as products under the U.S. Department of Agriculture's jurisdiction. My question is how would coordination efforts address these concerns? And would Mr. Glickman's concerns be better addressed if one entity had the resources and responsibilities for all the inspections?

Mr. PIERSON. I think it all boils down to, again, the issue of statutory authorities. What Congress has passed is the acts under which we operate. Those provide that basic difference, basic differences between what FDA does and how they carry out their functions and what we do as FSIS. There are just certain fun-

damental requirements there for our continuous inspection and our continuous presence.

Mr. DANNY DAVIS. But would not the products require as much review or as much inspection? What we say is, because of their statutory authority——

Mr. PIERSON. I think what you're driving to is what you would call a risk based inspection system. That's something that we're working on very hard, how to prioritize those risks and where do we best place the resources in that food system. And so we were of course identifying what are the risks, and at what point should these risks be best controlled. So we want to redeploy the inspection force such that we do address those priority issues. Certainly we need to collaborate as the laws now exist with FDA in those priorities.

I'll give you an example, the risk ranking that was done in collaboration with FDA for listeria monocytogenes. And we addressed those areas with the highest risk, and for instance on our part specifically passed a regulation that addressed listeria monocytogenes and its control in ready to eat meat and poultry. As a matter of fact, our regulatory compliance sampling as a result of that has shown significant reduction in terms of positive ready to eat samples for listeria monocytogenes.

So it's an example of where yes, there's collaboration and we did our risk ranking and identified where the greatest risks are and placed resources in that area. The type of model I believe you're driving at is the same thing or the same direction we should be going to. That's where we're headed.

Mr. DANNY DAVIS. Thank you very much, Madam Chairwoman. I have no further questions.

Ms. DAVIS OF VIRGINIA. Thank you, Mr. Davis. Mr. Deal.

Mr. DEAL. Thank you, ma'am.

Mr. Dyckman, in your report you talk about the area of claims of health benefits. And you point out that both FDA, USDA and the Federal Trade Commission all have that certifying responsibility to varying degrees. I assume that's a function that you would also recommend be consolidated, and if so, do you have a preference as to where that consolidation should occur?

Mr. DYCKMAN. I think it would follow the same lines as where the inspection activities would be consolidated. The issue there is again, different legislative responsibility, different legislative authorities. When we did our report on functional foods and dietary supplements, we found again big differences between the legislative authorities that each agency has, and that accounts for the differences in the quality of or the types of claims that different products can make, whether it's a dietary supplement, whether it's a food, whether it's a functional food.

So I would say that it would still follow wherever the inspection activities would go, that agency should have the lead on that as well.

Mr. DEAL. The reason I think that is a little more difficult question is that there are certain certifications both at the production level and at the processing level. If you're only at the tail end of the system, it's pretty hard to verify the claims that are inherent in the production phase of it.

Mr. DYCKMAN. No question about that. And the inconsistencies that we found relate to the testing evidence that has to be presented by the manufacturer depending on the type of product that's involved.

Mr. DEAL. Let me go to the border situation. We do have the border agency now that has that responsibility, I believe USDA still continues, and I presume FDA has some responsibilities there, too. Is that a function of border inspection that could be consolidated? It appears to me that there could be some consolidation. Does it make a difference whether the product that is coming across the border is in the process stage versus the unprocessed stage, and how would that kind of consolidation end, under what agency would it take place?

Mr. DYCKMAN. Representative Deal, you're getting into a line of questioning that is appropriate, but we haven't done the work to look at all the different factors. Obviously border inspections are different than food inspections at a plant. It could very well be that, and Homeland Security has responsibilities as well. So there's another agency involved.

I don't have the short answer for that question in terms of which is the most appropriate agency. It could be that the responsibilities, if you only take the inspection in food processing facilities and consolidate that, it could very well be that we might decide to leave some other responsibilities with the current agencies.

Mr. DEAL. This is my final point. The difference between standards of production and standards at the processing stages, we have some legislative problems there, and I've used the organic industry as an example. And I think it's a classic example where we, through the Organic Standards Board, have given them authority to set certain standards. But they are basically self-certifying, no pesticides, no commercial fertilizers, no GMOs, etc. But they have their own certifying agencies.

We found, as I was looking into it, a dairy farmer whose wife was his certifying agent, that he had complied. And if there is no testing at the processing stage to verify the things that are inherent in the production requirements, there is a huge inconsistency and I think quite frankly a misleading of the public and perhaps even some safety factors that ought to be considered.

So it's not a simple issue, and I think it does require a comprehensive review of everything that we have out there. Once again, a piecemeal approach may not produce us any better results than our piecemeal approach we currently have.

Mr. DYCKMAN. I agree with you. What I would hope though is that at some point, and it might occur next month, next year or in 5 years, that the Congress decides, well, the current system is not the best system, so let's begin. We have to begin somewhere. Let's put together a panel that is not going to decide whether or not we will consolidate, but how do we go about consolidating, what is the best way to revise and to restructure the current system, which is clearly a patchwork system.

Mr. DEAL. Thank you, Madam Chairwoman.

Ms. DAVIS OF VIRGINIA. Mr. Murphy, do you have any other questions?

Mr. MURPHY. Yes, I just want to followup on an area that has to do with how information is shared between all the agencies. For example, are there alerts or communications and training that takes place between the agencies, so people are going through the same training processes, or does everybody have their own, with training on how to do inspections? Any crossover there?

Mr. DYCKMAN. I'll let FDA and USDA respond.

Mr. BRACKETT. Thank you. Well, as I mentioned earlier, because our inspectors do have multiple authority, they do get specialized training. And it may be different than that for USDA, and I'll let Dr. Pierson talk about that. Because each of these commodities takes a special knowledge.

But we do communicate directly, calling each other, we know each other, when we have issues, we share them. We also serve on committees together to look at the scientific basis and the risk rankings for the different foods. And in fact, Dr. Pierson and I, Dr. Pierson is chair and I'm vice chair of the microbiological criteria for foods, in which we both use the scientific knowledge and share the scientific knowledge and issues with each other in deciding on what we're going to do.

Mr. PIERSON. The training that we provide for our inspection force is of course very specifically designed to inspect relative to the meat and poultry as well as egg product inspection acts and the regulations that we promulgate based relative to those acts. Those would be fundamentally different, of course, than under the Federal Food, Drug and Cosmetic Act. So you have to train according to those requirements, that's one.

There are some basic principles, quite frankly, that are similar, such as in the hazard analysis critical control point concept that's used for food safety management.

Mr. MURPHY. Is that training done together, between agencies, or is that separate?

Mr. PIERSON. No, because they are under the USDA, FSIS, all meat and poultry plants must have developed and implemented HACCP systems. And these HACCP systems, this rule as promulgated is of course relative to our authorities, too. Whereas FDA, Bob could speak to it relative to seafood, for example. So there are some differences relative to the basic approach to inspection. There are commonalities.

Let me mention if I could briefly, where you have this dual jurisdiction issue that our inspectors are trained on those overlap areas.

Mr. MURPHY. That's important to know, that they're capable of doing that. Also, is there any sharing of computer information files, data back and forth between agencies? Are the computers compatible in communicating that information back and forth between all these agencies?

Mr. PIERSON. As far as our inspection activities, because of the different approach, I think we don't have systems we share such as that. But we do in fact, when we work, for example, on risk assessments, collaboration on risk assessments, we would share back and forth.

Mr. MURPHY. But you have to share then in terms of producing a report, and that has to then, or I'm thinking, when you're dealing with, whether it's the feed or beef and poultry and also with the

grains and etc., whether it's in the early stages or it's in the processing, that if there's information that comes across in terms of risk alerts or management or training issues, that those would be shared across all agencies. Does that happen or does that not occur?

Mr. PIERSON. Certainly in issues, we definitely notify one another. I was thinking of an example, for instance, in the school lunch programs. If in fact there is an issue that might occur, there's a Food and Nutrition service under which there's a responsibility. We work very closely with Food and Nutrition Service if in fact there's an unfortunate event of a food-borne disease outbreak.

In fact, we then will work in collaboration with FDA when those involve potential FDA products. So there has to be a seamless operation to immediately share that information such that FDA is well aware of what's happening. As a matter of fact, we end up doing that, too, very closely in working with States.

Mr. MURPHY. Given that, it just seems to me to solidify the idea that if everybody's on the same mission and you begin to at least have some ways of communicating between folks, I still don't understand why we need different agencies to do it. Dr. Brackett.

Mr. BRACKETT. Thank you, Congressman Murphy. We do have, and are looking toward actually sharing real time data. For instance, in the President's budget there is a laboratory reporting network system known as E-Lexnet that is going to serve as the platform for both USDA as well as FDA and State laboratories. So we are cognizant of that, we are working toward that end.

Mr. MURPHY. Thank you, Madam Chairwoman.

Ms. DAVIS OF VIRGINIA. We're going to move on to the second panel, but I just want to leave Dr. Brackett and Dr. Pierson with this last question. If you were to design our food inspection agency today, would you use the system that we have today? If not, why not?

Mr. PIERSON. Coming from an academic background, that's like a prelim question.

Ms. DAVIS OF VIRGINIA. Yes, it's sort of a loaded question.

Mr. PIERSON. Thank you very much.

Before I came to USDA, I thought, gee, wouldn't that be nice to consolidate it into a single agency. But after experiencing the Federal Government and the Federal Government process and the agency, I'm not trying to avoid you, Madam Chairwoman——

Ms. DAVIS OF VIRGINIA. Sure you are, but it's OK.

Mr. PIERSON. But anyway, what I come out with is that before we just jump into such a thing, before we consider such a thing, we have to make darned sure what we're doing is the right thing, that we're protecting public health. And whatever that system might be, I think we have to build it upon assurance of public health and the outcome, if it's a single agency, if it's such as we have now, if it's redoing the acts, let's go one of those directions, let's pursue one of those. But let's not just jump into it without giving very careful thought and attention.

Ms. DAVIS OF VIRGINIA. I don't think you'll have any argument from me. I'm not one to want to jump into anything.

Mr. BRACKETT. Madam Chairwoman, I agree with Dr. Pierson. The critical thing is to maintain public health and to continue hav-

ing the safest food system in the world that we do have now and we do enjoy. A single food safety system or one involving several different agencies or a number of different agencies are two different models that one could use. I think it would take a complete fore-thinking of what we would be losing with the current system versus what would we be gaining, the underlying statutes as we mentioned earlier, to be sure that we don't lose public health, that we don't lose public trust.

Even though we have a number of different agencies involved now, I prefer to think of it less as a fragmented system and more as a tapestry.

Ms. DAVIS OF VIRGINIA. With that, gentlemen, I want to thank you all for your patience and your understanding, for being here today, and I hope we didn't grill you too much. I'm sure we'll have other questions as time goes on.

I'd now like to invite our second panel of witnesses to please come forward to the witness table. First, we will open with a statement from the Honorable Dan Glickman, former Secretary of Agriculture and Member of Congress. Then we will hear from Carolina Smith DeWaal, Director of Food Safety at the Center for Science and Public Interest. I want to thank you two, as well, for being so patient.

STATEMENTS OF DAN GLICKMAN, DIRECTOR, JOHN F. KENNEDY SCHOOL OF GOVERNMENT, HARVARD UNIVERSITY, AND FORMER SECRETARY OF AGRICULTURE; AND CAROLINE SMITH DEWAAL, DIRECTOR, FOOD SAFETY, CENTER FOR SCIENCE AND PUBLIC INTEREST

Mr. GLICKMAN. Thank you, Madam Chairwoman. Let me say that I spent 18 years in this body——

Ms. DAVIS OF VIRGINIA. So you understand.

Mr. GLICKMAN. And I also spent many times in this room, many hours in this room, which the Judiciary Committee has some of their subcommittees operating under at times. So to all of you here, Mr. Murphy who I don't know, Mr. Deal, who I did serve with, Mr. Davis, Mr. Van Hollen, it's a pleasure to be here.

As you know, now I'm at Harvard, not because I could get in, because Mr. Van Hollen was a good predecessor of mine, but I run a program there at the Kennedy School. I'm a little bit probably less partisan than I used to be. But this has been a terrific hearing. I think everybody has asked amazing questions. One of the best hearings I've ever heard on food safety, and it's a pleasure to be here with my friend, Caroline Smith DeWaal.

Let me just make a couple of comments. One of the big issues here is resources. USDA has all the resources. FDA has a pittance of resources. The truth of the matter is, one of the problems is that they have probably, USDA has probably more resources per problem than FDA does. So we have a mis-allocation of resources in terms of these issues.

One of the first things I would recommend to you is that should be a, the allocation of resources in food safety should be done on the basis of a comprehensive, qualitative and quantitative risk assessment. Mr. Murphy talked about this. To my knowledge, that has never been done. Who does what in the Federal Government

on food safety? What kinds of resources do they get, and what kinds of public safety protection is there in there?

Until you get to that question, you can't really decide how you want to reorganize this stuff. We can talk about pizza and chicken broth until we're blue in the face. But quite honestly, the real issue is the threat to the American people from contaminated and infected food. We have never done that kind of assessment to figure out where the threats are, where the resources are. Maybe we have mis-allocated them dramatically. I suspect that we have. And that's one of the things that maybe, I think that will take some legislation to do that. But that's something I would recommend to you.

The second thing is, I believe that we need to consolidate desperately. I was Secretary at a time when we went through the HACCP program, we had a lot of food safety problems, it was after the Jack in the Box situation, it was before the BSE issue, which by the way I think my successor has handled very, very well in quelling any kind of fears out there.

But you know, H.L. Mencken once said, for every complicated problem there is a simple and a wrong solution. I would like to tell you that this problem is simply solved by just creating a single food safety agency. But what happens to issues like GMOs which may be safety related or may be trade related? Sanitary and phytosanitary barriers of other countries, hormones, antibiotics. There are a whole litany of problems there that I suspect while we might be able to get a consensus in this room that are food safety related, out in the country side and among the constituency groups, I don't think you could do that.

On the other hand, if we were to start the system up today as I think Mr. Davis and you, Congresswoman, suggested, it would never look like the system we have today. So let me tell you where I think we ought to start. We ought to start with the inspection functions. We have 10,000 or so inspectors in the USDA or FSIS employees and about 10 percent of that at the FDA. We have a mis-allocation of inspectors.

One of the things I recommend you do is you look at this inspection force of food and we try to consolidate that inspection force. Mr. Murphy talked about cross training. We don't do any cross training to speak of, really quite honestly it's very nominal. And we could, as a first step toward consolidation, we could begin the process to cross train and cross deputize food safety employees so that they could do the various functions either at the border or at the meat and poultry plant or at an egg plant, or at a pizza plant or wherever else it is.

I suspect what you're going to find is that people are not necessarily, and the resources are not necessarily always where the threats are.

Now, to do what even I'm talking about is no simple task. There are an awful lot of people who have a stake in the status quo, and don't want any changes in the system whatsoever. Some employees, some companies, there are people who think the system is just fine the way it is.

But we are bound to face more serious food safety threats in the future. Where I think you need to go down the road is to allocate and focus your attention on what are the most serious food safety

threats, which are both naturally occurring, whether it's salmonella, e coli, listeria, campylobacter, all of the basic threats that we know people get, whether it's the unnaturally occurring, terrorist type or insidious type of activities, both in terms of internal processing plants and at our borders. And then focus on what resources are there necessary to employ enough inspectors at every one of these places of high vulnerability and cross train them, cross deputize them, and they're probably going to have to ultimately be subject to one agency or a lead agency in that process. Whether that's USDA or FDA or somebody else, I think that's the main road.

If you wanted to really start out, if you really wanted to protect the public interest, that's where I think you have to protect the public interest. Because if you have an inspection problem in south Florida, or on the border in North Dakota or some place else, and you don't have any FDA inspectors there or far too few USDA or some Homeland Security inspectors, and you want to get some others who are more in surplus positions, we can't do that right now. We can't cross deputize.

Now, the States and the Federal Government have some memorandum of agreement, but I must disagree a little bit with both speakers who were here today. The truth of the matter is, there is no seamless structure between the agencies. Everybody does their job the best they can. And by the way, most do a good job. Most of the employees are really hard working and doing their best. But there is not seamlessness there.

Let's look at the recent BSE crisis, which was handled very, very well. When there is a crisis at a national level, the agencies can usually get together pretty well. But on the day to day threats that occur, those are the problems that really worry me very, very much. So I would suggest that you look at the inspectors, focus on trying to consolidate their functions and if necessary, make the statutory changes to do that, to give them the authority to, and this is going to take a few years, this is nothing that's going to happen overnight.

And probably not get too hung up on one single food safety agency that you're going to end up with every trade problem in the history of the world, every export-import problem, all sorts of things that are perhaps not classic trade problems that we're going to find in that category because of turf battles here in the Congress, because of problems with industry and employee groups are really never going to get solved.

One final point I would say is this, and again, I would say, I think there have been better questions raised here in this hearing than I have heard in all the years that I was in USDA on this particular point. I would encourage you as members to be, one thing that always struck me about FAA is the oversight over FAA and the airline industry was impeccable in this country. Because one accident occurs and it's absolutely catastrophic usually. Not to mean that it's not perfect, and the accidents have produced what I call a better Federal oversight over safety issues. Even with airlines that are in problem areas financially, you don't really worry about the fact that they're not doing the work that needs to be done.

And I would encourage you in the Congress, and I encourage the White House to give this matter of food safety oversight continuing attention and not just when there's a BSE crisis. Because I'm telling you, that's what happens here.

I don't know if they kept it up, during the Clinton administration, we had the President's Council on Food Safety, which had all the various agencies that would meet periodically. I don't know whether that has continued to meet or not. It should. And it ultimately may be that the President is going to have to designate an agency to kind of be in charge, at least on paper, of all these kinds of situations.

But I would also encourage the White House to have this constant level of engagement. These people are trying to do the best job that they can. Unfortunately, they couldn't answer your last question because it was a political question. If I were them, I would be scared to death to answer that kind of question as well.

Ms. DAVIS OF VIRGINIA. I didn't expect them to answer it.

Mr. GLICKMAN. But what you've done is you've raised very, very good questions. This is a complicated issue. The science is evolving, the threats are evolving, the pathogens are evolving. They're even becoming more virulent all the time. And what you need is an inspection force, at least initially, it's a little bit like the armed services, we need an inspection force that's ready on the ground to protect the American people against the most basic threats there are. Then you move out after that to try to deal with perhaps some of the more comprehensive type problems.

Thank you.

[The prepared statement of Mr. Glickman follows:]

MEMORANDUM

To: Congresswoman Jo Ann Davis, Chairwoman Subcommittee on Civil Service and Agency Reorganization, Committee on Government Reform

From: Dan Glickman, Secretary of Agriculture

Date: March 29, 2004

Re: Hearing on "A System Rued: Inspecting Food" March 30, 2004

The following is a summary of my oral comments to be given at the aforementioned hearing.

1. Generally speaking, there is positive confidence by the public in the safety of the food supply, but the current system of federal regulation of food safety is complicated, cumbersome and not suited to the threats of modern times. The inspectors do a good job, but while meat and poultry are generally well regulated by USDA's multi-million dollar regulatory system, other products, largely under FDA's regulatory system, do not undergo as thorough an inspection process because of lack of resources.

2. Starting a legislative review from bottom up in this area is important and would probably result in recommendations for a significant consolidation of food safety federal regulatory and enforcement function. Unless, however, there is a substantial and long term commitment from the White House and key congressional leadership to support fundamental changes, the turf battles which inevitably will result from food safety consolidation make it nearly impossible to accomplish these changes in the foreseeable future. Frankly, a more radical and comprehensive re-structuring of these agencies would be the appropriate action but, barring a catastrophic food safety event affecting large numbers of Americans, it is doubtful that a political consensus could be reached among the various constituencies and interest groups to give Congress and the White House the political support they will need for such consolidation. Furthermore, the creation of the Department of Homeland Security no doubt creates a disincentive for the Congress to make fundamental changes in the short term.

3. Yet fundamental changes in our food safety system are needed to meet the evolving threats which now include the risks of bioterrorism to the food supply. At a minimum, the agencies involved need the statutory authority to better leverage and deputize the employees of other agencies. For example, USDA has its agencies (APIS, AMS and FSIS) at the border. Since FDA lacks sufficient border inspections, authority should be given to cross-deputize USDA inspections (and vice versa where relevant and appropriate). In my experience, FDA has been typically amendable to partnering with states in this fashion, but has generally opposed it on the federal level. Given the resource and political pressures that limit how much FDA or USDA will get from Congress, at a minimum there should be this kind of flexibility provided to the respective federal agencies, and their employees should be cross-trained to perform these functions, as relevant.

4. The allocating of resources in food safety functioning should be done on the basis of a comprehensive qualitative and quantitative risk assessment, which in my judgment, is still lacking and needs to be done. These assessments will probably lead to the conclusion that significant addition financial resources are necessary to carry out federal food safety functions.

5. Oversight over imported food, particularly in light of the recent BSE scare in Canada and the U.S., demand harmonization of agency inspection and enforcement procedures by the various agencies as quickly as possible. While the Federal Government by and large did a very professional job in handling the recent BSE crisis, it is reasonable to assume that with the additional testing of animals recently announced by the USDA, there may be more reported cases in the future. Our national system must be able cope with this and similar problems on a comprehensive and timely basis in order to ensure both a safe food supply and maintain high levels of consumer confidence in our food systems safety. The anticipation of future food safety threats, both from naturally occurring events as well as arising from criminal of terrorists activities, need much greater continuing attention from all federal agencies.

6. Both the White House and Congress must give much greater operational and oversight attention to the problems of food safety. In my experience, too little focus occurs in either the Congress or the White House barring a major case of BSE, or an epidemic of other food born-illness. The current oversight process is almost exclusively crisis driven. At times, some in the industry have, in my judgment, been very reluctant to give the federal agencies additional authorities they have needed to perform their missions to deal with additional threats. For example, we still do not have overall comprehensive statutory authority for mandatory recall of contaminated food products. While their concerns should be heard, the industry is the most vulnerable when public confidence in food safety is threatened. An active and engaged congressional and White House oversight

process can prevent future food safety problems, maintain consumer confidence, and insure the financial health of the industry.

Dan Glickman, former U.S. Secretary of Agriculture, is currently the Director of the John F. Kennedy School of Government at Harvard University. He is also a Senior Advisor at the law firm of Akin Gum Strauss Hauer and Feld. The views expressed herein are Mr. Glickman's personal views.

Ms. DAVIS OF VIRGINIA. Thank you very much. We appreciate all your insight and all the years that you were here to learn.

Mr. GLICKMAN. Sometimes those years don't give you insight. But I got the chance to say it anyway.

Ms. DAVIS OF VIRGINIA. When you get outside, you get the insight. [Laughter.]

Ms. DeWaal, thank you for your patience and you're now recognized for 5 minutes.

Ms. DEWAAL. Thank you so much, and it's so hard to follow former Secretary Glickman.

I'm director of food safety at the Center for Science in the Public Interest. I'm also a constituent of Representative Van Hollen, and I really appreciate the opportunity to testify today.

CSPI is supported by 850,000 subscribers, and we have no either Government or industry money, which means our views can be very independent. I've been monitoring this issue since 1997 and have been involved in the issues of food safety for well over a decade.

Nearly 100 years ago, Congress passed the food safety laws that form the basis of Government food inspection. Today, two Government agencies inspect the food supply. USDA checks meat and poultry processors daily, including inspecting each individual carcass, meat or poultry carcass, individually. FDA meanwhile has authority for all other food products, including many other high risk products, like seafood, fresh fruits and vegetables and raw eggs, but manages this mandate on a shoestring budget.

In 1997, the huge resource imbalance between FDA and USDA led CSPI to call on Congress to cerate a single, independent food safety agency, so that the Government could apply resources more equitably to all the foods that pose the greatest risk to the public. In 1998, the National Academy of Sciences published a report that also called for consolidation of food safety responsibilities under a single statute with a single budget and a single leader. This report, entitled, "Ensuring Safe Food from Production to Consumption," concluded that, "The current fragmented regulatory structure is not well equipped to meet current challenges."

Here are just a few examples. Food safety problems that start on the farm often fall through the cracks completely of agency jurisdiction. The same food processing plant may get two entirely different food inspections as we have seen with the pizza example. Quality inspections sometimes occur more frequently than safety inspections, as happens in the egg industry. New food safety programs like HACCP are implemented completely differently at USDA versus FDA. And multiple agencies may prolong the time that it takes to bring the benefits of new technologies to the consumer.

Let me highlight a few other examples. One is that the coordination with the State agencies that handle food safety is literally a nightmare. State laboratories that analyze food samples for chemical or microbiological contamination, which are critical in our fight against bioterrorism, for example, these labs have complained about the lack of uniform testing methods and about inconsistent reporting requirements with the Federal agencies. They have to provide samples to USDA, FDA, CDC and EPA.

And under the current structure, imported products are treated completely differently if they're regulated by FDA, which just does a border inspection and USDA, which actually goes to the country, they approve the program, they approve each individual plant and they check 20 percent of the meat or poultry that's crossing the border.

In a global marketplace, other countries are moving quickly to modernize their food safety programs. And the United States is falling behind, literally, when it comes to having a modern food safety statute and mandate. Numerous countries have already created unified food safety agencies that cover the entire food supply. And in Europe, especially, this effort was driven by the BSE crisis.

It's clearly not news to anyone that statutes designed when the model Ts were being driven are not suited to address modern hazards. But make no mistake, if the terrorists were to strike the U.S. food supply, consumer confidence in the Government's fractured food safety programs would plummet as far as confidence in airport security did following September 11th. Even Dr. John Bailar, the chairman of the National Academy of Sciences Committee calling for a more unified food safety structure, said "When bioterrorism is added to the mix, the case for prompt and sweeping change becomes compelling. While additional tinkering with the details of our food safety system might be helpful, the consolidation of responsibilities, authorities and resources for food safety into a single high level agency is critical."

Today, a unified agency operating under a modern food safety statute is truly an issue of national security. Thank you.

[The prepared statement of Ms. DeWaal follows:]

Statement of Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest

At the House Committee on Government Reform
Subcommittee on Civil Service and Agency Organization
"A System Rued: Inspecting Food."

March 30, 2004
Washington, D.C.

My name is Caroline Smith DeWaal, and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 850,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants. We accept no government or industry funding.

This past November, imported produce was implicated in one of the nation's most devastating outbreaks of foodborne illness. This provided more proof that the system to protect consumers from unsafe food is falling far short of its goal. Green onions imported from Mexico were the cause of this fatal Hepatitis A outbreak in Pennsylvania. What started out as a regular trip to a chain restaurant resulted in crippling illnesses for hundreds of individuals. At least 555 people fell ill and 3 people died from consuming the tainted produce. The outbreak sickened not only hundreds of Pennsylvania residents, but also restaurant employees and residents of six other

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Executive Director

states.[1] Beginning in August 2003, green onions imported from *the same farm* in Mexico had caused outbreaks in three other states.[2] These earlier illnesses provided a crucial warning that was ignored until it was too late.

The Food and Drug Administration (FDA) is responsible for ensuring the safety of many imported foods, such as the onions implicated in this Hepatitis outbreak. At a hearing of the House Appropriation Committee's Subcommittee on Agriculture on March 11, 2004, Lester Crawford, acting commissioner for the FDA, stated: "The FDA is overwhelmed by imports, which have increased fivefold since 1994." Due to FDA's lack of resources, a mere one percent of imported food is inspected. Crawford went on to state, "It's difficult for us, and we are missing the mark, but we pledge to do better."

Since 1999, CSPI has been compiling outbreak data from a variety of sources, organizing it by food group, and publishing it in a booklet called *Outbreak Alert*! In CSPI's *Outbreak Alert!* 2004 database, which summarizes 3,529 outbreaks, FDA-regulated foods, like seafood, produce, and eggs, were the largest contributor to foodborne illness outbreaks.[3] That is, 67% of all outbreaks in the database were caused by foods regulated by the FDA; the remaining 26% were caused by foods regulated by the USDA (meat and poultry products); and 7% were caused by foods regulated in part by both agencies. However, when examining the corresponding proportion of the federal budget allocated to these agencies, the paradox is apparent. The FY 2004 budget summaries show the U.S. Department of Agriculture (USDA) is allocated $899 million to keep the food supply safe, more than twice as much food-related funding as the FDA, at $413 million.

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[1] Dato V et al, *Hepatitis A Outbreak Associated with Green Onions at a Restaurant- Monaca, Pennsylvania, 2003.* Morbidity Mortality Weekly Report, November 28, 2003 /52(47);1155-1157

[2] Boodman S, *Raw Menace: Major Hepatitis A Outbreak Tied to Green Onions.* The Washington Post, Tuesday November 25, 2003.

[3] *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net.* Center for Science in the Public Interest. Updated and Revised March, 2004. CSPI, Washington, D.C.

In 1997, the huge resource imbalance between FDA and USDA led CSPI and other consumer organizations to call on Congress to create a single independent food-safety agency, so that the government could apply resources more equitably to all the foods that pose the greatest risk to the public. The National Academy of Sciences (NAS) published a report in 1998 that called for the consolidation of food-safety responsibility under a single statute, with a single budget and a single leader. This report, entitled *Ensuring Safe Food From Production to Consumption*, concluded that the "current fragmented regulatory structure is not well equipped to meet the current challenges."[4] CSPI has documented many gaps and weaknesses that support the NAS's conclusion:

Under the current structure, food-safety problems that start on the farm often fall through the cracks of agency jurisdiction. No federal agency today is responsible for overseeing food safety at the production level. While the Animal and Plant Health Inspection Service (APHIS) can quarantine farms and ranches due to disease outbreaks affecting the animals or plants, as they did recently to control BSE, the agency has no authority when it comes to human infections that originate in live animals or plants. At FDA, lettuce and other fresh vegetables and fruits are essentially unregulated for safety. While FDA published guidelines for farmers, these guidelines are legally unenforceable.[5] The use of animal manure on food crops is also not controlled, even though USDA, FDA, and EPA have jurisdiction over various farm practices. These are just some of the problems that fall through the cracks of the current system.

Under the current structure, multiple agencies fail to address glaring public health problems. Eggs are regulated both by FDA and USDA, but neither agency has developed an

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[4]Institute of Medicine, National Research Council, *Ensuring Safe Food From Production to Consumption.* (Washington, DC: National Academy Press, 1998), p. 12 [hereinafter cited as *Ensuring Safe Food*].

[5]US Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Guidance for Industry. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. (Washington, DC: US Food and Drug Administration, October, 1998).

effective containment strategy to prevent the spread of *Salmonella* Enteritidis (SE) in shell eggs. It took an agreement among three cabinet level officials to announce the Egg Safety Action Plan in 1999, but since then, little has changed. No agency has published regulations to require on-farm controls that could largely eliminated the *Salmonella* that infects eggs, sickening hundreds of thousands of consumers each year, and causing over 300 deaths. Today, nearly twenty years since SE inside eggs was first identified as a public-health concern by the CDC, consumers still await an effective strategy to eradicate SE in shell eggs.

Under the current structure, the same food-processing plant may get two entirely different food-safety inspections. The classic example is a processing plant that produces both pepperoni and cheese frozen pizzas. The pepperoni line will get daily visits from a USDA inspector to check on conditions in the plant as workers slice the pepperoni and apply it to the pizza.[6] The cheese line will be subject to FDA inspection on average once every five to ten years.[7] The minimal difference in hazard between the processing of cheese and pepperoni pizzas is not enough to justify the vast disparity in government inspection.

Under the current structure, some food-processing plants may get no federal food-safety inspections. Due to resource constraints, FDA has turned huge portions of its regulatory responsibility over to the states. The best example of this is in the area of shellfish production, where FDA relies totally on state inspectors. But FDA is now using state inspectors to conduct many different food inspections. A June 2000 Inspector General investigation documented that states conduct a growing percentage of the food-firm inspections under a variety of agreements

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[6] Michael R. Taylor, "Preparing America's Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?" *Food and Drug Law Journal,* Vol. 52, No. 1 (1997), p. 18 [hereinafter cited as *Preparing for the Twenty-First Century*].

[7] US Department of Agriculture, US Department of Health and Human Services, US Environmental Protection Agency, *Food Safety From Farm to Table: A National Food Safety Initiative. A Report to the President.* May 1997, p. 37 [hereinafter cited as *Food Safety from Farm to Table*], *Preparing for the Twenty-First Century*, p. 18.

with FDA. Over a three-year period, states conducted 60% of the food firm inspections that FDA recorded in its database. Increasingly, states are inspecting high-risk food firms.[8]

Under the current structure, quality inspections sometimes occur more frequently than safety inspections. There are many shell-egg plants that receive regular inspections from U.S. government inspectors, but the inspections are for quality, not for safety. All plants shipping eggs between states are visited by the Agricultural Marketing Service (AMS) each quarter and many plants also participate in a voluntary grading program where they receive continuous inspection by AMS.[9] Under the voluntary AMS program, government inspectors help ensure that each egg has a yolk of the proper diameter, but nothing in the program checks for the presence of SE.[10] Nor does FDA, the agency charged with food-safety oversight of shell eggs, check for SE during its infrequent inspections.[11]

Under the current structure, HACCP is a different system at FDA and at USDA. The Hazard Analysis and Critical Control Points (HACCP) systems for seafood, meat, and poultry share almost as many differences as similarities. For example, both frequent inspection and laboratory verification of product samples are essential to give the government appropriate oversight over plants utilizing HACCP. Otherwise, the HACCP program is little more than an industry honor system. While USDA requires both on-site inspection by government inspectors and two levels of laboratory verification of meat and poultry products, FDA requires neither for seafood products. FDA inspects seafood plants once every one to five years and made laboratory

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[8] Department of Health and Human Services, Office of the Inspector General, *FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability*. June 2000.

[9] 7 C.F.R. § 59.28; Poultry Division, AMS, USDA, "Quality Eggs for Volume Buyers." Brochure No. AMS-627, August, 1996.

[10] *Ibid.*

[11] Elizabeth Dahl and Caroline Smith DeWaal, *Scrambled Eggs: How a Broken Food Safety System Let Contaminated Eggs Become a National Food Poisoning Epidemic.* (Washington, DC: Center for Science in the Public Interest, 1997), p. 11 [hereinafter cited as *Scrambled Eggs*].

testing for HACCP verification optional for seafood processors.[12] Because of these weaknesses, FDA's seafood program has been a dismal failure, with fewer than 50% of seafood firms using comprehensive HACCP plans, and seafood continues to be a major contributor to foodborne illness outbreaks.[13]

Multiple agencies may prolong the time it takes to bring the benefits of new technologies to the consumer. Everyone is optimistic that new technologies will help solve many of the food-safety problems that exist today. However, several agencies are involved with the approval of new technologies, especially for meat and poultry products. We have seen examples where technologies designed by government scientists at one agency then spent years being considered for approval at another.[14] For several other technologies, like trisodium phosphate for poultry and irradiation for poultry and red meat, FDA approval was the last step that precedes a rulemaking process at USDA. Both approvals are necessary before products can be used in meat and poultry plants. This bifurcated process can take years to complete.[15]

Because of a complicated system of reviews by multiple agencies, new technologies can completely escape government review for food safety. For genetically modified foods, approval responsibilities for new plant varieties is done by three different federal agencies. USDA's APHIS has a mandatory review process to protect against plant diseases and pests that might

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[12] Caroline Smith DeWaal, "Delivering on HACCP's Promise to Improve Food Safety: A Comparison of Three HACCP Regulations." *Food and Drug Law Journal*, Vol. 52, No. 3 (1997), pp. 331-335.

[13] "FDA's Evaluation of the Seafood HACCP Program For Fiscal Years 2000/200." available at http//www.cfsan.fda.gov/~comm/seaeval2.html#evaluation

[14] Telephone conversation with John DeLoach, MS BioScience, Inc., Dundee, IL, April 1998.

[15] Rosanna Mentzer Morrison, Jean Buzby, and C. T. Jordan Lin, "Irradiating Ground Beef to Enhance Food Safety." *Food Review*, Vol. 20, No. 1 (1997), p. 34; US Department of Health and Human Services, Food and Drug Administration, "Irradiation in the Production, Processing, and Handling of Food; Final Rules."*Federal Register*, Vol. 62, No. 232 (1997), pp. 64102-64121; Memo from Robert Sindt, Burditt & Radzius, to Caroline Smith DeWaal, April 1, 1998; Meeting with Robert Sindt, Burditt & Radzius, James Elfstrum, Rhodia, and Jerry Carosella, Consultant, Regulatory Microbiology, Washington, D.C., April 3, 1998.

emerge from genetically modified seed stock. The Environmental Protection Agency (EPA) has a mandatory review process for genetically modified seeds with pesticidal qualities. FDA, meanwhile, utilizes a voluntary review process to address food-safety problems that might emerge from genetically modified foods. Under this system, FDA relies on an industry honor system that allows the biotech companies to decide whether and when they should consult with FDA prior to putting a product on the market.

Coordination with the state agencies that handle food safety is a nightmare. State laboratories that analyze food samples for chemical or microbial contamination have complained about the lack of uniform testing methods and about inconsistent reporting requirements for the federal agencies, including USDA, FDA, CDC, and EPA. This means that state labs may have to run multiple tests on a single food simply to meet the requirements of the various federal agencies. In addition, they waste valuable staff time transmitting the same information to different agencies, which each have their own customized system for reporting lab results. The lack of common data requirements for foods discourages many states from sharing their laboratory data with the federal agencies.[16]

In addition, the federal government has not established standard laboratory certification standards for state laboratories that test food for contamination. This means that in many outbreak and recall situations, a state lab test result will have to be repeated by a federal agency. This can result in a several-day delay in recalling food or informing the public, with a continuing risk to public health.

Under the current structure, imported products are treated differently at FDA and USDA. Imported meat and poultry products are subject to a two-stage approval process by

[16]"National Integrated Food Safety System. An Update on Work Group Activities: Laboratory Operations and Coordination," session at the 103rd Annual Educational Conference of the Association of Food and Drug Officials, June 5-9, 1999, San Antonio, TX; Association of Food and Drug Officials 1999 Resolution Number 99-09 Concerning National Standards for Computer-based Laboratory, Inspection and Surveillance Data Standards, June 7, 1999.

USDA. First, the exporting country's meat or poultry inspection safety system must be approved by USDA; then, the individual plant must be inspected by USDA before it can ship meat to the U.S. Even then, the meat is subject to random verification checks at the border. FDA meanwhile only has the authority to inspect food at the border and, even then, only has the staff to check one to two percent of import shipments.[17] FDA can't send inspectors to foreign countries except by invitation, even when they are checking the source of food involved in an outbreak in the U.S.

In a global marketplace, our system is falling behind the safety systems in use in other countries. Numerous countries have already created unified food safety agencies to cover the entire food supply. The effort was driven in Europe by the BSE crisis. Unified agencies now exist in at least three European countries, England, Netherlands, and Germany. Other countries, like New Zealand, have moved to a single food agency to address gaps and weaknesses in the food safety programs. The Food Safety Authority of New Zealand, FSANZ, took over government programs largely designed to certify companies that wanted to export food to other countries. With the unified agency, they are now focusing additional resources on improving the safety and quality of domestic foods.

These gaps and inefficiencies demonstrate that until we address the problems inherent in the food-safety regulatory structure, we will not be able to achieve a risk-based food-safety system. CSPI stands in good company in its call for fundamental reorganization. Over the last twenty years, many expert panels from the White House and Congress to the National Academy of Sciences and the General Accounting Office have all reached similar conclusions. More recently, a major industry trade association, the Food Marketing Institute (FMI), and Consumers

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[17]Lester Crawford, Acting Commissioner of the FDA, Testimony before theHouse Appropriation Committee's Subcommittee on Agriculture on March 11, 2004. Also, US General Accounting Office, "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable," (Washington, DC: US General Accounting Office, April 1998), p. 5 [hereinafter cited as *Safety of Imported Foods*].

Union, the publisher of *Consumer Reports* magazine, have called for a single food-safety agency.

It is clearly not news to anyone that statutes designed when the Model T was being driven are not suited to address modern issues, like mad cow disease, genetically modified foods, or even common foodborne bacteria. But make no mistake, if a terrorist were to strike the U.S. food supply, consumer confidence in the government's fractured food safety programs would plummet as fast as confidence in airport security did following September 11, 2001. Even Dr. John Bailar, the chairman of the NAS committee calling for a more unified food safety structure, said that "When bioterrorism is added to the mix, the case for prompt and sweeping change becomes compelling. While additional tinkering with the details of our food safety system might be helpful, the consolidation of responsibilities, authorities, and resources for food safety into a single high-level agency is critical."[18] Today, a unified agency operating under a modern food safety statute is truly an issue of national security.

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[18] Bailar III, John C, "Ensuring Safe Food: An Organizational Perspective." Layne S, et al.,*Fire Power in the Lab*,. National Academy of Sciences, 2001, p. 141.

Ms. DAVIS OF VIRGINIA. Thank you so much, Ms. DeWaal and Secretary Glickman.

We'll now go to the question and answer period, and I'll call on Mr. Davis, our ranking member, for questions.

Mr. DANNY DAVIS. Thank you very much, and I too want to thank the witnesses especially for their patience. Mr. Glickman, Dr. Brackett testified that the Department of Homeland Security has taken the lead in establishing national policy to defend the agriculture and food systems against terrorism. However, you testified that the creation of DHS creates a disincentive for the Congress to make fundamental changes in the short term.

DHS appears to be working collaboratively with the Department of Agriculture and the Food and Drug Administration to address food safety concerns as it pertains to terrorism. If DHS is actively involved in the process, do you still believe that Congress needs to act in the short or the long term?

Mr. GLICKMAN. First of all, I think that, my judgment is that the jury is still out on DHS and what they're doing in the bioterrorism areas that affect food and agriculture. I think they're trying their best, and I'm not privy to the systems that are going on there. But there has been an enormous amount of reorganization in the Government as a result of DHS. For example, Animal Plant Health Inspection Service at USDA, which is the lead agency for basically inspecting imports of animal products, other food products, has seen its mission further divided as a result of the Department of Homeland Security. Some of their mission is now in DHS, some of the mission remains in USDA.

So in effect, what we have done as part of that statute is further complexify it, as opposed to consolidating, we basically divided. What it's done, I suspect if you talk to people in USDA, and maybe this is just temporary, is that it's created morale problems and is has not enhanced a lot of the feeling that USDA is out there largely promoting its own food safety functions. That's to be, I assume that's to be expected because of what happened after September 11.

I guess my point is that the Department of Homeland Security is still feeling its own oats, and I'm not sure that is not going to interfere to some degree with the possibility of consolidating food safety functions. Because my guess is they're going to want to have more and more jurisdiction over these issues, not less and less.

Mr. DAVIS. Ms. DeWaal, how would you rate our system and the safeness of our system with that of other countries?

Ms. DEWAAL. I appreciate your question. I think we're blessed with a very safe food supply compared to many other regions of the world. That said, there is a lot we can improve. And unfortunately, our system, our fractured Federal system actually stands in the way of us correcting some well known food safety problems.

Our representative from GAO today mentioned the egg issue. We've known for almost 10 years that you could solve, you could virtually eliminate illnesses from eggs by instituting on-farm controls. We've known that. We've had pilot studies. USDA ran them. They were very, very effective. Yet we don't have a regulation in place that actually implements them, because it took them a bunch of years actually under the Clinton administration to just figure out who was in charge of eggs.

One agency today regulates chickens, another regulates eggs and a third regulates the meat from the chickens. In almost every problem we end up with that kind of division where almost three agencies are involved. So I think that we have some areas of the food supply that are very safe but other areas that desperately need improvement.

Mr. GLICKMAN. I just want to add one thing. One of the positive notes in all this is large sectors of private food industry have actually moved ahead of the Government in doing food inspection and setting up systems that are actually more stringent than what either the FDA or USDA requires. That's a trend we have to continue to encourage.

Mr. DANNY DAVIS. Ms. DeWaal, can I infer then that you're saying that it's really time to bite the bullet and go ahead and put in place an agency that has this responsibility?

Ms. DEWAAL. Exactly right. The rest of the world is really moving ahead of us in this area. You know, we're the United States, we don't want to be behind in anything. So I really think it is time to bite the bullet and move forward.

Mr. DANNY DAVIS. Thank you very much. I have no further questions.

Ms. DAVIS OF VIRGINIA. Thank you, Mr. Davis. Mr. Murphy.

Mr. MURPHY. Thank you, Madam Chairwoman, and welcome here.

I'm from Pennsylvania, so your comments about the hepatitis A outbreak are particularly a concern to me. I just want to followup with regard to this. In your written testimony you talk about meat that's imported is inspected by the USDA at two points, once onsite at the farm and once at a processing plant, then maybe inspected again somewhere after that. But plants that come in, vegetables that come in are only inspected once they reach this country and then only 1 to 2 percent?

Ms. DEWAAL. That's right.

Mr. MURPHY. Now, of that 1 to 2 percent, if you have several hundred bushels coming from the same farm, does that mean that, maybe green onions or something, 1 or 2 percent of that particular farm is inspected, or it's just 1 to 2 percent of anything? So a whole farm could go by with no inspection at all?

Ms. DEWAAL. In most cases, whole farms are going by and never being inspected. At FDA, they don't have authority to go to the foreign country to check.

Mr. MURPHY. But USDA does?

Ms. DEWAAL. USDA does.

Mr. MURPHY. Why not?

Ms. DEWAAL. It goes back to these hundred year old statutes that were just designed differently.

Mr. MURPHY. So even when there is an outbreak, it's tough to get authority to go back and inspect the farm in Mexico or wherever that might be?

Ms. DEWAAL. They can't go unless they're invited by the country. But USDA can go any time they want.

Mr. MURPHY. Clearly there's an arcane rule that needs to change to allow us to do that.

Also, you were here before when I asked the question about communicating between agencies. Mr. Secretary, I'm wondering, with your experience, if you can comment on that because part of my sense is if Congress wants to answer a question, we have to go to each agency and ask the same question. Hopefully then they'll give it to us. But then we have to fit the pieces together after that. Is that your understanding?

Mr. GLICKMAN. That's correct. It's absolutely correct. In a crisis, the agencies communicate rather well. Because usually the political pressures from the Congress are very great and the White House to get people together at the table at the same time. That's how this President's Council on Food Safety was ultimately created.

But these processes don't seem to have any sustained life to them. So right after the BSE epidemic, which thank God was only one case in this country, is over, or the e coli epidemic is over, we kind of go back to the way we were, everybody doing their own thing.

Mr. MURPHY. Let me add another layer to that. Then you have the State departments, whether it's a department of agriculture or a department of health, also trying to coordinate it. My assumption is they also face the same dilemma. So in Pennsylvania, we have the other issues with poultry and concerns about flu there. So they also then have to begin to talk to different agencies and coordinate that. But that's a day to day issue for them.

Mr. GLICKMAN. Yes, actually, FDA does have some agreement with States, they have these collaborative agreements. One thing I would tell you is, you may want to consider looking at the statutes to see if in fact the agencies are really authorized to have collaborative or joint operating agreements. And I'm not sure they necessarily are. For example, USDA's Forest Service and the Department of Interior now operate under joint operating agreements with respect to some park and forest facilities. I'm not sure, as a matter of fact, if there's different statutory formulas and bases, whether they can do that under current law.

Mr. MURPHY. Do you have anything to add to that, Ms. DeWaal?

Ms. DEWAAL. FDA does have agreements, cooperative agreements, for the inspections by the States. In fact, what we've seen over the years is more and more of the food safety inspections are actually being done at the State level. So Pennsylvania probably has a very active inspection program at the State level. Pennsylvania also was where the pilot study was run which showed the on-farm controls for salmonella in eggs was very effective.

So the States are very effective in this area, but they have trouble coordinating with the Federal Government.

Mr. MURPHY. Does that information then go up to the Federal level and the Federal people disseminate that to other States, or is that up to the States to figure that out between themselves?

Ms. DEWAAL. It's up to States to figure out. And again, during a couple of years during the 1990's there was an effort to bring the States together with the Federal Government. But in recent years, that effort has fallen apart. I know the States are anxious to get it going again, because they just need standards like consistent laboratory standards, and they need a way to interact with a Federal Government that is much more streamlined.

Mr. GLICKMAN. If there is a public health or an imminent disease problem, the Center for Disease Control is basically the agency of Government that tries to coordinate all this. Therefore, you've got another player in this game, which is CDC, which once there's an outbreak or once there's an epidemic, then they handle all the epidemiological data, all the transfer of information, a lot of the communications. And they are very engaged, by the way. I don't know what the resource needs are. But you can't really probably even consolidate a lot of these functions without considering what CDC's role is, because it's the disease prevention agency.

Ms. DEWAAL. But CDC then can't engage one of the Federal agencies until they know what food it is. So you have an outbreak going on, but they don't know which Federal agency to engage, because they don't know whether the food is regulated by USDA or FDA.

Mr. MURPHY. I appreciate the candor the two of you have brought to this situation, where it seems like there's a number of ongoing mistakes that have been made for decades. It reminds me of a Will Rogers quote where he says, good judgment comes from experience and lot of that experience comes from bad judgment.

Mr. GLICKMAN. My father used to tell me that all the time.

Mr. MURPHY. You learned well. [Laughter.]

Thank you, Madam Chairwoman.

Ms. DAVIS OF VIRGINIA. Thank you, Mr. Murphy. Mr. Van Hollen.

Mr. VAN HOLLEN. Thank you, Madam Chairwoman, and I want to thank both of you for being here today. Secretary Glickman, thank you for your service, and you're doing a good job from all reports up at the Kennedy School. Caroline, thank you for all you've done in this area over many, many years. I appreciate all your work in this area.

I'm just struck by the fact, Mr. Secretary, you started out by pointing out that we have this huge resource imbalance between USDA and FDA. Then I turned to Ms. DeWaal's testimony where she says in 1997, the huge resource imbalance between FDA and USDA led CSPI and other consumer organizations to call on Congress to create a single independent food safety agency, and it goes on to cite a 1998 National Academy of Sciences report.

It does remind me of the other point you raised, which is that so often, we respond to emergencies and there's a flurry of activity, and very quickly the political momentum behind any change gets lost. I think if there's one lesson coming out of the 9/11 Commission that can be generalized to all sorts of issues, which is where you have very credible evidence of a threat, it's important that we respond quickly and seriously to it. So I hope that we will not wait for another food type of emergency before we act on this issue.

With respect to consolidation, there's one question that sort of, dealing with all these budgets and resources that comes to mind, which is, are we talking about consolidating existing resources and better utilizing them, or in order to get the safety results that we need, are we going to at the same time we consolidate, we're going to have to add resources and manpower to this issue? And if it's going to be a question of actually not just reorganizing, but adding people, inspectors to the process, has anybody, I haven't had a

chance to look at the GAO report, has anyone taken a look at what additional manpower is required and what the cost would be to get the kind of system that we want that would really provide for food safety?

Mr. GLICKMAN. I think it's an excellent question. I do not believe there has been in recent years an independent, qualitative and quantitative risk assessment of food safety threats. So it's hard to really know how many inspectors we need.

My judgment is we need more than we have overall. Although on the USDA's side, in terms of meat and poultry inspection, because of all the new HACCP systems, in the future we may not need quite as many there as we have in the past. That's controversial and a lot of people in the inspection community might disagree with me.

But I suspect we need way more on the FDA side of the picture, then you need to make the law somewhat compatible in the process. But until you do that kind of assessment, you'll never really know.

Ms. DEWAAL. We are actually working with several Members, Representatives DeLauro and Latham on this side, and then Senator Durbin on the other side, on looking at this question of how to develop a risk based inspection system. So I hope that this committee would work with those Members or tackle your own issue of how to create this risk review, so that we can get inspection that's risk based today.

We have more inspectors inspecting chickens at a rate of 30 birds per minute than we have invested in any other area of food safety. And literally, we have Government employees who sit at one point on a line and watch birds, chickens plucked, broiler chickens fly by them. I've seen it in action, it's quite amazing. But it's amazing they can stay awake, too, because it's not an effective situation.

Mr. GLICKMAN. If I may add, just quickly, on the other hand, the new HACCP systems that are employed in many of the plants actually reduce that need, because they're a more science based system and they work very well. A lot of the pathogens you can't physically see as they go by, you've got to test these products to see what's in there.

But one other thing I would warn you about, especially at USDA, the relationship between the inspectors and the management of the Food Safety Inspection Service is, shall I say, historically very unstable. And to go down this road, there are a whole lot of labor-management issues that are going to have to be addressed that are not going to be easy to tackle.

Mr. VAN HOLLEN. One quick followup. You talked about chicken being one of the most inspected items. Seafood, on the other hand, I gather, is one of the least inspected items, and that comes under FDA, I understand. I think the HACCP standards for USDA with respect to poultry are very different and uneven compared to the fish. Can you just talk about seafood for a moment?

Ms. DEWAAL. Seafood has been a fascinating issue, and actually when Secretary Glickman was a member of the House of Representatives he worked on a seafood inspection bill back in the early 1990's. Basically, while meat and poultry are inspected every single day, regardless of whether it's pepperoni being chopped onto

a pizza or meat slaughter plant, seafood, they've actually improved now, they're up to once a year for the highest risk seafood plant.

So the bottom line is, we have like products that pose a comparable risk but are inspected entirely differently. The HACCP systems are also entirely different, because the agencies just don't have the same kind of legislative authority.

Ms. DAVIS OF VIRGINIA. Thank you, Mr. Van Hollen.

I guess you heard, we have bells and whistles going off, because we have three more votes. I'm just going to ask you one question, to you, Secretary Glickman.

Why do you think, this is an issue that has been studied for a long time, from what I'm gathering, why do you think any efforts to correct these deficiencies have pretty much gone by the way side and not brought any greater changes?

Mr. GLICKMAN. I think for several reasons. It's a fundamental question. One, the system is generally safe. It could be made safer, but it's generally safe. Second, American people have confidence in the safety of the system.

Ms. DAVIS OF VIRGINIA. Keep in mind that the purview of this committee is reorganization. So we're looking for efficiency.

Mr. GLICKMAN. Right. But you asked why hasn't anything been done. And I think one of the reasons it hasn't been done is the public hasn't been clamoring for this, with the exception of when there is a food safety crisis. Then you tend to gin up, there tends to be more interest, then it tends to come back down again.

My own experience after serving in the Congress, frankly, is the turf divisions between various congressional committees has a lot to do with this issue. I don't know if they are still as profound as they once were, but I suspect they are.

Ms. DAVIS OF VIRGINIA. Every bit.

Mr. GLICKMAN. Fourth, by and large the White House, previous White Houses, have not viewed food safety in the same general, same area as they have viewed, let's say homeland security in recent years, or terrorism or those kinds of issues. I suspect you can do some consolidation and save some money. But I'll tell you, my judgment is ultimately we're going to have to spend more money on this issue, not less. It's just you'd like to have it spent on the inspectors out there in the field who are actually protecting the public interest.

Ms. DAVIS OF VIRGINIA. Thank you both very much, and we will have some questions for the record that we will submit to you in writing. Rather than have you wait, we have three votes, it could be 45 minutes or so. So we will adjourn the hearing, and thank you both very much.

Hearing is adjourned.

[Whereupon, at 5:32 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

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April 15, 2004

The Honorable Jo Ann Davis
Chairwoman
Subcommittee on Civil Service
and Agency Organization
Committee on Government Reform
373 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Davis and Members of the Committee:

RE: March 30, 2004 Food Inspection Hearing

The Grocery Manufacturers of America, Inc. is pleased to submit its views about how government, consumers, and industry might best cooperate and collaborate to make certain that the system we have in place in the United States most effectively ensures the safety of our food supply, and how this system might be enhanced. We respectfully request that this letter be incorporated into the record of the hearing held by this Subcommittee on March 30, 2004 concerning this very important shared objective.

The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage and consumer product companies. Led by a board of 46 Chief Executive Officers, GMA applies legal, scientific and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry. With U.S. sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 states. Nothing is more fundamental or has a higher priority for us than food safety.

The U.S. Food Supply is Safe

The United States has the safest, most abundant and varied food supply in the world. We have achieved this enviable position not by luck or accident, but through the commitment of the food and agricultural industries and generations of dedicated public servants at the federal, state and local levels who work for our food safety regulatory agencies. The achievement of this partnership is reflected in the high confidence that American consumers have in the safety of their food supply.

According to the Gallup organization, 82 percent of consumers have confidence that the federal government adequately ensures the safety of the food supply. Surveys conducted by Peter Hart Associates through the 1990's show strong consumer support of the food safety regulatory system. That consumer confidence is not misplaced. We do in fact have a remarkably good record in assuring a safe food supply.

Admittedly, the system we have is not perfect, and can and should be enhanced; but neither is it broken. The idea of combining all federal food safety regulatory responsibilities into a single agency surfaces as a "solution" to perceived shortcomings of the current system. Careful examination of the current system, both achievements and challenges, demonstrates that a single food agency is not needed to attain further improvements in food safety. There is no assurance that a single food agency would materially improve food safety; there is assurance, however, that moving to a single food agency would be disruptive and costly.

We need to focus our efforts on identifying and solving real food safety problems. Creating a single food safety agency would accomplish neither of these critical goals. Creating a single food safety agency would not develop faster tests to identify, prevent and destroy dangerous pathogens. Rather than talking structure, we need to talk about the range of food safety risks and challenges we face today and devise strategies for solving these problems. The answers are not simple, and we should not buy into the misplaced idea that bringing everyone together under one agency would fix food safety problems. The agencies are today continuing to partner with each other in a joint commitment to enhance food safety. Let's make sure that our focus is on real problems and not on building a bigger bureaucracy that won't improve and may weaken our food safety system.

The Current Food Safety Regulatory System Works

Our current federal food safety system has evolved from its origins in the Pure Food and Drug Act of 1906 and the Meat Inspection Act of that same year into a sophisticated, science-based system that appropriately allocates responsibility among several federal agencies, principally the Food and Drug Administration, the U.S. Department of Agriculture and the Environmental Protection Agency. Important support of this national system is provided by other federal agencies -- including the National Institutes of Health, the Center for Disease Control, and the Department of Homeland Security – as well as numerous state and local agencies.

In their testimony before the Subcommittee, USDA's Dr. Merle Pierson and FDA's Dr. Robert Brackett described very well the respective and complementary roles of their agencies in regulating food to ensure its safety. They also explained quite clearly the shared responsibilities of allied federal and state agencies, as well as the work of industry, in using existing resources as effectively and efficiently as possible to get the job done. Dr. Pierson and Dr. Brackett both called for coordination and cooperation, not a fundamentally new structure.

Indeed, as they both pointed out, the Bush Administration established a Policy Coordinating Committee in 2002, led by the Domestic Policy Council and the National Economic Council, to study the possibility of consolidating federal food safety functions into a single federal agency. The Committee concluded that enhanced interagency coordination rather than consolidation would better serve the Administration's food safety goals. Similarly, President Clinton's Administration formed the President's Council on Food Safety which studied this issue and concluded that "reorganization by itself will not significantly change the food safety system's capability to assure public health protection and that no single structure for the food safety system provides the perfect solution". In addition, the Council concluded, "the current federal food safety system is providing a high level of public health protection but it can be strengthened."

Moreover, the government does not work alone in seeking to ensure food safety. Industry has long advanced the safety of our nation's food supply through its ongoing investments in research and development, and its leadership in adopting food safety assurance systems. In fact, the Hazard Analysis and Critical Control Points (HACCP) system, created and implemented voluntarily by the food industry in the 1960's, became so widely recognized for its effectiveness at enhancing the production and processing of safe food that both USDA and FDA have made its implementation mandatory for certain products.

The point is that the allocation of responsibility among multiple agencies is not inherently wrong or misguided. Rather, it reflects the informed judgment of lawmakers and government officials over many decades that different sectors of the food supply present different challenges and thus call for different inspection and regulatory systems. For example, meat and poultry regulation has traditionally been inspection and inspector intensive recognizing that animal slaughter presents different safety challenges than other food processing. Much attention is drawn to the rather unique situation in which similar products are sometimes inspected by different agencies, i.e. cheese pizza versus pepperoni pizza. This one overused example is a circumstance that is ripe for rhetorical points, however, that example in itself does not establish that the public health is not adequately protected under the current system. When different regulatory approaches and expertise are called for, dividing responsibility among different agencies through which such challenges can most comprehensively be addressed represents a logical and focused strategy. In short, food safety regulation is not a "one size fits all" situation.

Of final note, we should not underestimate the challenges that would be faced were an attempt made to combine the food safety regulatory activities into a single agency. The present system is based upon laws, regulations, policies, and even judicial interpretations that have evolved over several decades to address food safety and related challenges as they have arisen. Even if it made sense to consolidate the various agency functions if simply for the sake of consolidation, combining organizations inherently means a period of uncertainty, distractions, loss of focus and functionality.

The question has often been asked how we would design the nation's food safety system if we were starting from scratch. The reality is, however, that we are not starting from scratch. Food is regulated in accordance with a national system that, though complex, has worked well for generations; and it must be allowed to work without unnecessary tinkering and disruption. Now, perhaps more than at any time in our history, we need intense focus on the job at hand.

Recommendations for Improving the System

Although the present system is fundamentally sound and functioning effectively, there is room for improvement in our current system. We have four recommendations to enhance the current system that GMA believes will continue to ensure food safety, but do so even more efficiently.

1) Federal Regulatory Agencies Need Adequate Staffing and Resources

Consumers, and the food industry, are best served by strong food safety agencies that develop policy based on sound science. Although these agencies already do a good job, they must be afforded the resources that the increasing challenges of a global marketplace demand. Unfortunately, agency funding has not kept pace with these demands.

For example, although the responsibilities of the FDA have increased dramatically over the last several decades, the funds appropriated to FDA for its food safety related functions have fallen short. With a partnership among all interested parties, perhaps those within the Administration with responsibility for the federal budget and those in the Congress with appropriations jurisdiction can be persuaded to provide FDA with the funding it needs to maintain the position it has historically enjoyed domestically and internationally.

GMA has already taken a leadership role in this area. GMA has co-led a food industry coalition whose objective is to increase the awareness of the need for more resources at FDA and to provide creative ideas on how FDA might best make use of those additional resources. GMA has also created a Board-led task force of company CEOs committed to helping ensure that the case for additional FDA resources is made. More recently, and following the terrorist attacks on September 11, 2001, increased resources have been provided by the Congress, but full funding of this critical agency must remain a priority. Additional resources will be needed to address new and emerging food safety threats.

(2) The Food Safety System Must Be Based on Science

Our food safety system must emphasize scientific research. We must identify and fight the true causes of foodborne illness with the right scientific weapons. Those weapons can only be discovered through laboratory research and practical testing. Food safety research deserves high priority and funding. Good science has always been a critical component of sound food safety regulation.

It is incumbent, therefore, on all of us with a shared commitment to effective food safety regulation to think creatively about ways in which we can ensure that FDA and USDA truly have access to the best and brightest scientific minds in our country. For example, we are exploring ways in which bright young scientists might begin their careers with a fellowship at the FDA in much the same way that many of our finest doctors begin their careers at the National Institutes of Health.

(3) Enhanced Interagency Coordination Must be a Priority Goal

Collaboration, coordination, and consultation must be a full-time commitment of our federal and state regulators. We believe that examples of duplication or inconsistent regulation cited as reasons for a single food agency can be addressed by simpler and more sensible means.

The Secretaries of Agriculture and Health and Human Services must assure that agency heads fully collaborate in carrying out their shared missions, and in identifying and eliminating duplications and inefficiencies. Key food safety agencies heads should be (1) asking why failures in communication occur among the federal agencies; (2) identifying the substantive areas in which the responsibilities of the agencies overlap; and (3) implementing specific measures to improve communication and eliminate duplication.

A good example of progress in enhanced collaboration in the food safety area is the National Advisory Committee on Microbiological Criteria for Foods, an advisory committee that FDA and USDA co-sponsor, drawing upon government, industry, consumer and academic expertise. In addition, both FDA and USDA rely upon CDC's PulseNet to detect the source of foodborne illness outbreaks more rapidly. The agencies, with the support of the food industry, have also worked together effectively in the Fight Bac public education campaign. The Memorandum of Understanding between FDA and Customs and Border Protection and other such initiatives to implement strengthened biosecurity measures further demonstrate the willingness and incentive that agencies share to be better and smarter by working together.

Coordination of food safety efforts between federal and state regulators must also continue to be a priority. Food safety is a national responsibility, not just a federal agency responsibility. The collective inspectional and laboratory-based resources of the fifty states need to be marshaled in support of this paramount national goal. One such example of effective federal/state coordination is the Food Emergency Response Network (FERN), which is a national network of food laboratories – organized jointly by FDA and USDA – that can be called upon in a national emergency to test many more food samples in a short period of time than any one agency or state could handle alone. GMA supports development and funding of the FERN and similar federal/state cooperative efforts.

(4) Inspection of Imports

One of the most dramatic changes that have occurred with regard to our food supply is the extent to which we now have a global marketplace. FDA and USDA regulated products enter the United States from over two hundred countries. We must ensure that our regulatory agencies have the resources and tools to effectively regulate imported products.

FDA has a number of initiatives underway, the most significant of which is the implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which contains a variety of critically needed new authorities to better protect the food supply from the threat of bioterrorism. This new authority will give FDA the information of "where" and "when" articles of food are entering our borders and will give the FDA the ability to identify and stop, if necessary, products from countries that pose a perceived risk from entering our market.

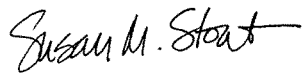
For many developing countries, access to the U.S. market is an important part of their effort to improve the economy and well being of their citizenry. Effective regulation of imported products must include a component that involves a partnership with the exporting countries so that we address problems at the source and not simply at the border or dock.

Conclusion

GMA and its member companies are firmly committed to the continued integrity and effectiveness of our food safety regulatory system. No one has a greater stake in the credibility of the system than our member companies. We are open to considering a wide range of ideas and proposals to improve our current system. Before we scrap a system that is regarded as the best in the world, however, we should fully explore strategies to enhance the current system through adequate funding, better coordination, application of the best science, and focusing of our food safety resources where they can do the most good.

Thank you for this opportunity to present our views.

Sincerely,



Susan M. Stout
Vice President, Federal Affairs

United States General Accounting Office
Washington, DC 20548

May 26, 2004

The Honorable Jo Ann Davis
Chairwoman, Subcommittee on Civil Service
and Agency Organization
Committee on Government Reform
House of Representatives

Subject: Posthearing Questions Related to Fragmentation and Overlap in the Federal Food Safety System

Dear Chairwoman Davis:

On March 30, I testified before your subcommittee at the hearing *A System Rued: Inspecting Food.*[1] This report responds to your request that I provide answers to follow-up questions from the hearing. Your questions, along with my responses, follow.

(1) Does the lack of a single official responsible for the operations of all food inspection programs in the federal government decrease the effectiveness of congressional oversight? How has the current system affected the oversight work of GAO?

As the Comptroller General stressed in his September 2003 testimony before the subcommittee,[2] the current structure of the food safety system in general, and the food inspection programs in particular, could be improved by reducing the number of entities charged with oversight, thereby enhancing accountability and increasing government efficiency. From a congressional perspective, the fragmented nature of the food inspection system results in divided, and perhaps diluted, responsibility for ensuring a safe food supply and protecting the public health. For example, congressional oversight committees and GAO must review and analyze multiple agencies' programs, policies, and budgets, in order to address questions of overall food safety oversight, rather than focus on food safety inspection programs under one agency's jurisdiction. In particular, it is difficult to compare program effectiveness when the agencies responsible for maintaining food safety are operating

[1]U.S. General Accounting Office, *Federal Food Safety and Security System: Fundamental Restructuring Is Needed to Address Fragmentation and Overlap*, GAO-04-588T (Washington, D.C.: Mar. 30, 2004).
[2]U.S. General Accounting Office, *Results-Oriented Government: Shaping the Government to Meet 21st Century Challenges*, GAO-03-1168T (Washington, D.C.: Sept. 17, 2003).

under different statutory requirements. In addition, for consumers as well as for GAO, it is at times difficult to determine which agency is responsible for ensuring the safety of a particular food product. For example, the Department of Agriculture (USDA) might be responsible for inspecting a particular food item, but once that item is used in a processed food product, it might be regulated by the Food and Drug Administration (FDA). Arbitrary jurisdictional lines of authority can make the current food safety inspection system difficult to assess and, more importantly, unresponsive to the needs of the public.

(2) Why should the Congress consider a major reorganization of the federal food inspection system at this time?

Beyond the issues of organizational inefficiency and confusing jurisdictional responsibilities, the vulnerability of our food supply to potential attack and deliberate contamination provides a new and compelling impetus for reorganizing the federal food inspection system. As several of our recent testimonies have stressed, bioterrorist attacks could be directed at many different targets in the farm-to-table continuum, including crops, livestock, and food products in the processing and distribution chain. Both FDA and USDA have taken steps to protect the food supply against terrorist attack, but it is, for the most part, the current food safety system that the nation must depend on to prevent and respond to this potential threat. At present, the federal agencies responsible for oversight of food safety have differing authorities. As a result, some inspectors provide daily inspections of certain food products, while others inspect much less frequently—every year to 3 years, on average. Consequently, FDA products are not receiving the same level of scrutiny as USDA products, potentially making FDA products more vulnerable to inadvertent as well as deliberate contamination. This is of particular concern in the case of imported food. Equally important, at a time of increasing budget deficits, the current distribution of inspection resources is not the most efficient use of federal resources. As my recent testimony pointed out, FDA has roughly 1,900 inspectors who must oversee about 57,000 facilities, whereas USDA has more than three times the number of inspectors at about 6,400 establishments—and this distribution of federal resources is not based on the food safety risk of particular products.

(3) Should such reorganization be in the form of putting all of the food inspection functions under an existing agency or should a new agency be created to handle all food inspection functions? Please briefly describe the pros and cons of either option.

In our view, consolidating all food safety functions (e.g. standard setting, inspection, risk assessment, research, and surveillance) under a single independent agency would offer the most logical approach to resolve long-standing problems, address emerging food safety issues, and better ensure a safe food supply. If, instead, all food safety authorities were consolidated under an existing agency, the advantages and disadvantages of charging USDA or FDA with those responsibilities must be considered. At present, USDA has more resources and possibly more experience with food product inspections because of its longer institutional history. However, USDA promotes agriculture, and that may be perceived as a conflict of interest. In contrast, FDA, as a public health agency, has a mission that aligns well with food safety, and it has established scientific expertise in preventing foodborne illness.

If reorganization is limited to the inspection functions alone, it is not cost effective, or reasonable, to create a new agency to take on solely these functions. In the current budgetary climate, it would be better to designate one current agency as the lead agency for all food safety inspection matters. Merging USDA's food inspection responsibilities into FDA would be an alternative that would separate market promotion activities from food safety activities—a criticism that is often raised about USDA's dual mission as promoter of agricultural and food products and at the same time overseer of their safety. Also, it would place food safety oversight under a public health agency. Merging FDA's food inspection activities into USDA has the advantage of needing to move fewer federal personnel. In either case, underlying the transference of inspection responsibilities is the fundamental need to reform the current legislative structure for food safety, so that the lead inspection agency would be able to focus its resources on the foods with the greatest risk to consumers.

(4) What are some of the characteristics that should be inherent in a streamlined federal food inspection system?

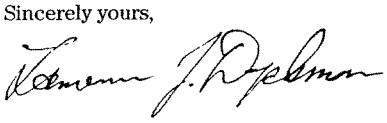
In our view, a unified, risk-based approach to federal food safety should characterize any new inspection system. A critical step in designing and implementing a risk-based food safety system is identifying the most important food safety problems, across the entire food system, from a public health perspective. Identifying these problems would help focus federal oversight resources. Comprehensive, uniform, and risk-based food safety legislation is needed to provide the foundation for this approach. We also believe that in order to be effective, a federal food inspection system should include performance standards to help evaluate the effectiveness of federal regulatory requirements for industry and its efforts to meet those requirements.

(5) In the event of some sort of consolidation of the food inspection functions into a "single agency," in either a new agency or an existing one, are there any food inspection functions that should remain outside the "single agency"? If so, please explain the necessity for keeping the function out of the "single agency."

From our perspective, reorganization of food safety authorities, including the consolidation of critical functions such as rule making, inspection, surveillance, and research, does not necessarily mean that all functions should be incorporated into a single food safety agency. In fact, we believe it may make sense to maintain some functions separately. If, for example, FDA's food safety authorities were subsumed under USDA, it might be desirable to keep functions such as foodborne illness surveillance in the Centers for Disease Control and Prevention, which is part of the Department of Health and Human Services. However, in the event of consolidation limited strictly to the food inspection functions, we believe that all food inspection functions should be incorporated into the single food safety agency.

We appreciate the opportunity to comment and hope that these responses are of assistance. If you have any additional questions, please do not hesitate to call me at (202) 512-3841.

Sincerely yours,



Lawrence J. Dyckman
Director, Natural Resources
and Environment

(360480)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 27 2004

The Honorable Tom Davis
Chairman
Committee on Government Reform
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to questions submitted for the record by former Chairwoman Jo Ann Davis of the Subcommittee on Civil Service and Agency Organization. The questions relate to the March 30, 2004, hearing "A System Rued: Inspecting Food." The Food and Drug Administration appreciated the opportunity to testify before the Subcommittee at that hearing. Our responses to the questions are enclosed. If you have further questions or concerns, please let us know.

Sincerely,

Patrick Ronan

Patrick Ronan
Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Henry A. Waxman
Ranking Member
Committee on Government Reform

The Honorable Danny K. Davis
Ranking Member
Subcommittee on Civil Service and Agency Organization
Committee on Government Reform

FDA Responses to Questions Submitted for the Record
by Chairwoman Jo Ann Davis
Subcommittee on Civil Service and Agency Organization

USDA & FDA

- **In what areas of food inspection is coordination the most difficult between agencies? Why?**

  We believe that there is no difficulty in coordination. As FDA described in its testimony, FDA and FSIS coordinate activities at the local level on a regular basis for those facilities and food safety and security activities for which we each have regulatory authority. The number of these joint jurisdiction facilities is small in comparison to the overall number for which FDA has oversight. The coordination is fruitful and substantive and provides comprehensive coverage of the food supply.

- **I would appreciate having additional information regarding the Hazard Analysis Critical Control Point inspection process. How is the HACCP used differently by each agency? Is it appropriate that agencies use this process differently?**

  HACCP is a systematic approach to food production and processing that requires the identification of specific hazards associated with a food and the process/food production system, the means to mitigate such hazards, steps to do so, and documentation that such steps are taken. Given the scientific basis upon which HACCP is formulated and the different types of hazards and production and processing techniques that are related to a specific food commodity, the expectation is that each HAACP plan is targeted and specific to the facility and food commodity and their respective hazards. Hence, while the HACCP tool is the same, the HACCP plans are different because of the varied hazards that have been shown to cause illness associated with different food products and or processes.

  Therefore, USDA's HACCP rules and FDA's HACCP rules are different because the scientific knowledge of the hazards associated with certain commodities and the technology/processing/equipment associated with those commodities are different.

- **It was brought out at the hearing that training requirements are the same for FDA inspectors and USDA inspectors. In addition, it was also stated that there are Memoranda of Understanding between the FDA and USDA for the purpose of having inspectors assist the other agency in areas of dual jurisdiction. Is there any reason why these inspectors should not be cross-trained so as to have full authority of both agencies, legal barriers notwithstanding?**

  The primary focus of the existing Memorandum of Understanding (MOU) for dual jurisdiction establishments is to facilitate an exchange of information between the agencies about establishments that are subject to the jurisdiction of both agencies. This exchange of

information is to permit more efficient use of both agencies' resources and to contribute to improved public health protection. While only a small percentage of the total food processing or manufacturing facilities in the U.S. are subject to inspection by both FDA and USDA, the notification and sharing of information through this MOU has been productive as it has led to recalls of both FDA- and USDA-regulated products.

With regard to your suggestion that FDA and USDA inspectors be cross-trained to have full authority of both agencies, there are many legal and cost considerations that would need to be addressed. However, we continue to evaluate the MOU and look for additional opportunities to enhance our public health responsibilities in the most efficient manner.

- **Additionally, Dr. Pierson said that, "[Where you have this dual jurisdiction issue that our inspectors are trained on those overlap areas." What arc the specific areas of overlap between the two agencies and what training is given to inspectors to deal with this?**

  Under the Federal Food, Drug, and Cosmetic Act (FDC Act), the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA), there are no food products that both agencies regulate. To the extent that a facility deals in food subject to the FDC Act as well as food that is subject to the FMIA or PPIA, both agencies have regulatory responsibilities in that facility. Each agency deals within its own area of expertise and jurisdiction at facilities that are common to both agencies. As mentioned earlier, FDA and USDA have signed an MOU that facilitates the sharing of information between the agencies about establishments subject to the jurisdiction of both agencies. FDA and USDA field offices notify their counterpart's office when significant findings are identified regarding a dual jurisdiction establishment.

- **We'd like you to address emerging concerns about the potential for deliberate contamination of our food supply by terrorist groups. As you know, the President has recently added agriculture and food to the list of critical infrastructures. In your testimony today, you've outlined the actions that your agency has taken to address this issue and the areas where there is interagency coordination. I commend you for your efforts. However, if a deliberate contamination event were to occur, would it not be more effective to have a single agency federal agency as the responsible lead agency to deal with such an emergency? If the creation of the Department of Homeland Security was created to meet the terrorist threat with a single agency, does not the same logic follow with deliberate acts against the nation's food supply?**

  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 White House 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.

From FDA's viewpoint, the important question is whether the various Federal agencies with food safety authorities are working together effectively. The answer to that question is yes. The existing system is working. The American food supply continues to be among the safest in the world. Food safety agencies are working more closely together than ever before, especially in the area of food security. FDA, CDC, FSIS and APHIS, EPA, and DOD are leading the Defense of the Food and Agriculture Supply efforts under HSPD-9 through our collective authorities, expertise, and resources. We are also coordinating and collaborating with the overall lead, the Department of Homeland Security.

- **If FDA and USDA disagree on procedures regarding a matter that requires they work together very closely, such as the BSE case last year, which agency ultimately makes the final decision on actions that will be taken? Can one agency make decisions that are binding on the other agency in times of emergency? -**

  FDA and USDA's FSIS and APHIS have worked very closely in developing a sound strategy for BSE prevention, control and response for both public health and animal disease. We all recognized early on that we needed to agree on and work under clear jurisdictional authorities at the federal as well as state levels. Accordingly, we established a BSE action and response plan that identifies the lead federal agency to take action depending upon the situation.

  In the Agency's view, legal, scientific and technical expertise is significantly more important to solving a food safety issue than the organizational component called upon. As we have discussed above, the federal food safety and animal health agencies have forged a coordinated effort to prevent, identify, and respond to BSE contamination in the food and animal supply. If all of the current resources were to be housed in one organization, it would not diminish nor eliminate the need for coordination even within that organization.

- **With regard to egg inspections, reports by GAO indicate that FDA has responsibility during production (known as shell eggs) and then the responsibility transfers to USDA when eggs are broken to create egg products. More than 10 years have passed since the problem of bacterial contamination of intact shell eggs was first identified. We understand that USDA and FDA have been working on egg safety standards for several years.**

  - **Why is it taking so long, over ten years, to develop a safety strategy for eggs?**

    In 1999, FDA, CDC and FSIS developed a comprehensive strategy for reducing foodborne illness associated with eggs and set forward public health improvement goals in 2005 and 2010 as part of Healthy People 2010. The strategy is working. CDC's human surveillance system annually reports on the progress made towards these public health goals and outcomes.

- **Are FDA and USDA getting any closer to developing standards for egg production and processing?**

  FDA and FSIS have worked with each other, as well as with CDC and the States, to put forward possible steps to reduce on-farm and processing contamination that may lead to contamination of eggs by Salmonella Enteriditis. We continue to do outreach on egg safety. On September 20, 2004, FDA published a proposed rule on egg safety standards for production. When implemented, the production changes defined by the regulation will significantly reduce the number of illnesses associated with eggs contaminated by Salmonella Enteritidis. During October and November, FDA is holding public meetings in three states to provide an overview of the proposed rule, to solicit comments on the rule, and to respond to questions. Interested parties may submit comments through December 21, 2004. The proposed rule is part of the joint and coordinated strategy by FDA and FSIS to more effectively deal with egg safety for both shell eggs and egg products. FDA and FSIS will continue to work closely together on measures to improve egg safety.

- **Will each agency issue separate rules for egg safety?**

  Each agency is working within its legal authority and jurisdiction to apply scientific knowledge of the sources of contamination to formulate standards that are practical and oriented toward FDA's and USDA's public health goals. Regardless of whether the rules issue concurrently, they have been developed with the same criteria, and in coordination with each other and stakeholders, and both have public health outcome goals in mind.

- **Doesn't a fragmented food inspection system make trading with foreign governments more burdensome than it should be because there is not one food inspection agency to deal with? What responsibilities does each agency bear in dealing with international trade of food?**

  In most countries in the world, including the U.S., responsibilities for food safety are divided among two or more federal agencies, each having specific responsibilities for particular sectors of the food industry and different authorities. As this is the norm rather than the exception, we do not feel that our system is "more burdensome" to our trading partners.

  The attached chart illustrates the existing roles of each U.S. agency for foods and agricultural products imported into the U.S. In the international trade arena, laws and regulations aimed at ensuring that imported foods and agricultural products do not present unacceptable risks to public, animal, or plant health are known as sanitary and phytosanitary measures (SPS measures). The chart is intended to provide foreign governments and industries with a basic understanding of U.S. "SPS Market Access Pathways," particularly with regard to which U.S. enforcement agency is

involved in SPS activities for particular food sectors.

FDA

- **It is clear, as we learned from Mr. Dyckman's testimony, that there is overlap in the food inspection system resulting in ineffective use of scarce resources. Perhaps thousands of food processors are subjected to regulation, inspection, and enforcement from both FDA and USDA.**

  Why can't there be a system whereby food manufacturers are only subjected to one federal system of inspection and enforcement?

  As we explained in response to an earlier question, there are no food products that both agencies regulate. To the extent that a facility deals in food subject to the FDC Act as well as food that is subject to the FMIA or PPIA, both agencies have regulatory responsibilities in that facility. Each agency deals within its own area of expertise and jurisdiction of both agencies.

  The question presupposes that all foods are produced in the same way and have the same inherent risks. It also presumes the same legal authority for all foods. The Federal Meat Inspection Act and the Poultry Products Inspection Act require that food products be approved for sale, that is, stamped by USDA inspectors. The Federal, Food, Drug and Cosmetic Act does not require pre-market approval, in general, for FDA-regulated food products. Hence, each agency's inspection authority, standards, and practices are different due to statutory mandate.

  In addition to the respective legal authority, inspections and inspection systems are based on the inherent risks in food production systems of growing, harvesting, processing, and manufacturing foods. Inspections and the standards they must assess are geared toward each food production system. Hence, the slaughter of meat and poultry has a set of standards that are different from those for the production of fruit and vegetable juice. Therefore, inspections of the varied facilities and foods are different and require different expertise. The notion of one inspection system implies all foods are amenable to the same standards and does not account for these inherent food safety production differences.

  It is important to note that only a small percentage of the total food establishments in the US are subject to inspection by both FDA and USDA.

- **Could you explain how the FDA inspection process differs from the USDA's and why fewer inspectors are needed? –**

  As previously discussed, this in part is based on the statutory provisions in which FSIS has to determine that product is not adulterated by providing a seal or stamp indicating that it has passed inspection. This requires the continuous presence of USDA inspectors during food manufacturing. The FDC Act does not contain a

similar provision and, therefore, provides FDA with more flexibility regarding allocation of its inspectional resources. Under the FDC Act, FDA utilizes a risk-based approach in which we conduct inspections more frequently of high-risk food establishments such as those producing low acid canned foods, medical foods, and infant formulas, than facilities that pose minimal risk, such as food warehouses.

- **On page 12 of your testimony, you state that consolidation of food safety activities may actually make the country more vulnerable to unsafe products than if the system is left as it currently is. Can you please elaborate on this?**

Most FDA Field personnel are not dedicated to only one aspect of consumer protection. For example, FDA import personnel located at border and port locations review and examine all FDA-regulated products which include foods, cosmetics, human drugs, human biological products, medical devices, radiological products, veterinary drugs, and animal feed. Similarly, FDA field personnel doing domestic work are available to respond to any number of emergencies or crisis situations. For example, in response to natural disasters, FDA staff will examine all FDA-regulated products, not just food establishments that may have been affected. This provides the agency great flexibility in responding to various crisis situations. If FDA field personnel were transferred to a new single food agency, this reallocation would diminish FDA's ability to potentially address issues involving the safety and efficacy of the other FDA-regulated commodities.

Revised November 2003

U.S. SPS Market Access Pathways* for Foods, Feeds and Agricultural Products

Any food or agricultural product that may present a viable risk to animal or plant health, e.g., most unprocessed foods, agricultural products, eggs, grains, feeds, fresh fruits & vegetables, all unprocessed and some processed milk & dairy, meats & poultry

CBP (Customs & Border Protection)

APHIS (Animal & Plant Health)

System-wide equivalence is not applicable. Pest- or disease-specific "alternative measures" are permitted routinely for market access.

Meat & poultry & processed eggs

All fresh & processed foods, except meat & poultry & processed eggs

FSIS (Food Safety)

An affirmative finding by FSIS that an exporting country's governmental inspection system is equivalent to the U.S. inspection system is required for market access. All establishments must be certified to FSIS by the exporting country's inspection authority. The eligibility of a country and its certified establishments is subject to change based on results of annual audits by FSIS.

- **For Meat, Poultry and Processed Eggs, significant market access gains are achieved by a finding by FSIS of equivalence to U.S. measures.**

Currently, 37 countries have been found by FSIS to be equivalent and are eligible to export meat or poultry or processed eggs to the United States. Approximately 990 establishments may export these products to the United States.

All other plant- or animal-derived processed foods, animal feeds & beverages, such as canned/dried/frozen foods, packaged foods, confections, honey, juices/waters, snack foods, dairy foods, seafood, dietary supplements

CBP (Customs & Border Protection)

FDA (Food Safety)

Alcoholic beverages

CBP (Customs & Border Protection)

TTB (Food Safety)

By mutual agreement, TTB and FDA share food safety enforcement responsibilities for alcoholic beverages. Currently, TTB is the principal enforcement agency.

No affirmative governmental demonstration of compliance with U.S. SPS (and TBT) measures or finding of equivalence is required for market access. No affirmative industry demonstration of compliance is usually required --- however, producers of infant formula, low acid/acidified canned foods, seafood and raw molluscan shellfish, juices and fluid milk do have special SPS market access requirements. For all foods, compliance by the regulated industry is expected and market access restrictions for particular producer/industry occur if U.S. requirements are violated. From December 12, 2003, all food and feed facilities must be registered and prior notice of food imports must be provided to FDA.

- **For All Other Foods and Feeds, little market access gain would be achieved by a finding of equivalence by FDA.**

Already, for almost all countries, any producer that can meet U.S. food safety (and TBT) measures is eligible to export product. More than 200 countries now export FDA/TTB-regulated foods and beverages to the United States. Well over 100,000 establishments export foods and related products to the United States.

Revised November 2003

- **Customs and Border Protection (CBP) is an agency of the Department of Homeland Security (DHS)**
- **The Food and Drug Administration (FDA) is an agency of the Department of Health and Human Services (DHHS)**
- **The Animal and Plant Health Inspection Service (APHIS) is an agency of the Department of Agriculture (USDA)**
- **The Food Safety and Inspection Service (FSIS) is an agency of the Department of Agriculture (USDA)**
- **The Alcohol and Tobacco Tax and Trade Bureau (TTB) is an agency of the Department of the Treasury**
- **"SPS" means Sanitary and Phytosanitary Measures pertaining to food safety, animal and plant health**
- **"TBT" means Technical Barriers to Trade and, with regard to foods, usually pertains to labeling requirements**

*Simplified representation of pathways -- individual agencies should be consulted for details concerning importation of any particular product.

MEMORANDUM

To: Chairwoman Jo Ann Davis,
House Government Reform Committee's Civil Service and Agency Organization Subcommittee

From: Deputy Undersecretary Dr. Merle Pierson,
United States Department of Agriculture's Food Safety Inspection Service

Re: Response to questions following the March 30, 2004 hearing titled,
"A System Rued: Inspecting Food".

Date: November 16, 2004

Remarks:

Please find enclosed the response to questions directed to USDA that were submitted for the Record on May 4, 2004.

USDA and FDA

SFSA1

In what areas of food inspection is coordination the most difficult between agencies? Why?

Response: The Food Safety and Inspection Service (FSIS) maintains a strong working relationship with its sister public health agencies, such as the Department of Health and Human Service's Food and Drug Administration (HHS-FDA). Cooperation, communication, and coordination are absolutely essential to effectively address public health issues. Since 1999, FSIS and HHS-FDA have had a Memorandum of Understanding (MOU) to exchange information on an on-going basis about establishments that fall under both jurisdictions. FSIS will continue engaging in substantive discussions with HHS-FDA and other agencies who share public health and food safety responsibilities.

Although FSIS and HHS-FDA work cooperatively, fundamental responsibilities in the Acts under which the two agencies receive their authority differ. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act one of FSIS' principal mandates is to conduct a continuous inspection program pursuant to which meat, poultry and egg products must be inspected and passed. FSIS must find that these products are not adulterated. Under the Federal Food, Drug and Cosmetic Act, HHS-FDA polices the industry through marketplace surveillance rather than mandatory premarket inspection.

SFSA2

I would appreciate having additional information regarding the Hazard Analysis Critical Control Point inspection process. How is the HACCP used differently by each agency? Is it appropriate that agencies use this process differently?

Response: FSIS and HHS-FDA both developed their Hazard Analysis and Critical Control Points (HACCP) regulations based on the principles adopted by the National Advisory Committee on Microbiological Criteria for Foods. However, the agencies' HACCP systems differ. Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS is required to provide slaughter inspection of livestock and poultry. Since HACCP is mandatory for all meat and poultry establishments regulated by FSIS, the agency conducts daily HACCP verification activities at all establishments.

SFSA3

It was brought out at the hearing that training requirements are the same for FDA inspectors and U.S. Department of Agriculture (USDA) inspectors. In addition, it was also stated that there are Memoranda of Understanding between the FDA and USDA for the purpose of having inspectors assist the other agency in areas of dual jurisdiction. Is there any reason why these inspectors should not be cross-trained so as to have full authority of both agencies, legal barriers notwithstanding?

Response: There are aspects of FSIS and HHS-FDA training that are similar. FSIS and HHS-FDA personnel, however, work in vastly different

environments, as dictated by the products within their jurisdiction. FSIS-trained inspectors are devoted primarily to continuous inspection operations in federally inspected plants, and FSIS' front-line inspectors in slaughter plants have no corollary at HHS-FDA. Although both agencies have HACCP programs, the agencies' HACCP systems differ as a result of differences in the products and product environments that each agency regulates. In addition, USDA conducts HACCP verification activities at least daily at all establishments.

FSIS and HHS-FDA collaborate on food security exercises at the Federal, State, and local levels that provide useful guidance in the event of an attack on the food supply. These joint exercises have proved very successful because they allow FSIS and HHS-FDA personnel to recognize and correct food safety and security vulnerabilities in a realistic, albeit simulated, environment.

SFSA4

Additionally, Dr. Pierson said that, "[W]here you have this dual jurisdiction issue that our inspectors are trained on those overlap areas." What are the specific areas of overlap between the two agencies and what training is given to inspectors to deal with this?

Response: In establishments that generate multiple products, some of which fall within FSIS' jurisdiction and others that are inspected by HHS-FDA, the agencies work to ensure that there is not a duplication of inspection resources. For example, if an FSIS inspector discovers a sanitary problem with a product under HHS-FDA's jurisdiction, the FSIS inspector would notify HHS-FDA.

SFSA5

We'd like to address emerging concerns about the potential for deliberate contamination of our food supply by terrorist groups. As you know, the President has recently added agriculture and food to the list of critical infrastructures. In your testimony today, you've outlined the actions that your agency has taken to address this issue and the areas where there is interagency coordination. I commend you for your efforts. However, if a deliberate contamination event were to occur, would it not be more effective to have a single agency federal agency as the responsible lead agency to deal with such an emergency? If the creation of the Department of Homeland Security was created to meet the terrorist threat with a single agency, does not the same logic follow with deliberate acts against the nation's food supply?

Response: The Department of Homeland Security (DHS) has the task of protecting the nation against terrorist threats, including those made upon the food supply. FSIS and HHS-FDA are keenly aware that cooperation, communication, and coordination are absolutely essential to quickly and effectively respond to threats to the food supply - particularly the threat of intentional contamination. Therefore, FSIS works closely with DHS, the White House Homeland Security Council, and HHS-FDA, to develop strategies to protect the food supply from an intentional attack.

In addition, FSIS and HHS-FDA collaborate on food security exercises at the Federal, State, and local levels that provide useful guidance in the event of an attack on the food supply. These joint exercises provided our agencies with excellent training opportunities, and have allowed FSIS and HHS-FDA personnel to develop enhanced skills and expertise in dealing effectively with food safety and security vulnerabilities.

SFSA6

If HHS-FDA and USDA disagree on procedures regarding a matter that requires they work together very closely, such as the BSE case last year, which agency ultimately makes the final decision on actions that will be taken? Can one agency make decisions that are binding on the other agency in times of emergency?

Response: Because there is an established network of inter-agency cooperation, situations are handled swiftly and effectively. The December 2003, discovery of a single case of Bovine Spongiform Encephalopathy (BSE) in Washington State provides an example of the effective cooperation between USDA, HHS-FDA and their Federal and State food safety partners. The Federal government's swift, coordinated and substantial reaction to the BSE diagnosis played a vital role in ensuring the safety of the food supply and maintaining high consumer confidence. FSIS, HHS-FDA, the Animal and Plant Health Inspection Service and other Federal agencies all participated in numerous briefings, planning meetings and international trade discussions related to the BSE situation, and as a result, the various agencies worked as one and spoke with a single voice on the issue.

Apart from the BSE issue, since 1999, FSIS and HHS-FDA have had a Memorandum of Understanding to exchange information on an on-going basis about establishments that fall under both jurisdictions. On the rare issues in which jurisdiction over a matter is not distinct, the relevant agencies work together in the initial stages of the investigation to determine the products implicated and, from that, the agency with jurisdiction. FSIS will continue to collaborate and partner with HHS-FDA and other agencies who share public health and food safety responsibilities.

SFSA7

With regard to egg inspection, reports by GAO indicate that FDA has responsibility during production (known as shell eggs) and then the responsibility transfers to USDA when eggs are broken to create egg products. More than 10 years have passed since the problem of bacterial contamination of intact shell eggs was first identified. We understand that USDA and FDA have been working on egg safety standards for several years. Why is it taking so long, over ten years, to develop a safety strategy for eggs? Are FDA and USDA getting any closer to developing standards for egg production and processing? Will each agency issue separate rules for egg safety?

Response: On May 19, 1998, HHS-FDA and FSIS published a joint advance notice of proposed rulemaking that sought to identify farm-to-table actions that would decrease the food safety risks associated with the consumption of shell eggs (63 FR 27502). Subsequently, the agencies began to explore all reasonable alternatives and gather data on the public benefits and the public costs of various regulatory approaches before proposing a farm-to-table food

safety system for shell eggs. This past year, FSIS completed a baseline study regarding the microbiological profile of pre-pasteurized liquid egg products in order to incorporate this previously unavailable data into the risk assessment on egg products. FSIS has assessed this data and incorporated it into a draft HACCP-based performance standard proposed rule for pasteurized egg products.

SFSA8

Doesn't a fragmented food inspection system make trading with foreign governments more burdensome than it should be because there is not one food inspection agency to deal with? What responsibilities does each agency bear in dealing with international trade of food?

Response: Over the years, the agencies involved with import and export of food products have successfully cooperated to assure that U.S. regulatory and trade concerns are met. For imported food, FSIS regulates those species requiring mandatory inspection in the U.S. under the FMIA, PPIA and EPIA. When meat, poultry and egg products are imported into the U.S., FSIS import inspectors ensure that each shipment is properly certified, examine each lot for general condition and labeling and conduct reinspection. HHS-FDA regulates remaining food commodities. In the international community, this is not an uncommon separation as meat and poultry have historically been more heavily regulated than other commodities traded internationally. Most activity related to food exports is in USDA, and involves cooperative efforts of FSIS for public health issues and the Animal Plant and Health Inspection Service (APHIS), for animal health issues. In most export matters, the Foreign Agriculture Service plays a facilitating role.

USDA

SFSA9

If all food inspection responsibilities were to be consolidated under a single agency, would USDA be the best place? Would the Undersecretary for Food Safety be capable of acting as the highest food safety official in the Federal Government, overseeing all food inspection programs?

Response: Over the years, there has been much discussion about consolidating all food safety, inspection, and labeling functions into one agency in an effort to increase the effectiveness of the food safety system. In 2002, the White House established a Policy Coordinating Committee (PCC), led by the Domestic Policy Council and the National Economic Council, to look into the single food agency issue. The PCC concluded that the goals of the Administration are better advanced through enhanced interagency coordination rather than through an effort to create a single food agency.

USDA routinely communicates and coordinates with other government entities to ensure a safe and secure food supply. With authority over meat, poultry and egg products, USDA's FSIS plays an integral role in ensuring the safety of America's 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. Cooperation, communication, and coordination are absolutely essential to effectively address public health issues.

The present statutory framework recognizes distinctions associated with the relative risks and hazards of foods and the food safety and food security issues that bear on public health. USDA's mission is to provide leadership on food, agriculture, and natural resources based on sound public policy, the best available science, and efficient management. Within USDA, the nearly 10,000 employees of the FSIS dedicate their careers and lives to protecting public health. USDA inspectors are in plants every day enforcing our nation's food safety laws. The statutes that are administered are clear and demand unwavering attention to ensuring that consumers continue to enjoy the safest and most abundant food supply in the world. It is this focused attention to food safety, food security, and public health that is best supported by the current organizational placement of the USDA food safety mission.

SFSA10

Is it possible for the USDA to operate under a risk-based science-based system, instead of exclusively under a science-based system?

Response: FSIS believes that it is essential for FSIS to establish risk-based approaches to inspection in order to best protect public health and to ensure food security in an environment with limited resources. Risk-based inspection has, for the most part, been implemented through HACCP-based initiatives since 1997, whereby FSIS has focused on verifying that the regulated industry's science-based food safety systems are properly designed and functioning. In addition, FSIS has taken substantive steps towards prioritizing inspection activity related to food safety (adulterants), with secondary emphasis on other consumer protections (misbranding). FSIS has announced that it will be developing risk-based verification testing programs for various pathogens, such as *Listeria monocytogenes* (See 68 FR 34221, June 6, 2003). Finally, FSIS has invested heavily in training and on ensuring that the inspection program personnel have the necessary skills and knowledge to apply critical thinking processes in order to discern weakness in the science-based food safety systems that present greater risk for adverse public health outcomes.

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