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FOOD SAFETY AND SECURITY: CAN OUR FRACTURED FOOD SAFETY SYSTEM RISE TO THE CHALLENGE?

HEARING

BEFORE THE

OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING, AND THE DISTRICT OF COLUMBIA SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

OCTOBER 10, 2001

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FOOD SAFETY AND SECURITY: CAN OUR FRACTURED FOOD SAFETY SYSTEM RISE TO THE CHALLENGE?

WEDNESDAY, OCTOBER 10, 2001

U.S. SENATE,
OVERSIGHT OF GOVERNMENT MANAGEMENT,
RESTRUCTURING, AND THE DISTRICT OF COLUMBIA,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1 p.m., in room SD–342, Dirksen Senate Office Building, Hon. Richard Durbin, Chairman of the Subcommittee, presiding.

Present: Senators Durbin and Voinovich.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. This hearing will come to order. I thank you all for coming today to discuss issues of food safety and security. Some of my colleagues are running a little bit late. This has been an unusual morning because we had a memorial service for Senator Mike Mansfield. Most of us have just gotten off the buses and many of my colleagues had to quickly return to their offices. They will be joining us in a few minutes. They are running a little bit late, but I thank you all for coming today.

The hearing will come to order and good afternoon. I am pleased to welcome you to this hearing of the Senate Subcommittee on the Oversight of Government Management. We are going to focus on food safety and security and the question: Can our fractured food safety system rise to today's challenge? Let me say at the outset—and will say repeatedly—we have the safest food supply in the world. That is something that bears repeating, because even though we are raising questions about how to improve the system, we start off with a food supply that is second to none. The question which we are going to be asking ourselves today is whether or not we can improve the system.

For many years now, I have worked on this issue, of food safety focusing on questions which involve hazards in food that are naturally occurring that can be avoided with appropriate inspection and processing. In the last several weeks this conversation has changed. It is no longer just about food safety. It is about food security, and that is one of the aspects which we also have to take into account. That is one of the reasons why I wanted to bring this group together today.

Our government structure divides responsibility for food safety and security between at least a dozen Federal agencies operating under 35 different Federal statutes. It is a system of divided responsibility. It is a system of rivalry, in some aspects, when it should be one of cooperation. It is duplicative, it is costly and it is unduly complicated. It is impossible to explain. In an age where our Nation's food supply is facing tremendous pressure from emerging pathogens to an ever-growing volume of food imports, from changing food consumption patterns to an aging population susceptible to food-related illness and even potential food security risks, we must have a system in place to ensure the safety of our food.

Now is the time to fundamentally set the course for a food safety system that is not only more efficient and effective, but one based on science, with the promise of sustaining the confidence of the consuming public. It is time for our government to have a single food safety agency. I do not believe there is a person in this room or in this city or this Nation that would say to us today that if they had to invent a food safety system, they would invent what we have in place.

Make no mistake, as I said, our country is blessed with safe and abundant food supplies, but we can do better. Foodborne illness is a significant problem. While food may never be completely free of risk, we have to strive to make our food as safe as possible. Americans at every level, Federal, State and local, industry and the consuming public, share this responsibility. The Center for Disease Control estimates that as many as 76 million Americans will suffer food poisoning this year. Of those individuals, 325,000 will be hospitalized, and more than 5,000 will die. Children and the elderly are especially vulnerable.

In terms of medical costs and productivity losses, foodborne illnesses cost the Nation billions of dollars annually. The situation is not going to improve without decisive action. In fact, the Department of Health and Human Services predicts that foodborne illnesses and deaths will increase 10 to 15 percent over the next decade from natural hazards. Over the past 25 years, the GAO and other organizations, including the National Academy of Sciences, have issued report after report describing the problems with Federal food safety oversight and the need for a single food agency. These organizations have made many recommendations for change.

I think it is time we make that fundamental lasting change that GAO has asked for. We need that single food agency. I introduced the Safe Food Act of 2001 last week. It combines the functions of USDA's Food Safety and Inspection Service, the FDA's Center for Food Safety and Applied Nutrition, FDA's Center for Veterinary Medicine, the Department of Commerce's seafood inspection program, and the food safety functions of several other Federal agencies. This new agency will be funded by the combined budgets of the consolidated agencies.

Following the events of September 11, we are more keenly focused on how varied aspects of America's homeland security, including our Nation's food supply, may be vulnerable to attack. Our Federal food safety system must be able to prevent potential food hazards from reaching the public. We must establish procedures on the farm and during the various stages of food processing to ensure

that no form of deliberate contamination reaches consumers. We also have to critically examine our import procedures to determine if they are adequate to protect the public from food-safety threats. A single food agency will help ensure that we have a cohesive process in place.

Last night, I met with David Byrne, who is the Health and Consumer Products Commissioner for the European Union. He is a man I met several years ago at a St. Patrick's Day parade in Chicago—he reminded me of that. He is trying at this point in time to establish this type of agency for the European Union. Now is the time for us to start that dialogue with the European Union, to continue a dialogue that may have started before, but in more earnest and sincere terms. As we look around the world to those countries which seek to import from the United States and export to our country, we have to establish some meaningful, scientific, reasonable standards, so that we know the product that is moving across the border is safe for everyone.

Overlapping jurisdictions of Federal agencies have really lessened accountability. A single agency focuses our policy and improves our enforcement. Let me just say that research could be better coordinated, as well, with a single agency. Currently Federal funding for food safety research is spread over more than a dozen different Federal agencies, and coordination is very limited. New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.

With the incidence of food recalls on the rise, it is important to move beyond short-term solutions. A single agency could more easily work toward long-term solutions. In this era of limited budgets, it is our responsibility to modernize and streamline the system. This Subcommittee has been discussing the weaknesses of the Federal food safety system for decades. I have not been here in that discussion for decades, but it has been going on that long. It is time to move forward. Let's stop discussing the need and actually make it happen. I am encouraging my colleagues on both sides of the aisle to help me to consolidate the food safety and security functions.

At this point I was going to recognize Congresswoman Rosa DeLauro, who I understand is on the way and may be here momentarily. When she does, I am going to invite her to come up and speak and interrupt the panel that may be speaking at the time—I hope everyone will understand—because of her schedule. Let me at this point welcome our first panel then. Robert Robinson is the Managing Director of Natural Resources and Environment with the U.S. General Accounting Office. He is accompanied by Keith Oleson, who is the Assistant Director of GAO's Natural Resources and Environment Division. Thank you for being here. We look forward to your testimony. It is customary for the Subcommittee to swear in all of our witnesses. So, if you would not mind standing, do you swear that the testimony you are about to give is the whole truth, and nothing but the truth, so help you, God?

Mr. ROBINSON. Yes, sir.

Mr. OLESON. Yes, sir.

Senator DURBIN. Thank you very much. Let me note for the record that the witnesses answered in the affirmative. Please, if you could limit your oral statements so that we can follow up with some questions——

Mr. Robinson.

TESTIMONY OF ROBERT ROBINSON,[1] MANAGING DIRECTOR, ACCOMPANIED BY KEITH W. OLESON, ASSISTANT DIRECTOR, NATURAL RESOURCES AND THE ENVIRONMENT, U.S. GENERAL ACCOUNTING OFFICE

Mr. ROBINSON. Thank you, Mr. Chairman, for this opportunity to weigh in on this matter of real national importance. As you know and have just mentioned, GAO has long called for the establishment of a single food safety agency responsible for implementing uniform and risk-based food safety legislation. I am here today to renew this call.

While we believe the case for such action has been compelling for some time, recent tragic events and the increased threats these actions portend for the future make the need for action all the more imperative. While the American food supply is generally safe, the 5,000 deaths and millions of illnesses attributed to foodborne pathogens each year provide ample evidence that the system needs improvement. The current regulatory system did not emerge from a comprehensive design, but rather was cobbled together piecemeal over many years. The patchwork that now exists hampers efforts to adequately address existing and emerging food safety threats, whether those risks involved inadvertent or deliberate contamination.

It has also led to an inefficient and inflexible deployment of resources, as well as inconsistent oversight and enforcement of products with comparable risk. With respect to resources, the current deployment is not particularly rational and certainly is not risk-based. FSIS and USDA spends about 70 percent of the Federal food safety regulatory dollar inspecting on a daily basis about 6,000 meat, poultry and egg establishments that collectively produce about 20 percent of federally-regulated foods. FDA, on the other hand, has less than half of FSIS's funding to oversee about 10 times more food production facilities and about four times more federally-regulated foods.

In this context, the resulting oversight of food production is quite inconsistent. Over the years, as I am sure you are aware, we have used a number of food items, including canned soup and frozen pizza, to put a specific face on the systems of irrationality. This time we will use a packaged sandwich. As you can see from our graphic, if you are producing a packaged open-faced meat or poultry sandwich, you get inspected daily by FSIS. If, on the other hand——

Senator DURBIN. Part of the Department of Agriculture?

Mr. ROBINSON. Yes. If, on the other hand, you are producing a closed-face sandwich with identical ingredients, you get inspected by FDA on average once every 5 years.

[1] The prepared statement of Mr. Robinson appears in the Appendix on page 45.

The current fragmented structure also has implications for food imports, an area of growing importance to our food supply. FSIS and FDA employ vastly different approaches. On the one hand, meat and poultry cannot be exported to the United States unless FSIS has determined that the exporting country has an equivalent food safety system. This allows FSIS to leverage its inspection resources. Also, until FSIS approves the release of imported products, they generally must be kept in a registered warehouse. Unlike FSIS, however, FDA does not have authority to require equivalency agreements and is thereby forced to rely on widely discredited port-of-entry inspections. Also, because FDA does not control imported foods prior to its approval for release, some adulterated imports have been released into U.S. commerce.

Now, of course, overhanging these long-standing limitations in the current food safety system is the prospect of deliberate terrorist contamination. The likelihood of such an attack is unknown. In a recent report we identified only two acts of deliberate food supply contamination over the past 15 years. However, based on the nature of our food system and the weaknesses we have already identified, we believe there is reason to doubt our system's ability to detect and quickly respond to an orchestrated bioterrorist attack. The U.S. food distribution system moves food from production to markets in hours. Even if contamination was detected by the extremely limited testing that occurs, vast amounts could already be in the hands of consumers. Furthermore, even if the current surveillance system worked as intended, the problem would not be typically identified until multiple illnesses were reported.

Our fragmented system would compound these inherent difficulties; for example, determining which Federal agency was responsible for responding could take precious time when speedy action would be absolutely essential. Similarly, split responsibility could impede timely laboratory testing and the ability to marshal the full range of Federal resources. Mr. Chairman, as you have mentioned, while no system can be foolproof, the fragmented system now in place is simply not good enough. A single food safety agency is needed now more than ever. In this regard, we are gratified to note that consolidation of food safety activities is supported by the National Academy of Sciences, the President's Council on Food Safety and a large number of former food safety officials. It is also consistent with the recent actions taken by a number of other nations, including Canada, Great Britain, Denmark, and Ireland.

Before concluding, I also want to make you aware of related work that you may find useful. This work was performed by us in 1998 when we issued a classified report to the full Committee that laid out the vulnerability of U.S. agriculture to a biological attack. We have updated that work and have prepared a classified briefing. The team is here and can present the information in a closed environment whenever called upon.

Thank you.

Senator DURBIN. Thanks, Mr. Robinson, and I will take you up on that, which, of course, will not be today, but we will do it in a different setting. You made reference to U.S. Department of Agriculture. Our former Secretary is here and many of us have worked with that Department and think very highly of it. I have equally

high regard for the Food and Drug Administration. Many people argue that we are dealing with two different cultures between these agencies, in terms of the way they look at their responsibility. As the GAO took a look at food inspection, did you note any differences in approach or application of science or different cultures?

Mr. ROBINSON. Well, differences in approach are pretty much across the board, and a lot of it has to do with different legislative authorities and requirements. Practically on every front, the authorities are different and, hence, the approaches almost necessarily are different. You could pretty much go down the line and identify those differences.

Senator DURBIN. Let's get down to basics. Some argue that the U.S. Department of Agriculture, because it has a responsibility to promote the products, consumption and the like, is not in a good position to be a watchdog over the agencies and the Department—the facilities and the businesses that it regulates through this inspection, whereas FDA takes a much different approach when it comes to approvals for medical devices and pharmaceuticals and the like. Did you note that in the GAO review of this process?

Mr. ROBINSON. Yes. This goes to the basic rationale that finally led us to conclude that an independent agency was the way to go. USDA fundamentally has the FAA problem. The same agency that is responsible for promoting the industry is also responsible for regulating the safety of the product, obviously conflicting interests. FDA, on the other hand, has a situation where the bulk of its resources have usually been devoted to the "D" part of the agency, leaving the "F" part of the agency in somewhat more of a stepchild environment when resource allocations decisions were to be made. So there is a fundamental——

Senator DURBIN. When I took a look at this issue to try to determine how we can move from where we are today to a single food agency, it was really tough to find a lot of parallels. The closest I could find was the creation of the Environmental Protection Agency, where we took a lot of different agencies and brought them together under one roof with one mission, and if I am not mistaken, it also involved a transition period before the EPA could really open its doors and get down to business. Do you have any thoughts on that aspect, moving from where we are today to a single food agency? Have you seen any examples in other countries where they have tried to accomplish this?

Mr. ROBINSON. Yes, a few years ago we did joint work with our Canadian Office of Auditor General counterparts. We issued a joint report with them on food import controls, and that report led the Canadians to take action. They have moved pretty aggressively or much more aggressively than we have to establish a single food safety agency and although early, the signs seem to be positive. As I mentioned in my statement, the British have moved in that direction, as have other Nations and the EU is now considering it, as you mentioned.

I think the arguments are so compelling—the inefficiencies and the gaps and the overlaps are so obvious it almost raises the question as to what is holding the move to rationality back. There

seems to be growing conceptual agreement on the basic decision of consolidation. What remains to be worked out is the details.

Senator DURBIN. There are three things holding us back. I can tell you what they are: One is Congress, where committees have jurisdiction and do not want to give it up; the other would be the agencies currently involved that are fearful of losing jurisdiction; and the third are people who are regulated. They are fearful of change. You put those three together and you can explain why for 30 or 40 years this grand idea has gone nowhere. Maybe the events of September 11 will give us the impetus to change.

One last question before I recognize my friend, Congresswoman DeLauro. You made a reference to the international aspect of this and clearly that is something we have to take into account, and you noted that the FDA, aside from random border inspection, frankly does not do much by way of inspecting food production overseas; is that correct?

Mr. ROBINSON. Yes. I think currently it is about 1 percent of imports under their jurisdiction are inspected. With additional resources that have been requested, that percentage could rise a few points. But essentially you have to ask yourself if raising that inspection level from 1 percent to 3 percent—it does not move you a lot further down the road; whereas I think leveraging resources, like FSIS is allowed to do, to ensure that foreign nations that will be the source of our food imports have installed systems comparable to ours and are implementing those systems based on testing, is a far more efficient way, and I think, ultimately much more effective and a more confidence-inducing way of proceeding.

Senator DURBIN. Well, I have taken a big enough task, dealing with trying to consolidate our domestic food safety inspection, but I really believe, as I said at the outset, that this should be discussed in a global context. As we are talking about our allies now who are struggling against terrorism worldwide, I think we can find the same type of alliances when it comes to food safety and security, so that trade can continue with peace of mind. My conversations yesterday with the European Union led me to believe that they are ready for this, as well. It not only will help us when it comes to food safety and security, but in trying to find some common ground and resolution to many other intractable food safety issues between the EU and the United States. I hope that will be part of it.

If I could ask you and Mr. Oleson to just stay where you are for a moment, I am going to turn over the microphone to my friend, Congresswoman DeLauro, who has been a leader on this issue in the House. Thank you for coming.

TESTIMONY OF HON. ROSA L. DELAURO,[1] A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CONNECTICUT

Ms. DELAURO. Thank you so very much, Mr. Chairman and my good friend. I apologize to my colleagues at the table. I will try to be brief. I would just like to say to my colleague, the Chairman, Senator Durbin, that it has been an honor and a pleasure to work with him. I sat on the Agricultural Appropriations Committee

[1] The prepared statement of Ms. DeLauro appears in the Appendix on page 66.

when Senator Durbin was the chair over there. This is an issue in which he has really taken such a leadership role, and I am pleased that we are going to continue to work on this effort, and I am grateful to hear about your conversations with the European Union as to what we might be doing with our allies overseas.

Our Nation's food safety is of critical importance, we all agree with that. The Center for Disease Control and Prevention says that each year 76 million people get sick and 5,000 people die from a food-related illness. I had a personal experience with this problem. When I was a child I contracted Salmonella. I was hospitalized for almost 2 weeks. I was so young that I did not know why my parents had put me into this situation, away from them and so forth, and I am told, though I do not remember, that I refused to talk to them when I did get out of the hospital.

The numbers are staggering nationwide, of people getting sick and people who are dying, and they do not include a vast number of unreported illnesses. The situation is not going to improve without some decisive action. Also, in terms of what happened on September 11, we need to be concerned about the safety of our food from a bioterrorist attack. According to Raymond Zilinskas, who is a senior scientist with the Monterey Institute of International Studies, the most likely scenario for a biological weapons attack would be foodborne or beverageborne attack, using Salmonella, Shigella, or Staphylococcal toxins.

Tommy Thompson, the Secretary of Health and Human Services, on October 3 submitted a request to OMB for additional money for bioterrorism programs. In addition to other priorities, he identified food safety as a vital area that needs to be addressed. The Secretary has requested money for 200 imported food inspectors and 100 domestic food inspectors. I might add that several months ago on the debate on this year's agricultural appropriation, I offered an amendment, which would have provided $90 million for 1,600 FDA inspectors for imported food and $73 million for 630 domestic inspectors. It was defeated, but I think now more than ever we have to go back to that effort.

Clearly, what we need is to have a comprehensive strategy, a unified strategy. There are several agencies with different and conflicting missions that ensure our food safety. There is no standardization for inspections. Processed food facilities may see an FDA inspector once every 5 to 6 years. Meat and poultry is inspected daily. We need to do something. Everyone here is agreeing.

In 1998 the National Academy of Sciences' study concluded that, "A model food safety system would have a unified mission, a single official who is responsible for food safety at the Federal level and who has the authority and the resources to implement science-based policy and all Federal activities related to food safety." It makes sense in order to protect our food supply to consolidate food safety activities into a single agency. I introduced the legislation in the House of Representatives, like my colleague on the Senate side. It establishes that independent agency with responsibility for all Federal food safety activities. It would transfer food safety inspection and food labeling activities to a new agency from the several agencies that now are engaged in that process.

We have 32 co-sponsors of the legislation. It is bipartisan. People understand that this is the direction that we need to move in. This is just plain good government, in my view. I might also add, in his campaign President Bush publicly supported the idea of uniting all food safety responsibility under one agency. On June 9, he said in Philadelphia, "The Federal Government is responsible for the safety of our Nation's food supply. The way things work now, there is one agency that inspects cheese pizza. There is another that inspects pepperoni pizza. There is one agency that inspects food grown outside of the United States, another for food grown here inside the United States. Apparently the revolutionary idea that maybe these functions could be combined has not dawned on anybody yet."

It is time to create a 21st Century approach to our food safety system, particularly because we have got this problem in the United States, but globalization, aging population, faster production, distribution of food increases people being at risk. I thank you for the opportunity to have me here today to testify. This is good common sense. I look forward to working with my colleague on this. I thank you again for your leadership and I thank you for letting me cut into the line.

Senator DURBIN. Congresswoman DeLauro, thank you and I know your beeper went off, so you are going to have to make a mad dash. I would just say that the one thing that we have to step back and do—so many times now on Capitol Hill—is say if terrorism disappeared tomorrow and our prayers were answered, would this still be a good idea? I think the answer is clearly yes, but terrorism has not disappeared and we have to put it into the equation now. I think it really adds an element of immediacy to this debate and perhaps it will move us off dead center, where we have been too long. Thank you for your leadership in the House. You are excused. Thank you very much.

Mr. Robinson, I understand that some of the people who have headed up these agencies in the past at FSIS and FDA, once liberated from government service, have announced that they always thought this was a pretty good idea. Have you run into that?

Mr. ROBINSON. We have obviously done some exploration with individuals and touched base with eight or ten folks, and I think is a pretty clear consensus, as I mentioned earlier, that conceptually, consolidation makes all the sense in the world and it ought to be pursued aggressively.

I do want to make the point, though, it is not just consolidation of bureaucracies. You have 35 laws, as you mentioned, out there that also need to be rationalized. The basis for a lot of action is legislative in nature, and that is going to have to be addressed to make a single food safety agency realize the promise that so many of us believe it can.

Senator DURBIN. Thank you.

Mr. Oleson, is there anything you would like to add?

Mr. OLESON. The individuals we contacted, former administrators of FSIS and former commissioners of FDA, former Under Secretary of Agriculture, former Secretary of Agriculture, all concur that consolidation needs to take place and they all agree that one thing that should be consolidated is the inspection activities, at

least. There are some differences after we get past that on what should be included, but inspection is one you can start with, as your bill clearly recognizes, Senator.

Senator DURBIN. Good. I appreciate both of you coming today. Thank you very much for your testimony and continued work. Maybe before GAO does another couple dozen reports making this recommendation, Congress will actually do something.

Mr. ROBINSON. Well, the paper on the 1992 report, our first one on the subject, is starting to yellow. [Laughter.]

Senator DURBIN. Thanks for joining us. We appreciate it.

Mr. ROBINSON. We will be in contact with your staff relative to the classified briefing.

Senator DURBIN. Thank you very much.

I want to welcome our next panel: Dr. Elsa Murano, the recently confirmed Under Secretary of Agriculture for Food Safety, thank you very much for being with us today; Dr. Bernard Schwetz, who is the Acting Principal Deputy Commissioner of the Food and Drug Administration with the U.S. Department of Health and Human Services; accompanied by Joseph Levitt, the Director for the Center for Food Safety and Applied Nutrition from the U.S. Department of Health and Human Services; and a good friend, former colleague and a great public servant, Dan Glickman, former Secretary of Agriculture, who is now in private practice with Akin, Gump, Strauss, Hauer, and Feld. I want to make sure to announce that so, when you get back, your partners will forgive you for the time you have given us this day.

As I said earlier, it is customary to swear in the witnesses, and I hope you will please stand and allow me to administer the oath. Do you swear the testimony you are about to give is the whole truth, and nothing but the truth, so help you, God?

Ms. MURANO. I do.

Mr. SCHWETZ. I do.

Secretary GLICKMAN. I do.

Senator DURBIN. The record will indicate the witnesses answered in the affirmative, and I would ask you to, if you would, please give 5-minute opening statements, and your whole statement will be submitted for the record.

Dr. Murano, would you be kind enough to start?

TESTIMONY OF HON. ELSA MURANO, PH.D.,[1] UNDER SECRETARY OF AGRICULTURE FOR FOOD SAFETY, U.S. DEPARTMENT OF AGRICULTURE

Ms. MURANO. Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to appear at today's hearing and discuss our Nation's food safety system and structure. I am Dr. Elsa Murano, Under Secretary for Food Safety at the U.S. Department of Agriculture. As you know, I am a newcomer to USDA, having just been confirmed as Under Secretary on September 26, and I was sworn in October 2. I am honored to be serving in this important position and I am committed to the hard work ahead. I know there are many important food safety issues before the Congress,

[1] The prepared statement of Ms. Murano appears in the Appendix on page 68.

and I look forward to working closely with you to make progress on those issues.

I have been a researcher and teacher in the field of food safety. My research efforts have led me to investigate pathogens such as E. coli O157:H7, Listeria Monocytogenes, and Salmonella. I believe my experience as a scientist and educator and my perspectives as an outsider looking in will be valuable as I begin this new position. FSIS's mission is to ensure that the Nation's commercial supply of meat, poultry and egg products is safe, wholesome and correctly labeled and packaged. FSIS's goal is to protect the public health by significantly reducing the prevalence of foodborne hazards in meat, poultry and egg products. FSIS has a long, proud history of protecting the public health, dating back to 1906.

Although changes have been made over the years to the inspection program, the most dramatic change occurred when FSIS published a Pathogen Reduction/Hazard Analysis and Critical Control Point—HACCP—systems rule in 1996. Under HACCP, industry is accountable for producing safe food. Government is responsible for setting appropriate food safety standards, maintaining vigorous inspections to ensure those standards are met, and maintaining a strong enforcement program to deal with plants that do not meet regulatory standards.

Our food safety system is being challenged by many factors. They include emerging pathogens, an increase in international trade, new food products in the marketplace, a growing segment of the population at greater risk of contracting foodborne illnesses and gaps in education all along the farm-to-table chain. On September 19 the Bush Administration published its review of the food and agricultural system with a view toward identifying critical needs for the next century. The report, titled "Food and Agricultural Policy, Taking Stock for the New Century," details the enormous changes that have taken place in food and agriculture. Food safety certainly is a vital part of food and farm policy, and the report emphasizes this.

I would like to provide more details today about two key areas of the food safety infrastructure and the importance of integrated food safety programs. Let me begin with the USDA food safety infrastructure. Inspection of meat, poultry and egg products is an important part of that infrastructure. FSIS currently has approximately 10,000 employees, the bulk of which are stationed in the field. More than 7,600 inspection personnel are stationed in approximately 6,000 meat, poultry, and egg plants. FSIS also certifies foreign programs as possessing public health safeguards that are equivalent to the U.S. program and reinspects imported product as it enters the United States.

FSIS is also responsible for assessing State inspection programs that regulate meat and poultry products that may be sold only within the State in which they are produced. There are currently 27 states that have a State meat or poultry inspection program and operate under cooperative agreements with FSIS. Another part of the FSIS food safety program involves its three multidisciplinary laboratories, which conduct laboratory testing for microbiological contamination, chemical and animal drug residues, pathological

conditions, processed product composition, and economic adulteration.

FSIS also conducts compliance and enforcement activities to address situations where unsafe, unwholesome or inaccurately-labeled products have been produced or shipped. Surveillance is another part of the infrastructure. A strong food safety system must have a mechanism for identifying new food safety problems rapidly. USDA conducts surveillance of the food supply and HHS Centers for Disease Control and Prevention, in partnership with State and local health departments, conducts surveillance for human foodborne illness.

Outbreak responses is also key. Because coordination is essential, we have taken steps to expedite communication during large, multistate outbreaks. One mechanism is the Foodborne Outbreak Response Coordinating Group, FORCG, a partnership established to better respond to interstate outbreaks of foodborne illness. USDA, HHS and EPA formed this partnership. This interagency group has coordinated and developed procedures for managing outbreaks, sharing information on potential sources of outbreaks and pathogens, and coordinating interdepartmental activities.

A similar group, the Food Emergency Rapid Response and Evaluation Team, FERRET, has been established within USDA to coordinate the activities of USDA agencies. USDA participates in PulseNET, a national network of public health laboratories supported by HHS. These laboratories aid outbreak response by performing DNA fingerprinting of foodborne bacteria and comparing results through an electronic database maintained by CDC.

Research is another important part of the food safety infrastructure. FSIS is not a research agency, but works through the Agricultural Research Service to meet its research needs. Risk assessment is another important part of the food safety infrastructure. You can never completely eliminate foodborne health hazards, and resources are limited. Risk assessments help us to set priorities.

Education also figures prominently. Partnerships have been key in education. The *Fight Bac* campaign is sponsored by the Partnership for Food Safety Education, a public-private partnership with participation from USDA, HHS, and the States. I provided you folders containing some of the outreach and educational materials we use in the food safety education campaign. There are even a couple of brochures in Spanish, Mr. Chairman, that you may enjoy.

Like every infrastructure, the food safety system requires periodic review, ongoing reinforcement and appropriate modernization just to keep pace with continuously emerging and often unique challenges. What has become very clear is that the services USDA provides, from eliminating foodborne pathogens to protecting against plant and animal pests and diseases to encouraging farm practices that stress conservation—all are interrelated and must continue to be carefully and comprehensively coordinated. We can do more to examine whether Federal food safety agencies can improve the services they provide, but this should be done by a careful step-by-step process and by continued coordination with other agencies involved in the food safety system.

Mr. Chairman, thank you again for this opportunity to discuss our Nation's food safety system and structure, and I look forward to any questions you may have.

Senator DURBIN. Thanks, Dr. Murano. I will have some questions. Dr. Schwetz, from the FDA.

TESTIMONY OF BERNARD SCHWETZ, PH.D., D.V.M.,[1] ACTING PRINCIPAL DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JOSEPH LEVITT, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SCHWETZ. Good afternoon, Mr. Chairman. I am Bernard Schwetz, the Acting Principal Deputy Commissioner of the Food and Drug Administration. I am appearing here today on behalf of the Department of Health and Human Services. Thank you for this opportunity to discuss the Federal food safety system. Ensuring the safety of the food supply is a top priority for HHS. I am pleased to be here today with my colleague from USDA, Dr. Elsa Murano, Under Secretary for Food Safety.

The American food supply does continue to be the strongest and the safest in the world. Great strides have been made in recent years that have strengthened the Federal food safety system. The Federal food safety program includes new surveillance systems, better prevention programs, faster outbreak response, enhanced education and better coordinated and focused research and risk-assessment activities. Food safety agencies are working more closely together than ever before, but our world is constantly changing and we must continue to change with it. Indeed, we cannot rest until we have built a strong and credible food safety system that addresses the full range of food safety issues, one that is built on scientific expertise, that is risk-based and recognizes and responds to new risks, that provides a critical inspection presence, that has the same level of protection to consumers from both domestic and imported foods, that efficiently stewards new technologies to the market and that effectively educates and communicates with consumers.

Within HHS, the Food and Drug Administration has jurisdiction over 80 percent of domestic and imported foods that are marketed in interstate commerce. This jurisdiction includes all food products except meat, poultry, and egg products, which are regulated by USDA. FDA seeks to ensure that foods are safe, sanitary, nutritious, wholesome, and properly labeled. HHS's Center for Disease Control and Prevention has an important complementary public health role. As the lead Federal agency for conducting disease surveillance, CDC monitors the occurrence of illness in the United States attributable to the food supply.

The disease surveillance systems coordinated by CDC are an essential information network for providing early warnings about dangers in the food supply, for demonstrating progress in reducing foodborne illness and for indicating new or changing patterns of foodborne illness. Both the FDA and CDC work closely with our

[1] The prepared statement of Dr. Schwetz appears in the Appendix on page 74.

Federal food safety partners and with State and local health food safety officials.

While the current system is working, the system needs to be strengthened to address the current challenges. The goal of HHS is to work with our Federal and State partners as well as with academia, industry, consumer organizations and Congress, to build on the current foundation, resulting in a strong and credible food safety system that addresses the full range of food safety issues. The system has three simple steps: To identify risks, to take action, and to measure results.

In identifying risks we must ensure a strong science base, which is the foundation of any successful food safety system. We must also develop, enhance, and maintain surveillance systems that can quickly and accurately identify food safety risks in human food and animal feed supplies and manage disease risks effectively. These surveillance systems are the key to an effective emergency response capability.

In taking action we must start with prevention. We need strong risk-based prevention standards to prevent contamination of all human foods and animal feeds over the farm-to-table continuum. As these risk-based standards are developed, we need education and training programs so that those in the industry and the public can effectively utilize them to reduce the risk of illness. In addition, domestic inspections of the food industry are essential to ensure that the appropriate preventive controls are implemented.

While FDA uses a risk-based system to prioritize its inspections and now inspects firms that produce high-risk foods on an annual basis, we still need to provide more frequent coverage for all the firms. For imported food, we need a strong inspection and monitoring program to ensure that imported foods meet the same level of protection as domestic foods. For both domestic and imported food, we need to maintain an adequate enforcement program to be sure the rules are followed. We also need science-based methods to measure results so we know how we are doing. When implemented, the framework I have just described would minimize foodborne illness and injury, maximize consumer confidence and enhance global competitiveness.

As food may be a medium for spreading infectious diseases, let me address the Department's approach to the challenges of bioterrorism. The broad goals of a national response to bioterrorism are to detect the problem, control the spread of the epidemic, and treat the victims. Our approach to this challenge has been to strengthen public health infrastructure to deal more effectively with epidemics and other emergencies, and to hone our emergency health and medical response capacities at the Federal, State and local level. We have also worked to forge new partnerships with organizations related to national security. Our efforts have been focused on improving the Nation's public health surveillance network to quickly detect and identify the biological agent that has been released, strengthening the capacities for medical response, especially at the local level, expanding research on disease agents that might be released, developing new and more rapid methods for identifying biological agents, and improve treatments and vaccines and improving information and communication systems, among other activities.

Thank you for this opportunity to discuss our food safety program. HHS appreciates your continued interest and leadership in improving food safety. I look forward to working with you and the Subcommittee on ways to continue to improve the safety of the Nation's food supply. I would be happy to answer questions.

Senator DURBIN. Thank you, Dr. Schwetz. Secretary Glickman.

TESTIMONY OF HON. DAN GLICKMAN, AKIN, GUMP, STRAUSS, HAUER, AND FELD, L.L.P.[1] FORMER SECRETARY OF AGRICULTURE, U.S. DEPARTMENT OF AGRICULTURE

Secretary GLICKMAN. Thank you. I am one of those liberated souls that—speaking for myself. But it is a pleasure to be before this Subcommittee and my senior statesman, Senator Durbin, a great leader. Let me just say that I agree with the statement that we have the safest food in the world, and our safety system is the best in the world, and part of that is due to the very talented workforce at FSIS and APHIS and the Agriculture Marketing Service people in the FDA and the other agencies, and I also would say things are better coordinated now than they were 10 years ago among the various agencies.

But if the current system did not exist and we started from scratch to put it together, it would not look like it does now. We would not design it that way. We would make some structural changes. I believe the United States needs fundamental organizational change in the way the Federal Government handles food safety. After working on these issues both in the House, as a House member from Kansas, and as Secretary, during that 6-year period when Federal food regulation underwent the most significant changes in a century and faced some of its most severe tests, particularly in the courts, I have concluded that the basic structure is flawed and needs rebuilding.

Senator Durbin, I commend you for doggedly pursuing this problem, and appreciate the opportunity. In my statement I start out with a few things about Federal food safety statutes now. These are substantive statutes. I am not going to repeat them. They are in the statements, but things like we have called for before, for example, the ability for the government to level civil penalties, the ability for USDA and FDA to order recalls which are not there. There is a need for FDA and USDA to have the authority to act against food when epidemiological evidence links it to disease, not just in those instances when the food is infected with pathogens.

We need a lot more resources, particularly in the FDA, to do its business, and FDA needs an adequate food manufacturing database. Currently, USDA knows where meat and poultry is processed because of Federal recordkeeping requirements. The FDA does not have complementary information. So all these things, many of which continue to build on what others have said, I think need to be mentioned, because notwithstanding what we do with organization and restructuring the Federal Government, the substantive laws need to be strengthened to give the government appropriate authority to do its jobs.

[1] The prepared statement of Secretary Glickman appears in the Appendix on page 94.

But on the regulatory structure, one of the lessons we learned during the Clinton Administration was, short of outright organizational changes the need for much greater coordination across food safety-related agencies was a high priority, and that led to a number of interagency entities, the President's Council on Food Safety, a Joint Institute for Food Safety Research, and other items. While all of these efforts vastly improve the overall Federal response to this problem, they suffer fundamental flaws that a consolidated Federal regulatory agency would remedy. First and foremost is the central control of resources.

While joint planning, communication and coordination facilitate a united response to food safety, at the end of the day, unless control over spending is vested in a single authority, there will remain bureaucratic and institutional obstacles to achieving the ends that we want to achieve. A unified centralized structure brings with it another asset, a central decisionmaking entity who is in charge, who is accountable for the problem—an example is the Starlink episode. The Starlink corn episode, while not probably a traditional food safety issue, it highlights that flaw.

Most strikingly, many questioned the initial wisdom of a split registration for this particular product, and the ability of the system to keep the corn in separate segregated marketing channels, one for animals and one for human consumption. Regrettably, those deficiencies were realized in what happened. Now, fortunately we have not seen that kind of problem in the magnitude on the human side of the picture, but we have seen it in a variety of animal-related issues, and it could have easily happened here.

I have long felt that while we went through the process in the Clinton Administration of improving coordination and dealing with some of the substantive issues, that we did not want to let a heated debate over reforming the structure interfere with our primary goal. I urged a go-slow approach to organizational revision during the period of enormous food safety change that we went through in the last 8 years. I did not want to either divert the attention from the reform process, nor permit disagreements over structure to stop that.

But the fact of the matter is that the time is now, to bring these functions together, and I am confident a successful rationalization of the Federal food safety regulatory structure will require bold strokes. A piecemeal approach will leave us essentially where we are, with a fragmented, and duplicative system.

Now, finally I might make a couple of comments about terrorism and related threats. As we look at the threat from chemical or biological attack or other terrorist threats, too frequently agriculture and food received scant attention. We got a wake-up call last month, not only from the savage viciousness of the attack, but also from the new kind of threats we face. For example, the grounding of the Nation's fleet of crop dusters drove that point home.

While at USDA, we launched a multiagency review of agriculture's exposure to non-conventional threats. Without revealing the specific threats, nor the steps we are taking to protect ourselves, let me simply state that the problem is immense, as are the consequences and the effort we need to protect from it. Consider again the Starlink episode, which I referred to. That is a telling

lesson of how quickly and pervasively an undesired product can contaminate our food supply, or consider a few years ago when Karnal Bunt first infested this country. To eradicate this wheat fungus, we prevented the farmers from whose land the infected wheat originated from planting wheat at all for 3 years.

The point these episodes illustrate is that even comparatively benign contaminants to our food supply can spread dramatically, especially given the size and concentration in much of our food distribution and processing, and may need profound and long-lasting steps to recover. I should point out that while agents such as botulism or anthrax affecting food and water get a lot of attention, media attention—American agriculture could also be gravely threatened by outbreaks of more traditional problems like foot-and-mouth disease and BSE.

The solution partially lies with reform structures and organizational changes. It also partly lies with good statutory authority given to the agencies—fair statutory authority—and I am confident that you will do that. In closing, let me repeat the three points I want to emphasize with you: One, we need to reorganize and consolidate our Federal food safety regulators; two, we need just as urgently to make improvements to our underlying food safety statutes; and, third, an integrated food safety regulatory structure is critical to meeting the new challenges of terrorism we face.

All of this is needed to ensure our highest priority, which is continued public confidence in the safety of our food system, which is the linchpin of both our public health, as well as the economic health of American agriculture.

Thank you, Mr. Chairman.

Senator DURBIN. Thank you, Secretary Glickman. Let me start with some questions.

Dr. Schwetz, you said at one point—I do not know exactly, but paraphrasing you—we should view food as a medium for bioterrorism. I think that is really one of the elements that underlies this hearing today. Can you give me a description of how food could be a medium for bioterrorism?

Dr. SCHWETZ. Well, yes, I would be happy to do that, Mr. Chairman. What I really do not want to do is talk in any detail that would provide——

Senator DURBIN. No, I do not want you to.

Dr. SCHWETZ [continuing]. A roadmap for people to do things that we do not want to have happen. But because we have an agricultural process that produces a lot of food, either from the United States or imports from outside the United States that is distributed widely, common food items that we either import and consume as they are, or foods that are processed within the United States, there are a relatively small number of food that represent a large part of what we consume, and it would be possible for one of those to become the medium of some agent that would be distributed that would accomplish what a terrorist might want to do, is to reach a large number of people relatively quickly through some means that they would not necessarily expect there to be a problem.

Senator DURBIN. Dr. Murano, our lives have all changed since September 11 at every level, governmental and personal. How have

things changed in the outlook of your agency at the U.S. Department of Agriculture, FSIS, and other food safety inspection since September 11?

Ms. MURANO. Well, Mr. Chairman, I think September 11 changed everybody. Let me begin by saying that. At the agency we took a hard look, and are right now taking a hard look at what systems we have in place and how to improve upon them. Thankfully, we have 7,600 inspectors inspecting meat and poultry in every plant in the United States. Having them in place as a matter of our standard operating procedures, gives us an advantage, as a public health agency, which is what FSIS really is.

We are about food safety, and what we do is inspect these products to try to prevent to the greatest extent possible any foodborne outbreaks, which is one of the main goals of the agency. We can always do better, and I assure you, again without really saying too much as far as details, that we are looking at what other ways we can improve our system. Certainly the entities that I mentioned in my testimony, FORCG and FERRET, have been crucial for us to be able to ascertain how to better coordinate activities, not only within USDA, but also with our partner in health, HHS.

Senator DURBIN. Let me follow up on that, and just staying with the food security aspects that we have now raised since September 11, and without asking for any detail for the same reason that Dr. Schwetz mentioned, has there been a gathering of the various food safety inspection agencies at the Federal level, of all the different agencies, to sit down and to try to map out a common strategy to protect the security of America's food supplies since September 11?

Ms. MURANO. Let me answer that, Mr. Chairman, by saying that as soon as I was confirmed, we had a meeting of FERRET, which are agencies within USDA that have to do with food emergency rapid response. We are working right now with our partners in HHS to get FORCG to look at what its charter is, what it is doing, the activities that it has done in the past and how we can improve those. We have meetings scheduled very soon, and we have had conversations with our partners at HHS to pursue these avenues. So I assure you that we are extremely cognizant of the fact that, now more than ever—and I agree with the words that you said at the beginning of this session—at this time of war, we have to work together.

Senator DURBIN. Have there been special meetings called since September 11 of these agencies, to talk about food security?

Ms. MURANO. Yes, sir.

Senator DURBIN. Is there more evidence of cooperation among these agencies?

Ms. MURANO. I can safely tell you yes, and perhaps one of the reasons is a simple reason—well, two reasons. The one I just stated is the fact that this emergency has brought us together as Americans and certainly has elevated the importance of these issues and has made us want to work together more than ever. Second, because there are a lot of new faces, not just mine. When you have a lot of new faces, people perhaps do not have the past histories of animosity that might preclude reaching over and meeting each other. So we have been able to get together very well and very quickly.

Senator DURBIN. Have you talked about coordinating inspections? We know there is such a wide variety of inspection standards when it comes to food at the Federal level. Since September 11, have you addressed that possibility of coordinating these inspections?

Ms. MURANO. It is one of the issues that we are discussing.

Senator DURBIN. Dr. Schwetz, same question. Since September 11, what has happened in terms of the food security issue at FDA and what has happened in terms of your relationship with other agencies?

Dr. SCHWETZ. I would reinforce what has already been said, that we have had meetings between a number of Federal agencies, even going beyond HHS and USDA, to bring agencies together to discuss what are the areas where we need to be communicating more effectively to deal with these kinds of issues, where are weaknesses that we have where resources need to be put now to strengthen——

Senator DURBIN. Can you tell us any of those weaknesses that we might address at the congressional level? Is there a need for some funding that is readily apparent to you, in light of September 11, where we should look at it immediately?

Dr. SCHWETZ. They are matters of the proper legislation and authority to be able to do the kinds of things that we have limits to now, and some of them have already been discussed.

Senator DURBIN. Can you give us examples?

Dr. SCHWETZ. The ability to hold product once we have a suspicion that something might be wrong, civil money penalties to a greater extent than we have worked out these arrangements with Customs and other agencies and with States. So there are some legislative changes that need to be made, but primarily the vulnerability of the FDA is not having enough people to be able to man the spots that we need to have covered, to have the inspectors, to have the laboratory capabilities to back up the sampling that would follow questions of terrorist action. So between resources and legislation, those are two major areas.

Senator DURBIN. Secretary Glickman raised an important point. I want to ask him a question about it directly, but about the whole question of the authority to withhold food product based on epidemiological concerns, as opposed to pathogens. Is that another element or another area where you see need for legislative change?

Dr. SCHWETZ. Yes, that would be.

Senator DURBIN. So at this moment in time, if we suspected or even knew that there was a source of food in the United States that posed a danger because of bioterrorism or epidemiological contamination, does the FDA or the USDA, have the authority to take that product off the market?

Dr. SCHWETZ. I cannot answer that exactly, but I would assure you that we would look between the Federal agencies, between USDA, between Customs, whatever authorities we have collectively, we would work as hard as we could to keep that from spreading.

Senator DURBIN. I am sure you would. Anyone in good conscience would, but clearly Members of Congress, in good conscience, need to give you the clear authority to do it.

Dr. SCHWETZ. Yes.

Senator DURBIN. Secretary Glickman, that is a point that I think we ought to spend a moment on. But your belief now is that the current law does not empower the agencies to do this? Though they might find some way to do it, it is not a clear delegation of authority.

Secretary GLICKMAN. At best, it is unclear, and USDA was specifically challenged in this, in one particular instance, where we did not have complete success, let me say. You might find some general authority under some welfare clause provision of the Constitution or some other agency, FEMA or somebody, but I do not believe it is clear.

Senator DURBIN. Well, so that we understand this for the record, should we ever—and God forbid that we do—run into a situation of biological contamination, acts of bioterrorism on the food supply, it is your understanding—and I believe that the other witnesses are in agreement—that we do not have the statutory authority at this moment to remove product from market, off the shelves, away from consumers, absent some specific change in the law?

Secretary GLICKMAN. I do not believe so. I think that probably, if you had a national emergency with bioterrorism, we would find it somewhere. But I do not think we have it clearly enough to deal with the non-terrorist problem, and therefore we would not necessarily be able to jump to the terrorist problem.

Ms. MURANO. Mr. Chairman, may I interject a little bit here?

Senator DURBIN. Sure, Dr. Murano.

Ms. MURANO. As you probably know, FSIS has the authority to seize and detain products. So that is a very important authority that we do have, and that certainly is one of the ways that one can stop an outbreak from spreading any further.

Senator DURBIN. And let me ask you to follow up on that. Secretary Glickman made note of the fact that the USDA needs authority to recall food from the market. You were talking about stopping and detaining the delivery, but recalling food from the market is not in your list of current authorities; is that right?

Dr. SCHWETZ. That is correct.

Senator DURBIN. Is that your understanding, Dr. Murano?

Ms. MURANO. That is correct. I would say food safety is the primary issue, obviously, with my colleagues at HHS and certainly with the Food Safety and Inspection Service. When there is an outbreak situation, recalling product as rapidly as possible is extremely important. I think we all agree with that. The real question, I suppose, is who should have the responsibility to do that? That is something worth exploring, and I think that is what the Secretary is alluding to.

Secretary GLICKMAN. Mr. Chairman, I would just say most companies, in my experience, would voluntarily and cooperatively work this issue, but because of mass communication and dissemination of food, and the logistics problems, you could imagine a circumstance, even if a cooperative company would be involved in doing it, you could not get the food fast enough back into the hands of either the government or the company itself.

Senator DURBIN. So we have two things that have come out so far, and one is the use of these epidemiological standards for the monitoring of the food supply, something clearly that needs to be

done, and, second, the ability to recall the product clearly in the law, where there is a national issue or urgency involved in it. Those two things seem very clear.

Now, Secretary Glickman, you also talked about the imposition of fines, and what are you alluding to there?

Secretary GLICKMAN. Well, right now I would say the Department of Agriculture has the ultimate penalty, the nuclear bomb, so to speak, because what it can do—it could withdraw the mark of inspection. It can close a factory down, which is obviously a critical power. But, in some cases, you want to move more creatively and quickly without having to shut a factory down, without having to cause people to lose their jobs, and civil penalties are not within the ambit of USDA's authority, as they are in the Consumer Product Safety Commission and, I believe, other agencies.

Senator DURBIN. Dr. Murano, you made the point that you are brand-new and, in that respect, have newer faces and less baggage and less of a history. Your background is in science, I take it?

Ms. MURANO. Yes, sir. I am a scientist.

Senator DURBIN. As you take a look at the Federal laws involving food safety and inspection, do you see that common scientific thread that weaves through these 12 different agencies and 35 different laws?

Ms. MURANO. Well, Mr. Chairman, certainly if you are asking me common sense science, I am not going to go there.

Senator DURBIN. No one is going to go there based on common sense.

Ms. MURANO. But let me say that I think we all recognize that using science as the basis for what we do for food protection is the goal that we want to achieve, and risk assessment within the risk analysis system is one way to achieve it, as I discussed in my opening remarks. Following that thought, I would like to say again that because food safety is our goal and what FSIS does, because it is a public health agency, anything that would improve the safety of our food supply is something that we are interested in doing.

I would like to say one more thing regarding recalls. In exploring this issue, we have to obviously think about whose responsibility it should be for our food supply. Should it be the responsibility of the people who make it, or should it be the government's responsibility? There are some extremely complex issues that are embedded within that question. So it is something that we have to look at very carefully.

Senator DURBIN. I am going to ask one semi-scientific question, and forgive me, as a liberal arts lawyer, if I do not state it very artfully, but, Dr. Schwetz, is there any mechanism in place now where you can monitor contamination beyond the obvious Salmonella, E. coli, to those new threats that we are considering, the bioterrorist threats? Are there ways to monitor these things?

Dr. SCHWETZ. Yes. The bacteriological and the other detection procedures for being able to identify viruses and bacteria and other organisms that might be included, those procedures are, for the most part, available. Many of them have been used clinically for many years. So the methods to identify those organisms are available for our use. We have adapted those so we can identify those organisms in food or other places where they might come into con-

tact with food. So the methods are available to identify the organisms.

Senator DURBIN. The last question I will ask of the three principals on the panel goes to this culture between the FDA and the USDA. This is a battle I have been witnessing for 20 years. Sometimes it is a friendly relationship and sometimes not so friendly, but it appears that the two agencies really view their missions in different terms, and one of the reasons we do not have a single food agency is because there are those who just love the USDA and every part of it and do not want to give up anything, on Capitol Hill and the population at-large, and others who feel the same about the FDA. But many argue that they really are two different philosophies, two different cultures that come to this business of food inspection. I would like to first ask Secretary Glickman, what is your thought on that?

Secretary GLICKMAN. Well, Senator, I really do not think that is as big a factor. I will tell you, after the Congress reorganized the Department of Agriculture in 1994, you created a separate Food Safety and Inspection Service and pulled it out of the marketing and regulatory programs, basically—I must tell you my experience with those folks at FSIS led me to believe that they were among the toughest government regulators that I saw, and people of high integrity.

Now, the fact of the matter is they were officed in the same building and basically were in the same venue with people who had promotion functions, as well. I do not really think that is the critical problem here, because I think the system can kind of trudge along probably all right with coordination the best you can. I just do not think, given the modern world of pathogens and threats, that you cannot do it very well without some sort of central accountability there, and that is why I think this needs to be done.

I think in the old days, this may have been a problem. I really do not think it is as much of a problem anymore.

Senator DURBIN. Dr. Schwetz, you have been at FDA for awhile. What is your observation?

Dr. SCHWETZ. Yes, I have been with the FDA for a little over 8 years now, and my observation is that the working relationship is far different today than it was 8 years ago. There are a number of things that have happened in the past few years that have forced us to work together more effectively than we ever did before, and I think for the most part we have come to realize that we do have partners in other agencies that we have to depend on, we have to work with, for example, to keep things like BSE out of the country, and foot-and-mouth disease. So the readiness plans that we have developed, the science that we have shared, the people that we have kind of moved back and forth to tap the intelligence that we have between the agencies, there is a lot more of that today than there ever has been.

Senator DURBIN. Dr. Murano, you are the new person in town, but do you see a difference in the mission between the FDA and your food safety responsibilities at USDA?

Ms. MURANO. Mr. Chairman, when I talk to my colleagues in FDA who are scientists like myself, we are scientists and we have the same view in terms of what we want to do to achieve a safer

food supply. So, at that level, certainly I know that we have kindred spirits. What we have to do is forget what the relationships have been in the past. I know that probably sounds extremely naive of me to say that, but I am going to give it my best and I know my colleagues at HHS will, as well, because we are in a new day. We are facing threats that we never imagined we would have to be facing and we are committed to working together.

We are Americans. We have an incredible challenge ahead of us, and we have to meet that challenge. This is the time to do it.

Senator DURBIN. Thank you very much. Senator Voinovich.

OPENING STATEMENT OF SENATOR VOINOVICH

Senator VOINOVICH. Thank you, Mr. Chairman, for holding this hearing. This is the third hearing that I have participated in on this subject of oversight of food safety, and I commend the Chairman for his long-standing interest in this area. I am not going to go into my full opening statement, but I would like to say to you, as a follow-up to this hearing—I would like to request that the administration witnesses submit for the record a comprehensive list of all the Federal agencies involved in food safety, from the Animal and Plant Health Inspection Service at the Department of Agriculture to the U.S. Customs Service, along with a description of the function the agency serves, the current personnel levels at the agency, the personnel needs of the agency in terms of both numbers and skills. I know that is not new information, because I know from talking to Sean O'Keefe allegedly that request has gone out to various agencies about where they stand in terms of their personnel.

Senator VOINOVICH. It is my understanding the Food Safety Inspection Service at the Department of Agriculture is working to attract health inspectors with a stronger service background to improve the agency's oversight. I think this kind of information would be very useful to this Subcommittee in our deliberations.

In terms of questions, in the governmentwide high-risk area of human capital management, GAO says the following about the Department of Agriculture: "Organizational cultural problems, including resistance from the affected USDA agencies and employees, have hampered department-wide reorganization and modernization efforts. Further, the Nation's food safety system, in which USDA plays a major role, continues to suffer from inconsistent oversight, poor coordination and inefficient deployment of services."

Do you feel—and I am asking this of the administration witness—do you feel that the human capital management as it relates to food safety oversight is an issue only at the Department of Agriculture, or does it span across various departments and agencies involved in our Federal food safety oversight system? If the problem does include the entire food safety system, would a consolidation—that is what this is all about—would a consolidation of food safety oversight into one central agency improve this organization culture that is resistant to change?

Ms. MURANO. I would like to answer that by saying I think we all know that managing people is always a challenge, no matter what organization you are talking about, whether it deals with food safety or it does not deal with food safety. I am aware of great ef-

forts that are taking place right now to modernize the workforce of the Food Safety and Inspection Service. I have been very impressed with the effort that these folks have begun already with their new consumer safety officers, to bring a highly technically-trained individual to inspection plants.

There are also efforts to—and, in fact, right now there are epidemiologists on staff, as well, who are dispatched in cases where there might be a foodborne illness outbreak suspected. So it is not, I do not think, any more the perhaps-stereotypical view that people have held over what inspectors are. We have extremely highly-trained people and have worked really hard in that last few years to modernize the workforce. There has been a reorganization at FSIS to better serve or better accomplish the services that FSIS is supposed to provide.

Is there room for improvement? Absolutely, there always is room for improvement, and that is what I am here for, and that is what the administrator at FSIS has as a top priority, because that is one of the two things that FSIS does and does very well—inspect our food supply in a way that is effective and in a way that is done in a transparent way, and that is accountable. That is the key feature of any activity that one conducts. You must be accountable to the people that you serve and to your superiors.

The second activity, of course, has to do with regulations, and to base those on science is a key feature of FSIS as an agency. So I think we need to start looking at what the agency has accomplished in the last few years under Secretary Glickman, who certainly has been witness to some of those planning activities, and I am happy to tell you that those are being realized right now, even as we speak.

Would better cooperation and some consolidation be a way to go? We are very open to discussing any way that will improve the safety of our food supply, because that is our commitment.

Senator VOINOVICH. Well, the fact of the matter is that we have been talking about this—the Chairman of the Subcommittee, what, you have been working on this for 20 years? We keep talking about something is going to happen, and even though there are some really good things that each agency is doing and we have a fine system, I do not think it is where it ought to be. From a governmental point of view, as I look at this organization, speaking as a former mayor and governor, it is a crazy patchwork that does not make sense and, to me, needs to be reorganized to get the job done, to eliminate the duplication, take advantage of the strengths that we have in the various departments and get the job for the public.

I know some of the industrial people are worried about it because we will have some kind of a super-czar agency that might harass them or whatever the case may be. But I would like you to tell me if you have seen any better coordination in the last couple of years. I think it has gotten to the point where you need to reorganize this operation.

Mr. Schwetz, I would like your opinion. What do you think?

Dr. SCHWETZ. Our feeling is that reorganization by itself, Senator, is not going to make our food safety system a lot better than it is today. We have already gained a lot of benefit in the last few years by virtue of better funding, to be able to do the work which

represents the underpinnings for a safer food supply. So there has been a lot of progress made, and we think that even within the existing system more progress can continue to be made.

If the decision is made that there would be a single food agency, it is not a matter of reorganization. The legislative underpinnings to determine the authorities have to be redetermined. The right kind of budget support has to be there to deal with the risks that we would identify are the primary risks to deal with in the food supply. So we have to have the right funding, we have to have the right laws, we have to have the right kinds of expertise within that agency or within our existing agencies to be able to deal with the risks that we have.

One of the concerns that we have, also, is that even within a large organization where you have an office of this and you have an office of that, you still have different cultures between various components of a large organization. So we would have to work awfully hard to be sure that we do not have those same kinds of differences between components of a new organization that we all cite today as those examples at the margins of our organizations now that make it look like we have two different approaches or two different people looking at the same problem. So reorganization by itself is not going to be a simple thing and it will not be enough to really——

Senator VOINOVICH. Reorganization is never simple. I have been through it several times in both capacities, but the issue is, have we gotten to the point now where we need to do that? What do you think of Chairman Durbin's bill?

Senator DURBIN. Put him on the spot.

Senator VOINOVICH. What do you think about it? Is the administration at all interested? Of course, they have got their hands full right now. I am sure they are not thinking about this problem, but where are we?

Dr. SCHWETZ. The new bills do address some of the problem, but one of the difficulties that we recognize, for example, within the Food and Drug Administration itself, is that we have certain components of the agency that are specifically assigned to food safety, but the way we are organized there are also parts of each one of our components of the agency, that even though they might be assigned to drugs or to veterinary drugs or to other statutory authorities, that still involves food safety. So it is very difficult to say that this is the part of the FDA that deals with food safety, because there is a large part of it that also deals with drugs, deals with devices, and deals with biologics. They also have people who deal with food safety issues. So that makes it very difficult to think about how the Food and Drug Administration would work if the food part of it was taken out and took out the research capabilities, took out the field capabilities, all of which are shared between food questions and questions of other products that we regulate. The same question exists if you expand it between agencies.

Ms. MURANO. The administration has not taken a position on this issue, but I would like to say again that my office is open to discussion on this subject.

Senator VOINOVICH. Mr. Glickman, you have been there. What do you have to say about it?

Secretary GLICKMAN. I agree with you. I would say that, at a minimum, budgets, planning and accountability for food safety ought to be in one place. Now, the devil is always in the details. I was just thinking as you were talking, the inspection functions—those of you who know the difficulties in the relationships between inspectors and FSIS at USDA, and that has got a long history and culture, know that that is a significantly different relationship than certainly you have at FDA, where you hardly have any inspectors at all. So, as you say, this has to be done very intelligently. It has to be very inclusive in order to not create a revolution in the process, but that should be no reason not to try to do it.

I think that is why I think somebody suggested—I think the GAO suggested you start at the inspection, try to bring them together, because that is where the rubber hits the road in terms of finding problem product. But I go back to this thing, there has got to be some central budgeting and central accountability in this process, as well. If you do not have it, then it is not worth anything.

Senator DURBIN. Thank you very much. Let me ask one last question of Dr. Murano and Dr. Schwetz. Since September 11, there has been a heightened awareness of national security and a lot of efforts to coordinate the U.S. response, and I am one who applauds Governor Ridge joining the administration in his new capacity with the Homeland Defense Agency. But can you tell me whether or not either of your agencies, USDA and the FDA, have been included in these national security briefings and discussions since September 11?

Ms. MURANO. I can tell you, Mr. Chairman, that we are very much included, and that is all I will say.

Senator DURBIN. OK. Dr. Schwetz.

Dr. SCHWETZ. Yes, we are also very much included with a lot of the discussions that are going on between agencies and with the National Security Council.

Senator DURBIN. Thank you. Thank you very much. I want to thank this panel for the contribution they made today. We appreciate you coming by.

I am now pleased to welcome the next panel and invite them to come forward: Dr. Michael Jacobson, Executive Director of the Center for Science in the Public Interest; John Cady, President and Chief Executive Officer of the National Food Processors Association; Dr. Peter Chalk, Policy Analyst with RAND Corporation; Manly Molpus, President and Chief Executive Officer, Grocery Manufacturers of America; and Tim Hammonds, President and Chief Executive Officer, Food Marketing Institute.

Thank you all for coming. If you will remain standing behind your appropriate name places, I will swear you in, as custom of the Subcommittee. Please raise your right hand. Do you solemnly swear to tell the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. CADY. Yes.

Mr. CHALK. Yes.

Mr. HAMMONDS. Yes.

Mr. JACOBSON. Yes.

Mr. MOLPUS. Yes.

Senator DURBIN. Thank you very much. Let the record indicate that the witnesses have answered in the affirmative.

Dr. Jacobson, would you be kind enough to begin?

TESTIMONY OF MICHAEL F. JACOBSON, PH.D.,[1] EXECUTIVE DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Mr. JACOBSON. Thank you very much Senator Durbin. My name is Michael Jacobson. I am the Executive Director of the Center for Science in the Public Interest. CSPI is an education and advocacy organization based in Washington that focuses on food safety and nutrition. We are supported largely by the 800,000 subscribers to our Nutrition Action Healthletter and by foundation grants.

As we have heard earlier, CDC estimates that contaminated food causes 76 million illnesses and 5,000 deaths every year. Over the past decade several notorious outbreaks of foodborne illness, named after such companies as Jack-in-the-Box, Schwan's, and Sara Lee, have demonstrated that unintentionally-contaminated food is all too common, all too deadly. More recently, the terrorist attack has spurred widespread concern about intentional contamination of our food supply and the government's ability to minimize that risk. Those concerns are not unfounded. Last year, a CDC committee warned that terrorists might try to contaminate our food supply with such pathogens as clostridium botulinum, and E. coli O157:H7.

The recent National Academy of Sciences report agreed, explaining that biological agents could be produced quickly and inexpensively. We saw how easily bacteria can be used as a weapon when in 1984 members of a religious commune in Oregon contaminated 10 salad bars with Salmonella, sickening 751 people. Be it bioterrorism or sloppy manufacturers, we are relying on old laws to regulate new hazards. The Safe Food Act of 2001, introduced by Senator Durbin, offers a much-needed corrective to one of the major defects in our Nation's food safety system.

Food safety oversight is balkcanized among at least nine Federal agencies, from the Department of Agriculture to the Bureau of Alcohol, Tobacco and Firearms. That fragmented responsibility, compounded by inflexible statutory restrictions, results in many gaps, inconsistencies and inefficiencies in government oversight. For example, as we have heard many times over the past 5 or 10 years, makers of pepperoni pizzas get inspected every day, while makers of cheese pizzas get inspected only once every few years, even though both kinds of pizzas pose similar risks, I had not learned until today about open-faced versus closed-faced sandwiches, which takes this issue to ludicrous heights.

Currently, the FDA, which has just 150 inspectors to ensure the safety of four million shipments of imported food, inspects less than 1 percent of those shipments. Eggs, depending on whether they are in the shell or processed, are overseen by either FDA or FSIS, and a third agency grades them for quality. Meanwhile, no agency is trying to prevent Salmonella contamination from ever happening back on the farm.

[1] The prepared statement of Mr. Jacobson appears in the Appendix on page 100.

For crops that are genetically engineered to produce a pesticide, the EPA evaluates the safety of the pesticidal chemical while the FDA reviews the safety of the whole plant except for the pesticide. EPA's process is open and mandatory, while the FDA's process is secret and voluntary. Frankly, that kind of jury-rigged system is nuts. Professor John Bailar of the University of Chicago, who authored a paper published by the National Academy of Sciences, concluded, "Our country needs a single independent food safety agency. When bioterrorism is added to the mix, the case for prompt and sweeping change becomes compelling."

A sensible system, food safety system, would allow officials to deploy resources when and where they are needed most. For instance, judging from CSPI's database of foodborne-illness outbreaks, foods regulated by the FDA caused four times as many outbreaks as do foods regulated by USDA. However, the FDA has only about one-tenth as many inspection personnel, and there is no way to transfer inspectors from factories producing lower-risk canned beef stew to packers distributing higher-risk fresh alfalfa sprouts. That mismatch between risk and resources has led CSPI and other consumer groups to call on Congress and the President to develop a single coherent food safety statute that would be implemented by a single independent food safety agency.

CSPI strongly supports the Safe Food Act of 2001, which, if passed, would result in a major and long-needed upgrading of our food safety system. We also would strongly support a parallel and equally-essential effort to develop a unified food safety statute.

Thank you very much, Senator, both Senators, for your continuing leadership to improve food safety and for giving me the opportunity to offer CSPI's views.

Senator DURBIN. Thanks, Dr. Jacobson. Mr. Cady.

TESTIMONY OF JOHN CADY,[1] PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL FOOD PROCESSORS ASSOCIATION

Mr. CADY. Thank you, Mr. Chairman, for this opportunity to testify about our ability to ensure food security within the framework of our current regulatory system. My written testimony, which I will not read, outlines in greater detail our thoughts, not just on this subject, but also on the broader issue of whether we need a single food safety agency. I will make a few opening comments and look forward to your questions, sir.

First, Mr. Chairman, I want to salute both you and the Ranking Member and former Chairman of the Subcommittee, Senator Voinovich, for your leadership on food safety issues. You have my commitment to continue to work with you and the Subcommittee on how we can best improve the management of our food safety regulatory systems.

Mr. Chairman, the National Food Processors Association is the Nation's largest food-only trade association and its voice on scientific, technical and regulatory issues involving food safety. There are a lot of food-trade associations, as you know, which reflect the great diversity and reach of our industry, but NFPA's focus has long been on research, science, food safety, manufacturing practices

[1] The prepared statement of Mr. Cady appears in the Appendix on page 108.

and emergency situations for our 350-member food companies. We have special expertise in the area of food security, which has long been a top priority of our industry, specifically in the area of tampering and contamination.

Mr. Chairman, we have great confidence in our food safety regulatory system for protecting the integrity of our food supply, both for domestic and imported foods. We believe both Secretary Veneman and Secretary Thompson and their respective agencies have done an outstanding job of responding to the tragic events of September 11. We are confident that they have worked closely with their regulated industries to ensure that the systems are in place to adequately address threats to our food supply. Through our association the industry has also created an alliance for food security, which is coordinating the industry's efforts and communications with Federal agencies.

We recognize that the food safety system is not perfect. We have long advocated for more resources for the Food and Drug Administration to ensure it can perform its core mission. In particular, FDA's information tracking system for imported foods, called Oasis, needs to be updated. More research to develop better sampling and testing techniques are needed to get a more rapid response. We understand that the Bush Administration is advocating more inspectors at our borders and ports to make sure that nothing slips through, and I have been told that Governor Ridge will focus on food safety and food security as part of the new Office of Homeland Defense, where he will be looking at budgets and the need for new legislative authorities.

Given the vast powers that FDA already has over imported foods, we do not believe, however, that additional authorities at this time are necessary, and any emergency regulatory actions taken during this period of crisis should have sunset provisions considered. It is also very important that we do nothing that has the unintended consequence of lessening consumer confidence in our Nation's food supply. Our Nation's outstanding food safety record has led to a high and justified level of consumer confidence in our food supply. It would do a serious disservice to consumers to send a message that our food supply is unsafe, especially in light of the tragic events of September 11 and the war in which we are now engaged. We must all watch what we say, how we say it, and understand that our words greatly impact the public.

On your proposal for a single food safety agency, Mr. Chairman, we commend you for your thoughtful approach to a very difficult issue, NFPA, however, is not yet prepared to endorse this proposal. In fact, as I noted in our written statement, we believe all the objectives that you outlined in the bill can be achieved by better utilizing existing authorities, starting with the Cabinet Secretaries, to both coordinate and allocate resources and streamline overlaps in jurisdiction before seeking any kind of new legislation. A new management layer, which I see a single food agency to be, is simply not necessary at this time. Rather, we endorse a single food safety policy that would be implemented on a unified basis across the existing agencies.

Thank you, Mr. Chairman and Senator Voinovich, and I look forward to your questions.

Senator DURBIN. Thanks, Mr. Cady. Mr. Chalk.

TESTIMONY OF PETER CHALK, PH.D.,[1] POLICY ANALYST, RAND CORPORATION

Mr. CHALK. Mr. Chairman, and Members of the Subcommittee, thank you very much for this opportunity to provide testimony on this very important subject. I am a policy analyst at RAND who has spent most of the last 10 years studying terrorism. The views I will be presenting are my own and should in no way be reflected as representing RAND or of any of the sponsors of its research.

Over the last 7 years considerable investments have been made in infrastructure protection within the United States, and this has led to an increasingly well protected infrastructure that now spans the ambit from conventional bombings right through to more exotic acts of biological terrorism. Agriculture, however, is one area where not too much attention has been paid in this regard, and I would suggest that this is problematic for two main reasons.

Agriculture is absolutely critical to the economic, social and political stability of the United States. Certainly, in economic terms it is of utmost importance. It is the country's largest single employer, $50 billion is raised every year through agricultural exports. Cattle farmers and milk producers alone earn between $50 billion and $54 billion through meat and milk sales. The disruption of this highly critical sector would cause a tidal economic wave effect that would impact, not only on the sector itself, but also on the individual and the consumer.

For a number of reasons, agriculture does remain vulnerable to either deliberate acts of sabotage or indeed, to naturally occurring outbreaks.

First, the disease susceptibility of animals in general has risen as a result of biotechnic modifications that have served to lower the natural disease resistance of animals to pathogens.

Second, there are many more diseases that are both highly contagious and infectious to animals than is the case with human beings. We know of at least 22 that currently exist. Most of these are also environmentally hardy and many livestock are not routinely vaccinated against them.

Third, diseases tend to spread very quickly amongst animal populations simply because of the intensive and concentrated nature by which they are housed, bread and transported within the United States. A typical dairy can be expected to have at least 1,500 lactating cows, with some of the larger facilities having between 5,000 and 10,000 animals. Stopping an outbreak of a highly infectious disease at any one of those facilities would be very difficult.

We also have a proliferation of food processors—particularly at the lower end or the smaller end of the scale—that lack adequate internal quality control, may not have very viable product recall plans; and also, largely do not undertake effective screening of seasonal employees, which exacerbates the potential of insiders getting in. I should have stress that this problem exists at the medium and lower end of the scale. And finally, the increased production of genetically modified foods has also increased the possibility of ex-

[1] The prepared statement of Mr. Chalk appears in the Appendix on page 113.

tremists and radicals carrying out acts of violence against GM foods, and we have certainly seen aspects of that in Europe.

The impact of a major agricultural disaster in this country would be enormous. Economically, we would have effects that could cross at least three levels: Direct economic impacts resulting from containment procedures and eradication procedures; indirect economic effects resulting from compensation paid to farmers who were affected by the loss of their products—in the UK, the recent foot-and-mouth disease outbreak has resulted in over $1 billion in compensation costs alone being paid; and finally, international costs in the form of protective trade embargos that are imposed by major trade partners against the affected country, in this case, the United States.

Beyond that we would also probably get a loss of political support and confidence in government. A major agricultural disaster would undoubtedly cause people to lose confidence in the food supply, and it could also cause them to question the effectiveness of existing WMD preparedness in general. In addition, the actual mechanics of instituting a viable response to a major agricultural disaster could elicit public criticism in the form of reaction to mass culling and disposal operations.

Finally, we could have social instability as a result if an act led to a major public health scare, and here we are talking about a foodborne disease outbreak or the introduction of an animal disease outbreak that is also zoonotic in its implications.

A number of areas do need to be substantially increased and enhanced in preparation for public infrastructure protection of agriculture. We need more diagnostic training. We need an overhaul of the veterinarian curriculum with more emphasis given on large-scale husbandry, better standardized links between the criminal justice communities, intelligence communities and the USDA.

I do support your own suggestion here of instituting a single agency to stream line and rationalize the oversight for food safety within this country. Thank you very much.

Senator DURBIN. Thank you, Mr. Chalk. Mr. Molpus.

TESTIMONY OF C. MANLY MOLPUS,[1] PRESIDENT AND CHIEF EXECUTIVE OFFICER, GROCERY MANUFACTURERS OF AMERICA

Mr. MOLPUS. Thank you, Mr. Chairman and Members of the Subcommittee. I appreciate the opportunity to appear before you this afternoon and compliment the Chairman and Members of the Subcommittee for giving us this opportunity for an exchange of views on the important issue of food safety. The testimony I am providing this afternoon is endorsed by a number of additional food trade organizations, specifically, the American Frozen Food Institute, the American Bakers Association, International Dairy Foods Association, and the Snack Food Association.

GMA-member companies make and market the world's best known brands of foods and beverages around the world. Our members represent approximately 90 percent of the branded food and

[1] The prepared statement of Mr. Molpus appears in the Appendix on page 127.

beverage products sold in the United States. So nothing is more fundamental or has a higher priority for us than food safety.

The United States, as the Chairman indicated in his opening remarks, 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 agriculture industries and generations of dedicated public servants. The achievements of this partnership are 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 food. That consumer confidence is not misplaced. We do, in fact, have a remarkably good food safety record.

The system we have is not perfect however, and it can be enhanced, but before we embark on a radical restructuring of the food safety regulatory system, we believe we should be absolutely convinced that there is no better way to address the issues of concern. During the Clinton Administration, the President's Council on Food Safety 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 a perfect solution."

Today's food safety system has evolved into a sophisticated science-based system that appropriately allocates responsibility among several Federal agencies. The allocation of responsibility among multiple agencies is not inherently wrong or misguided. Rather, it reflects the informed judgment of lawmakers and government food safety officials over many decades that different sectors of the food supply present different challenges and, thus, call for different inspection expertise and different focus of regulatory resources. When fundamentally different regulatory systems are called for, dividing responsibility among agencies represents a logical approach. In short, food safety regulation is not a one-size-fits-all situation.

We should not underestimate the challenges that would be faced in combining all food safety regulatory activities. From the experience of many of our member companies, it is difficult and disruptive to implement a merger. Combining organizations inherently means a period of uncertainty, distraction, loss of focus and efficiency. Now, perhaps more than any time in our history, we need to stay focused on the job at hand. Having said that, this does not mean that we seek to maintain the status quo. There is room for improvement of our current system and we have four recommendations.

First, consumers in the food industry are best served by strong food safety agencies which develop policy based on sound science. I would like to focus particularly on FDA. 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 failed to keep pace. GMA has already taken a leadership role in this area. For some time we have provided leadership to a food industry coalition whose objective is to increase the awareness of more resources at FDA.

We have at GMA a board-led task force of CEOs committed to helping assure that the case for additional FDA resources is made. For the past several years GMA has urged Congress to fully fund increases in FDA's budget for food safety, and I think it is worthwhile mentioning today that the Congress, with the help of several appropriators on the Subcommittee, including the Chairman, is about to, for the first time, approve the FDA's full budget request.

Second, our food safety system must emphasize science and research. We must identify and fight the true causes of foodborne illness with the right scientific weapons. Good science has always been a critical component of sound food safety regulation, and it is incumbent, therefore, on all of us with the shared commitment to effective food safety regulations to think creatively about ways to bring more science to FDA, and better scientists. We might do this through a fellowship program, such as what doctors go through at NIH and come out of NIH. We might have a fellowship program bringing young scientists to FDA.

Third, collaboration, coordination and consultation should be a full-time commitment for all our Federal and State regulators. The Secretaries should make it absolutely clear as they carry out their shared missions that their job is to eliminate duplications and inefficiencies. A good example has been the joint agency work on food-safety research.

Fourth and finally, one of the most dramatic changes that occurred with regard to our food-safety supplies is the extent to which we now have a global marketplace. FDA regulated products enter the United States from more than 100 countries. We must ensure that our regulatory agencies have more resources and tools to effectively regulate imported products.

In 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 systems. But before we scrap a system that is regarded as the best in the world, we should fully explore strategies to enhance the system through adequate funding, better coordination, the best science, and continued innovation.

Thank you, Mr. Chairman.

Senator DURBIN. Thank you, Mr. Molpus. Mr. Hammonds.

TESTIMONY OF TIM HAMMONDS,[1] PRESIDENT AND CHIEF EXECUTIVE OFFICER, FOOD MARKETING INSTITUTE

Mr. HAMMONDS. Chairman Durbin and Senator Voinovich, thank you for inviting me here today. My name is Tim Hammonds and I am the president and CEO of the Food Marketing Institute. FMI is the national trade association representing the retail supermarkets and food distribution industry. I will summarize here today, but with your permission, will submit my full statement along with FMI's board-adopted policy in support of designating a single food agency for your record.

[1] The prepared statement of Mr. Hammonds with an attachment appears in the Appendix on page 138.

In our view, this hearing is especially timely because our current Federal food safety system is ill-equipped to deal with today's challenges. Clearly, no one now designing a regulatory system to maintain the wholesomeness and integrity of our food would ever design anything remotely resembling what we have today. The case for designating a single food agency, then centralizing resources and responsibility, was compelling in May of the year 2001 when FMI's board of directors adopted that position. The need for such a system now is imperative.

We believe this could be accomplished without disturbing the oversight authority of the current committees of jurisdiction in the House and the Senate. You will note that we are on record in support of designating a single food agency, not in support of creating an entirely new agency. We believe too much expertise would be lost, too much of our existing credibility would be squandered, and too much time would be wasted if we attempt to create an entirely new agency from scratch. In our view, the best course of action would be to centralize resources, responsibility and authority within one of the existing agencies, then elevate the status of this group to a level appropriate to our new challenges.

In the wake of the attacks on America on September 11, we have begun to look for vulnerable areas in our society. The safety of our food supply is a legitimate subject for inquiry, but under that microscope, it is clear that now when additional funds are needed to ensure food security, we can ill afford the current system's lack of coordination and the resulting waste of resources. Should a crisis arise, either real or manufactured as a hoax, the deficiencies of our current system would become glaringly obvious. For example, let's assume a tampering hoax is staged. The public needs rapid reassurance from a credible source. Under current policy that could easily involve multiple government agencies.

Since it is rare that a single agency has complete jurisdiction over the entire scope of a major food safety problem, it has been our experience that none of the agencies step forward in times of crisis. It becomes impossible to find a spokesperson who can rapidly clarify the facts and reassure the public. Far more typically, the public is faced with a lengthy delay while our overlapping bureaucracies creep into some sort of action, culminating eventually in a message of reassurance to the public.

To the issue of whether a coordinator would be enough to oversee the existing agencies, we have an open mind on that, but we are doubtful. Although some improvements could certainly be made, there would still be overlapping jurisdictions and gaps.

Let me emphasize that none of this is due to the lack of skill or dedication of those working within our various food safety agencies. Quoting from the 1998 report of the commission to ensure safe food from production to consumption, "These are dedicated, capable people, but they operate within an institutional framework that is out of date and poorly designed to accomplish the critical goals that food safety regulation in this field must achieve. The increasing complexity of food production and delivery and the exploding internationalization of the U.S. food supply impose added pressures on the Federal regulatory apparatus which was constructed in similar times."

Our FMI board of directors is open to other solutions that would improve food safety oversight; however, we find it difficult to come up with a simpler or more direct approach than designating a single food safety agency. Thank you, Mr. Chairman and Members of your Subcommittee, for the opportunity to speak with you today on behalf of the members of the Food Marketing Institute.

Senator DURBIN. Thanks, Mr. Hammonds.

I would like to ask Mr. Cady and Mr. Molpus a question, because from your testimony you appear to be skeptical of this notion—I guess that is a kind way of putting it, but let me just ask you this, Mr. Cady, first: Do you agree that what ever food safety inspection standard we have, it should be based on science?

Mr. CADY. Well, coming from a science organization, sir, the answer is obviously yes. It needs to be based on science. It needs to be risk-based. It needs to be properly budgeted for, which we have not done over the years, especially in the FDA arena. It also needs to be one that has a policy that emanates from science and risk assessment, that is permeated throughout a unified food safety system.

Senator DURBIN. Do you think our current system is based on science?

Mr. CADY. I believe that the majority of our system is currently based on science, but I caution that I do not believe we have gotten far enough into the risk-assessment arena, where we can make better use of the resources that we do have available. But I think the science that is done by the agencies has improved tremendously over the years and I think that the agencies coordinating activities are making it even better.

Senator DURBIN. Can you then tell me the scientific basis for daily inspections at the U.S. Department of Agriculture and quadrennial inspections through the Food and Drug Administration?

Mr. CADY. Well, I think, again, if you look at the risk involved in the Department of Agriculture inspections—and there are historic issues, sir, that I am not saying we cannot take care of and that the department could not make better—but there are historic issues based on animals that are being processed. Eighty percent of my members' food, however, is not regulated by FSIS, and so you look at—Mr. Jacobson even mentioned—somebody who is making a high-acid tomato product in Ohio, as an example. Is that the same as some other product that perhaps has more risk than that does? I think we have not made good use of that particular tool in the risk-assessment area.

Senator DURBIN. You have made several points and I do not want to blend them together. I am trying to keep them separate. The point about funding, adequate inspection and the like is certainly one that no one argues with, I do not believe. But I do believe that Dr. Jacobson's initial point is the important one here. The current system is not based on science. The current system is so disparate in terms of the application of inspection, for example, that it is hard for me to rationalize why daily inspection of agriculture through the Department of Agriculture, Poultry, and Meat makes sense, but inspection once every 4 or 5 years through the Food and Drug Administration still makes sense.

I have to tell you that I think what drove the USDA into daily inspection was not the wisdom Mr. Molpus refers to, but Upton Sinclair scared Americans into finally initiating some sort of a Federal responsibility for inspecting meat. If you ever read it, as most of us have, you can understand why. Chicago has changed a lot, incidentally, since the book was published. But, there just is not any consistent science here.

Mr. CADY. I disagree, of course, with Mr. Jacobson on that. I think the science is there. I am not sure when you get into the inspection system—what I understand you are saying is—I think the science is there, how it is carried to the inspection system, throughout the inspection system, I guess is what your question is. Again, if you have limited dollars and you have limited inspectors, you have to go to a risk-based system, and that makes better use of your resources, and we have not done that fully.

Senator DURBIN. You said in your testimony no additional authority is necessary. Now, that is a very broad statement in light of what we just heard from former Secretary Glickman——

Mr. CADY. No, I was talking about over the ports and that particular area. I do not believe—again the lawyers have to argue this out and I am not a lawyer, but from what our discussions have been on this with lawyers, we believe that they can do what they need to do today at the ports in order to beef up security.

Senator DURBIN. Let's go to a specific point then, so I can have your testimony on the record. Former Secretary Glickman has noted the fact that the agencies, USDA and FDA, do not have authority today to deal with products that have been subject to epidemiological contamination as opposed to pathogen. Do you believe that the law should be changed so that they have that authority?

Mr. CADY. I think we have to look at those authorities and we have to decide whether or not that is good for the system and good for the whole food safety system. Please remember that the industry spends millions and millions of dollars a year on food safety systems of their own and we get into these situations such as civil and monetary penalties, and criminal penalties, which exist today for adulterated food. The question I have always had is that when somebody goes out—and this has happened—and makes a bad decision on shutting down a plant under a mandatory system, let's say, what recourse does that particular plant or company have if the decision is not correct? Essentially they are out of business. So, my point is, it needs to be looked at. If they need authority in that particular area, then I am not against opening it up and talking about it at all.

Senator DURBIN. Well, I would like to ask Mr. Molpus. You said something in your testimony—it is part of the record now—and it says that the current system—you were referring to the current system—reflects the informed judgment of law makers and government officials over many decades, that different sectors of the food supply present different challenges and thus, call for a different inspection and regulatory system. That seems to suggest that there is some sort of divine plan here behind our food and safety inspection, or at least a coordinated—let's use that, a coordinated thinking and "wisdom"—you used the word wisdom—behind our current

system. Do you find wisdom in a system that treats an opened-faced sandwich different than a closed sandwich?

Mr. MOLPUS. Well, with all due respect, Mr. Chairman, the Congress must find that to have some wisdom. What I think has been said here numerous times today—and I think it bears repeating—many of these issues flow from the fact that the Congress, in passing the statutes that created the inspection systems for food in total, created different statutes with different laws that affect different segments of the industry. Congress created, as you eloquently alluded to, the Meat Inspection Act after Upton Sinclair's in "The Jungle." As you may remember, I was president of the American Meat Institute in the first life where we met, and that is a different statute than the one that is dealing with other foods.

And to your point with the questioning of Mr. Cady, the intensity that we want in a meat plant every day, intensive inspection that is mandated by law—that can be changed by the Congress. It will not be changed by bringing all the agencies together. We have a lot of fun poking fun at pizza. Pizza has been one of the most successful products in the history of the American food industry. It has managed to survive this quagmire of government inspection. It has been a tremendous success with consumers and in the industry, and combining the agencies, putting all the agencies in one house, would not solve that pizza problem. It would not solve, I do not think, the open-faced sandwich problem. If there is any point that needs to be made here today, it is underlying statutes—and that is what I was trying to make in my testimony—it is underlying statutes separately passed by the Congress that drive different types of approaches to inspection.

Senator DURBIN. That is why we are here today, those underlying statutes and that so-called wisdom that brings us to this point where we are so embarrassed today by what we have. Let me ask you, as I have asked Mr. Cady, Secretary Glickman makes the point about epidemiological contamination. Do you think the FDA and USDA should have authority when it comes to epidemiological contamination as it does for pathogens?

Mr. MOLPUS. Well, essentially we are not regulated by USDA. I have seen nothing that makes me think FDA needs that authority or I did not hear them say they desired that authority. I do not think we have had those kind of issues with the type of foods that FDA regulates.

Senator DURBIN. Mr. Molpus, based on Dr. Schwetz's testimony, I do not see how we can take that position. He has said in his testimony that food is a medium for bioterrorism. I do not want to create panic, but I want to be realistic. I do not want something to happen tomorrow and hear, "Why didn't you even talk about it in Congress the day before?" That is why I think that what the Secretary has suggested is a reasonable suggestion, to give these agencies the authority to deal with bioterrorism. God forbid we ever need it, but they should have that authority. Should they not?

Mr. MOLPUS. Well, I will tell you this, Senator, they have never talked to us about needing that authority that I am aware of. It has never been an issue in the regulation of the foods that I represent. If it is an issue, then we are willing in these particular times to sit down with the agency and rediscuss and reevaluate

some of these legislative needs. They may be on an emergency basis, some things we need to do. Whether that is one of them or not, I could not tell you today.

Senator DURBIN. I think that is a reasonable position. Dr. Jacobson, could you comment on that suggestion from Secretary Glickman about the epidemiological protection?

Mr. JACOBSON. I am not sure what the underlying laws here are, but my sense was that Secretary Glickman was saying if a food is linked to health problems without proof of a particular organism, then the government should be able to take action. And I think that it is patently obvious that government should be able to take action, because it might take weeks or months to track down a particular organism—like we saw with mad cow disease. It is a new organism in our experience.

I would like to step back, if you do not mind. I am very disappointed that the industry is not supporting the best possible food-safety system. Yes, we need changes in the statutes and we need reorganization, and I think former Secretary Glickman was very clear about this. Neither by itself will work. We need to do the two things sequentially or at the same time, but move in that direction. If there were a tragedy where you have FDA and FSIS fighting over whether the beef broth was 1 percent or 3 percent beef, and so we do not know who is going to regulate it, it would be a crying shame that actions were not taken because we had this crazy statutory patchwork and bureaucratic mess. And if we did have that tragedy, I think the food industry and opponents of action in Congress would feel extraordinarily embarrassed.

Senator DURBIN. I think you are right. I am going to turn it over to my colleague here, Senator Voinovich, and I will just make one comment. I find that there is a resistance in some areas to the changes which we are discussing. When it comes to government agencies, there is only one thing that can bring someone who is involved in this area around to my point of view and that is leaving civil service. Once they are out of the private sector, they seem to think that this is nothing but the best idea in the world.

Senator Voinovich.

Senator VOINOVICH. In the high-risk series update published January 2001 by the General Accounting Office—and by the way, they put human capital as a new high-risk area—they cite the Department of Agriculture's organizational culture, especially in its role of overseeing food safety, as an example of an agency that faces human capital challenges. Although food safety is not deemed a high-risk issue, GAO has listed food safety oversight as one of the major management challenges facing the Department of Agriculture.

GAO has explained that they feel the problem is not isolated to the Department of Agriculture, but rather than identifying it as a governmentwide problem, they chose to focus on the USDA. Now, these problems have been around a long, long time. I would be interested, Mr. Cady, and Mr. Molpus, what suggestions have your organizations made over the years to these agencies, and what kind of response have you received? I know you mentioned, finally, that they funded the budget.

Senator DURBIN. This year.

Senator VOINOVICH. This year—but what recommendations have you made and what kind of response have you gotten back over the years, and what makes you think that now that we have an additional challenge that things are going to be different in terms of coordination between the agencies and the commitment of resources that need to be made? You mentioned—I think Mr. Molpus, you talked about consumer—more resources; science and research coordination; regulated, updated products and so forth. They are all out there, and what is really being done? And how do you respond to the fact that it has not been done and it does not require some new way of accomplishing this issue?

Mr. MOLPUS. Senator, I think the FDA has made some considerable progress. I think over the last 4 years there has been a significant or a noticeable decrease in the diagnosed cases of Salmonella and Listeria. They have set forth some targets for 2005, which, in reduction of these foodborne illnesses, they have almost reached those targets already. There is continual innovation and progress. I think what we are saying from industry is, it could be faster. There could be more resources. They have been a resource-starved agency, and with additional resources and the application of better and improved science and technology, and given that we all say that they are best in the world, I think they can get the job done without going through the distraction of a structural reorganization.

Senator VOINOVICH. But the fact is, they have not gotten the job done. It is an issue of priority in terms of somebody coordinating it and saying that this is a national problem.

I was interested in Mr. Hammond's testimony. You are saying that we have had outbreaks. Why don't you share with me an example of a couple of them where you could not get somebody to step up to the table and clarify it? If we had something like this right now, how would we deal with it in a way that the public would feel confident that something was happening, Mr. Hammonds?

Mr. HAMMONDS. Well, almost any of the outbreaks would serve as an example. Perhaps the clearest was our Chilean grape situation, which in hindsight turned out not to be a huge problem, but at the time it was impossible for us to find someone from the government willing to step forward and reassure the public. But retailers and T.V. news cameras can always find a supermarket. Retailers turned out to be the ones out front on that, and the ones doing as best we can to give the public reassurance.

I would point out that in the middle of the food distribution system, groups tend to be regulated by single agencies or have very clear lines of authority. When you arrive closer to the consumer and you get into the supermarket, one way or another we are regulated by everyone. So we see the kinds of overlaps, the kinds of gaps and therefore, the kinds of time we waste trying to get a credible analysis of the situation and a reassuring statement out of the government. So, perhaps we deal with a more difficult problem than those earlier in the distribution system, but it is a problem.

Senator VOINOVICH. The manufacturers are saying the system is OK, and those of you that are out there, retailers, say this system is not working, and you're concerned that you get the wrong infor-

mation out there and you cannot move in on it and this will have a devastating impact on your businesses. People stop buying whatever the case may be, and it just ratchets down. It is interesting with the airlines, the enormous cascading that has gone on in this country in other areas. Everyone is saying now, if you really want to do something about the economy, get the planes flying and get them up in the air and make people feel secure. One or two items like this just have—it was the egg thing at one time and it just ripples across. So, there seems to be a difference of opinion here between Mr. Molpus, Mr. Cady and you, Mr. Hammonds, and you are all on the private sector side of this thing.

Mr. MOLPUS. It is rare that we disagree. The point that it goes to we have a different relationship with the agencies than the supermarket industry and a lot of this goes to the view and experience that we have had with the agency versus someone else's experience. We have not had the experience of having indecisiveness about who is in charge during the time of any sort of a food safety crisis that we have dealt with. We are looking at throwing out some atypical examples and coming to conclusions, rather than looking at the vast majority of incidents. It is fairly clear. You can talk about the pizza issue, but it is fairly clear that the products are at USDA and that they deal with them through the system and the products that are at FDA and that they deal with them.

Mr. JACOBSON. Do not forget the $100 billion worth of products whose labeling and safety is overseen by the Bureau of Alcohol, Tobacco and Firearms. The Treasury Department does not put this at the top of its list when you are asking the Secretary for what the issues are. We have seen cases where beer was contaminated with nitrosamines, which are cancer-causing substances. Wine and liquors were contaminated with urethane, another cancer-causing substance, and these substances developed during the manufacturing processes. Wine contains sulfites, which is deadly to a small percentage of the population. It causes acute reactions.

When we went to the Bureau of Alcohol, Tobacco and Firearms, they did not have the foggiest idea of what to do about these things. It took a fair length of time before they learned how to coordinate with the FDA. That may be at the extremes, but we are talking about a lot of product being consumed that falls largely outside the ambit of FDA or USDA. That is something I think should be expressed in your bill. But, I think Mr. Molpus is right. Usually things work out fine and we do have a pretty safe food supply in this country. Most people do not die of food poisoning, just 5,000 a year. Is that OK? We need to be concerned about where the problems are and maybe it is one-tenth of 1 percent of all the food or decisions that are being made, but that is where the problems are going to occur. That is what we should anticipate and prevent.

Mr. CADY. I would like to make a couple of comments, if I could. One, my association is responsible for working with our companies relative to recalls when they occur, and in the 14 years that I have been associated with this, I have never had a problem determining or having the agencies determine as to who is responsible or in charge of that particular recall. So, I can just say that I have not seen that fall through the crack in terms of responsibility.

You made a couple of statements earlier, both of the Senators did, relative to why doesn't this thing work then, if we think it is such a great system. I think it is like anything else. If you have two companies that merge, there is a CEO that drives the issue in terms of bringing those two companies together, not only in terms of their culture, but also in terms of their production issues, marketing issues. What has not occurred in the government aspect of managing this system, in terms of coordination and communication, is the accountability taken over by, and I start at the Secretary level, to make sure that the coordination and the communication exists. What we really do is, we usually talk about it at these type of hearings and the Secretaries may talk about it, but it gets pushed down to the working level agencies that actually do it, and it is harder to do that.

I think that we need my suggestion, in terms of trying to clear up some of this pizza issue, which I love to hear about—I do not think it is a food safety issue. I think it is a department issue, in terms of who should be responsible for pizza, which is a great product, but it is not a food safety issue. But, I think from that you can get a lot more out of this system. Are there some legislative things that need to change? Probably. Are there some department responsibilities that could be put together? Probably. Are there better ways we can do risk assessment? Certainly. But, I think people have to focus on it and carry it through, and I do not believe in my tenure in this town that that has occurred.

Senator VOINOVICH. Well, the question I have is, and I challenge you today, is to come up with those recommendations about the things that you think need to be done in terms of coordination, in terms of resources and some of the things that you have talked about now and in your testimony.

Mr. CADY. We will do that.

Senator VOINOVICH. And, to see if you can get that kind of attention given to it—I have, and I have been here a short time—but, getting agencies to coordinate their activity around here is very, very difficult.

Mr. CADY. Well, let me add that we brought up the EPA a little while ago. One of the concerns I have with going to a single food agency from a government bureaucracy perspective is that I look at the EPA, and after 30 years—and you go back to see what it was supposed to do and how much was supposed to be encompassed in that—and I can tell you that in my relationships with the EPA as a new agency now of 30 years, the coordination and communication amongst and between is not particularly good—I am not sure how it was before then. I was not here at that time—but it has not been that terrific because we have a new agency.

I also think we need to talk about food safety from a political perspective, Mr. Chairman. Food safety cannot be politicized and I am concerned about what a single food agency, at the end of the day, headed by a politically appointed administrator, would amount to, and I think that——

Senator VOINOVICH. If your analogizing it to EPA, I agree.

Mr. CADY. That is my point, sir. That is how I feel about it.

Senator DURBIN. I might just say in defense of the EPA——

Mr. CADY. OK, Senator.

Senator DURBIN. The standards for air and water quality over the last 30 years dramatically improved. We focused our resources on a mission and we really achieved a lot. There is more to achieve and you will find, I think, some bureaucratic tangles in virtually every single agency.

Mr. Cady, you talk about a CEO driving this kind of combination. We may have that in place. As quoted earlier, Presidential candidate George W. Bush was in favor of this concept that we are talking about today and I have spoken to him about it. He understands it then and now, and I think in the context of September 11, understands there is a new dimension to it. I might also add, as I did earlier, I think Governor Ridge is going to have some voice in this, as he should, to talk about whether or not this is part of the security of our Nation. I trust Tom Ridge a lot, because I have known him for so long, and I hope as soon as he can get his head above water that I can talk to him about this, too.

Mr. CADY. I think you will see that happen, and food security and food safety, I think, is going to be a large part of his focus once he gets organized.

Senator DURBIN. Dr. Chalk, before we break here, let me go back to some of the points you have made, and one of them I felt was particularly important when it came to our agricultural exports being such a large part of American food processing in agriculture. I think the point you made here is the share of products sold overseas is more than double that of other U.S. industries. So one of the points I made early on was the hope that this is not just a monologue in the United States, but becomes a dialogue with other countries, so that we can start establishing standards one to the other, with some hope that we can harmonize the way we produce food so that it is safe and secure as it crosses borders. I do not know if that is the point that you are alluding to as well.

Mr. CHALK. Absolutely, and I think that any initiatives that are taken on that basis are overdue and only to the good. One only has to look at the numerous examples of countries that have been affected by major animal disease outbreaks: Taiwan, the United Kingdom recently, Argentina this year, to catalog the enormous economic destruction that can be wrought on those countries, not only in the term of immediate protective embargoes, but the ripple effect that can go on for many years. Taiwan is still suffering from the 1990–1997 outbreak, and actually has not recovered. So, I think that any institution of cross-border standardization has to be part of the overall solution, particularly in a globalized world.

We are no longer dealing with countries that can view what occurs within their own borders stopping at that border. We are in an international system. Where the trading of commodities is more global and rapid than ever. Therefore, it is incumbent that we do have some sort of globalized or at least regionalized standardization across borders.

Senator DURBIN. Can you imagine that first meeting with the EU when we sit down and say, in our wisdom, based on our view of science, we think that a whole egg should be inspected perhaps once every day and that a broken egg inspected once every 4 years? When you get down to it, there is no way we can say that with a straight face and that reflects the current system in America.

The last question I have for you, Dr. Chalk, is you make a point here about confidence in government, and I think what has happened in Europe is instructive of where we are today. I think there are some parallels here, because in Europe, government did not respond to a very serious concern of consumers, whether it was BSE or antibiotics in animal feed or some of these other concerns that people had, GMOs for that matter, and as a result the stage was taken over by people who did not bring science to the party. They brought a lot of fear to the party. As a result, I think, many of these government agencies were discredited in Great Britain and in the European Union. Now they are struggling to re-establish their credibility.

Well, we have a new world, too. We have a new challenge where I think consumers are going to look to us. What have we learned from September 11 based on some of the things we have heard in the testimony at the hearing today? What are we going to do, as a government, to respond to what people are legitimately concerned about? Sadly, bioterrorism is one of those that is back on the stage. I hope we have a credible governmental response so that people believe they can have confidence, not only in their government, but equally important, or more important, in the safety of our food supply.

I will just close as I started. We have the safest food supply in the world. It bears repeating. We can do better and what we have heard today are, I think, some suggestions and examples of ways that we can improve it. I want to thank all those who attended. I want to announce that the record of the hearing will remain open for 1 week for Subcommittee Members to submit statements or additional questions for witnesses.

I thank my colleague, Senator Voinovich, for joining me.

Senator VOINOVICH. Can I just make one last comment?

Senator DURBIN. Certainly.

Senator VOINOVICH. I was quite pleased to hear that the Department of Agriculture and the Food and Drug Administration are working together with the administration. That was very comforting to me. I would hope that those of you who represent the industry would be making your recommendations also about things that you see that are out there that we ought to be concerned about, because you are actually out on the front lines dealing with these problems. I think your input would be very, very important and I am sure well-received.

Mr. CADY. We have a process going now just doing that in terms of the alliance that are running, in terms of information, working with the government, working with both agencies, so that the communication is flowing both ways. And I think it is going to work well, sir.

Mr. MOLPUS. The conversations with FDA are daily.

Senator VOINOVICH. Good. Thank you.

Senator DURBIN. Thank you, witnesses. I thank you, Senator Voinovich. The Subcommittee stands adjourned.

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

APPENDIX

United States General Accounting Office

GAO

Testimony
Before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, Committee on Governmental Affairs, U.S. Senate

For Release on Delivery
Expected at 10:00 a.m. EDT
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FOOD SAFETY AND SECURITY

Fundamental Changes Needed to Ensure Safe Food

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

GAO-02-47T

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the federal food safety system and whether the system's current design can meet the food safety challenges of today. While the food supply is generally safe, each year tens of millions of Americans become ill and thousands die from eating unsafe foods, according to the Centers for Disease Control and Prevention (CDC). As we have stated in previous reports and testimonies, fundamental changes are needed to ensure a safer food supply. My testimony today provides an overview of the nation's fragmented food safety system, the problems that it causes, and the changes necessary to create lasting improvements. In addition, I want to bring to your attention some work GAO has done addressing deliberate food contamination and federal research on and preparedness for bioterrorism in light of the tragic events of September 11, 2001.

In summary, the current food safety system is a patchwork structure that hampers efforts to adequately address existing and emerging food safety risks, whether those risks involve inadvertent or deliberate contamination. The current system is not the product of a comprehensive planning process; rather, it was cobbled together over many years to address specific health threats from particular food products. The resulting fragmented organizational and legal structure causes inefficient use of resources, inconsistent oversight and enforcement, and ineffective coordination, which together hamper federal efforts to comprehensively address food safety concerns. Many states modeled their organizational structure for food safety on the federal system and thus face the same issues.

It is now widely recognized that food safety issues must be addressed comprehensively—that is, by preventing contamination through the entire food production cycle, from farm to table. A single, food safety agency responsible for administering a uniform set of laws is needed to resolve the long-standing problems with the current system; deal with emerging food safety issues, such as the safety of genetically modified foods or deliberate acts of contamination; and ensure a safe food supply. While we believe that an independent agency could offer the most effective approach, we recognize that there are short-term costs and other considerations associated with setting up a new government agency. A second option would be to consolidate food safety activities in an existing department, such as the U.S. Department of Agriculture (USDA) or the Department of Health and Human Service (HHS). Regardless, however, choosing an organizational structure only represents half the job. For any

single food safety agency to be ultimately successful, it will also be necessary to rationalize the current patchwork of food safety legislation to make it uniform and risk-based.

Background

Despite spending more than $1 billion annually on the federal food safety system, food safety remains a concern. For example, between May and November 2000, sliced and packaged turkey meat contaminated with *Listeria monocytogenes* caused 29 individuals in 10 states to become ill. In April and May of this year, imported cantaloupes contaminated with a pathogenic strain of *Salmonella* were linked to 54 illnesses and 2 deaths in 16 states, and in June six people in California were sickened, two of whom died, from eating oysters contaminated with *Vibrio vulnificus*. CDC estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year. In medical costs and productivity losses, foodborne illnesses related to five principal pathogens cost the nation about $6.9 billion annually, USDA estimates.[1]

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 (FSIS), in USDA, is responsible for the safety of meat, poultry, and processed eggs, while the Food and Drug Administration (FDA), in HHS, is responsible for the safety of most other foods. Other agencies with food safety responsibilities and/or programs include HHS' Centers for Disease Control and Prevention; USDA's Agricultural Marketing Service (AMS), Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), and Grain Inspection, Packers and Stockyards Administration (GIPSA); the Department of Commerce's National Marine Fisheries Service; the Department of the Treasury's U.S. Customs Service and Bureau of Alcohol, Tobacco, and Firearms; the Environmental Protection Agency (EPA); and the Federal Trade Commission. Appendix I describes the food safety roles and responsibilities of these 12 agencies and shows each agency's food safety funding and staffing level for fiscal year 2000.

State and local governments also conduct inspection and regulation activities that help ensure the safety of foods produced, processed, or sold

[1]The five principal pathogens are *Campylobacter spp.*, *Salmonella* (nontyphoidal), *E. coli* O157:H7, *E. coli* non-O157 STEC, and *Listeria monocytogenes*.

within their borders. State and local governments would generally be the first to identify and respond to deliberate acts of food contamination.

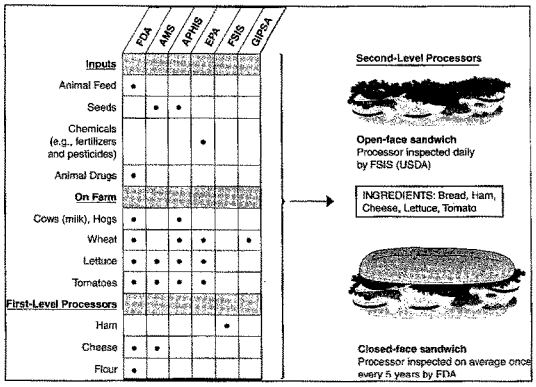
Fragmented System Hampers the Effectiveness of Food Safety Efforts

During the past 25 years, we and other organizations, such as the National Academy of Sciences, have issued 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, food safety problems persist, largely because food safety responsibilities are still divided among several agencies that continue to operate under different regulatory approaches.

The federal regulatory system for food safety did not emerge from a comprehensive design but rather evolved piecemeal, typically in response to particular health threats or economic crises. Addressing one new worry after another, legislators amended old laws and enacted new ones. The resulting organizational and legal patchwork has given responsibility for specific food commodities to different agencies and provided them with significantly different regulatory authorities and responsibilities.

The number of agencies involved in regulating a sandwich illustrates the fragmented nature of the current food safety system. Figure 1 shows the federal responsibilities for regulating production and processing of a packaged ham and cheese sandwich and its ingredients. The responsible regulatory agency as well as the frequency with which inspections occur depends on how the sandwich is presented. FSIS inspects manufacturers of packaged open-face meat or poultry sandwiches (e.g., those with one slice of bread), but FDA inspects manufacturers of packaged closed-face meat or poultry sandwiches (e.g., those with two slices of bread). According to FSIS officials, the agency lacked the resources to inspect all meat and poultry sandwich manufacturers, so it was decided that FSIS would inspect manufacturers of the less common open-face sandwich, leaving inspection of other sandwich manufacturers to FDA. Although there are no differences in the risks posed by these products, wholesale manufacturers of open-face sandwiches sold in interstate commerce are inspected by FSIS daily, while wholesale manufacturers of closed-face sandwiches sold in interstate commerce are generally inspected by FDA on average once every 5 years. (See app. II for a list of other food products with similar risks that have different inspection frequencies because they are regulated by different agencies.)

Figure 1: Federal Agencies Responsible for Safety of Packaged Ham and Cheese Sandwich



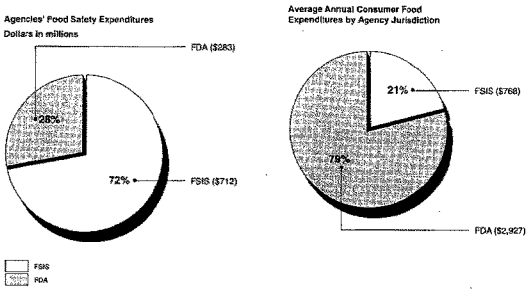
Because the nation's food safety system evolved piecemeal over time, the nation has essentially two very different approaches to food safety—one at USDA and the other at FDA—that have led to inefficient use of resources and inconsistencies in oversight and enforcement. These problems, along with ineffective coordination between the agencies, have hampered and continue to impede efforts to address public health concerns associated with existing and emerging food safety risks. The following examples represent some of the problems we identified during our reviews of the nation's food safety system.

- **Federal food safety expenditures are based on legal requirements, not on risk.** As shown in figure 2, funding for ensuring the safety of products is disproportionate to the level of consumption of those products because the frequency of inspection is based not on risk but on the agencies' legal authority and regulatory approach. Likewise, funding for ensuring the safety of products is disproportionate to the percentage of

foodborne illnesses linked to those products. For example, to ensure the safety of meat, poultry, and processed egg products in fiscal year 1999, FSIS spent about $712 million to, among other things, inspect more than 6,000 meat, poultry, and egg product establishments and conduct product inspections at 130 import establishments. FSIS' expenditures reflect its interpretation of federal law as requiring daily inspection of meat and poultry processing plants and its traditional implementation of its statutory inspection mandate through continuous government inspection of every egg products plant and every meat and poultry slaughter plant, including the examination of every carcass slaughtered. These plants account for about 20 percent of federally regulated foods and 15 percent of reported foodborne illnesses. In comparison, FDA, which has responsibility for all foods except meat, poultry, and processed egg products and has no mandated inspection frequencies, spent about $283 million to, among other things, oversee some 57,000 food establishments and 3.7 million imported food entries. These establishments and entries account for about 80 percent of federally regulated foods and 85 percent of reported foodborne illnesses.[2]

[2] *Food Safety: Overview of Federal and State Expenditures* (GAO-01-177, Feb. 20, 2001) and *Food Safety: Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures* (GAO/T-RCED-00-300, Sept. 20, 2000).

Figure 2: FSIS' and FDA's Food Safety Expenditures and Consumers' Annual Food Expenditures by Agency Jurisdiction



Source: Prepared by GAO from fiscal year 1999 FSIS and FDA expenditure data and 1999 U.S. Bureau of Labor Statistics data.

- **Federal agencies' authorities to enforce food safety requirements differ.** USDA agencies have the authority to (1) require food firms to register so that they can be inspected, (2) ~~presume that food firms~~ are involved in interstate ~~commerce and thereby be subject to~~ federal regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, and (4) temporarily detain any suspect foods. Conversely, FDA lacks such authority and is often hindered in its food oversight efforts. For example, both USDA and FDA oversee recalls when foods they regulate are found to be contaminated or adulterated.[3] However, if a USDA-regulated company does not voluntarily conduct the recall, USDA can detain the product for up to 20 days while it seeks a court order to seize the food. Because FDA does not have detention authority, it cannot ensure that tainted food is kept out of commerce while it seeks a court-ordered seizure. As another example, while FDA is responsible for overseeing all seafood-processing firms operating in interstate commerce, the agency does not have an effective system to identify the firms subject to regulation because there is no registration requirement for seafood firms, ~~and it cannot assume that~~

[3] *Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls* (*GAO/RCED-00-195*, Aug. 17, 2000).

seafood firms operate in interstate commerce. As a result, some firms may not be subjected to FDA oversight, thus increasing the risk of consumers' contracting a foodborne illness from unsafe seafood.[4]

- **USDA and FDA implementation of the new food safety approach is inconsistent.** Since December 1997, both USDA and FDA have implemented a new science-based regulatory approach—the Hazard Analysis and Critical Control Point (HACCP) system—for ensuring the safety of meat, poultry, and seafood.[5] The HACCP system places the primary responsibility on industry, not government inspectors, for identifying and controlling hazards in the production process. However, as we discussed in previous reports,[6] FDA and USDA implemented the HACCP system differently. While USDA reported that in 1999, 96 percent of federally regulated plants were in compliance with the basic HACCP requirements for meat and poultry, FDA reported that less than half of federally regulated seafood firms were in compliance with HACCP requirements. In addition, while USDA collects data on *Salmonella* contamination to assess the effectiveness of its HACCP system for meat and poultry, FDA does not have similar data for seafood. Without more effective compliance programs and adequate performance data, the benefits of HACCP will not be fully realized.

- **Oversight of imported food is inconsistent and unreliable.** As we reported in 1998, the meat and poultry acts require that, before a country can export meat and poultry to the United States, FSIS must make a determination that the exporting country's food safety system provides a level of safety equivalent to the U.S. system.[7] Under the equivalency requirement, FSIS has shifted most of the responsibility for ensuring product safety to the exporting country. The exporting country performs the primary inspection, allowing FSIS to leverage its resources by focusing its reviews on verifying the efficacy of the exporting countries' systems. In addition, until FSIS approves release of imported meat and poultry

[4] *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204, Jan. 31, 2001).

[5] In January 2001, FDA finalized regulations requiring HACCP for fruit and vegetable juices.

[6] *Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System* (GAO/RCED-00-16, Dec. 8, 1999) and *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204, Jan. 31, 2001).

[7] *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable* (GAO/RCED-98-103, Apr. 30, 1998).

products into U.S. commerce, they generally must be kept in an FSIS-registered warehouse. In contrast, FDA lacks the legal authority to require that countries exporting foods to the United States have food safety systems that provide a level of safety equivalent to ours. Without such authority, FDA must rely primarily on its port-of-entry inspections to detect and bar the entry of unsafe imported foods. Such an approach has been widely discredited as resource-intensive and ineffective. In fiscal year 2000, FDA inspections covered about 1 percent of the imported food entries under its jurisdiction. In addition, FDA does not control imported foods or require that they be kept in a registered warehouse prior to FDA approval for release into U.S. commerce. As a result, some adulterated imports that were ultimately refused entry by FDA had already been released into U.S. commerce. For example, in 1998 we reported that in a U.S. Customs Service operation called "Bad Apple," about 40 percent of the imported foods FDA checked and found in violation of U.S. standards were never redelivered to Customs for disposition. These foods were not destroyed or reexported as required and presumably were released into U.S. commerce.

- **Claims of health benefits for foods may be treated inconsistently by different federal agencies.** Because three federal agencies are charged with enforcing different statutes, a product's claim of health benefits might be denied by one agency but allowed by another.[8] FDA, the Federal Trade Commission, and USDA share responsibility for determining which claims regarding health benefits are allowed in labeling and advertising of foods and dietary supplements. FDA has authorized only a limited number of specific health claims for use on product labels. However, the Federal Trade Commission 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. Furthermore, USDA has not issued regulations to adopt any of the FDA-approved health claims for use on the products that it regulates, such as pot pies, soups, or prepared meals containing over a certain percentage of meat or poultry. Rather, USDA reviews requests to use a health claim, including those approved by FDA, on a case-by-case basis.

- **Effective enforcement of limits on certain drugs in food-producing animals is hindered by the regulatory system's fragmented**

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

organizational structure. FDA has regulatory responsibility for enforcing animal-drug residue levels in food producing animals. However, FDA in conjunction with the states have only investigated between 43 and 50 percent of each year's USDA animal-drug residue referrals made between fiscal year 1996 and 2000. According to FDA officials, the agency lacks the resources to conduct prompt follow-up investigations and does not have an adequate referral assignment and tracking system to ensure that investigations are made in a timely manner. FDA has relied on the states, through contracts and cooperative agreements, to conduct the bulk of the investigations. FDA only has resources to investigate repeat violators. As a result, animal producers not investigated may continue to use animal drugs improperly putting consumer health at greater risk.

In the absence of a unified food safety system, federal agencies have attempted to coordinate their efforts to overcome fragmentation and avoid duplication or gaps in coverage. While we believe that interagency coordination is important and should be continued, history has shown that such efforts are difficult to conduct successfully. The following examples represent some of the coordination problems we have found.

- **Fragmented organizational structure poses challenges to U.S. efforts to address barriers to agricultural trade.** The organizational structure for food safety complicates U.S. efforts to address foreign sanitary and phytosanitary (SPS) measures. SPS measures are designed to protect humans, animals, or the territory of a country from the spread of a pest or disease, among other things. However, the U.S. Trade Representative and USDA are concerned that some foreign SPS measures may be inconsistent with international trade rules and may unfairly impede the flow of agricultural trade. In 1997, we reported that the federal structure for addressing foreign SPS measures was complex because 12 federal agencies had some responsibility for addressing problems related to SPS measures and that no one agency was directing federal efforts.[9] We found, among other things, that the involvement of multiple agencies with conflicting viewpoints made it difficult to evaluate, prioritize, and develop unified approaches to address such measures. While, the U.S. Trade Representative and USDA took some actions to respond to our report, including establishing mechanisms to improve interagency coordination and decision-making, it remains to be seen whether such actions will effectively address the coordination problems over the long run.

[9] *Agricultural Exports: U.S. Needs a More Integrated Approach to Address Sanitary/Phytosanitary Issues* (GAO/NSIAD-98-32, Dec. 11, 1997)

- **Different statutory responsibilities may limit the ability of agencies to coordinate successfully.** As we reported in August 1998, because FDA and FSIS have different statutory responsibilities, important information about animal feed contaminated with dioxin (a suspected carcinogen) and animals that had consumed this feed was not effectively communicated to the food industry.[10] FDA and FSIS worked together to decide on the preferred course of action for handling the contaminated feed and animals, and each agency was responsible for communicating its decisions to producers or processors under its jurisdiction. However, the agencies did not necessarily communicate all required actions to all affected parties. For example, when officials from FDA, the agency responsible for regulating animal feed, met with meat and poultry producers, their primary concern was with the contaminated feed, not with the animals that had consumed it. Thus, they did not necessarily tell these producers about the actions they should take for their affected animals. FSIS, the agency responsible for regulating meat and poultry processors, sent word of dioxin-testing requirements to the processors and trade associations but did not notify meat and poultry producers, over which it has no jurisdiction.

- **The need for extensive coordination may impede prompt resolution of food safety problems.** Despite FSIS' and FDA's efforts to coordinate their efforts on egg safety, more than 10 years have past since the problem of bacterial contamination of intact shell eggs was first identified and a comprehensive safety strategy has yet to be implemented. In 1988, for the first time, some intact shell eggs were discovered to be contaminated internally with the pathogenic bacteria *Salmonella enteritidis*. In 1992, we reported that due to coordination difficulties resulting from the split regulatory structure for eggs, the federal government had not agreed on a unified approach to address this problem.[11] In July 1999, we reported that the federal government still had not agreed on a unified approach to address the problem.[12] In July 2000, FDA and FSIS issued a "current thinking" paper identifying actions that would decrease the food safety

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

[11] *Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination* (GAO/RCED-92-59, Apr. 21, 1992).

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

risks associated with eggs. However, as of September 2001, comprehensive proposed regulations to implement these actions had not yet been published.

- **Continuity of coordination efforts is hampered by changes in executive branch leadership.** The President's Council on Food Safety, created in 1998, was tasked with developing a comprehensive strategic plan for federal food safety activities. In August 2000, the council agreed to initiate an interagency process to address our recommendation that FDA and the Department of Transportation,[13] among others, enhance food safety protections by developing a strategy to regulate animal feed while in transport. While the council published its strategic food safety plan in January 2001 that included numerous "action items" and recommendations for improving the federal food safety system, the council did not address a transport strategy for animal feed. Moreover, the council has not met since publishing the strategic plan, and it remains to be seen whether the new administration will act on the council's recommendations. For example, the council's strategic plan included an action item to allocate enforcement resources based on the potential risk to public health, but the President's fiscal year 2002 budget showed little change in the allocation of food safety resources among agencies.

Fundamental Changes Needed to the Federal Food Safety System

We continue to believe, as we testified in 1999,[14] that a single, independent food safety agency administering a unified, risk-based food safety system is the most effective solution to the current fragmentation of the federal food safety system. While there are difficulties involved in establishing a new government agency and opinions differ about the best organizational model for food safety, there is widespread national and international recognition of the need for uniform laws and consolidation of food safety activities under a single organization. Both the National Academy of Sciences and the President's Council on Food Safety have joined us in calling for fundamental changes to the federal food safety system, including a reevaluation of the system's organizational structure. Likewise, several former senior-level government officials that were responsible for federal food safety activities have called for major organizational and legal

[13] *Food Safety: Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed* (GAO/RCED-00-255, Sept. 22, 2000).

[14] *Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based, Inspection System* (GAO/T-RCED-99-256, Aug. 4, 1999).

changes. Internationally, four countries—Canada, Denmark, Great Britain, and Ireland—have each recently consolidated their food safety responsibilities under a single agency. Several other countries or government organizations may be considering this option as well, including Argentina, Chile, Hong Kong, the Netherlands, and the European Union.

In an August 1998 report, the National Academy of Sciences concluded that the current fragmented federal food safety system is not well equipped to meet emerging challenges.[15] The academy found that "there are inconsistent, uneven, and at times archaic food statutes that inhibit use of science-based decision-making in activities related to food safety, and these statutes can be inconsistently interpreted and enforced among agencies." As such, the academy concluded that to create a science-based food safety system current laws must be revised. Accordingly, it recommended that the Congress change federal statutes so that food safety inspection and enforcement are based on scientific assessments of public health risks. The academy also recommended that food safety programs be administered by a single official in charge of all federal food safety resources and activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

According to the academy's report, many members of the committee tasked to conduct the study believed that a single agency headed by one administrator was the best way to provide the central, unified framework critical to improving the food safety system. However, assessing alternative organizational approaches was not possible in the time available or part of the committee's charge. Therefore, the committee did not recommend a specific organizational structure but instead provided several possible configurations for illustrative purposes. These were

- forming a Food Safety Council of representatives from the agencies, with a central chair appointed by the President, reporting to the Congress and having control of resources;
- designating one current agency as the lead agency and making the head of that agency the responsible individual;

[15] *Ensuring Safe Food from Production to Consumption* (Institute of Medicine, National Research Council, National Academy Press, Washington, D.C., August 1998).

- establishing a single agency reporting to one current cabinet-level secretary; and
- establishing an independent single agency at the cabinet level.

The committee also proposed that a detailed examination of specific organizational changes be conducted as a part of a future study. Such a study would be in keeping with the Congress' intent, as expressed in the fiscal year 1998 conference report on food safety appropriations. This conference report directed that if the academy's study recommended an independent food safety agency,[16] a second study be conducted to determine the agency's responsibilities to ensure that the food safety system protects the public health.

In response to the academy's report, the President established a Council on Food Safety and charged it to develop a comprehensive strategic plan for federal food safety activities, among other things.[17] The Council's Food Safety Strategic Plan, released on January 19, 2001, recognized the need for a comprehensive food safety statute and concluded that "the current organizational structure makes it more difficult to achieve future improvements in efficiency, efficacy, and allocation of resources based on risk."[18] The council analyzed several organizational reform options. Two of the options involved enhanced coordination within the existing structure, and the other two involved consolidation of responsibilities, either within an existing organization or a stand-alone food safety agency. The council's analysis of the options found that coordination may lead to marginal improvements but do little to address the fragmentation, duplication, and conflict inherent in the current system. The council concluded that consolidation could eliminate duplication and fragmentation, create a single voice for food safety, facilitate priority setting and resource allocation based on risk, and provide greater accountability. The council

[16] *Making Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies' Programs for the Fiscal Year Ending September 30, 1998, and for Other Purposes*, Conference Report (H. Rept. 105-252, Sept. 17, 1997).

[17] The President's Council on Food Safety comprises, among others, the Secretaries of Agriculture, Health and Human Services, and Commerce; the Administrator of the Environmental Protection Agency; and the Assistant to the President for Science and Technology.

[18] The Food Safety Strategic Plan is available on the Internet at http://www.foodsafety.gov/~fsg/cstrpl-4.html

recommended the development of comprehensive, unifying food safety legislation to provide a risk-based, prevention-oriented system for all food, followed by the development of a corresponding organizational reform plan.

Former key government food safety officials at USDA and FDA have acknowledged the limitations of the current regulatory system. As shown in table 1, many former government officials recognize the need for and support the transition to a single food safety agency. Some of these officials believe the single agency could be consolidated within an existing department, and others favor an independent agency. Regardless, they all recognize the need for legislative overhaul to provide a uniform, risk-based approach to food safety.

Table 1: Former Food Safety Officials Who Support Legislative Reform and Consolidation of Food Safety Activities

Name	Former government position and agency	Period of service
Mr. Dan Glickman	Secretary of Agriculture, USDA	1995-2001
Dr. Jane Henney	Commissioner, FDA, HHS	1998-2001
Dr. Catherine Woteki	Under Secretary for Food Safety, USDA	1997-2001
Dr. David Kessler	Commissioner, FDA, HHS	1990-1997
Mr. Michael Taylor	Administrator, FSIS, USDA and Deputy Commissioner for Policy, FDA, HHS	1994-1996 1991-1994
Dr. Russell Cross	Administrator, FSIS, USDA	1992-1994
Dr. Lester Crawford	Administrator, FSIS, USDA	1987-1991
Ms. Carol Tucker-Foreman	Assistant Secretary for Food and Consumer Services, USDA	1977-1981

Source: GAO

Although in the past the U.S. food safety system has served as a model for other countries, recently Canada, Denmark, Great Britain, and Ireland have taken the lead by consolidating much of their food safety responsibilities in a single agency in each country. As we reported in 1999,[19] responding to heightened public concerns about the safety of their food supplies, Great Britain and Ireland chose to consolidate responsibilities in agencies that report to or are represented by their ministers of health. The British consolidated food safety activities into an independent agency, represented before Parliament by the Minister of Health, largely because of the agriculture ministry's perceived mishandling of an outbreak of *Bovine Spongiform Encephalopathy* (commonly referred

[19] *Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems* (GAO/RCED-99-80, Apr. 20, 1999).

to as "mad cow" disease). Public opinion viewed the agriculture ministry, which had the dual responsibilities of promoting agriculture and the food industry and regulating food safety, as slow to react because it was too concerned about protecting the cattle industry.

Canada and Denmark were more concerned about program effectiveness and cost saving and accordingly consolidated activities in agencies that report to their ministers of agriculture, who already controlled most of the food safety resources. For example, Canada did not face a loss of public confidence, as did Great Britain and Ireland, but instead faced a budgetary crisis; it therefore sought ways to reduce federal expenditures. Denmark reorganized the whole Ministry of Agriculture, and all food regulation is now in the newly created Ministry of Food, Agriculture, and Fisheries.

Bioterrorism and Deliberate Acts of Food Contamination

Recent events have raised the specter of bioterrorism as an emerging risk factor for our food safety system. Bioterrorism is the threatened or intentional release of biological agents (viruses, bacteria, or their toxins) for the purpose of influencing the conduct of government or of intimidating or coercing a civilian population. These agents can be released through food as well as the air, water, or insects. To respond to potential bioterrorism, federal food safety regulatory agencies need to be prepared to efficiently coordinate their activities and respond quickly to protect the public health. Under the current structure, we believe that there are very real doubts about the system's ability to detect and quickly respond to any such event.

To date, the only known bioterrorist act in the United States involved deliberate contamination of food with a biological agent. In 1984, a religious cult intentionally contaminated salad bars in local restaurants in Oregon to prevent people from voting in a local election. Although no one died, 751 people were diagnosed with foodborne illnesses. Since then federal officials identified only one other act of deliberate food contamination with a biological agent that affected 13 individuals in 1996, but numerous threats and hoaxes have been reported. Both FDA and FSIS have plans and procedures for responding to deliberate food contamination incidents,[20] but the effectiveness of these procedures is largely untested for contamination involving biological agents. Therefore,

[20]A number of federal, state, and local agencies have responsibility for responding to deliberate acts or threats of food contamination. Besides FDA and FSIS, other federal agencies include CDC, the Federal Bureau of Investigation, and USDA's Office of Inspector General.

we recommended in 1999 that FDA and FSIS test their plans and procedures using simulated exercises that evaluate the effectiveness of federal, state, and local agencies' and industry's responses to various types of deliberate food contamination with a biological agent.[21]

Moreover, in September 2001 we reported that coordination of federal terrorism research, preparedness, and response programs is fragmented.[22] Separately, we reported that several relevant agencies have not been included in bioterrorism-related policy and response planning.[23] For example, USDA officials told us that their department was not involved, even though it would have key responsibilities if terrorists targeted the food supply.

Conclusions

To conclude, Mr. Chairman, 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, including acts of deliberate contamination involving biological agents; and ensure the safety of the nation's food supply. In addition, the National Academy of Sciences 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. While we believe the case for a single food safety agency has been compelling for some time, recent events make this action more imperative. Numerous details, of course, remain to be worked out but it is essential that the fundamental decision to create such an agency be made and the process for resolving outstanding technical issues be started.

Matters for Congressional Consideration

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

- enacting comprehensive, uniform and risk-based food safety legislation and

[21] *Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination* (GAO/RCED-00-3, Oct. 27, 1999).

[22] *Combating Terrorism: Selected Challenges and Related Recommendations* (GAO-01-822, Sept. 20, 2001).

[23] *Bioterrorism: Federal Research and Preparedness Activities* (GAO/01-915, *Sep. 28, 2001*).

- commissioning the National Academy of Science or a blue ribbon panel to conduct a detailed analysis of alternative organizational food safety structures and report the results of such an analysis to the Congress.

Recommendation for Executive Action

Pending Congressional action to establish a single food safety agency and enact uniform, risk-based legislation, we recommend that the Secretary of Agriculture, the Secretary of Health and Human Services, and the Assistant to the President for Science and Technology, as joint chairs of the President's Council on Food Safety, reconvene the council to facilitate interagency coordination on food safety regulation and programs.

Contact and Acknowledgments

For future contacts regarding this testimony, please contact Robert A. Robinson at (202) 512-3841. Individuals making key contributions to this testimony included Lawrence J. Dyckman, Keith W. Oleson, Stephen D. Secrist, Diana P. Cheng, Maria C. Gobin, Natalie H. Herzog, and John M. Nicholson Jr.

Appendix I: Food Safety Responsibilities and Fiscal Year 2000 Funding and Staffing Levels at 12 Federal Agencies

Dollars in millions

Agency	Fiscal year 2000 funding[a]	Fiscal year 2000 staffing
Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), is responsible for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. The Federal Food, Drug, and Cosmetic Act, as amended, is the major law governing FDA's activities to ensure food safety and quality. The act also authorizes FDA to conduct surveillance of all animal drugs, feeds, and veterinary devices to ensure that drugs and feeds used in animals are safe, effective, and properly labeled and produce no human health hazards when used in food-producing animals.	$323[b]	2,828[b]
Centers for Disease Control and Prevention (CDC), within HHS, is charged with protecting the nation's public health by leading and directing the prevention and control of diseases and responding to public health emergencies. CDC conducts surveillance for foodborne diseases; develops new epidemiological and laboratory tools to enhance surveillance and detection of outbreaks; and performs other activities to strengthen local, state, and national capacity to identify, characterize, and control foodborne hazards. CDC engages in public health activities related to food safety under the general authority of the Public Health Service Act, as amended.	29	66
Food Safety and Inspection Service (FSIS), within the U.S. Department of Agriculture (USDA), is responsible for ensuring that meat, poultry, and some eggs and egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, abeled, and packaged. FSIS carries out its inspection responsibilities under the Federal Meat Inspection Act, as amended, the Poultry Products Inspection Act, as amended, and the Egg Products Inspection Act, as amended.	649[c]	9,545
Animal and Plant Health Inspection Service (APHIS), within USDA, is responsible for ensuring the health and care of animals and plants. APHIS has no statutory authority for public health issues unless the concern to public health is also a concern to the health of animals or plants. APHIS identifies research and data needs and coordinates research programs to protect the animal industry against pathogens or diseases that are a risk to humans to improve food safety.	[d]	[d]
Grain Inspection, Packers and Stockyards Administration (GIPSA), within USDA, is responsible for establishing quality standards and providing for a national inspection system to facilitate the marketing of grain and other related products. Certain inspection services, such as testing corn for the presence of aflatoxin and starlink, enable the market to assess the value of a product on the basis of its compliance with contractual specifications and FDA requirements. GIPSA has no regulatory responsibility regarding food safety. Under a memorandum of understanding with FDA, GIPSA reports to FDA certain lots of grain, rice, pulses, or food products (which were officially inspected as part of GIPSA's service functions) that are considered objectionable under the Federal Food, Drug, and Cosmetic Act, as amended, the U.S. Grain Standards Act, as amended, and the Agriculture Marketing Act of 1946, as amended.	[d]	[d]
Agricultural Marketing Service (AMS), within USDA, is primarily responsible for establishing quality and condition standards and for grading the quality of dairy, fruit, vegetable, livestock, meat, poultry, and egg products. As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. AMS also runs a voluntary pesticide data program and carries out a wide array of programs to facilitate marketing. It carries out these programs under more than 50 statutes, including the Agricultural Marketing Agreement Act of 1937, as amended; the Agricultural Marketing Act of 1946, as amended; the Egg Products Inspection Act, as amended; the Export Apple and Pear Act, as amended; the Export Grape and Plum Act, as amended; the Federal Seed Act; and the Food Quality Protection Act. AMS is largely funded with user fees.	13[e]	26[e]

Dollars in millions

Agency	Fiscal year 2000 fundinga	Fiscal year 2000 staffing
Agricultural Research Service (ARS), within USDA, is responsible for conducting a wide range of research relating to the Department's mission, including food safety research. ARS carries out its programs under the Department of Agriculture Organic Act of 1862; the Research and Marketing Act of 1946, as amended; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended.	82	222
National Marine Fisheries Service (NMFS), within the Department of Commerce, conducts voluntary seafood safety and quality inspection programs under the Agricultural Marketing Act of 1946, as amended, and the Fish and Wildlife Act of 1956, as amended. NMFS provides inspection and certification services for fishery products for human consumption, as well as for animal feeds and pet foods containing a fish base.	[f]	165[f]
Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or distributed in the United States and setting maximum allowed residue levels for pesticides on food commodities and animal feed. EPA conducts these activities under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Federal Food, Drug, and Cosmetic Act, as amended.	171	1,076
Federal Trade Commission (FTC) enforces the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. FTC's food safety objective is to prevent consumer deception through the misrepresentation of food.	[g]	[g]
U.S. Customs Service, within the Department of the Treasury, is responsible for collecting revenues and enforcing various customs and related laws. Customs assists FDA and FSIS in carrying out their regulatory roles in food safety.	[g]	[g]
Bureau of Alcohol, Tobacco, and Firearms, within the Department of the Treasury, is responsible for administering and enforcing laws covering the production (including safety), use, and distribution of alcoholic beverages under the Federal Alcohol Administration Act and the Internal Revenue Code.	[g]	[g]
Total	**$1,267**	**13,928**

[a]Fiscal year 2000 appropriated funds.

[b]FDA's data includes funding and staffing for various programs across FDA that are involved with food safety activities, including the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the National Center for Toxicological Research, and the field components for these centers.

[c]FSIS' total funding for fiscal year 2000 was $751 million, which includes appropriated funds, reimbursements, and trust funds.

[d]The agency did not specify its food safety resources.

[e]AMS' funding and staffing are for Food Quality Protection Act information gathering only.

[f]NMFS' activities were funded through $12.4 million in user fees, not appropriated funds. Funding and staffing levels are for both safety and quality inspection activities.

[g]We did not obtain these agencies' food safety budgets due to the small amount of funds for these activities in previous years.

Source: Federal agencies' data.

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

Manufacturing plant inspected daily by FSIS	Manufacturing plant inspected on average about once every 5 years by FDA
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: Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

STATEMENT OF THE HONORABLE ROSA L. DELAURO
SENATE GOVERNMENT AFFAIRS SUBCOMMITTEE ON OVERSIGHT AND GOVERNMENT MANAGEMENT
WEDNESDAY OCTOBER 10, 2001

Mr. Chairman and members of the Committee, thank you for the opportunity to testify on this important health issue that affects all American families. I would especially like to thank Chairman Durbin for his leadership in introducing the Safe Food Act of 2001 in the Senate. We have worked closely on this issue for many years, and I look forward to working together in the future.

Our nation's food safety is of critical importance. According to the Centers for Disease Control and Prevention, each year 76 million people get sick and 5,000 people die from a food-related illness. I have had personal experience with this problem. When I was child, I contracted salmonella, a food borne illness. I was put in a hospital quarantine for several days, away from my parents and family.

While these numbers are staggering, they do not even include the vast number of unreported illnesses. The situation is not going to improve without decisive action. In fact, the incidence of food borne illnesses and deaths is likely to increase between 10 percent and 15 percent over the next decade as new and stronger bacteria develop in new and unexpected places.

In the wake of September 11th, we must also be concerned about the safety of our food from a bioterrorist attack. According to Raymond Zilinskas, a senior scientist with the Monterey Institute of International Studies, "The most likely scenario for a biological-weapons attack (would be a) food borne or beverage borne attack using salmonella, shigella, or staphylococcal toxins".

On October 3rd, the Secretary of Health and Human Services, Tommy Thompson, testified that he has submitted a request to OMB for additional money to fund bioterrorism programs at HHS. In addition to other priorities, he identified food safety as a vital area that needs to be addressed. The Secretary has reportedly requested money for 200 imported food inspectors and 100 domestic food inspectors.

During the debate on this year's Agriculture Appropriations bill, I offered an amendment which would have provided $90 million for 1,600 FDA inspectors for imported food, and $73 million for 630 domestic inspectors. Now more than ever, the safety of our food supply is of critical importance.

Currently, there is no comprehensive strategy to protect America's families from food borne illness. Several agencies, all with different and conflicting missions, work to ensure our food safety. For example, there is no standardization for inspections - processed foods facilities may see an FDA inspector once every five to six years, while meat and poultry is inspected daily. Clearly, something must be done.

In 1998, a National Academy of Sciences study concluded that, "a model food safety system should have a unified mission and a single official who is responsible for food safety at the federal level and who has the authority and the resources to implement science-based policy in all federal activities related to food safety". It makes sense for the safety of our food to consolidate food safety activities into a single food safety agency.

To address this critical public health issue, on May 1, 2001, I introduced the Safe Food Act in the House of Representatives. Like Senator Durbin's bill, this legislation would:

- establish an independent agency called the Food Safety Administration with responsibility for all federal food safety activities; and
- transfer food safety, inspection, and food labeling activities to the new agency from:
    - the Food Safety and Inspection Service at the Department of Agriculture,
    - the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine at the Food and Drug Administration, and
    - the National Marine Fisheries Service at the Department of Commerce.

Currently, the Safe Food Act enjoys 32 cosponsors who understand that a single Food Safety Administration will protect America's families against food borne illnesses.

I believe the Safe Food Act is a common sense approach to address our nation's food safety crisis. It is good government. It would consolidate and streamline the various agencies that are responsible for protecting our food and put authority into one food safety administrator. In his campaign, President Bush also publicly supported the idea of uniting all food safety responsibility under one agency.

In a June 9, 2000, speech in Philadelphia he stated that "the federal government is also responsible of the safety of our nation's food supply. The way things work now, there's one agency that inspects cheese pizza. There's another that inspects pepperoni pizza. There is one agency that inspects food grown outside the United States. Another that inspects food grown here inside the United States. Apparently, the revolutionary idea that maybe these functions could be combined hasn't dawned on anybody yet." In 2001, it is time to create a twenty-first century approach to our food safety system.

More importantly, I believe it is good for people. Food borne illness is a growing problem in the United States. Globalization, an aging population, and faster production and distribution of food increase the risk of people getting sick. The problem is now further exacerbated by the threat of bioterrorism. People should not have to worry about the meals they cook for their families. Protecting Americans from food borne illness should be our highest priority.

Thank you again for the opportunity to testify today. I look forward to working with the Committee and Senator Durbin on this vital public health issue.

STATEMENT OF
DR. ELSA MURANO
UNDER SECRETARY FOR FOOD SAFETY
U.S. DEPARTMENT OF AGRICULTURE

BEFORE THE SENATE GOVERNMENTAL AFFAIRS COMMITTEE
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING
AND THE
DISTRICT OF COLUMBIA

October 10, 2001

Introduction

Mr. Chairman, Members of the Subcommittee, I appreciate the opportunity to appear at today's hearing and discuss our nation's food safety system and structure. I am Dr. Elsa Murano, Under Secretary for Food Safety at the U.S. Department of Agriculture. As you know, I am a newcomer to USDA, having just been confirmed as Under Secretary on September 26. I am honored to be serving in this important position and am committed to the hard work ahead. I know there are many important food safety issues before the Congress, and I look forward to working closely with you to make progress on those issues.

Let me take a moment to discuss my background. I am a native of Havana, Cuba and immigrated with my family to the United States as a small child. I earned a Bachelor of Science degree in biology from Florida International University, a Master of Science degree in anaerobic microbiology from Virginia Tech, and a Ph.D., in Food Science, also from Virginia Tech. I have been a researcher and teacher in the field of food safety, both at Iowa State and Texas A&M Universities. My research efforts have led me to investigate pathogens such as *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*. My approach in this work has been to investigate safe methods to control or eliminate them from the farm-to-table chain. I believe my experience as a scientist and educator, and my perspectives as an "outsider looking in" will be valuable as I begin this new position.

FSIS and Its Place in the Food Safety System

I believe it is critical to first understand the circumstances under which our current food safety system came into being. It is also valuable to consider the food safety responsibilities that USDA's Food Safety and Inspection Service (FSIS) is statutorily required to carry out.

FSIS' mission is to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, as required by the Agency's authorizing statutes. FSIS' goal is to protect the public health by significantly reducing the

prevalence of foodborne hazards in meat, poultry, and egg products. The FSIS Strategic Plan for 2000-2005 calls for a further 25 percent reduction in the number of foodborne illnesses resulting from consumption of products the Agency regulates. Although existing public health data make it difficult to isolate specific contributions to achieving an overall reduction in foodborne illness, we can and do take action to monitor and control the prevalence of the foodborne hazards that can cause illness.

FSIS has a long, proud history of protecting the public health. Although the Agency under the current name was established by the Secretary of Agriculture on June 17, 1981, its history dates back to 1906.

In 1890, the U.S. passed a meat inspection law to assure European markets that meat from the United States was safe. However, the Meat Inspection Act of 1906 signaled the real beginning of domestic inspection in the United States. A year earlier, Upton Sinclair published his book, *The Jungle*, portraying unsanitary conditions in Chicago slaughterhouses. The book caused a public and political outcry. Meat sales around the country dropped nearly a third. The 1906 Act began a system of continuous daily inspection in slaughterhouses using organoleptic (sight, smell, touch) inspection to detect unsanitary conditions and adulterated products. Poultry inspection began in 1926, on a voluntary basis, and in 1957, Congress passed the Poultry Products Inspection Act, which established mandatory, daily, continuous inspection of poultry products. The 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Products Act brought imported meat and State inspection programs under the Federal system and require foreign and State inspection programs to be "equivalent" or "at least equal to" the Federal inspection program.

Since the 1967 and 1968 amendments, the next dramatic change to meat and poultry inspection occurred when FSIS published the landmark Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems rule on July 25, 1996. The rule addresses the original organoleptic inspection system's limitations in dealing with the problem of pathogenic microorganisms (harmful bacteria) on meat and poultry products. The rule clarifies the respective roles of government and industry in food safety, and therein makes better use of government resources in addressing food safety risks. Industry is accountable for producing safe food. Government is responsible for setting appropriate food safety standards, maintaining vigorous inspection to ensure those standards are met, and maintaining a strong enforcement program to deal with plants that do not meet regulatory standards.

With the shift in recent years toward greater mass production and distribution of food, and greater globalization in food trade, the identification and tracking of potential food hazards has become a much more complex activity. In response, FSIS has developed strong partnerships with Federal, state, local, and foreign public health agencies and stakeholders to better coordinate the investigation of and response to food safety hazards and outbreaks of foodborne illness. These partnerships are vital to FSIS' ability to effectively perform its public health mission.

Meeting Future Challenges

I agree with you wholeheartedly that Federal agencies with food safety responsibilities must be prepared to meet current and future food safety challenges. Our food safety system is being challenged by many factors. They include emerging pathogens, an increase in international trade, new food products in the marketplace, a growing segment of the population at greater risk of contracting foodborne illness, and gaps in education all along the farm-to-table chain.

On September 19th, the Bush Administration published its review of the food and agricultural system with a view toward identifying critical needs for the next century. The report, titled, *Food and Agricultural Policy—Taking Stock for the New Century,* details the enormous changes that have taken place in food and agriculture. It is a strategic planning tool that will help us frame the debate for food and farm policy for the future.

Food safety certainly is a vital part of food and farm policy, and the report emphasizes this. I'd like to provide more detail today about two key areas—the food safety infrastructure and the importance of integrated food safety programs.

USDA's Role in the Food Safety Infrastructure

Let me begin with the food safety infrastructure. U.S. agriculture is hugely successful at delivering abundant, affordable, safe and nutritious food. The pillar of success is largely due to an extensive physical and institutional infrastructure.

Inspection of meat, poultry and egg products is an important part of that infrastructure. FSIS currently has approximately 10,000 employees, the bulk of which are stationed in the field. More than 7,600 inspection personnel are stationed in approximately 6,000 meat, poultry, and egg plants and are responsible for the inspection of more than 8.5 billion birds, 133 million head of livestock, and 3.5 billion pounds of liquid egg products annually. In FY 2000, FSIS facilitated the export of an estimated 10 billion pounds of meat and poultry to approximately 100 countries throughout the world and began work on a new system to automate the certification of meat and poultry exports. Agency personnel also reinspected 3.7 billion pounds of imported meat and poultry from 31 countries. Eight million pounds of egg products were imported.

To ensure the safety of imported products, FSIS maintains a comprehensive system of import inspection, linking all U.S. ports of entry through a central computer system. This allows FSIS to establish compliance histories for countries and plants exporting to the U.S. and to communicate instantly among ports when problems are found at any individual port of entry. This system is one part of FSIS' efforts to verify the effectiveness of foreign inspection systems and to support its sister agency, the Animal and Plant Health Inspection Service (APHIS) in preventing the entry of meat or poultry products that present an animal disease threat to U.S. livestock.

In light of recent events in Europe regarding BSE, dioxin and other food safety crises, the manner in which FSIS certifies foreign programs as possessing public health safeguards that

are "equivalent" to the U.S. program is a subject of heightened interest. Annually, FSIS reviews all foreign inspection systems in countries eligible to export meat and poultry to the U.S. In FY 2000, FSIS reviewed the documentation of and performed on-site audits in 31 countries exporting meat and poultry products to the United States and was satisfied that each country had implemented systems equivalent to U.S. Sanitation Standard Operating Procedures (SSOPs), HACCP systems, and *Salmonella* testing programs, required for domestic plants.

FSIS is also responsible for assessing State inspection programs that regulate meat and poultry products that may be sold only within the State in which they were produced. If a State chooses to end its inspection program or cannot maintain the "at least equal to" standard in the inspection law, then FSIS assumes responsibility for inspection. There are currently 27 states that have a State meat or poultry inspection program and operate under cooperative agreements with FSIS. In these States, Federal funding is provided for up to one-half of the State's cooperative inspection program as long as the State maintains a program "at least equal to" the Federal program.

Another part of the FSIS food safety program involves its three multi-disciplinary laboratories, which conduct laboratory testing for microbiological contamination, chemical and animal drug residues, pathological conditions, processed product composition, and economic adulteration. FSIS performed tests on more than 371,000 product samples in FY 2000.

FSIS also conducts compliance and enforcement activities to address situations where unsafe, unwholesome, or inaccurately labeled products have been produced or shipped. The objective of these activities is two-fold -- one, to make a critical appraisal of compliance with meat and poultry regulations, and two, as a result of certain critical appraisals, to take enforcement action where necessary. In FY 2000, more than 49,000 compliance reviews were conducted. As a result of these reviews and other activities, approximately 34 million pounds of meat, poultry, and egg products were detained for noncompliance with the respective laws, and many criminal convictions and injunctions were obtained against firms and individuals for violations of the meat and poultry inspection laws. In addition, industry voluntarily recalled more than 5 million pounds of meat, poultry, and egg products.

Surveillance is another part of the infrastructure. A strong food safety system must have a mechanism for identifying new food safety problems rapidly. USDA conducts surveillance of the food supply, and HHS' Centers for Disease Control and Prevention (CDC), in partnership with State and local health departments, conducts surveillance for human foodborne illness. In July 1995, HHS and USDA began a collaborative project in several sites to collect more precise information on foodborne illnesses. FoodNet is an active surveillance system that helps us to better quantify the incidence of foodborne illness, better identify the causes of those illnesses, and help document the effectiveness of new food safety control measures.

Outbreak response also is key. In the past, an outbreak most likely affected a small local population and involved locally prepared food products with limited distribution. Increasingly, outbreaks involve larger populations and are likely to be multi-state or even international.

Delay in identifying the causative agent can allow the outbreak to spread. Because coordination is also essential, we have taken steps to expedite communication during large, multi-state outbreaks. One mechanism is the Foodborne Outbreak Response Coordinating Group (FORC-G)—a partnership established to better respond to interstate outbreaks of foodborne illness. USDA, HHS, and EPA form this partnership. This interagency group has coordinated and developed procedures for managing outbreaks, sharing information on potential sources of outbreaks and pathogens, and coordinating inter-departmental activities. A similar group—the Food Emergency Rapid Response and Evaluation Team—FERRET—has been established within USDA to coordinate the activities of USDA agencies.

USDA participates in PulseNet, a national network of public health laboratories supported by HHS. These laboratories aid outbreak response by performing DNA fingerprinting of foodborne bacteria and comparing results through an electronic database maintained by CDC. PulseNet permits rapid and accurate detection of foodborne illness outbreaks and traceback to their sources, including detection of a linkage among sporadic cases. PulseNet has been key in enabling Federal agencies to rapidly detect and control outbreaks of foodborne illness.

Research is another important part of the food safety infrastructure to better understand the basic science of food safety in order to design better diagnostic tools and interventions to improve food safety. FSIS is not a research agency, but works through the Agricultural Research Service to meet its research needs. FSIS' role is to articulate to ARS and to the private sector what its food safety research needs are in order to spur innovation and increase knowledge that can serve to reduce foodborne illness.

Risk assessment is another important part of the food safety infrastructure. Risk assessments are becoming increasingly important as a way of ensuring that our food safety resources are well spent. We can never completely eliminate foodborne health hazards, and resources are limited. Risk assessments help us to set priorities.

Education also figures prominently. Government needs to empower the public and private sector to take its proper responsibility for food safety. Education is necessary all along the farm-to-table chain, from producers on the farm to consumers in the home. Partnerships have been key in education. The "Fight BAC!" campaign is sponsored by the Partnership for Food Safety Education, a public-private partnership with participation of USDA, HHS, and the States. The campaign was created to reduce the incidence of foodborne illness by educating Americans about safe food handling practices. I believe there is much more we can do to educate food handlers, but this campaign is a good example of how a cooperative approach can work.

Integrated Food Safety Programs

Like every infrastructure, the food safety system requires periodic review, ongoing reinforcement, and appropriate modernization just to keep pace with continuously emerging and often unique challenges. What has become very clear is that the services USDA provides, from eliminating foodborne pathogens, to protecting against plant and animal pests and

diseases, to encouraging farm practices that stress conservation—all are interrelated and must continue to be carefully and comprehensively coordinated. For example, while animal health and food safety issues are housed in two separate USDA agencies, APHIS and FSIS work very closely together on issues of concern to both agencies. FSIS also coordinates closely with the Food and Nutrition Service and the Agricultural Marketing Service with regard to commodities purchased by AMS for the National School Lunch Program. The point of these examples is to illustrate the difficulty of isolating the food safety functions from USDA without affecting the integrity of the infrastructure as a whole.

This is true not only within USDA, but within government. As I described USDA's food safety infrastructure, I hope you noticed that every activity carried out by USDA has a partnership component. For example, outbreak response involves not only USDA but also HHS' Centers for Disease Control and Prevention. Even inspection is carried out with the help of State inspection programs.

We can do more to examine whether Federal food safety agencies can improve the services they provide. But this should be done through a careful, step-by-step process. As a first step, I would like to have the chance to meet and work with my colleagues on key food safety issues. In recent years, Federal food safety agencies have made strides in working together, and this Administration is committed to building on these accomplishments.

Commitment to Future of Food Safety

While there are many challenges facing our food safety system, substantial progress has been made in recent years. I will continue to pursue enhancements in the safety of our food system by establishing a seamless, science-based process and by strengthening coordination with other agencies involved in the food safety system.

Mr. Chairman, thank you again for the opportunity to discuss our nation's food safety system and structure. I look forward to continuing the dialogue on this issue in the future and would be happy to answer any questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Statement of

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Food and Drug Administration

Before the

Committee on Governmental Affairs

Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia

United States Senate

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FOR RELEASE ONLY UPON DELIVERY

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Bernard A. Schwetz, D.V.M., Ph.D., Acting Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration (FDA or Agency). Thank you for this opportunity to discuss the Federal food safety system and to provide testimony on behalf of the Department of Health and Human Services (HHS). Ensuring the safety of the food supply is a top priority for HHS and the Administration. I am pleased to be here today with my colleague, Dr. Elsa Murano, Under Secretary for Food Safety in the U.S. Department of Agriculture (USDA).

The American food supply continues to be among the safest in the world. Great strides have been made in recent years that have strengthened the Federal food safety system. The Federal food safety program includes new surveillance systems, better prevention programs, faster outbreak response, enhanced education, and better coordinated and focused research and risk assessment activities. Food safety agencies are working more closely together than ever before.

But our world is constantly changing, and we must continue to change with it. Indeed, we cannot rest until we have built a strong and credible food safety system that addresses the full range of food safety issues: one that is built on scientific expertise with recognized stature worldwide; that is risk-based and recognizes and responds to new risks; that provides a credible inspection and product sampling presence; that has the same level of protection to consumers from both

domestic and imported food; that efficiently stewards new technologies to the market; and that effectively educates and communicates to consumers.

By way of background, while FDA has lead responsibility within HHS for ensuring the safety of food products, HHS's Centers for Disease Control and Prevention (CDC) 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 United States attributable to the food supply. The disease surveillance systems coordinated by CDC are an essential information network for early warnings about dangers in the food supply and progress in reducing foodborne illness, and for indicating 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 to the implicated products and works closely with FDA 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. In addition, just as FDA works with State and local food safety counterparts, CDC works extensively with State and local 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 posed by our food supply.

I will now discuss some of the challenges we face, describe the food safety system toward which we should strive, mention some recent food safety accomplishments, and describe where we need to go from here.

While much progress has been made in improving the safety of the food supply, it is important not to underestimate the significant challenges we face. I would now like to discuss some of these challenges.

Food Safety Challenges

While the American food supply is among the safest in the world, there are still too many Americans stricken by illness every year caused by the food they consume, and some die as a result. The CDC has estimated that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. There are many reasons for this. People are eating a greater variety of foods, particularly seafood and fresh fruits and vegetables. As many of these foods are becoming available all year round, safety concerns associated with transportation and refrigeration arise. The rising volume of imported foods increases dramatically the number of potential sources of food contamination. People are eating more of their meals away from home. In fact, fifty cents of every food dollar is spent on food prepared outside the home. As more food workers become involved in preparing our meals, the opportunity for disease-causing errors also increases. This problem is especially important for

persons at greatest risk who eat foods prepared in hospitals, nursing homes, and childcare centers. Indeed, persons at highest risk for foodborne illness – children, the elderly, pregnant women, and immuno-compromised persons – now comprise nearly a quarter of the population.

Other significant changes are the emergence of new foodborne pathogens and the ability of existing pathogens to overcome traditional food barriers such as temperature and acidity. We are aware of more than five times the number of foodborne pathogens today than we were half a century ago, and we continue to discover more. Many of these pathogens can be deadly, especially to those at highest risk.

Framework for a Strong and Credible Food Safety System

The goal of HHS is to strengthen our food safety system to address the full range of food safety issues. This system has three simple steps:

1) to identify risks;
2) to take action; and
3) to measure results.

In identifying risks, we must ensure a strong science base which is the foundation of any successful food safety system. We must also develop, enhance, and maintain surveillance systems that can quickly and accurately identify food safety risks in the human food and animal

feed supplies and manage disease risks effectively. These surveillance systems are the key to an effective emergency response capability.

In taking action, we must start with prevention. That is how we, ultimately, will be most successful. We need strong risk-based prevention standards to prevent contamination of all human foods and animal feeds over the farm-to-table continuum. As these risk-based prevention standards are developed, we need education and training programs so that those in the industry and the public can effectively utilize them to reduce the risk of foodborne illness and minimize harm if illness develops.

Education is not enough. We need to verify. Domestic inspections of the food industry are essential to ensure application of appropriate preventive controls. And for imported food, we need a strong inspection and monitoring program to ensure that imported foods meet the same level of consumer protection as domestic foods. For both domestic and imported food, we need to maintain an adequate enforcement program to be sure the rules are followed.

Finally, we need science-based methods to measure results so we know how we are doing. The FoodNet system described below provides information on pathogens. We need similar mechanisms for other foodborne hazards. If implemented, such a framework would minimize foodborne illness and injury, maximize consumer safety and confidence, and enhance global competitiveness.

Recent Accomplishments

Even in the face of many challenges, there has been substantial progress in reducing to the greatest extent possible foodborne illness due to microbial contamination. Thanks to the budgetary support provided by Congress, this multi-agency effort has successfully built a strong foundation for a state-of-the-art, science-based food safety system and has promoted partnering among the key Federal agencies, States, academia, industry, and consumers. We intend to take a comprehensive approach that addresses all food safety hazards - microbiological, chemical, and physical - for products under FDA's jurisdiction.

As mentioned above, we now have in place newer surveillance systems, stronger prevention programs, faster outbreak response, and a risk-based philosophy that guides our research, risk assessments, and educational efforts. Preventive controls implemented by the Federal agencies, such as good agricultural practices for produce and eggs and HACCP systems for meat and poultry, have already shown results. There are also numerous interagency and Federal/State partnerships that have been formed to utilize more efficiently our collective resources.

I would now like to highlight just a few of the recent food safety achievements.

Surveillance

The primary objective of the American system of public health is to prevent disease before it occurs. Surveillance and monitoring are critical to meet this objective.

FoodNet Surveillance Network. A strong food safety system starts with knowing where the problems are and identifying new problems rapidly. The Foodborne Diseases Active Surveillance Network (FoodNet) is part of CDC's Emerging Infections Program. It is a collaborative project of the CDC, USDA, FDA, and nine States. This project began in 1995 to more precisely characterize the incidence and trends in foodborne illnesses, and to conduct systematic investigations to help public health officials better understand the epidemiology of foodborne disease in the U.S. Now expanded to nine sites covering 36 million people (13 percent of the U.S. population), FoodNet provides a strong network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne diseases, and identifying the source of specific foodborne diseases, all with a view toward developing and implementing effective prevention and control measures.

PulseNet. PulseNet, developed by CDC, enables a national network of public health laboratories to "fingerprint" bacteria that may be foodborne and compare results through an electronic database maintained by CDC. Now a collaborative effort among CDC, FDA, USDA, and all 50 States, PulseNet permits early and accurate detection of food-borne illness outbreaks

that in the past have often gone undetected or were not recognized until they became very large. PulseNet has been key in rapidly detecting and containing numerous outbreaks of foodborne illness, including multi-state outbreaks. For example, PulseNet aided in the identification of a multi-state outbreak of *Salmonella* Agona infections linked to toasted oats cereal. Since the illnesses were dispersed among 20 States, the comparative matching of the disease-causing organisms made possible via PulseNet facilitated the epidemiological investigation that led to the recall of two million pounds of contaminated product. Without PulseNet, it is unlikely that these cases would have been identified as coming from the same source. Similar systems are now under development for viruses and parasitic agents that produce foodborne illness.

eLEXNET. The electronic Laboratory Exchange Network (eLEXNET), a seamless, integrated, secure network, was developed by FDA to provide access to critical food testing data in Federal, State, and local food safety laboratories. eLEXNET has not only facilitated data information sharing and communication, but has also provided a means for collaboration among food safety experts. It has the potential to connect the nationwide food testing laboratories and provide an early warning notification system to identify potentially hazardous foods and more quickly contain their distribution and consumption.

To date, the eLEXNET system has been piloted with two Federal laboratories, four State laboratories, and two local laboratories. We are soliciting additional State and local participants.

The initial pilot covered *Escherichia. coli* O157:H7 but we are currently expanding it to cover three other pathogens - *Salmonella*, *Listeria*, and *Campylobacter.*

Antibiotic Resistance. The National Antibiotic Resistance Monitoring System (NARMS) was established in 1995 as an interagency cooperative activity between CDC, FDA, and USDA to monitor emerging resistance to antibiotics in foodborne pathogens, beginning with *Salmonella*. Since its inception, new sources of isolates, an increased number of isolates, and additional disease-causing agents have been added to the system. NARMS facilitated the recognition that *Salmonella* Typhimurium DT 104, a strain highly resistant to antibiotics, was widespread in the U.S. This prompted CDC to warn State health departments of its presence and provide preventive steps to minimize its spread.

Prevention Standards

The most significant reduction in foodborne illness will be achieved through the development and implementation of successful prevention programs.

Hazard Analysis and Critical Control Point (HACCP). HACCP systems represent a systematic approach to the identification and control of the biological, chemical, and physical hazards that are reasonably likely to occur in a particular food in a particular production process. There are a vast array of microbiological, physical, and chemical hazards that have the potential

to affect the safety of foods. HACCP is a risk-based, food safety management system that helps food manufacturers determine which hazards are reasonably likely to affect their products and then to develop safety assurance programs targeted to the specific steps that must be controlled to safeguard consumers. Because these systems are designed to identify and control microbial, chemical, and physical hazards that are reasonably likely to occur, they significantly reduce the risk that the final product will contain hazards that could cause human illness or injury.

FDA implemented seafood HACCP in December 1997. It requires all 4,100 seafood processors, covering 150 species of fish, to implement complete HACCP systems. Now in its fourth year, we are seeing across-the-board progress by the seafood industry and we have implemented a "mid-course correction" to focus that program where the public health issues are most significant. This year, FDA also finalized HACCP regulations for fruit and vegetable juices which will take effect next year. It is estimated that this will prevent at least 6,000 illnesses per year. FDA also has incorporated HACCP into its Food Code, a guidance document that serves as model legislation for state and territorial agencies that license and inspect food service establishments, retail food stores, and food vending operations in the U.S.

Good Agricultural Practices (GAPs). In 1998, FDA published a guide for growers and packers of fresh fruits and vegetables. The "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" provides science-based guidance to help reduce microbiological hazards common to the growing, harvesting, washing, sorting, packing, and transporting of fruits

and vegetables. The guide addresses key areas where precautions should be taken to ensure safety: water quality, worker hygiene, field and facility sanitation, manure management, and transportation. This guide was produced in consultation with USDA and has been published in four languages. Since its publication, the agencies have been working together to educate the agricultural industry – both domestically and internationally – on the recommendations included in the guidance.

Sprouts. In 1999, in response to several foodborne illness outbreaks associated with sprouts, FDA issued a warning to consumers of the potential hazards associated with eating raw sprouts and issued guidance documents for the sprouts industry. These documents, "Reducing Microbial Food Safety Hazards for Sprouted Seeds" and "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" advise sprout growers and seed suppliers of the steps they should take to reduce microbial contamination.

In addition to issuing the guidance documents, last year FDA and the California Department of Health Services produced and distributed an educational video on good agricultural and manufacturing practices for sprout producers. To assess the extent to which the sprout industry is following the recommended practices, the Agency issued a special assignment last year to inspect 150 sprout producers. FDA is also working with academia and the sprout industry on research to identify techniques to prevent contamination.

Bovine Spongiform Encephalopathy (BSE). HHS, USDA, and other partners are working together to prevent BSE from entering the U.S. BSE is a fatal disease that causes progressive, neurological degeneration in cattle. It is one of a family of diseases called transmissible spongiform encephalopathies (TSEs). One TSE disease that affects humans is Creutzfeldt-Jakob Disease (CJD). A form of this disease, variant CJD (vCJD), appears to be related to the BSE disease of cattle. There is strong scientific evidence that the same agent that causes BSE in cattle is also the agent that causes vCJD in people. So far, there have been cases of vCJD reported in the United Kingdom and elsewhere in Europe, believed to occur in people who consumed beef products contaminated with the infective BSE agent. It is important to note that there are no reported cases in the United States of BSE in U.S. cattle or vCJD in Americans.

In January, HHS established an Interdepartmental Steering Committee for BSE/TSE Affairs. I chair this committee which includes representatives of FDA, CDC, the National Institutes of Health (NIH), USDA, the U.S. Trade Representative, the Office of Management and Budget, the U.S. Customs Service (Customs), the Department of State, the Department of Defense, the State Association of Feed Control Officials, the National Association of State Departments of Agriculture, and the White House Office of Science and Technology Policy. This committee assures ongoing coordination between agencies, integrated contingency planning in case BSE or vCJD is found in the U.S., and coordination of risk communication plans by the various agencies.

In addition, HHS is working closely with USDA in developing a report that USDA will submit to Congress regarding actions taken by Federal agencies to prevent foot and mouth disease, BSE, and related diseases. This report will discuss the economic impact, animal and human health risks, risk management, and steps to strengthen safeguards against these diseases.

Education

An essential element of ensuring the safety of the food supply is the education and training of industry, Federal, State, and local agriculture and health officials, and consumers in prevention programs across the farm-to-table spectrum. I have noted a couple of the educational materials developed for industry - good agricultural practices for fresh produce and guidance for the sprout industry to prevent contamination.

Enhancing school-based prevention efforts to educate the next generation about food safety is another important element. This month, in partnership with the National Science Foundation, the Agency is launching "Science and Our Food Supply," a curriculum for middle and high school students that will instruct our youth in the scientific principles of food safety and prevention. Also, in collaboration with FDA and several states, CDC is leading development of a model coordinated school health and food safety program.

An example of consumer education is the "Fight Bac" program to prevent illness by raising awareness of potential hazards in storing, cooking, and serving foods. This program is part of the Partnership for Food Safety Education, a public-private partnership that includes HHS, USDA, the States, consumer groups, and industry. Consumer education efforts seem to be paying off. Surveys of consumer behavior indicate that more people are washing their hands and their cutting boards to prevent cross-contamination between raw and other foods. Fewer people are eating risky raw foods.

The foodsafety.gov web site, established in early 1999 by FDA in close cooperation with CDC and USDA, is visited an estimated 40,000 times each month. The site has information for consumers, industry, health professionals, food safety educators, and others. To raise awareness and educate heath professionals, HHS and USDA also collaborated with the American Medical Association to develop a physician education program on the diagnosis and management of foodborne illness.

Research and Risk Assessment

Research and risk assessment are critical to ensuring the strong scientific basis necessary for our regulatory programs to be effective. The Department must be able to keep pace by learning more about foodborne diseases and their causes and by developing new scientific methods for detecting and preventing foodborne hazards. A strong science base is a prerequisite to meeting

the food safety challenges and to maintaining our leadership role both nationally and in the new global economy.

In 1999, HHS and USDA created the Joint Institute for Food Safety Research (JIFSR). JIFSR coordinates planning and priority-setting for food safety research across government agencies and with the private sector. This coordination optimizes food safety research investments, channels Federal resources to research priorities, and helps avoid research redundancies. JIFSR also seeks to foster the effective translation of research results into practice along the farm-to-table continuum.

HHS has been a leader in food safety research and maintains technical expertise in a wide range of disciplines that affect the safe and wholesome production, packaging, and formulation of foods, dietary supplements, and cosmetics. FDA leads international standard setting efforts in food hygiene, food labeling, bioengineering of foods, and chemical contaminants. While FDA maintains a strong research and risk assessment program, the diversity and types of scientific expertise and knowledge are ever-expanding. Consequently, FDA recognizes it must leverage both academia and industry expertise as well and has done this through three cooperative agreements or consortia. The National Center for Food Safety and Technology (NCFST) at the Illinois Institute of Technology is devoted to research and evaluation of better food processing and packaging technology. The Joint Institute for Food Safety and Nutrition at the University of Maryland is devoted to risk assessment, agricultural practices and education, such as

international Good Agricultural Practices training programs, and establishment of the Center for Risk Analysis and clearinghouse for risk assessment. The University of Mississippi has a collaborative program to work in the area of the safety of dietary supplements. FDA will work to strengthen these existing collaborations and will develop additional partnerships with other universities that have strong food safety research programs.

FDA has also strengthened its scientific foundation through extramural research grants to support research in the areas of BSE, produce safety, egg safety, HACCP system validation, food service or retail practices, and consumer practices. Examples of such projects include the development of simple, reliable methods for extraction and detection of viruses from a variety of food products, research to improve produce safety by developing and applying novel non-thermal food processing technologies, and the development of improved sampling and detection methods of low levels of *Salmonella* Enteritidis in eggs.

CDC conducts a limited amount of applied research, particularly to understand and optimize public health practice for the prevention and control of diseases. Examples include efforts to develop assays for detecting and subtyping foodborne pathogens for which adequate testing methods do not currently exist; identify the causative agents for foodborne outbreaks of unknown etiology, as well as pathogens responsible for sporadic cases of foodborne illness; evaluate new strategies for reducing illness; and identify behavioral and other risk factors associated with

foodborne disease. In addition, NIH also conducts scientific research on the health effects and genomics of foodborne pathogens.

Improved Protection for Imported Foods

The increasingly global nature of the portion of the food supply that FDA regulates presents significant challenges. To help keep unsafe foods out of U.S. markets, FDA works closely with Customs. FDA and Customs have established a procedure to prevent the distribution of unsafe imported food by requiring that shipments from "bad actor" importers be held in a secure storage facility at the importers' expense until released by FDA. FDA has also established procedures to enhance interagency coordination and to efficiently use Customs' civil monetary penalties procedures against importers who attempt to enter food into the U.S. by means of a material false statement, act, or omission. In January, FDA published a proposed rule to require marking food shipments refused entry for safety reasons to deter the practice of "port shopping" in which importers whose cargo is denied entry at one port attempt to re-introduce it at another port.

FDA has also led a series of food safety workshops literally around the world in Central America, South America, the Southern Pacific region, Asia, and Africa. These workshops educate foreign governments and food producers on the food safety standards needed to meet U.S. requirements. In addition, CDC has increased its efforts to build investigative capacity throughout the world

and to expand systems such as PulseNet globally in order to rapidly identify international outbreaks. CDC is working in these areas in collaboration with the World Health Organization.

Next Steps

As stated earlier, HHS is committed to building a strong and credible food safety system. We must enhance our ability to identify risks, take action, and measure results. Specifically:

- To enhance our ability to identify risks, we must strengthen our science base. We need to expand the FoodNet, PulseNet, and eLEXNET programs, described earlier, and assess adequate detection and response capacity in every State. Existing collaborations with our academic and private sector partners need to be strengthened and new partnerships need to be forged.

- We need to take action to make improvements in inspections of domestic and imported foods. The Agency has redirected its field force to perform annual inspections of firms that produce foods at highest risk for microbiological contamination. FDA is working to enhance the infrastructure and capabilities of the field laboratory to increase the number of sample analyses of both domestic and imported foods. To help ensure that imported foods meet the same level of consumer protection as domestic foods, HHS is seeking to increase its overseas presence and is providing technical assistance to foreign countries.

- We will continue to measure results to ensure that the food safety activities are effective.

Thank you for the opportunity to discuss our food safety program and our continued efforts in this area. We look forward to working with the Subcommittee on ways to continue to improve the safety of the nation's food supply. I would be happy to answer any questions.

Statement of
The Honorable Dan Glickman[1]

Before
A hearing of the
Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia
Committee on Governmental Affairs
On
Federal Food Safety Oversight:
Does the Fragmented Structure Really Make Sense?

10:00 AM, Wednesday, October 10, 2001
342 Dirksen Senate Office Building
Washington, D. C.

Chairman Durbin: We all claim, rightfully so, that the US food supply is the safest in the world -- because the US federal food safety system is the best in the world. But if the current system did not exist and we started from scratch to put together a food safety system, I doubt few of us would design one to look like the structure that has evolved over the last century.

The US need's fundamental organizational change in the way the federal government handles food safety. After having worked long on food safety problems while in the House of Representatives then at the helm of the Department of Agriculture (USDA) for six years, during which federal food regulation underwent its most profound changes in a century and faced some of its most severe tests, I have concluded that the basic structure is flawed and needs rebuilding. I commend you, Senator Durbin, for doggedly pursuing this problem, and appreciate the opportunity you have given me to share with you today my views.

As important as I believe it is to reform the federal food safety regulatory structure, I believe it is as important to modernize some of the underlying federal food safety statutes -- perhaps more important. Therefore, before I turn to the central question before the subcommittee, I want urge the Congress to consider other legislative matters I believe will enhance our already exemplary food safety system. As Congress and the nation turns attention to lessons learned from the September 11 terrorism attacks, especially on steps we need to take to protect ourselves in this new world, I think the subject you are examining is relevant. I want to offer my thoughts on that issue, too.

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[1] Dan Glickman was secretary of agriculture from 1995 through 2000; he is now a partner in the public law and policy practice in the Washington, D. C. office of the law firm Akin, Gump, Strauss, Hauer, and Feld L.L.P. The views presented here are his own and do not represent or suggest those of the firm or its clients.

Modernizing Food Safety Statutes

In the course of the several reforms the Clinton Administration made to food safety regulation, in 1998 the President formed the President's Council on Food Safety, a cross-agency, multi-disciplinary task force that Secretary Shalala, Assistant to the President for Science and Technology Lane, and I chaired. *The Food Safety Strategic Plan* the Council issued last January examines in detail the matter before the subcommittee and makes several recommendations, including a staged approach for consolidating federal regulatory functions; I commend it to the subcommittee as it continues its work in this area. That plan also recommends improvements to the nation's basic food safety laws I believe are necessary and will outline.

Fundamentally, Congress should clarify that current statutory authorities extend to preventive food safety control measures. For example, USDA's new hazard analysis and critical control point (HACCP) meat and poultry safety regime relies on sampling and testing protocols, many of which made possible by current technological developments and many more not employed under the old inspection system. As we grow more sophisticated in combating food borne pathogens, I expect these trends in technology and testing will continue. Although most industry participants have been very cooperative in HAACP compliance, I suspect some in the industry may initially be reluctant to comply with new testing requirements and may seek to challenge them.

In fact, this very thing happened in a celebrated case during my tenure at USDA involving a meat processing facility's failure to meet standards integral to the HACCP system. After the plant's repeated failures, USDA withdrew its inspectors from the plant, closing it, and then found itself in federal court defending the very testing requirements that identified the adulterated product. Technology will advance, new tests will become integral to future efforts, and federal food safety agencies, primarily USDA and the Food and Drug Administration (FDA) need the legal certainty to put into place the most effective tests possible.

Existing law needs a related reform: FDA and USDA should have the authority to act against food when epidemiological evidence links it to disease, not just in those instances when the food is infected with pathogens. This is particularly important for protecting consumers against food safety threats that current testing methodologies cannot detect.

There are a series of reforms needed to enable food safety regulators to respond to the outbreak of food safety problems. For example, USDA's ability to respond to food safety problems is, in many ways, severely limited. It possesses one real tool, the ability to withdraw its inspectors from a meat or poultry plant, thus effectively closing that plant. USDA needs a range of enforcement authorities, including the ability to levy civil fines for safety violations; FDA needs similar authority.

USDA needs authority to recall food from the market, urgently. Federal regulators can order a wide variety of defective products off the market, but not pathogen-laden meat and poultry. One of the reasons contemporary food safety problems are so virulent is that they can spread so quickly. It is an outgrowth of the modernity and advancements in our manufacturing

and distribution systems – a contaminated lot of ground beef made in the midwest can be in supermarkets and restaurants coast-to-coast in hours. We no longer have the luxury of time; our regulators should be able to get that product off the market immediately instead of being forced to engage in a time-consuming, back and forth with the manufacturer in the hope of ultimately persuading the company to act voluntarily. Similarly, FDA needs authority to stop sales.

FDA needs an adequate food manufacturing database. USDA currently knows where meat and poultry is processed because of federal record keeping requirements, but FDA does not have complimentary information. None of these policies nor preventive programs will succeed fully unless they rest on full and adequate information. Thus, FDA needs access to companies' inspection and distribution information and food manufacturers should be required to register with FDA and keep records necessary for tracking food safety problems.

We currently require that imported meat and poultry products be produced under food safety system equivalent to the US system. That same standard should be applied to other foods.

This is not an exhaustive list of changes the underlying statutes require, but those, in my view, that rise to the highest priority. These are matters that will, I presume, require and receive further scrutiny before Congress acts, but there is one other action Congress can, and should, take immediately: All of the food safety agencies and activities need adequate funding.

FDA's inspection program is woefully underfunded, enabling it to perform only the barest of spot checks. Not only do we need a better system of ensuring the safety of foodstuffs manufactured outside the US and bound for our market, we need to be sure FDA has enough resources - dollars and individuals - to inspect the growing amount of imported food we eat.

By the same measure, USDA needs to be confident it will have sufficient resources to staff fully its inspectors, both those inspecting meat and poultry as well as those who protect our food supply at our ports of entry, and, critically, train them and install and maintain the infrastructure necessary to respond to contemporary food safety threats.

Finally in this regard, we cannot neglect the need to invest in the future of food safety, and that means making sure federal researchers have adequate resources to investigate emerging pathogens and preventive measures.

Building a Modern Regulatory Structure

One of the lessons we learned during the Clinton Administration was, short of outright organizational changes, the need for much greater coordination across food safety-related agencies. That led to creation of a number of interagency entities. In addition to the President's Council on Food Safety I mentioned previously, we created the Joint Institute for Food Safety Research, the Risk Assessment Consortium, and in cooperation with federal and non-federal public health officials created the Foodborne Outbreak Response Coordinating Group-FORCE-G-and the Joint Institute for Food Safety and Applied Nutrition.

While all of these efforts vastly improved the overall federal response to this problem, they suffer fundamental flaws that a consolidated federal regulatory would remedy. First and foremost is central control of resources. While joint planning, communication, and coordination facilitate united responses to food safety, at the end of the day unless control over spending is vested in a central authority, there will remain bureaucratic and institutional obstacles to ending duplication and achieving the efficacy and efficiency of a centralized structure.

A unified, centralized structure brings with it another asset-a central decision making entity. Some argue, with validity, that the current system has its advantages, the primary one being the diversity of views brought to bear on this problem. We certainly do not want to lose that value; neither, can we permit ourselves to be crippled by differences of opinion – and we have seen that in the past.

The recent Starlink corn episode highlights that flaw, as well as perhaps others. Most strikingly, many questioned the initial wisdom of a split registration for the product, and the ability of the system to keep the corn in separate, segregated marketing channels – one for animals and one for human consumption. Regrettably, those deficiencies were realized.

That episode was exacerbated by two other inherent vulnerabilities in the current system. First, it exposes us to the danger of the delays arising from attempting to reach consensus among differing food safety agencies. In addition, we should not tolerate a system that permits an aggrieved party to forum shop between federal agencies in search of an ally that might slow the interagency consensual decision making process.

I have long held, and continue to believe, that the first federal priority is ensuring the adequacy of its food safety system, no matter where its functions reside nor how confusing its organizational chart may appear. We cannot let a heated debate over reforming the structure-and it will be a heated debate-interfere with our primary goal. That is why I have taken this opportunity to delve into those matters in such depth.

In addition, I have urged a go-slow approach to organizational revision during the period of enormous food safety change that we went through in the last eight years. I did not want either to divert attention from the reform process nor permit disagreements over structure to stop it. That process is now largely complete, and it is time to examine the structure we have – and it needs change.

I am not sure I will offer today the paradigm of the new system, other than to urge the subcommittee to take a comprehensive view of the need for change, including bringing together all related federal food safety efforts. That includes not just the obvious and visible functions in the USDA and FDA, but also those at the Commerce Department responsible for seafood and at the Environmental Protection Agency with jurisdiction over chemicals.

In addition, we should embrace the public health components with the Department of Health and Human Services and the several ancillary plant and animal health functions in USDA and finally, all of the federal food safety research entities. Finally, I have said nothing about the relationship of the federal food safety system and the state and local governments, but I know we need greater coordination and I urge the subcommittee to examine this facet of the problem, too.

In the end, I am confident a successful rationalization of the federal food safety regulatory structure will require bold strokes; a piecemeal approach will leave us essentially where we are with a fragmented, duplicative system.

That leaves one final part of the federal government that needs to embrace this attempt: The Congress. It must not permit its organizational biases and instinctive opposition to ceding authority impede this debate.

Protecting the Nation's Food Supply from Terrorism and Related Threats

As I said at the outset, I welcome the attention Congress, the Administration, and the country have turned to protecting our food supply from terrorist attack. As we look at the threat from chemical or biological attack, or other terrorist threats, too frequently agriculture and food receive scant attention. We got a wake up call last month, not only from the savage viciousness of the attack, but also from the new kinds of threats we face – the grounding of the nation's fleet of crop-dusters drove that point home.

When I was at USDA, we launched at multi-agency review of agriculture's exposure to non-conventional threat. Without revealing the specific threats, nor the steps we are taking to protect ourselves, let me simply say that the problem is immense, as are the consequences, and the effort we need to protect from it.

Consider, for instance, the Starlink episode to which I just referred. That is a telling lesson of how quickly and pervasively an undesired product can contaminate our food supply. Or, consider a few years ago when Karnal bunt first infested this country. To eradicate this wheat fungus, we prevented the farmers from whose land the infected wheat originated from planting wheat for three years. The point these episodes illustrate is that even comparatively benign contaminants to our food supply can spread dramatically, especially given the size and concentration in much of our food distribution and processing, and they require profound and long-lasting steps to recover. Biological or chemical attack would increase these costs exponentially. And, I should add that while agents like anthrax or botulism affecting the food and water in this country get much of the media attention, American agriculture could also be gravely threatened by outbreaks of more traditional problems such as FMD and BSE.

This is truly a problem whose solution partially lies with reformed structures and organizational changes. The new office of homeland protection, no matter what shape it ultimately takes, must give protecting the food system high priority. A rationalized food safety system will contribute to enabling us to respond to terrorist threat and attack in addition to its more traditional food safety roles. In addition, to the extent Congress keeps those authorities

sufficiently funded, we will ensure we have the resources on the ground not only to detect threats, but to help in the national response.

Conclusion

In closing, let me repeat the three points I want to leave with you: One, we need to reorganize and consolidate our federal food safety regulators. Two, we need, just as urgently, to make improvements to our underlying food safety statutes. Third, an integrated food safety regulatory structure is critical to meeting the new challenges of terrorism we face. All of this is needed to ensure continued public confidence in the safety of our food system, which is the linchpin of both our public health, as well as the economic health of American agriculture.

Thank you.

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Testimony of Michael F. Jacobson, Ph.D.
Executive Director

Before the Senate Committee on Government Affairs
Subcommittee on Oversight of Government Management
Hearing on "Federal Food Safety Oversight:
Does the Fragmented Structure Really Make Sense?"

Washington, D.C.
October 10, 2001

My name is Michael Jacobson, and I am the executive director of the Center for Science in the Public Interest (CSPI). CSPI is an advocacy and education organization focused on food-safety and nutrition issues. We are supported principally by the 800,000 subscribers to our *Nutrition Action Healthletter*.

Food-safety experts estimate that contaminated food causes up to 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year.[1] While those estimates illuminate the magnitude of the problem, for many consumers, the aggregate numbers mean less than the notorious food-poisoning outbreaks, named after such companies as Jack in the Box, Sizzler, Odwalla, or Sara Lee. Those well-publicized episodes have awakened consumers–some of

[1] Paul S. Mead et al., *Food-Related Illness and Death in the United States*, 5 Emerging Infectious Diseases (1999), available at <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>.

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whom have experienced miserable cases of food-poisoning themselves–to the fact that unintentionally contaminated food is a risk that must be reduced.

The Threat of Bioterrorism

The terrorist attack on the U.S. has spurred widespread concern about the vulnerability of our food supply to intentional contamination–and the ability of our nation's food-safety system to minimize the risks. Just last week, members of the Senate Appropriations Committee (including Senator Durbin) discussed food-safety issues prominently in a hearing on bioterrorism.

Those concerns are not unfounded. Last year, the Centers for Disease Control and Prevention's (CDC) Strategic Planning Workgroup on Biological and Chemical Terrorism warned that terrorists might try to contaminate our food supply.[2] While it may not be possible to predict when or how such an attack might occur, the workgroup concluded, the consequences of being unprepared could be devastating.[3] Among the potential biological agents that the CDC cited were the foodborne pathogens *Clostridium botulinum*, *Salmonella* spp., *E. coli* O157:H7, and *Vibrio cholerae*.[4]

Biological agents may be particularly attractive to terrorists, the National Academy of Sciences (NAS) has explained, because those agents "may be produced in ways that are relatively fast, inexpensive, and easily concealed and that do not require vast knowledge or technical

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[2] Centers for Disease Control and Prevention, *Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response; Recommendations of the CDC Strategic Planning Workgroup*, 49 Morbidity and Mortality Weekly Report No. RR-4 (2000) [hereinafter *CDC Biological and Chemical Terrorism*].

[3] *CDC Biological and Chemical Terrorism*, at 1.

[4] *CDC Biological and Chemical Terrorism*, at 5-6, Box 3.

skill."[5] Biological agents also are easy to transport and distribute.[6] We saw how easily biological agents could be used for terrorism when, in 1984, members of a religious commune in Oregon contaminated ten restaurant salad bars with *Salmonella typhimuirum,* sickening 751 people.[7] It took a year-long investigation to link the commune to the outbreak,[8] but far faster action is required now that threats of widespread terrorism are involved.

Prevention Strategies, Not Just Response Plans, Are Needed

Recent discussions of chemical and biological terrorism have alerted the public to the possibility that we may be confronted with intentional contamination of food, water, or air. While every effort must be made to prevent those acts in the first place,[9] it is clear that better food inspection offers a critical avenue to protect our food supply from both intentional and unintentional contamination.

Bioterrorism is just the latest example of the problem with relying on old laws to regulate new hazards. Senator Durbin's Safe Food Act of 2001 offers a much-needed strategy during this time of crisis to correct some of the deficiencies in our federal food-safety system that have left

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[5] John C. Bailar III, *Ensuring Safe Food: An Organizational Perspective*, *in* Firepower in the Lab: Automation in the Fight Against Infectious Diseases and Bioterrorism, 133, 139 (Scott P. Layne et al. eds., National Academy of Sciences, 2000) [hereinafter *Firepower*] (Microbiological agents, in particular, can reproduce themselves and can be made in ton-sized lots.).

[6] *Firepower*, at 139.

[7] Thomas J. Torok et al., *A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars*, 278 JAMA 389, 393 (1997) [hereinafter *JAMA*].

[8] *JAMA,* at 393. Also, in 1996, a dozen laboratory workers in Texas became infected with *Shigella dysenteriae* after eating pastries that investigators concluded were intentionally contaminated. Shellie A. Kolavic et al., *An Outbreak of* Shigella dysenteriae *Type 2 Among Laboratory Workers Due to Intentional Food Contamination*, 278 JAMA 396 (1997).

[9] Although the USDA's Animal and Plant Health Inspection Service (APHIS) has vowed to step up its Foreign Animal Disease surveillance, a new Inspector General report has shown that APHIS's tools for tracking foreign meat and poultry coming into this country are woefully inadequate. Office of Inspector General, U.S. Department of Agriculture, Report No. 50601-003-CH, Assessment of APHIS and FSIS Inspection Activities to Prevent the Entry of Foot and Mouth Disease Into the United States (July 2001) [hereinafter *OIG APHIS Report*].

consumers–and the food industry itself–vulnerable. Today, for example, the Food and Drug Administration (FDA) must ensure the safety of nearly four million food shipments entering the U.S. from more than 100 different countries.[10] But the FDA has only 150 people available to conduct those inspections. Not surprisingly, less than one percent of those four million shipments are inspected.[11]

Moreover, the responsibility for food safety is split among 12 different federal agencies–from the Department of Agriculture to the Bureau of Alcohol, Tobacco and Firearms. That fragmentation requires many major food issues to be addressed by at least three different government agencies. Balkanization and inflexible restrictions on applying resources results in many gaps and inconsistencies in government oversight, as we have seen in the case of mad cow disease, or BSE.

The Animal and Plant Health Inspection Service (APHIS) has for years banned imports of cattle and beef products from countries with documented cases of bovine spongiform encephalopathy (BSE). Unfortunately, APHIS's bans may look better on paper than they are in practice. A recent Inspector General report found that APHIS couldn't adequately track shipments of banned products to ensure that they were disposed or re-exported.[12]

And while APHIS is responsible for cattle health, it doesn't have authority over cattle feed, which is how BSE can spread. Jurisdiction over animal feed rests with the FDA, which is too strapped for resources to adequately enforce its BSE prevention measures, while also ensuring that fish, eggs, and other FDA-regulated foods are safe.

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[10] General Accounting Office, Food Safety: Overview of Federal and State Expenditures 4 (2001) [hereinafter *GAO Food Safety Expenditures*].

[11] *GAO Food Safety Expenditures*, at 4.

[12] *OIG APHIS Report.*

Meanwhile, the safety of the beef that consumers eat is governed by yet another agency, the Food Safety and Inspection Service (FSIS). To date the FSIS has treated BSE-related issues as "quality" rather than "safety" issues, and the enforcement of human-food-safety controls has been minimal. As new concerns have arisen about the use of animal diseases as terrorist weapons, and now that BSE has spread from Europe to Japan, it is clear that we need better accountability and control within our food-safety system.

Other gaps in food-safety protection remain. The FDA, which shares with the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA) the regulation of GE plants that are used for human food, does not approve them or even require a safety review before they are sold to consumers. Nor does FDA give the public an opportunity to comment on GE foods before they are introduced into the food supply.[13] The FDA says that, to date, all biotech companies have voluntarily consulted with the agency before marketing their foods. However, that "behind-closed-doors" system does little to instill public confidence in the safety of this powerful and potentially valuable new technology.

This year, the FDA proposed to mandate that companies notify the agency of their intent to market GE foods and to submit specific information for agency review. That's a step in the right direction, but CSPI has urged FDA to both review and actually approve the safety of every genetically engineered crop before it is marketed. We have been pleased to work with Senator Durbin's staff in developing legislation to improve the FDA's system for regulating GE foods.

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[13] By contrast, before a new GE food crop may be commercialized, it must be approved by APHIS to protect from pests and diseases. And if the bioengineered plant contains a plant pesticide, it must pass a safety review by the EPA as well. Both APHIS and EPA seek public input before approvals are granted.

Strengthening the Federal Food-Safety System

A stronger, federal food-safety system is an essential component of a defense against terrorist attacks on the food supply and also would help to prevent foodborne illnesses due to unintentional product contamination.

Consumers have become sensitized to the issue of microbiological contamination of food, in part, because of much better reporting of food-poisoning outbreaks. Several years ago, CSPI began tracking food-poisoning outbreaks, so we could better identify which foods were actually making people sick. CSPI's database of foodborne-illness outbreaks documents more than 1,600 outbreaks over the last decade. Even so, our database includes only a small fraction of the outbreaks that actually have occurred, because outbreaks so often go unreported.

Foods regulated by the FDA, such as vegetables, eggs, and seafood, account for almost 80 percent of the outbreaks in our database. The FDA has about 770 food inspectors for its 57,000 plants, so, on average, a single FDA inspector has responsibility for 74 food plants. By contrast, USDA has approximately 7,600 inspection personnel for about 6,500 meat, poultry, and processed-egg plants. That imbalance between risk and resources led CSPI and other consumer organizations to call on Congress and the President to develop a single, coherent food-safety statute that is implemented by a single, independent food-safety agency. Such an agency could allocate its resources according to risk. In contrast, USDA's meat and poultry inspectors cannot be assigned to inspect plants that produce fish, shell eggs, or other FDA-regulated foods, even in the face of documented health problems or new health risks.

Whether the problem is intentional food contamination by bioterrorists or unintentional contamination by a dirty food plant, our food-safety system is flawed. The challenges are so

great, in fact, that they led Professor John Bailar, the chair of the committee that wrote the NAS' report *Ensuring Safe Food from Production to Consumption*, to conclude recently:

> A council of agency chiefs would not be able to deal rapidly and effectively with the full range of possible microbiological, chemical, and physical hazards, as well as with the integrity of the food supply itself. . . . Our country needs a single independent food safety agency. . . . When bioterrorism is added to the mix, the case for prompt and sweeping change becomes compelling.[14]

That is why CSPI strongly supports the Safe Food Act of 2001. That bill provides a blueprint of how our food-safety system should be designed. We would support a parallel–and equally essential–effort to develop a unified food-safety statute.

The costs of combining the existing agencies need not be more than the cost of the existing system. The FDA told the House Agricultural Appropriations Committee it would need $670 million dollars to inspect the 57,000 domestic food plants under its jurisdiction once per year and to inspect just 10 percent of food imports. If FDA inspected domestic food plants twice per year and 20 percent of imports, it would need $1.3 billion. While that is a significant cost, it would still fund only very modest inspection goals, especially compared to the government's daily inspection of meat and poultry processors.

Consumers want all high-risk food–not just meant and poultry–inspected much more than every year or two. And if we are to erect firewalls against food bioterrorism, it is clear that Congress needs to dramatically increase funding for FDA's food program. Failing to spend the money could lead to terrible tragedies. In the long run, combining agency functions will likely not only provide more protection, but also will be more economical.

Weaknesses in our government programs could set the stage for a crisis in consumer confidence, a crisis that we would like to see prevented. This is why we support the creation of

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[14] *Firepower*, at 141.

an independent food-safety agency with responsibility from farm-to-table. Such an agency must be strongly oriented to protecting public health as a means of protecting public confidence. So far, other nations, including the United Kingdom and New Zealand, are ahead of the U.S. in unifying their food-safety activities. It is time that the U.S. joined those leaders.

Thank you for your continuing leadership to improve food safety and for giving me the opportunity to share CSPI's views on food-safety priorities.

Testimony of
John R. Cady
President and CEO
National Food Processors Association
Before the
Senate Government Affairs Subcommittee
Oversight of Government Management, Restructuring
And the District of Columbia
Washington, D.C.
Wednesday, October 10, 2001

Mr. Chairman: My name is John Cady, and I serve as President and CEO of the National Food Processors Association. NFPA is the largest food-only trade association in the United States, representing the $500 billion U.S. food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, consumer outreach and international affairs. NFPA's members produce and package the branded and private-label food and beverage products found in retail and wholesale stores using a variety of processing and packaging technologies. With three laboratory centers in the United States – including one just three blocks from the White House – our mission is to provide the best scientific and technical services to the nation's food processors, and translate our unique food safety and food science expertise into sound public policy.

I am pleased to have this opportunity to testify before this Committee on the important topic of the current structure and effectiveness of the federal food safety regulatory system, and how it protects consumers from food hazards and threats to our food security.

I would like to begin by thanking you, Mr. Chairman, for your leadership on the issue of food safety. We are pleased that you are holding this hearing, which has great potential to assure consumers that America does, in fact, enjoy one of the safest food supplies anywhere, and that policy makers such as President Bush, Secretaries Veneman and Thompson, Senator Voinovich and yourself are committed to making it even better. While we may not always agree, we do appreciate your support for a strong U.S. food safety system, a goal strongly shared by the food industry as well.

In the short time that I have to speak today, I would like to make three points:

First: **Our current food safety system not only works, but works well.** There continues to be strong evidence that America's food safety regulatory system ensures that the food products that consumers purchase in their neighborhood grocery stores, or that are delivered to their local restaurants, are safe. The Centers for Disease Control and Prevention (CDC) reports a decreasing trend across the United States in illness due to nine common food pathogens.

Second: **It is important than any actions we take regarding food regulation neither lessen public confidence in food safety nor compromise the effectiveness of our existing programs.** This is especially true in light of the tragic events of September 11th. With newfound interest in potential terrorist threats, Americans deserve to know that the food industry and federal agencies have long fought to ensure that our products present minimal risk from contamination, whether the result of naturally present bacteria or tampering. We are redoubling our commitment and increasing our vigilance to ensure that systems are in place to minimize and, if possible, eliminate threats to our food security.

Third: We strongly believe that the best way to improve our nation's already admirable record on food safety is to **continue progress towards a unified science- and risk-based food safety policy**, including increased communications and improved coordination, rather than focusing on the creation of a new bureaucracy in the form of a single food agency.

Let me start by addressing our current food safety system. It continues to be a model of success that is envied and emulated around the world.

As I mentioned earlier, recent statistics from the CDC point to a decline in foodborne illness from a number of pathogens. Additional data indicate that there have been significant improvements in recent years, too, in food safety-related consumer behaviors – fewer people eating risky raw foods and more people washing hands and cutting boards to prevent dangerous cross-contamination between foods, for example. Evidence of declines in foodborne illness can be seen when targeted resources and coordination are added to food safety programs. Our ability to identify where the true risks lie and to assess changing trends in foodborne illness can be attributed in large part to food safety surveillance tools such as "PulseNet," "FoodNet" and the "National Antimicrobial Resistance Monitoring Network." NFPA is a strong supporter of adequate resources for these programs.

The recent implementation of Hazard Analysis and Critical Control Points (HACCP) in the seafood, meat and poultry industries has refocused both industry and regulators on identifying the controls truly critical to ensure a safe food product. Although we are still working out implementation issues, NFPA continues to believe that HACCP is the best approach to managing food safety issues. The Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are increasingly turning to risk assessments to identify where resources should be focused to have the greatest impact on reducing foodborne illness. Risk assessments on pathogens in eggs, beef, shellfish and ready-to-eat foods have shown us that this can be an effective basis for developing science-based risk management decisions. Thus NFPA also continues to support risk assessment as a critical food safety tool.

These evolving approaches to foodborne disease surveillance, food safety management and identification of risks have been developed through coordination among various agencies. Our system has evolved successfully over the past 94 years to meet new challenges and growing responsibilities. It is no accident that our nation's food safety regulatory system has evolved from a single food safety agency in 1907 – the Bureau of Chemistry within the Department of Agriculture – into the system we have today. The National Canners Association, NFPA's predecessor organization, was formed that same year as the industry's scientific and technical arm for food safety and has also evolved into the NFPA to address the changing food safety challenges.

As a result of our nation's outstanding food safety record, consumers generally have a high – and justified – level of confidence in the safety of food. It is vital that any efforts to enhance the effectiveness of our food safety system do not have unintended consequences that could lessen consumer confidence in our nation's food supply. It would do a serious disservice to consumers to send any kind of message that our food supply is unsafe, especially in light of the tragic events of September 11th.

Americans deserve to know that the food industry and federal agencies have fought long and hard to ensure that our products are free from contamination. We must continue to communicate steps that we are taking to further enhance food safety and communicate that food safety is everyone's responsibility. Industry's newest priority is to work with the regulatory agencies to ensure that our systems can and will address food security in light of the tragedies of September 11th. That is why NFPA helped launch the Alliance for Food Security, the food industry's effort to coordinate and communicate with federal agencies to ensure we minimize all threats to our food safety system. In addition, at a time when foreign governments are using food safety as an excuse to erect non-tariff trade barriers, actions that lessen confidence in the safety of the U.S. food supply could also have a serious impact on international trade of U.S. food products.

Are there ways that the current system could be made more effective and efficient? Absolutely. Industry obviously spends many millions of dollars to ensure the safety of food products and we continue to look for ways to improve safety where needed. We can, and we should, use risk assessment to target our food safety resources. We should develop consistent and science-based standards for safe food. We must coordinate and prioritize food safety research and education programs by the various Federal agencies and take more proactive, preventive approaches. It is vital that we better coordinate the response to foodborne illness outbreaks from the local level to federal agencies. We should eliminate outdated and duplicative regulations and better integrate federal food safety activities with State and local agencies. The good news is this: All of these efforts can be undertaken right now, under existing statutes. We do not need to create a new management layer in the form of a new agency to make that happen. However, it is the responsibility of the Congress to ensure both that adequate resources are provided and that resources are being spent wisely to ensure our public health needs are met. If we

want to continue ensuring a proper level of protection of our public health, or if we choose to enhance it, we as a country must pay for it – certainly more so than we have in recent years.

NFPA believes that the way to achieve such improvements is through the creation of a unified food safety policy, drawing on the best expertise throughout various departments and agencies. This means a truly science- and risk-based policy and system with uniform requirements to ensure that the same food safety guidelines will be followed and enforced. A unified policy is needed to provide cohesion and promote the sharing of technology, information and resources to better ensure food safety.

There is a precedent for this approach, in nutrition labeling. Both FDA and USDA under separate authorities and with different processes, enforce virtually identical nutrition labeling rules. States are limited to promulgating and enforcing rules identical to the federal rules, by preemption provisions of the federal statutes, which ensure uniformity. The Nutrition Facts label for foods works exceedingly well, enforced by different federal agencies. Why can't there be a similar strategy for Good Manufacturing Practices, HACCP and other food safety requirements, along with similar inspection procedures for like products?

Improved government agency coordination clearly can be achieved. In fact, efforts to improve coordination already have shown dramatic results. We would cite the significant progress made on egg safety, where improved information sharing and coordination among the regulatory agencies have resulted in demonstrable improvements and a greater level of food safety. Food safety risk assessments have been coordinated agency efforts. The Joint Institute for Food Safety Research serves to coordinate federal food safety research efforts. And the FoodNet program, as I mentioned earlier, which coordinates state and federal health and regulatory agencies' efforts to track foodborne illness outbreaks, has given us important information that is being used to help better target our food safety resources.

We are not convinced that a new layer of management, led by a single administrator, would achieve the goal of enhanced U.S. food safety. In fact, we have seen many times that coordination within a department or agency can be equally difficult as coordination among several organizations. Frankly, the solution is much more fundamental; what is needed is the commitment to coordination and communication to improve the efficiency and effectiveness of the system, rather than a single entity. Consistent nationwide safety programs and enforcement are vital. This is why NFPA and many others in the food industry support efforts to pass legislation establishing national uniformity for safety warnings on foods, and we urge Senator Durbin and the other members of this Committee to join us in the effort. Effective agreement over coordination can strengthen our food system if the department secretaries demand it. The public should not have to bear the expense or the disruption inherent in forming a new government agency when

equivalent results can be achieved with less expenditure and havoc through improved coordination and communications.

Indeed, NFPA is concerned that, in the process of attempting to radically modify the food safety regulatory structure, harm would likely be done to the effectiveness of our overall food safety system. What expertise within various departments are we willing to give up for the sake of having a different organizational chart? To what extent could the creation of a "Food Safety Czar" lead to politicizing our food safety programs? How would we "merge" differing approaches, philosophies and cultures? Merging cultures is an important issue. Not all inspectors are created equal – inspecting meat and poultry presents very different issues and requires very different expertise than inspecting fruit and vegetable canning facilities. FDA, for example, is extremely different from USDA - Food Safety and Inspection Service (FSIS) in philosophy, culture and approach. Should we really expect inspectors and other key personnel to do their jobs better through merging?

It is questions like these that lead us to believe that, in light of the success of our current system, we should continue existing efforts to modify the current system and make it more effective. There is no credible evidence that the Secretaries of Health and Human Services, and Agriculture, nor the food safety agencies themselves, are letting problems that could threaten human health slip through the cracks. The over-used example of the enforcement of cheese versus pepperoni pizza is hardly sufficient to warrant the creation of a new agency – that problem should first be addressed by the departments. It certainly is not a food safety issue.

In closing, I want to stress that our current food safety system has done an outstanding job of protecting consumers, resulting in a record of food safety in this country that is second to none. Improved coordination, along with risk assessment and food safety education, can further enhance the effectiveness of our food safety system, but these should be done in ways that do not reduce consumer confidence. A new government agency isn't the answer to anything except for those who believe government, and more of it is the only answer to any problem. NFPA and the food industry stand ready to work with Congress, as well as with FDA, USDA, and the States to help create a unified food safety policy that includes all of our food regulatory agencies, recognizes the expertise and capabilities of each and eliminates resource-wasting duplication of effort among them.

Mr. Chairman, thank you for the opportunity to speak before this Committee on this important subject.

TERRORISM, INFRASTRUCTURE PROTECTION AND THE US FOOD AND AGRICULTURAL SECTOR

Testimony of Dr. Peter Chalk

Policy Analyst, RAND Washington Office

Before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, U.S. Senate

October 10, 2001

The opinions and conclusions expressed in this written testimony are the author's alone and should not be interpreted as representing those of RAND or any of the sponsors of its research.

TERRORISM, INFRASTRUCTURE PROTECTION AND THE US FOOD AND AGRICULTURAL SECTOR

Statement by Dr. Peter Chalk,* Policy Analyst, RAND Washington Office

INTRODUCTION

Thank you Mr. Chairman and distinguished Members of the Senate Subcommittee on Oversight of Government, Management, Restructuring and the District of Colombia the opportunity to testify on this important subject.

Over the past decade, many states, particularly in North America and Western Europe, have made substantial investments in improving their ability to detect, prevent and respond to terrorist threats and incidents. This has fed into an increasingly well-protected public infrastructure throughout much of the developed world where, at a minimum, effectively developed vulnerability-threat analyses have been used to maximize both anti-terrorist contingencies and consequence management modalities. This investment in preparedness, training and response has helped with the development of viable incident command structures that now span the ambit of potential terrorist attacks,

* This testimony is based on the author's cumulative knowledge of terrorism and threats to the US food supply. No Federal government grants or monies were used to prepare this written testimony. **The opinions and conclusions expressed both in this testimony and the published work from which it is derivsd are entirely the author's own and should not be interpreted as representing those of RAND of any of the sponsors of its research.**

from conventional bombings to more "exotic" biological, chemical, radiological and nuclear incidents.

Agriculture is one area that has received very little attention in this regard, however. Indeed, in terms of accurate threat assessments, response structures and preparedness initiatives, the sector continues to exist as a glaring exception to the wide-ranging emphasis that has been given to critical infrastructure protection in this country.

This testimony aims to expand the current debate on public infrastructure protection and bio-terrorism by assessing the vulnerabilities of agriculture and the food chain to a deliberate act of agro-terrorism. For the purposes of this testimony, agro-terrorism will be defined as the deliberate introduction of a disease agent, either against livestock or into the food chain, for purposes of undermining stability and/or generating fear. Depending on the disease agent and vector chosen, it is a tactic that can be used either to generate cause mass socio-economic disruption or as a form of direct human aggression.

THE IMPORTANCE OF THE US AGRICULTURAL AND FOOD SECTOR AND IS VULNERABILITY TO SABOTAGE

Agriculture and the general food industry remain absolutely critical to the social, economic and, arguably, political stability of the US, indirectly constituting roughly two percent of the country's overall domestic gross domestic product (GDP). One in eight people work in some component of agriculture - more if food production is included - making the industry one of the US' largest employers.[1] Cattle and diary farmers alone earn between US$50 and US$54 billion a year through meat and milk sales, while roughly US$50 billion is raised every year through agricultural exports. The share of produce sold overseas is more

[1] Comments made by Noreen Hynes during the International Conference on Emerging Infectious Diseases (ICIED), Atlanta, Georgia, July 16-19 2000.

than double that of other US industries, which gives agriculture major importance in terms of the American balance of trade.[2]

These figures represent only a fraction of the total value of agriculture to the country, as they do not take into account allied services and industries such as suppliers, transporters, distributors and restaurant chains.[3] The down stream effect of any deliberate act of sabotage/destruction to this highly valuable industry would be enormous, creating a tidal wave effect that would be felt by all these sectors, impacting, ultimately, on the ordinary citizen him/herself.

Unfortunately, the agricultural and food industries remain highly vulnerable to deliberate (and accidental) disruption. Critical considerations in this regard include:

- The increased disease susceptibility of farm animals as a result of steroid programs and husbandry practices instituted to elevate the volume and quality of meat production as well as meet the specific requirements of potential vendors. These bio-technic treatments have increased the stress levels of exposed livestock and, in doing, have inadvertently served to lower their natural resistance to viral and bacterial infections.[4]
- The existence of a large number of agents that are both lethal and highly contagious to animals, many of which livestock are not routinely vaccinated against. At least 22 such diseases are known to exist. The bulk of these ailments are both environmentally hardy - being able to

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[2] Ellen Shell, "Could Mad Cow Disease Happen Here?" *The Atlantic Monthly* 282/3 (1998): 92; "Stockgrowers Warned of Terrorism Threat," *The Chieftain*, August 19, 1999.

[3] Terence Wilson et al., "A Review of Agroterrorism, Biological Crimes and Biological Warfare Targeting Animal Agriculture," paper supplied to the author, 22.

[4] Author interview with Animal and Plant Health Inspection Service (APHIS) officials, Washington D.C., July 1999.

exist for long periods of time in organic matter - and reasonably easy to acquire and/or produce.[5]

• The ease and rapidity by which infectious animal diseases are able to spread, reflecting the intensive and concentrated nature farming practices in the US. Most diaries in the country can be expected to contain at least 1,500 lactating cows at any one time, with some of the largest facilities housing as many as 5,000 to 10,000 animals. An infectious outbreak at one of these facilities would be extremely difficult to contain and could necessitate the wholesale destruction of all the animals. Models developed by the US Department of Agriculture (USDA) suggest that a disease such as Foot and Mouth (FMD) could spread to as many as 25 states in as little as five days through the regulated movement of animals between farm and market.[6]

• The proliferation of food processors lacking sufficient security and safety preparedness measures. Several thousand facilities exist in the US, the bulk of which are characterized by lax internal quality control - typically only a fraction of the produce that originates from these

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[5] Principal among these include:
- Foot and Mouth Disease
- Classical Swine Fever Virus
- African Swine Fever Virus
- Rinderpest
- Rift Valley Fever
- Avian Influenza
- Newcastle Disease
- Bluetongue
- Venezuelan Equine Encephalomyelitis Virus
- Vesicular Stomatis
- Lumpy Skin Disease

[6] Author interview with US Department of Agriculture (USDA) officials, Washington D.C. and Riverdale, Maryland, 1999-2000. See also J. Ekboir, *The Potential Impact of Foot and Mouth Disease in California: The Role and contribution of Animal Health Surveillance and Monitoring Services* (Davis, CA: Agriculture Issues Center, 1999).

plants is actually subjected to end of line testing and screening - minimal bio-security and surveillance, inadequate product recall procedures and highly transient, unscreened workforces.[7] These sites represent ideal locations for the deliberate introduction of bacteria and toxins such as salmonella, *E. coli*)157 and botulism. Moreover, because most processed food is disseminated to a wider "catchment" area in a relatively short period of time, a single case of contamination could have significant health ramifications well beyond the immediate source of introduction.

- The increased production of genetically modified (GM) commodities. This particular development has served to exacerbate the potential threat of extremist violence being directed against both the food and agricultural industries. Problems in this regard have already occurred, with varying degrees of seriousness, throughout Western Europe, particularly in the UK and France.

IMPACT OF A MAJOR ATTACK AGAINST AGRICULTURE AND/OR THE FOOD CHAIN

The impact of a major agricultural/food-related disaster in the US would be enormous and could easily extend beyond the immediate agricultural community to affect other segments of society. It is possible to envision at least three major effects that might result.

Mass economic destabilization

Perhaps one of the most immediate effects of a major act of biological agro-terrorism would be to create, mass economic destabilization, generating costs that could be expected to cross

at least three levels. First, there would be direct economic losses resulting from containment measures and the destruction of disease-ridden livestock. A study by the USDA has concluded, for instance, that if African Swine Fever (ASF) were ever to become entrenched in the US, the cost over a ten-year period would be $5.4 billion.[8]

Second, indirect multiplier effects would accrue both from compensation costs paid to farmers for the destruction of agricultural commodities and losses suffered by both directly and indirectly related industries. Over 1 billion GBP was paid in compensation to farmers affected by the recent FMD outbreak in the UK (claims for each farm were in the range of 116,000GBP); tourism receipts were also hit hard as a result of cancellations brought about by the quarantine of farms located in or near popular holiday destinations such as the Lake District.[9]

Finally, international costs in the form of protective trade embargoes imposed by major external trading partners would be manifest. Very much indicative of the potential scale of these losses was a blanket ban that was imposed on Taiwanese pork exports following a particularly devastating outbreak of FMD between March and July 1997. The embargo caused Taipei's GDP by a full two percentage points almost overnight.[10]

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[7] Author interview with California Department of Health (CDHS) officials, Sacramento, August 2000.

[8] See C. Renlemann and Spinelli, "An Economic Assessment of the Costs and Benefits of African Swine Fever Prevention," *Animal Health Insight* (Spring/Summer 1994).

[9] "Spring Returns to Rural Britain, But Not Tourists," *The Washington Post*, March 16, 2001; "After Foot and Mouth," *The Economist*, May 5th, 2001; "Farmers Paid 1Bn Pounds for Culled Animals," *The Daily Telegraph*, June 30th, 2001.

[10] Overall costs of the FMD outbreak ran to US$378.6 million during the four months. For further details see P.C. Yang, R.M. Chu, W.B. Chung and H.T. Sung, "Epidemiological Characteristics and Financial Costs of the 1997 Foot and Mouth Disease Epidemic in Taiwan," *Vet Rec* 145/25 (1999).

Loss of Political Support and Confidence in Government

A successful act of agro-terrorism would also serve to undermine confidence and support in government. Releasing contagious agents and contaminants against livestock or introducing them into the food chain would undoubtedly cause people to lose confidence in the safety of the food supply and could lead to questions over the effectiveness of existing contingency planning against weapons of mass destruction in general. Critics would also undoubtedly demand why the intelligence agencies failed to detect that an attack was imminent and why the agricultural sector was left exposed.

The actual mechanics of dealing with an act of agro terrorism may act as an additional trigger for public criticism. Mass eradication and disposal are likely to be particularly controversial and could quite easily elicit protest (and possibly violence) from animal rights and environmental groups. Containing a major disease outbreak would almost certainly necessitate the slaughter of hundreds of hundreds of thousands of animal. Euthanizing such volumes would be sure to generate widespread opposition from farmers, animal rights groups and possibly even the public (despite being a scientifically justifiable method of viral containment), particularly if culling operations involved the slaughter of susceptible, but non-disease showing livestock (fire breaker operations). The fact that the US has not experienced a major cattle or sheep outbreak in the era of public TV is especially important in this regard as it effectively means that no visual point of reference has been available to prepare the public at large for the consequences of containing such a catastrophe.[11]

Indeed, even countries that have been subjected to major agricultural disasters can be affected by such dynamics. The UK provides a case in point. The mass depopulation operations

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[11] Author interview with USDA and APHIS officials, Washington D.C. and Riverdale, Maryland, 1999-2000.

initiated to try and stem the 2001 FMD outbreak (many of which targeted seemingly health animals) engendered significant opposition from farmers, politicians (citing government over-reaction) and the public at large.[12] This, despite the fact that Britain had already lived through the enormity of the mad cow disaster in the early 1990s.

Social instability

Beyond immediate economic and political impacts, bio-terrorist assaults against agriculture and/or the food chain have the potential to create mass panic, particularly if the catastrophe had a direct public health impact. The outbreak of a contagious zoonotic disease or a major food contamination scare would be most significant in this regard, especially in the event that human deaths actually occurred. Terrorists could use this to their advantage, allowing them to create a general atmosphere of fear and anxiety without actually having to carry out indiscriminate civilian-oriented attacks.

The 1999 West Nile Virus outbreak in New York provides a partial insight into the type of mass panic that could be unleashed if a large-scale zoonotic epidemic were, in fact, to become entrenched in the US. The disease, which was previously unknown to America, quickly spread to humans, several of whom subsequently died as a result of massive heart and liver failure. An unprecedented public health scare ensued, the dimensions of which were further exacerbated by the epidemiological difficulty (at least initially) of definitively determining the pathogen's type, source and transmission mode.[13]

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[12] Author interview with British Broadcasting Corporation (BBC) correspondent, March 2001. See also "This Wretched Cult of Blood and Money," *The Times*, May 23, 2001; "The Cruelty of This Cull," *The Sunday Times*, May 20, 2001; and "Tactics Used on Half the Farms 'Were Inefficient,'" *The Daily Telegraph*, May 22, 2001.

US THREAT SCENARIOS

There are several ways by which a deliberate act of agricultural sabotage or terrorism could occur on US soil, using a variety of different causative agents and dissemination methods. Attacks directed against either the cattle industry or instituted via the food chain, however, pose the most serious threat in terms of latent run-on effects and general social disruption. Possible threat scenarios could embrace:

- The introduction of a zoonotic pathogen designed to kill both animals and humans. One possible agent would be screwworm myasis. The disease is endemic throughout the world and remains prevalent in areas close to the US (such as Panama). It can also spread quickly and can be easily introduced to cattle. Moreover, the graphic flesh-eating nature of the infection would undoubtedly have a resounding psychological impact on the public and, if not quickly contained, precipitate a mass social scare.[14]
- The introduction of a non-zoonotic pathogen designed to undermine support and confidence in government and cause widespread economic disruption. The most viable agent in this instance would be Foot and Mouth Disease, which is easy to introduce, environmentally hardy and highly

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[13] Comments made during a special panel on West Nile Virus during the International Conference on Emerging Infectious Diseases (ICEID), Atlanta, Georgia, July 2000.

[14] Author interview with Californian Department of Food and Agriculture (CDFA) officials, Sacramento, California, August 2000. See also United States Animal Health Association, *Foreign Animal Diseases* (Washington D.C.: USDA Committee on Foreign Animal Diseases, 1998), 372-76.

infectious - remaining one of the most transmissible virus currently known to medical science.[15]

- An attack carried out further down the food chain, either for blackmail purposes or as a form of direct aggression against humans. Packing plants dealing with fresh fruits and vegetables and small-scale food manufacturers, particularly those specializing in ready-to-eat and/or aggregated products represent the greatest threat. This is because they either lack adequate bio-security provisions, do not use heat in the processing stage (a good "front-end" barrier against pathogenic contamination) or deal in pre-prepared produce that does not require cooking (a good "back-end" defense against microbial introduction). Likely contaminant agents could include easy to produce bacteria such as salmonella (which can be grown in a domestic kitchen) and *E. coli* 0157 (which is commonly shed by cattle) or highly potent toxins such as botulism.[16]

POLICY RECOMMENDATIONS

The US - more by luck than design - has not experienced a major agricultural or food-related disaster in recent memory. There has, as a result, been no real appreciation of either the consequences or threat potential of such an event taking place in this country. This has been reflected in the make up of the US agricultural emergency preparedness and response, which have yet to be given the resources necessary to develop into a truly integrated and comprehensive system that is capable of addressing mass, multi-focal contingencies. Equally, general bio-security

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[15] Comments made during the "Agro-Terrorism: What is the Threat?" Workshop, Cornell University, Ithaca, New York, November 12-13, 2000.

[16] Comments expressed by Jannel Kause during the "Bioterrorism in the United States: Calibrating the Threat," Seminar, Carnegie Endowment for International Peace, Washington D.C., January 2000.

and surveillance at many of the country's food processing and rendering plants remains woefully inadequate, with most also lacking effective and viable product recall/trace-back plans.

Specific weaknesses include:

- A lack of resources, particularly in relation to mitigating and containing large-scale disease outbreaks.
- Insufficient personnel with training in foreign animal disease (FAD) recognition and treatment.
- A declining diagnostician pool in general as a result of insufficient educational support for veterinary science.
- An emergency management program that is essentially designed to deal with only one or two localized animal disease outbreaks at a time.
- Inadequate forensic coordination between the agricultural and domestic criminal justice communities.
- An emergency response program that relies on an unreliable passive disease reporting systems, and which is hampered by a lack of communication and trust between regulators and producers.
- Insufficient food surveillance and inspections at processing and packing plants.
- Inadequate response modalities to deal with food-borne diseases.

Measures can and, indeed, should be initiated to augment the effectiveness of the general agricultural/food response structure in the US. At least six policy recommendations can be made for the short and medium term.

First, more investment should be made in human, physical and logistical infrastructure, especially with regard to FAD diagnostician training; regular preparedness and response

exercises and programs; appropriate diagnostic facilities capable of supporting high level research into virulent foreign and exotic animal diseases; and integrated electronic communication systems between emergency management staff and field response personnel.

Second, the overall veterinary science curriculum should be reformed, with a greater emphasis on large-scale animal husbandry and foreign/exotic disease recognition and treatment.

Third, more attention needs be given on how to involve accredited local/state veterinarians in the USDA's overall emergency management system (which would fulfill an important "force multiplier" function).

Fourth, better coordinated and more standardized links between the US agricultural, criminal justice and intelligence communities need to be fostered, especially in the context of epidemiological investigations to establish whether a disease outbreak was deliberately orchestrated or the result of a naturally occurring phenomenon.

Fifth, a viable national agricultural insurance scheme that can be used to compensate farmers in the event of a major agricultural disaster needs to be developed (something that would also help to heighten the effectiveness of the passive disease reporting system upon which the USDA relies).

Sixth, more effective bio-security, surveillance and emergency response at food processors and packing plants should be instituted, especially those that exist at the smaller end of the scale. Immediate measures that could be usefully initiated include more effective site security, increased background checks on seasonal employees and the development of clearly documented, well-rehearsed product recall plans.

Over the longer-term, concrete moves should be encouraged to standardize and rationalize food and agricultural safety within the confines of a single Federal agency that has both budgetary and programmatic powers over a wide spectrum of

functional domains and jurisdictions. Such a body would help to streamline the patchwork of largely uncoordinated food safety initiatives that currently exists in the US, many of which have sought to only individually enact specific preparedness and response objectives. In addition, it would contribute substantially to the development of a national emergency animal and food disease response plan that both reduces conflicts and eliminates unnecessary duplication of effort.

Thank you for your time. I will be happy to respond to any questions that you might have.

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Testimony of
C. Manly Molpus
President and Chief Executive Officer
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Senate Committee on Governmental Affairs

October 10, 2001

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to appear before the Committee this morning to discuss how we might best go about guaranteeing that the systems we have in place in the United States to ensure the safety of our food supply remain the envy of other nations throughout the world.

GMA member companies make and market the world's best-known and most trusted brands. Our members represent 90% of the branded food and beverage products sold in the United States. Nothing is more fundamental or has a higher priority for us than food safety.

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 and 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. GMA 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.

The system we have is not perfect, but should be enhanced. Before we embark on radical restructuring of the food safety regulatory system, we should be absolutely convinced that there is no better way to address the problems. In our view the system is not broken but it does need changes and more resources.

Our 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 Department of Agriculture and the Environmental Protection Agency.

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 more safety challenges than other food processing. When fundamentally different regulatory systems are called for, dividing responsibility among different agencies represents a logical approach. In short, food safety regulation is not a "one size fits all" situation.

We should not underestimate the challenges that would be faced were we to attempt to combine the food safety regulatory activities into a single agency. Mr. Chairman, I know from the experience of many of my member companies how difficult and disruptive it can be to

implement a merger. Even when a merger is ultimately successful—and not all of them are—combining organizations inherently means a period of uncertainty, distractions, loss of focus and functionality. Now, perhaps more than at any time in our history, we need intensive focus on the job at hand.

Having said that, this does not mean we seek to maintain the status quo. There is room for improvement in our current system. We have four recommendations to improve the current system that I would like to share briefly with the committee:

First: Adequate staffing and resources

Consumers, and the food industry, are best served by strong food safety agencies – including the Food and Drug Administration, the US Department of Agriculture, Environmental Protection Agency, and state and local health agencies – which 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.

I'd like to focus particularly on the FDA. 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 failed to keep pace. With a partnership among all interested parties, we can persuade those with responsibility for the Federal budget and those in the Congress with appropriations jurisdiction to provide FDA with the funding it needs to maintain the position it has historically enjoyed as the world's most respected food safety regulatory body. I am pleased to say that GMA has already taken a leadership role in this area. For nearly a year now, GMA has co-led a food-industry wide 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 CEOs committed to helping ensure that the case for additional FDA resources is made. I think it is worthwhile mentioning that

Congressional appropriators for the very first time are about to approve FDA's full budget request.

Second: Research and 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 truly has 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.

Third: Better coordination

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 agency 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 including, where necessary, the transfer and consolidation of responsibilities and associated personnel.

The previous Administration's President's Council on Food Safety 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".

A good example of progress in enhanced collaboration in the last Administration was the agreement by FDA and USDA to jointly coordinate in setting priorities for food safety research through the creation of the Joint Institute for Food Safety Research.

Fourth: Improved Import Inspection:

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

Inspection at our borders needs to be increased with training for these new inspectors along with adequate tracking technology for advance notice of products seeking entry into our country. In particular, we need to be able to identify products from countries that pose the greatest perceived risk, whether due to lack of strong food safety systems or other potential threats, and take necessary steps to ensure the safety of those products. 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.

In 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; we should fully explore strategies to enhance the current system, through adequate funding, better coordination, the best science and continued innovation.

Thank you again Mr. Chairman for the opportunity to testify. I would be pleased to respond to questions that you and the other Members of the Committee may have.

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Testimony of Tim Hammonds
President and CEO
Food Marketing Institute

Before the Subcommittee on Oversight of Government Management,
Restructuring and the District of Columbia
U.S. Senate Committee on Governmental Affairs

Food Safety and Security: Can Our Fractured
Food Safety System Rise to the Challenge?

October 10, 2001
Washington, DC

Good morning Senator Durbin, Senator Voinovich and members of the subcommittee. I am Tim Hammonds, president and CEO of the Food Marketing Institute. FMI is the national trade association representing the retail supermarkets and food distribution industry.

Thank you for holding this hearing on our food safety system. In light of recent events, it could not be more timely. I'm honored to have the opportunity to testify before you today.

I will submit my oral testimony along with FMI's Board-adopted policy on Designating a Single Food Agency for the record. In the interest of the subcommittee's time, I will summarize the key points.

This hearing is especially timely because our current federal food safety regulations are ill equipped to deal with today's challenges. More than a dozen federal agencies have jurisdiction over various parts of our food supply. There are over 35 laws that govern food safety. This

patchwork quilt creates inconsistencies, gaps, overlaps and a duplication of effort that is becoming increasingly unworkable. As these agencies struggle to cope with the many inconsistent statutes and regulations under which they operate, more than 50 interagency agreements have been negotiated in an attempt to bring some degree of order to the process. As this system has evolved piecemeal over nearly a century, it has become primarily reactive rather than working to anticipate and prevent problems.

Clearly no one now designing a regulatory system to maintain the wholesomeness and integrity of our food would ever design anything remotely resembling what we have today. The case for designating a single food safety agency then centralizing resources and responsibility was compelling in May of 2000 when FMI's Board adopted that position; the need for such a system now is imperative. In addition, we believe this could be accomplished without disturbing the oversight authority of the current committees of jurisdiction in the House and Senate.

In the wake of the attacks on America of September 11th, we have begun to look for vulnerable areas in our society. The safety of our food supply is a legitimate subject for inquiry. Put under that microscope, it's clear that now when additional funds are needed to assure food security, we can ill afford the current system's lack of coordination and the resulting waste of resources.

Should a crisis arise, real or manufactured as a hoax, the deficiencies of the current system would become glaringly obvious. For example, let's assume a tampering hoax is staged. The public needs rapid reassurance from a credible source. Under current policy, that could easily involve multiple government agencies. Since it is rare that a single agency has complete jurisdiction over the entire scope of a major food safety problem, it has been our experience that none of the Agencies step forward in times of crisis. It becomes impossible to find a spokesperson who can rapidly clarify the facts and reassure the public. Far more typically, the public is faced with a lengthy delay while our overlapping bureaucracies creak into some sort of action culminating in a message to the public.

To the issue of whether a coordinator would be enough to oversee the existing agencies, we have an open mind but are doubtful. Although some improvements could certainly be made, there would still be overlapping jurisdictions and gaps. Let's just consider the task of assuring the public as to the safety of imported foods. Responsibility for imported foods is split between the Food and Drug Administration and the Department of Agriculture, which rely in part on the

Custom's Department's statutory authority over imports. FDA and USDA use very different approaches for imported foods under their jurisdiction. This was well documented in the 1998 General Accounting Office report with the unflattering title: *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable.*

Both USDA and FDA independently evaluate foreign country food systems. Under this system, a country may be acceptable for USDA purposes yet failed by the FDA. USDA and FDA inspectors work at the same ports of entry yet cannot share duties. A USDA inspector may be idle if there are no meat or poultry products at the dock, yet products under FDA-jurisdiction may go uninspected due to a lack of personnel. USDA maintains one database, and FDA maintains another. It's clear that the inspection of products arriving at our ports is inefficient. A more coordinated approach between all of our food safety agencies is needed along with a greater willingness to share resources.

Let me emphasize that none of this is due to a lack of skill or dedication of those working within our various food safety agencies. Quoting from the 1998 report of the *Committee to Ensure Safe Food from Production to Consumption*, a committee formed by the Institute of Medicine and the National Research Council.

"*Officials who direct or carry out diverse functions under the multiplicity of statutory mandates are capable and dedicated, as are their state and local counterparts. They perform remarkably well, given their budgetary and statutory constraints, but they operate within an institutional framework that is out of date and poorly designed to accomplish the critical goals that [food safety] regulation in this field must achieve. The increasing complexity of food production and delivery and the exploding internationalization of the U.S. food supply impose added pressure on the federal regulatory apparatus which was constructed in simpler times.*"
[National Academy of Sciences report, page 79]

Our FMI Board of Directors is open to other solutions that would improve food safety oversight. However, we find it difficult to come up with a simpler or more direct approach than designating a single food agency.

Thank you Senator and members of the subcommittee for the opportunity to speak with you today on behalf of the members of the Food Marketing Institute.

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It's Time To Designate A Single Food Safety Agency

A Position Paper Adopted by the Food Marketing Institute Board of Directors
May 6, 2000

Food Marketing Institute
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The Food Marketing Institute (FMI) is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members including their subsidiaries — food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of more than $300 billion — three-quarters of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Its international membership includes 200 members from 60 countries.

It's Time To Designate A Single Food Safety Agency
A Position Paper Adopted by the Food Marketing Institute Board of Directors
May 6, 2000

The time has come to consider a major change in the way we monitor and regulate our foods to ensure that the American food supply remains without question the safest, most wholesome and least expensive in the world. Food Marketing Institute makes this proposal because we believe new challenges have arisen that, taken together, threaten to overwhelm the ability of our current regulatory system to respond effectively. We believe that designating a single agency responsible for the safety of our food is essential if we are to maintain a food supply that remains the envy of the world.

The American regulatory system charged with maintaining the safety, integrity and wholesomeness of our food supply has evolved piecemeal over a full century. Changes to this system have been made in response to problems as they have arisen one-by-one, not as part of a well thought out strategic plan. It should be no surprise that a system begun in the early 1900s would now find itself facing very different challenges requiring very different responses.

These challenges include diets vastly different than was the case in the early 1900s, accompanied by a dramatic expansion of foods prepared and eaten away from home; new breeding, processing and preservation technologies unknown when our current system was designed; true globalization of our food supply presenting challenges reaching beyond our own borders; and the emergence of new, virulent foodborne pathogens that require a coordinated prevention and control strategy reaching across all commodity groups.

Our current regulatory system is ill-equipped to deal with these challenges. More than a dozen federal agencies have jurisdiction over various parts of our food supply. This patchwork quilt creates inconsistencies, gaps, overlaps, and duplication of effort that are becoming increasingly unworkable. As these agencies struggle to cope with the many inconsistent statutes and regulations under which they operate, more than 50 interagency agreements have been negotiated in an attempt to bring some degree of order to the process. However, the deficiencies that remain become glaringly obvious in times of crisis.

The public is never in more need of assurance than when a food safety crisis arises. It is precisely at those times when our current regulatory structure prevents effective action. Since it's rare that a single agency has complete jurisdiction over the entire scope of a major food safety problem, it becomes impossible to find a spokesperson who can rapidly clarify the facts and reassure the public. Far more typically, the public is faced with a lengthy delay while our overlapping bureaucracies creak into some attempt at a coordinated response. While the search for who knew what and when goes on, the crisis worsens and public confidence erodes. As this occurs, the public may be exposed to risk longer than necessary and the reputations of companies, and sometimes companies themselves, can be needlessly destroyed.

Congress itself has made several attempts to address modernizing our food regulatory oversight system. Most recently, Congress asked the National Academy of Sciences (NAS) to assess the effectiveness of the current food safety system in the United States and to provide recommendations on scientific and organizational changes needed to ensure an effective science-based food safety system. The resulting *Committee to Ensure Safe Food from Production to Consumption*, formed by the Institute of Medicine and the National Research Council, issued its report in 1998.

Key conclusions reached by the NAS committee in assessing the current system of regulating food safety in the United States include the following:

> *"Officials who direct or carry out diverse functions under the multiplicity of statutory mandates are capable and dedicated, as are their state and local counterparts. They perform remarkably well, given their budgetary and statutory constraints, but they operate within an institutional framework that is out of date and poorly designed to accomplish the critical goals that regulation in this field must achieve. The increasing complexity of food production and delivery and the exploding internationalization of the US food supply impose added pressure on the federal regulatory apparatus which was constructed in simpler times."*
> [NAS page 79]

> *"The major statutory shortfall of the current system is that: There are inconsistent, uneven, and at times archaic food statutes that inhibit use of science-based decision-making in activities related to food safety, and these statutes can be inconsistently interpreted and enforced among agencies."*
> [NAS page 87]

This report presents a damning assessment of the current system for regulating our food supply. As this system has evolved piecemeal over almost a full century, it has become primarily reactive rather than being designed to anticipate and prevent problems before they become critical. Statutory and budgetary limitations prevent the application of scientific risk assessments across all foods that would allow the flexible assignment of resources to the areas of greatest need. The result is that resources tend to become dedicated to solving yesterday's problems and only with great difficulty can they be redirected to meet tomorrow's challenges. Even when one agency rises to an emerging challenge, there is seldom the ability to coordinate an approach across all agencies.

The Current Regulatory Structure

It's easy to see why coordinated, consistent approaches are seldom possible when we look at the current structure of our regulatory system. Regulating the food supply involves dealing with an extraordinarily broad range of issues including ensuring basic food safety, addressing human and animal nutrition, dealing with naturally occurring foodborne pathogens, protecting our environment, monitoring the incidence of diseases, developing an effective program of research, and overseeing a wide variety of means of delivering information to consumers including labels, advertising, and education.

These responsibilities are disbursed across nearly twenty federal agencies and departments along with numerous state and local offices spread throughout the country. At least 50 interagency agreements have been implemented in an attempt to plug the gaps in authority and duplication of effort that inevitably occur in such a complex system. In many cases, these efforts are augmented by a variety of private sector partnerships.

This system has been expanding and evolving since the 1906 Pure Food and Drugs Act created the USDA Bureau of Chemistry. That bureau was renamed the Food and Drug Administration in 1930 and moved from the Department of Agriculture to become a separate agency within the Department of Health and Human Services in 1953. Today, the primary agencies involved at the federal level include the Department of Agriculture, the Department of Health and Human Services, the Environmental Protection Agency, the Department of Commerce, the Department of Defense, the Federal Trade Commission, and the Department of Treasury.

The U.S. Department of Agriculture operates the Agricultural Marketing Service; the Animal and Plant Health Inspection Service; the Agricultural Research Service; the Cooperative State Research, Education and Extension Service; the Economic Research Service; the Food Safety and Inspection Service; and the Grain Inspection, Packers and Stockyards Administration.

The U.S. Department of Health and Human Services operates the Centers for Disease Control and Prevention; the National Institutes of Health; and the Food and Drug Administration. The FDA, in turn, oversees the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the National Center for Toxicological Research.

The U.S. Department of Commerce operates the National Marine Fisheries Service. The U.S. Environmental Protection Agency operates the Office of Prevention, Pesticides, and Toxic Substances. The Department of the Treasury operates the U.S. Customs Service, and the Bureau of Alcohol, Tobacco, and Firearms, which regulates the production, distribution and labeling of alcoholic beverages. The Federal Trade Commission regulates the advertising of food products.

The Case for Reform

As effective as our agencies may have been, they now face challenges very different from those they were originally created to solve. Today's world is increasingly complex with a resulting need for integrated policies balanced across the domestic and international issues of health, safety, trade, economic viability, scientific validity, political realities, and social concerns.

It's not just that our current complex and fragmented system creates gaps and overlaps. It's that our agencies use very different approaches, often mandated by law, to address the very same issues depending on jurisdiction. Products that are perceived as identical in the minds of consumers are often regulated by different agencies administering different approaches because jurisdiction is frequently split.

One well-known example is pizza. The Food and Drug Administration regulates pizza until toppings reach 2 percent or more of cooked meat or poultry. At that point, it falls under the jurisdiction of the Department of Agriculture. Thus, a plant that produces only cheese pizza is subject to inspection by FDA, which is likely to occur only infrequently; while a plant that produces pepperoni pizza is subject to daily inspection by USDA, even though the agency has already inspected the animal from which the pepperoni is made and the processing of the meat into pepperoni. To complicate matters further, an integrated pizza processing plant is simultaneously regulated by inspectors from both the USDA and the FDA operating under two very different sets of guidelines.

Taking another example, in most state and local jurisdictions local health departments oversee restaurants while local agriculture departments oversee supermarkets. This means that a stand-alone restaurant will often be regulated by an agency totally different from the agency that would regulate another branch location, run by the same restaurant chain, operating under the same name, but located inside a supermarket.

Sometimes authority for approval and administration is even handed off in mid-stream. For example, jurisdiction over eggs changes several times along the farm-to-table continuum. FDA is responsible for the safety of eggs on the farm; USDA has authority over the safety of eggs during handling and transportation; and FDA is responsible for eggs again at retail. Moreover, although FDA is given jurisdiction over shell eggs, the safety of processed or liquid eggs is the responsibility of USDA.

In addition to the obvious inconsistencies, the current system is designed more to encourage rivalries between the agencies than to foster cooperation. Today, each individual agency battles for its own authority and budget. Seemingly arbitrary divisions of authority that have arisen over time invite agencies to step over their boundaries at the expense of another regulatory body in an attempt to expand their turf and, therefore, their budgets. This wasteful rivalry can also develop for more subtle reasons.

Take the case of food safety research. Food research is conducted in three different agencies within the Department of Agriculture, in two different agencies within the Department of Health and Human Services, in the National Marine Fisheries Service, in the Environmental Protection Agency, and in the Department of Defense. Food safety research is a small part of the total research budgets of each these agencies and, thus, not the number one priority for any of them. Although attempts at coordination are made, there is neither a way to eliminate all of the needless duplication that occurs nor is there a way to be sure a comprehensive research agenda is carried out.

If these and hundreds of other examples of inconsistency, duplication and inertia that could be cited are not yet enough to make a persuasive case for reform, there are three clear examples of growing challenges that do.

The first is the arrival of modern food biotechnology. While this technology holds great promise, it does blur our current regulatory boundaries and, in an increasing number of cases, actually erases the line between food and drugs. Treating the so-called "super salmon" as a drug for the purposes of regulatory approval is only the most recent example. Companies are left wondering just how the regulatory process is going to work and just what standards will be applied. The public is left wondering as well.

The second example of the pressing challenges facing regulators and the regulated community is the arrival of what have come to be called "functional foods" or

"nutraceuticals". It is becoming increasingly difficult to fit today's products into the neat boxes of foods, drugs, or dietary supplements that existing laws create. Under the existing system, the classification of a product will determine the extent of pre-market regulatory oversight. The controversy surrounding new products that are marketed as replacements for margarine or butter, but include substances that are intended to provide enhanced nutritive properties, is recent example of this phenomenon.

The third example that dramatically illustrates the need for reform is the regulation of foods imported into the United States and our parallel export negotiations with other countries. Authority for assuring the safety of imported foods is split between the Food and Drug Administration and the Department of Agriculture, which rely in part on the Customs Department's statutory authority over imports. Yet both FDA and USDA use very different approaches for foods under their jurisdiction. This was well documented in the 1998 General Accounting Office report with the unflattering title: *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable.*

The Department of Agriculture requires exporting countries to obtain certification that their own domestic control systems for meat and poultry are equivalent to those of the United States. Certification of equivalence is granted after satisfactory on-site visits. Once certification is granted, imports are permitted with only limited random inspection of individual shipments.

In contrast, the Food and Drug Administration relies on physical inspections at ports-of-entry for imported foods under its jurisdiction using a standardized sampling procedure. In some cases, FDA agreements are reached with other countries to conduct in-country inspections of their production and processing facilities. However, not all agencies with responsibility for the safety of imported foods are empowered to negotiate similar reciprocal agreements with other nations to establish equivalent standards.

These systems are not coordinated and they point out the inefficient and ineffective use of resources in our current system. Both FDA and USDA independently evaluate foreign country systems, meaning a country may be "acceptable" to USDA but "failed" by FDA. USDA and FDA may both have inspectors working at the same ports of entry without being able to share duties. Consequently, a USDA inspector may be idle if there are no meat or poultry imports at the dock, while FDA-regulated foods are coming into the same port uninspected because FDA personnel are not available. Two separate and distinct databases are used to select which shipments are to be inspected without regard to risk or priorities.

Because customers expect products to be available in their supermarkets year-round without regard to season, imports are necessarily a large and growing part of our food supply. Given this reality, it's clear a more coordinated approach between FDA and USDA is needed along with a greater willingness to share resources.

It's also clear that in today's global world, our trading partners are increasingly likely to protect their own farmers by disguising trade barriers as food safety standards. The need to be sure all food safety restrictions are truly science-based, and not simple non-tariff trade barriers, demands a coordinated approach between our research facilities, our regulatory agencies, and our trade negotiators.

Conclusion

The system by which we regulate the safety of our food supply must be redesigned to address the current and future challenges of our rapidly evolving food system. Food Marketing Institute believes it's time to consider the designation of a single food agency as the appropriate vehicle to meet those challenges.

FMI does not believe an appointed "czar" within the existing structure, or even an appointed coordinating committee, would carry sufficient authority to allocate budgets and resources appropriately nor would an appointed coordinator or committee eliminate the inevitable rivalries that exist between different agencies charged with essentially the same functions.

FMI believes the only way to carry out meaningful, long-lasting reform of our food regulatory system is to designate a true single agency with total regulatory authority for the safety of our entire food system. Since the resources needed for such an agency already reside within our current agencies, the challenge is primarily one of reallocation. We believe this could be done at a minimum of expense. Indeed, we believe it's likely that eliminating the duplication that now exists would result in substantial budget savings while improving overall performance. We recognize the difficulties inherent in a change of this magnitude. However, we believe it is something that can be—should be—done.

In considering how best to make decisions about a single food safety agency, FMI suggests five guiding principles.

- First, the single food safety agency must build on the credibility we already enjoy with our international trading partners and the American shopping public. Although our current system is in serious need of reform to meet the challenges of the future, we are still the standard of excellence for the world. Great care must be taken not to erode the confidence of the public or of the international community.
- Second, total authority for all federal food safety oversight activities must be centralized including approval, inspection, labeling, standard setting, risk assessment, research, education, and responsibility for monitoring and managing disease outbreaks. Eliminating duplication, closing the gaps that exist, and resolving inconsistencies among the various existing agencies would be given top priority.

- Third, a commitment must be made to integrate federal food safety activities with those of state and local agencies. This includes speaking with one voice on safety standards to encourage each state to adopt the Model National Food Code and collaboration with state and local authorities to ensure uniform enforcement.
- Fourth, oversight from production to consumption must be based on scientific risk assessments that flexibly allocate inspection, research, and regulatory resources to maximize effectiveness. Sound science must be the guiding principle for aligning our scarce resources with the most pressing consumer food safety needs.
- Fifth, our domestic single food safety agency must be equally dedicated to assuring the safety of all foods imported into the United States. Consumers have every right to expect all domestic foods and imported foods to be equally safe.

Now that we have entered a new millennium, it's time to move to a modern food safety regulatory system truly able to address today's challenges and fully capable of preparing us for the future.

TESTIMONY

SUBMITTED ON BEHALF OF THE

UNITED FOOD AND COMMERCIAL WORKERS

INTERNATIONAL UNION (UFCW)

BEFORE

THE COMMITTEE ON GOVERNMENTAL AFFAIRS

SUBCOMMITTEE ON

OVERSIGHT OF GOVERNMENT MANAGEMENT, RESTRUCTURING AND THE DISTRICT OF COLUMBIA

FEDERAL FOOD SAFETY OVERSIGHT:

DOES THE FRAGMENTED STRUCTURE REALLY MAKE SENSE?

OCTOBER 10, 2001

On behalf of the 1.4 million members of the United Food and Commercial Workers International Union (UFCW), we are glad to present testimony in support of a single food safety agency. The UFCW is North America's largest private sector union, nearly a million and half people working together to improve their lives and their communities. UFCW members are in many different industries, but are concentrated in retail food, meatpacking, poultry, and other food processing industries.

Whenever American families sit down to share a meal, chances are, most of what they'll eat has passed through the hardworking hands of the UFCW members who work in these industries. Thousands of other UFCW members work in the health care industry, in department stores, and in the garment manufacturing, distillery and winery, chemical, and textile trades.

The products that we make run the entire gamut; from bacon to baked goods, from candy to corn chips, from barbecue sauce to horseradish sauce, from salt and pepper to salsa, from catfish to deli meat. We process and prepare meat whether it is boxed, frozen, stewed, smoked, or kosher. These meat products end up in soup, on pizza, in frozen dinners, and on salads. They are name brands and store brands, and we are proud to make them all.

It is clear to see why UFCW members have a dual concern about food safety. Not only are our health and lives at stake, so are our livelihoods. Disruptions and work stoppages due to food-born illness, regardless of the cause, are of critical concern to UFCW members and their families. We were a founding member of the Safe Food Coalition, a coalition of consumer, public interest, and food science groups working to improve our nation's food safety system. It will come

as no surprise to the Members of this Committee—or to the public—that we also consume what we produce. Congressional observers have often compared the process of lawmaking to the process of sausage-making, remarking that observing the process leads one to avoid the final product. UFCW members have the unique distinction of having a great view of both processes, and we are hopeful that the legislative process will yield something that both food workers and food consumers need and deserve; a single food safety agency.

Those of you who read Upton Sinclair's classic work The Jungle, will remember that the book was not just about how animals were turned into food, it was also about how the people who turned the animals into food were treated. We must never divorce the two; everything that we eat is processed and prepared by people, workers who need jobs so that they can feed themselves and their families. They literally produce food for us—for you and me—so that they can provide food for themselves.

Earlier this year, a fascinating book examining our food processing system entitled, Fast Food Nation was a national bestseller. In that book, author Eric Schlosser details some of the problems with our piecemeal food safety system. In summary, he notes that "A frozen cheese pizza is inspected by FDA. If there is some sliced pepperoni on it, it is inspected by USDA. Vegetarian vegetable soup is inspected by FDA. Beef vegetable soup by USDA. Eggs in the shell are inspected by FDA. Processed eggs by USDA. Milk from a dairy cow is inspected by FDA. When the cow is slaughtered, the meat is inspected by USDA. A USDA inspector is in every meat, poultry and processed egg plant every day. FDA inspectors may visit food processing plants once every ten years." And, as others have noted, genetically modified crops must be approved by the Animal and Plant Health Inspection

Service. If a bioengineered plant has pesticidal properties, it must pass a safety review by the Environmental Protection Agency. All told, there are 12 different government agencies that share responsibilities for our nation's food safety system.

The current system is as complicated as it is indefensible. What is more problematic is its inefficiency. It is true that our nation is among the safest food systems in the world, but that is of little comfort to the hundreds of thousands of consumers who are hospitalized because of contaminated food. And it is of no comfort whatsoever to those whose loved ones have perished from food-born illness. It is also true that our food safety system is probably safer than at any time in our nation's history. But to advocate for reform and modernization is to acknowledge that further improvement is not merely preferable, but essential.

Even President George W. Bush, when campaigning in Pennsylvania in June 2000, noticed the discrepancy in the food safety system. In discussing, "Getting Results From Government," he said,

> The federal government is also responsible for the safety of our nation's food supply. The way things work now, there's one agency that inspects cheese pizza. There's another that inspects pepperoni pizza. There is one agency that inspects food grown outside the United States. Another that inspects food grown here in the United States. Apparently, the revolutionary idea that maybe these functions could be combined hasn't dawned on anyone yet.

Well, that revolutionary idea is shared by many of us. That is why we are proud to support S. 1501 introduced by Sen. Durbin of Illinois and H.R. 1671, legislation introduced by Representative

Rosa DeLauro. Both of these bills would create a single food safety agency. We look forward to working with Rep. DeLauro, Sen. Durbin, with the Members of this Committee, with other Members of the House and the Senate, and with the Bush Administration in making this proposal a reality. Interestingly enough, the support for a single agency is not only bicameral and bipartisan, it also unites disparate interests outside of the Capital. Many of our employer industry groups also support a single food safety agency, as do consumer groups, public interest organizations, and food science organizations. The near unanimity of industry and consumer interests demonstrates the timeliness of this important issue.

While there is agreement over what must be done, there is no detail or agreement about how to achieve it. We would like to spell out some specific suggestions over what the new agency should achieve.

First, food safety must be the single overriding principle of the agency. Market promotion, payments to producers, export credits, and rural development should remain the purview of the Department of Agriculture. Vaccine research; device evaluation; and reproductive, abdominal, and radiological devices should remain under the domain of the Food and Drug Administration in the Department of Health and Human Services. A critical assessment needs to be undertaken to ensure that the appropriate food safety divisions are structured within the new agency. The need to ensure that internecine bureaucratic struggles are minimized is crucial to the success of the overall mission.

Second, this is a role for government. As the largest private sector union in North America, we have more than a passing appreciation for the private sector; it is primarily private sector workers

that we are privileged to represent. But the function of ensuring the safety of the nation's food system must rest with the government. Any attempt to privatize, outsource, or contract out the responsibilities of inspectors will do more than undermine the confidence in the system. It will ensure the failure of this reform.

Third, this consolidation may bring greater efficiencies to the system, but in order for the agency to succeed in its mission, additional resources must be allocated. Consolidation brings with it the opportunity to increase the number of inspectors in the non-meat food processing sector regulated by FDA. It is a travesty that, according to the Center for Science in the Public Interest, nearly 80 percent of identifiable food outbreaks were linked to foods regulated by FDA. But it is no surprise, given the fact that FDA's budget for regulating food is only 26 percent of the federal government's food inspection budget. The answer is not to reduce inspectors from the USDA facilities; obviously the number of inspectors contributes to keeping down the number of instances of contamination. The answer is to increase the number of inspectors for the FDA industries and to increase the frequency of inspections.

We believe that starting with the existing consensus, and recognizing the principles as we have described them is a framework for enacting legislation in the 107th Congress which will put us on a path to creating a single food safety agency.

There is, however, an additional reason to speed consideration and reform of this process. The events of September 11 have shaken and saddened us all. If that human tragedy—or any a similar tragedy—could be avoided in any way, the people of our nation and the members of our union would rally to that cause. The threat of bioterrorism, and the notion that someone may attempt to

intentionally place pathogens or microbiological agents in our nation's food supply must be considered. Such an act of terrorism could paralyze the nation's economy and health. The potential loss of life, of debilitating illness, of economic dislocation is staggering. We would be less than responsible if we did not attempt to address this possibility prior to it occurring. The members of the UFCW stand with you in protecting and ensuring the safety of our food system.

In summary, there is much work to be done. It is simpler to state our support for a single food safety agency than to wrestle with the difficult organizational, programmatic, scientific, and governmental issues that must be resolved. But only after that commitment has been made, can the process of reinvention and consolidation begin. Our goal is simple; we need a rational, 21st century food safety system. One that combines the experience of government inspectors with the best science that is available and the hands-on experience of frontline food workers. We need the government resources and the political commitment to succeed. We need a single food safety agency whose primary mission is safe food for consumers.

Thank you for the opportunity to present this testimony. We would be glad to respond to any questions.