

**FEDERAL EFFORTS TO MITIGATE VULNERABILITIES
IN THE FOOD SUPPLY CHAIN**

HEARING

BEFORE THE

**SUBCOMMITTEE ON EMERGING
THREATS, CYBERSECURITY, AND
SCIENCE AND TECHNOLOGY**

OF THE

**COMMITTEE ON HOMELAND SECURITY
HOUSE OF REPRESENTATIVES**

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

JULY 24, 2007

Serial No. 110-59

Printed for the use of the Committee on Homeland Security



Available via the World Wide Web: <http://www.gpoaccess.gov/congress/index.html>

U.S. GOVERNMENT PRINTING OFFICE

48-933 PDF

WASHINGTON : 2009

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

COMMITTEE ON HOMELAND SECURITY

BENNIE G. THOMPSON, Mississippi, *Chairman*

LORETTA SANCHEZ, California,	PETER T. KING, New York
EDWARD J. MARKEY, Massachusetts	LAMAR SMITH, Texas
NORMAN D. DICKS, Washington	CHRISTOPHER SHAYS, Connecticut
JANE HARMAN, California	MARK E. SOUDER, Indiana
PETER A. DeFAZIO, Oregon	TOM DAVIS, Virginia
NITA M. LOWEY, New York	DANIEL E. LUNGREN, California
ELEANOR HOLMES NORTON, District of Columbia	MIKE ROGERS, Alabama
ZOE LOFGREN, California	BOBBY JINDAL, Louisiana
SHEILA JACKSON LEE, Texas	DAVID G. REICHERT, Washington
DONNA M. CHRISTENSEN, U.S. Virgin Islands	MICHAEL T. McCAUL, Texas
BOB ETHERIDGE, North Carolina	CHARLES W. DENT, Pennsylvania
JAMES R. LANGEVIN, Rhode Island	GINNY BROWN-WAITE, Florida
HENRY CUELLAR, Texas	MARSHA BLACKBURN, Tennessee
CHRISTOPHER P. CARNEY, Pennsylvania	GUS M. BILIRAKIS, Florida
YVETTE D. CLARKE, New York	DAVID DAVIS, Tennessee
AL GREEN, Texas	
ED PERLMUTTER, Colorado	
VACANCY	

JESSICA HERRARA-FLANIGAN, *Staff Director & General Counsel*

ROSALINE COHEN, *Chief Counsel*

MICHAEL TWINCHEK, *Chief Clerk*

ROBERT O'CONNOR, *Minority Staff Director*

SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

JAMES R. LANGEVIN, Rhode Island, *Chairman*

ZOE LOFGREN, California	MICHAEL T. McCAUL, Texas
DONNA M. CHRISTENSEN, U.S. Virgin Islands	DANIEL E. LUNGREN, California
BOB ETHERIDGE, North Carolina	GINNY BROWN-WAITE, Florida
AL GREEN, Texas	MARSHA BLACKBURN, Tennessee
VACANCY	PETER T. KING, New York (<i>Ex Officio</i>)
BENNIE G. THOMPSON, Mississippi (<i>Ex Officio</i>)	

JACOB OLCOTT, *Director & Counsel*

DR. CHRIS BECK, *Senior Advisor for Science & Technology*

CARLA ZAMUDIO-DOLAN, *Clerk*

DR. DIANE BERRY, *Minority Senior Professional Staff Member*

(II)

CONTENTS

	Page
STATEMENTS	
The Honorable James R. Langevin, a Representative in Congress From the State of Rhode Island, Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science:	
Oral Statement	1
Prepared Statement	2
The Honorable Michael T. McCaul, a Representative in Congress From the State of Texas, Ranking Member, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology:	
Oral Statement	4
Prepared Statement	5
The Honorable Bennie G. Thompson, a Representative in Congress From the State of Mississippi, Chairman, Committee on Homeland Security	
Oral Statement	6
Prepared Statement	7
The Honorable Donna M. Christensen, a Delegate in Congress From the U.S. Virgin Islands	36
The Honorable Bob Etheridge, a Representative in Congress From the State of North Carolina	40
The Honorable Marcy Kaptur, a Representative in Congress From the State of Ohio	38
WITNESSES	
PANEL II	
Dr. David Acheson, Assistant Commissioner, Food Protection, U.S. Food and Drug Administration:	
Oral Statement	8
Prepared Statement	11
Mr. Dan Baldwin, Assistant Commissioners, Office of International Trade, U.S. Customs and Border Protection:	
Oral Statement	28
Prepared Statement	30
Dr. Carol Maczka, Assistant Administrator, Office of Food Defense and Emergency Response, Food Safety Inspection service:	
Oral Statement	16
Prepared Statement	17
Dr. Tom McGinn, Chief veterinarian and Director, Food and Agriculture Security, Office of Health Affairs, U.S. Department of Homeland Security:	
Oral Statement	22
Prepared Statement	24
PANEL II	
Dr. Craig Henry, Senior Vice President, Chief Operating Officer, Scientific and Regulatory Affairs, Grocery Manufacturers Association and Food Products Association	61
Mr. Shaun Kennedy, Deputy Director, National Center for Food Protection and Defense, University of Minnesota—Twin Cities Campus:	
Oral Statement	47
Prepared Statement	49

(III)

IV

	Page
Dr. Allen Mathys, Vice President for State and Federal Regulations, Grocery Manufacturers Association and Food Products Association:	
Prepared Statement	63
Dr. Lee M. Myers, State Veterinarian, Assistant Commissioner of Animal Industry, Georgia Department of Agriculture:	
Oral Statement	54
Prepared Statement	56

APPENDIX

Additional Questions and Responses:	
Responses from Dr. David Acheson	71
Responses from Dr. Craig Henry	90
Responses from Dr. Tom McGinn	91
Responses from Dr. Lee M. Myers	96

FEDERAL EFFORTS TO MITIGATE VULNERABILITIES IN THE FOOD SUPPLY CHAIN

Tuesday, July 24, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY,
AND SCIENCE AND TECHNOLOGY,
Washington, DC.

The subcommittee met, pursuant to call, at 10:21 a.m., in Room 311, Cannon House Office Building, Hon. James R. Langevin [chairman of the subcommittee], presiding.

Present: Representatives Langevin, Christensen, Etheridge, Green, Kaptur, Thompson (ex officio) and McCaul

Mr. LANGEVIN. The subcommittee will come to order. The subcommittee is meeting today to take testimony on Federal Efforts to Mitigate Vulnerabilities in the Food Supply Chain.

Good morning. I would like to thank our witnesses for being here today. This hearing was originally scheduled, as you know, for last Thursday, but we had to postpone the hearing due to the House-Senate Conference Committee on the 9/11 bill. So I appreciate the witnesses' flexibility and patience, and I sincerely thank you all for coming back here today on what I know is a very important subject.

Recent months have brought increased attention to vulnerabilities in the United States' food supply chain. Today's hearing will present us with both the public and private sector perspectives on how best to secure our food distribution networks. In the last year, we have witnessed food-borne illness outbreaks associated with spinach lettuce, and peanut butter, among others. This spring, incidents including the melamine contamination of vegetable proteins used in pet foods, the diethylene glycol contamination of toothpaste and drug residues in fish demonstrate how intentional food adulteration can pose a far greater challenge than unintentional contamination.

Now, many of these incidents were traced back to problems associated with the Chinese food supply. And it is evident that China's food and drug safety standards are often weak, poorly enforced or both, though I am encouraged by recent indications that China's food and drug administration will be making their processes more transparent in order to ensure more stringent safety measures.

Unfortunately, China isn't the only problem country. Developing nations in Africa and parts of Latin America also have significant

food safety issues, and it would be shortsighted to place the blame on one country or one region. This is a global problem and has the potential to cripple the food supply throughout the United States. We are here today to figure out how, in working with both the private sector and public sector partners, we can mitigate vulnerabilities and secure our food supply chain here at home.

Just as the Nation's food sector is comprised of a variety of distinct businesses and operations, so, too, is the Federal Government's effort in defending the food supply from intentional attacks and natural hazards. Now it is not an easy task, and there is a lot of work that we must complete, but we all understand what is at stake.

Now I am reminded that, 100 years ago, Upton Sinclair's investigation into the Chicago meatpacking plants led to the formation of the Food and Drug Administration in the United States. That investigation is still relevant today and demonstrates the need for transparency in ensuring the safety of these systems.

In fact, in 2004, the President issued Homeland Security Presidential Directive 9 to help achieve this goal. HSPD-9 establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters and other emergencies. In March 2005, the GAO identified confusion over the Department of Homeland Security's role in agroterrorism. The GAO voiced concern that the agency hadn't yet evolved into its leading role under Homeland Security Presidential Directive 9. Though 2 years have passed, significant problems still remain. Now, as the DHS Office of the Inspector General reported in a February 2007 review of Homeland Security food defense activities, the enormity of the food sector and the complexity of government oversight pose substantial challenges to the food defense and critical infrastructure protection. The complexity of both systems has resulted in the recent publication of several reports critical of the bureaucracies associated with these efforts.

In February 2007, GAO designated the Federal oversight of food safety as a high risk area for the first time. GAO found that a fragmented system, whereby 15 agencies collectively administer at least 30 laws related to food safety, causes inconsistent oversight, ineffective coordination and inefficient use of resources. This report found several management problems that reduced the effectiveness of the agencies' routine efforts to protect against agroterrorism. For example, GAO noted that weaknesses in the flow of critical information existed among key stakeholders.

Also, in February, the Department of Homeland Security's Inspector General issued a record that found that DHS, USDA and HHS were failing to meet their obligations under HSPD-9 to prepare an integrated food defense plan. The Inspector General recommended that DHS pursue recruitment, hiring and retention of staff with expertise in matters of post-harvest food defense; work collaboratively with USDA and HHS on grants and other funding mechanisms to carry out food defense missions; and identify a single senior DHS official to be accountable for coordinated implementation of all DHS food sector responsibilities; and provide this official with clear authorities and adequate staffing to perform this function.

Now, I hope that the officials before us today can discuss their efforts to improve some of the issues that have been raised. The integrity of our Nation's food supply is critical to our national, economic and health security. There is much work to be done to fully secure our food supply chain, and we must act swiftly to shore up the remaining vulnerabilities. That concludes my opening statement.

The chair now recognizes the ranking member of the subcommittee, the gentleman from Texas, Mr. McCaul, for the purpose of an opening statement.

[The statement of Mr. Langevin follows:]

PREPARED STATEMENT OF THE HONORABLE JAMES R. LANGEVIN, CHAIRMAN, SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

GOOD MORNING. I'D LIKE TO THANK OUR WITNESSES FOR BEING HERE TODAY. THIS HEARING WAS ORIGINALLY SCHEDULED FOR LAST THURSDAY, BUT WE HAD TO POSTPONE THE HEARING DUE TO THE 9/11 CONFERENCE, SO I APPRECIATE THE WITNESSES' FLEXIBILITY AND PATIENCE AND I THANK YOU ALL FOR COMING BACK TO BE HERE TODAY.

Recent months have brought increased attention to vulnerabilities in the United States' food supply chain. Today's hearing will present us with both the public and private sector perspectives on how to best secure our food distribution networks. In the last year, we have witnessed food-borne illness outbreaks associated with spinach, lettuce and peanut butter, among others. This spring, incidents including the melamine contamination of vegetable proteins used in pet foods, the diethylene glycol contamination of toothpaste, and drug residues in fish demonstrated how intentional food adulteration can pose a far greater challenge than unintentional contamination.

Many of these incidents were traced back to problems associated with the Chinese food supply. It is evident that China's food and drug safety standards are often weak, poorly enforced or both, though I am encouraged by recent indications that China's Food and Drug Administration will be making their processes more transparent in order to ensure more stringent safety measures. Unfortunately, China isn't the only problem country. Developing nations in Africa and parts of Latin America also have significant food safety issues, and it would be short-sighted to place the blame on one country or in one region. This is a global problem, and has the potential to cripple the food supply throughout the United States.

We are here today to figure out how—in working with both private sector and public sector partners—we can mitigate vulnerabilities and secure our food supply chain here at home. Just as the nation's food sector is comprised of a variety of distinct businesses and operations, so too is the Federal government's effort in defending the food supply from intentional attacks and natural hazards.

It's not an easy task, and there is a lot of work that we must complete, but we all understand what is at stake. I am reminded that, 100 years ago, Upton Sinclair's investigation into the Chicago meatpacking plants led to the formation of the Food and Drug Administration in the United States. That investigation is still relevant today and demonstrates the need for transparency in ensuring the safety of these systems.

In fact, in 2004 the President issued Homeland Security Presidential Directive 9 (HSPD-9) to help achieve this goal. HSPD-9 establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. In March 2005, GAO identified confusion over the Department of Homeland Security's role in agroterrorism. The GAO voiced concern that the agency hadn't yet evolved into its leading role under Homeland Security Presidential Directive 9 (HSPD-9). though two years have passed, significant problems remain.

As the DHS Office of the Inspector General reported in a February 2007 review of homeland security food defense activities, "the enormity of the food sector and the complexity of government oversight pose substantial challenges to food defense and critical infrastructure protection." The complexity of both systems has resulted in the recent publication of several reports critical of the bureaucracies associated with these efforts.

In February of 2007, GAO designated the federal oversight of food safety as a high-risk area for the first time. GAO found that a fragmented system—whereby 15 agencies collectively administer at least 30 laws related to food safety—causes inconsistent oversight, ineffective coordination, and inefficient use of resources. This report found several management problems that reduce the effectiveness of the agencies' routine efforts to protect against agroterrorism. For example, GAO noted that weaknesses in the flow of critical information existed among key stakeholders. Also in February, the Department of Homeland Security's Inspector General issued a report that found that DHS, USDA, and HHS were failing to meet their obligations under HSPD-9 to prepare an integrated food defense plan.

The Inspector General recommended that DHS pursue recruitment hiring, and retention of staff with expertise in matters of post harvest food defense; work collaboratively with USDA and HHS on grants and other funding mechanisms to carry out food defense missions; and identify a single senior DHS food sector responsibilities, and provide this official with clear authorities and adequate staffing to perform this function.

I hope that the officials before us today can discuss their efforts to improve some of the issues that have been raised. The integrity of our nation's food supply is critical to our national, economic and health security. There is much work to be done to fully secure our food supply chain, and we must act swiftly to shore up the remaining vulnerabilities.

Mr. MCCAUL. Thank, Mr. Chairman.

Thank you for holding this hearing. I would like to start out by pointing out that the United States' food supply is among the safest in the world. Still, public health officials estimate that over 5,000 people die and many more get sick from food-borne illnesses each year. Recent incidents of nonterrorist-related food contamination, such as the E-coli outbreaks in produce and antibiotics in fish from China, show just how easy it would be for a terrorist to manipulate our food supply against us and to utilize it as a weapon of mass destruction. I don't want to overstate the threat posed by terrorist attacks against food supply. In fact, there are very few recorded acts of intentional food contamination, I believe only two in the United States. But there is no question that the food supply chain is vulnerable, and I am not very confident that we are protecting this critical asset.

The U.S. food and agricultural sector is comprised of more than 2 million farms, approximately 900,000 firms and 1.1 million facilities, almost entirely under private ownership. This sector accounts for about 20 percent of the Nation's economic activity, and we cannot afford to have consumer confidence undermined. Federal efforts to ensure the safety of our food supply have historically been fragmented. There are at least 30 different food safety laws and a patchwork of regulations administered by 15 different agencies. Subtle differences between food products can dictate which agency regulates it. For example, if a packaged ham sandwich is open-faced, it is regulated by the USDA. If it has two slices of bread, it is regulated by the FDA. That is almost comical when you think about it.

What is needed here is a cross-agency perspective, one plan that provides a single framework to ensure that all agencies' goals are complementary and reinforcing, not redundant. We can and must do better. There are some encouraging signs, including the recent establishment of DHS's Office of Health Affairs and the consolidation of agriculture inspectors within Customs and Border Patrol's overall antiterrorism mission.

The focus of today's hearing is on the food safety and food defense efforts. It is a sensitive topic, and I hope that we hear more

about what we are doing to enhance the protection of our food supply rather than on the vulnerabilities themselves. We certainly don't want to advertise our specific vulnerabilities, so please consider this in your testimony.

And with that, I yield back the balance of my time.

PREPARED OPENING STATEMENT OF THE HONORABLE MICHAEL MCCAUL, RANKING MEMBER, SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

- The United States' *food supply is among the safest in the world*. Still, public health officials estimate that over 5,000 people die (and many more get sick) from food borne illnesses each year. Recent incidents of non-terrorist related food contamination, such as the E. coli outbreaks in produce and the antibiotics in fish from China showed just how easy it would be for a terrorist to manipulate our food supply against us and to utilize it as a weapon of mass destruction.

- Yesterday I traveled back to Washington from my home district in Texas via airplane. Like many other Members of Congress I travel by plane frequently, either back and forth from my district or on House business. And every time I board an aircraft I think of 9/11 and of the potential danger of air travel posed by terrorists to myself and my family. Now imagine that feeling of apprehension every single time you pick up your fork to eat dinner or drink a glass of milk. It would change the way we live.

- I don't want to overstate the threat posed terrorist attacks against the food supply. In fact there are very few recorded acts of intentional food contamination (and only 2 in the US). And an attack on the food supply does not have the explosive effect of an incident like 9/11 or a nuclear bomb that is typically associated with groups like al-Qa'ida.

- But there is no question that the food supply chain is vulnerable—and I am not so confident that we are protecting this critical asset. The U.S. Food and Agriculture Sector comprises of more than 2 million farms, approximately 900,000 firms, and 1.1 million facilities, *and is almost entirely under private ownership*. This sector accounts for about 20% of the Nation's economic activity when measured from inputs to tables of consumers at home and away from home. We cannot afford to have consumer confidence undermined.

- I am concerned when I hear the terms "inconsistent oversight", "ineffective coordination", and "inefficient use of resources," associated with the Federal Government's handling of food and agriculture defense activities. We *MUST* and we *CAN* do better.

- *The Homeland Security Act of 2002* assigned DHS the lead coordination responsibility for protecting the Nation against terrorist attacks, including agroterrorism. Subsequent homeland security presidential directives provide more detailed guidance. DHS was assigned this coordinating role because Federal efforts in this area have historically been fragmented. There are at least 30 different food safety laws and a patchwork of regulations administered by 15 agencies. With such a fragmented approach, I question whether the government can really provide useful guidance to the private sector in protecting the food supply chain? Subtle differences in a food products presentation result dictate which agency regulated the product. For example, if a packaged ham sandwich is open-faced, it is regulated by the USDA; if it is a closed sandwich (2 sliced of bread as opposed to one, FDA is the regulating agency.

- DHS is admittedly somewhat late to the game in its efforts to protect the Nation's food supply as the other leading agencies with missions in this area, FDA and USDA, have long histories of protecting the Nation's food products. But there was, and still is, a lack of coordination between those two agencies. For example, USDA and FDA each provided to DHS separate Food and Agriculture Sector Specific Plan(s) to fulfill the National Infrastructure Protection Plan—that is two separate plans for the same sector. What is needed here is a cross agency perspective, one plan that provides a single framework to ensure all agencies' [USDA, FDA, DHS] goals are complementary and reinforcing, not redundant.

- We are encouraged with the recent establishment of DHS' Office of Health Affairs. The Secretary's designation of this Office as the single focal point for internal and external coordination on the Department's food and agriculture responsibilities demonstrates that this sector is starting to get recognition as critical infrastructure that needs protecting.

- The challenges posed by food defense are not easy. I don't want to give the impression that I think protecting this critical infrastructure will take simple physical

security measures such as that we use to secure chemical facilities and nuclear power plants. *Food is not a fixed asset.* It moves into and across the country rapidly so it can be eaten before it perishes without enough time to detect whether there has been contamination. There are several opportunities whether in manufacturing, processing, packaging, or transit for would-be terrorists to gain access to products and introduce harmful agents.

- A positive example that shows how DHS can contribute to reducing fragmentation and compartmentalization is their effort to consolidate the *agriculture inspector function within Customs and Border Patrol's* overall antiterrorism mission. There are 131 million conveyances entering this country every year and with the volume of trade continuing to increase dramatically, CBP is best positioned to meet the agriculture inspection demands. CBP has developed a sophisticated, streamlined and efficient process to identify and target high risk shipments which is being applied to identify high risk agriculture shipments. Although when the agriculture inspection function transferred from USDA to DHS, there certainly were cultural and managerial differences to overcome, they have been overcome with the support of both agencies. Now they are focused on strengthening CBP's capability to apply their automated targeting and risk analysis techniques to agriculture. Transferring the inspector function back to USDA would be a step in the wrong direction back toward an inefficient and fragmented approach to safeguarding the Nation's imported goods. USDA would have to rebuild capacity and create a new capability to automatically target high risk agriculture goods, rather than leverage mechanisms employed by CBP.

- DHS and our Committee need to *engage stakeholders in the agriculture community*, and establish direct relationships with those stakeholders and regularly solicit input. As I learned in drafting H.R. 1717, which authorizes the National Bio—and Agro-Defense Facility, it is critical to engage the private sector and state and local officials in the policy discussions. Doing so will build trust between the homeland security and agriculture communities and facilitate information sharing that is in the best interest of the Nation.

- Which brings me to my last point. The focus of today's hearing is on food safety and food defense efforts. It is a sensitive topic. I hope today what we hear is more about what the Federal and State governments and the private sector are doing to enhance the protection and defense of our food supply, than on the vulnerabilities themselves—which have been mentioned in certain press pieces recently. We certainly don't want to advertise our specific vulnerabilities so please consider this in giving your testimony. . . .

Mr. LANGEVIN. Thank the gentleman. The chair now recognizes the chairman of the full committee, the gentleman from Mississippi, Mr. Thompson, for the purposes of an opening statement.

Mr. THOMPSON. Thank you very much. I would like to begin by thanking the distinguished chairman for reconvening the previously postponed hearing today. The theme of this hearing is extremely fitting, given the circumstances this past year, where our Nation has had to deal with issues of pet food, spinach, peanut butter and, more recently, bans on toothpaste and even the FDA ban on seafood products. The major threat to the food agriculture sector is a crisis of confidence, where a poorly prevented or recognized event causes people to question the safety of food regionally or nationally. The time to address whether our food infrastructure is designed to mitigate our abilities is before an occurrence and not after the fact.

We have been extremely fortunate that our agriculture has been safe, but we have got work to do if we want to be more secure. Currently, 15 agencies collectively administer at least 30 laws related to food safety, causing ineffective oversight, inefficient coordination and inconsistent agency leadership.

One concern I look forward to hearing our witnesses address today is the current agency leadership structure in place in the event of a food-borne emergency. HSPD-9 sets out to address this by establishing the Department of Homeland Security as having

the lead role in policy coordination in an event of national significance. However, a recent GAO report says that USDA is not planning for DHS to assume the lead coordinating role if an outbreak among poultry occurs that is sufficient in scope to warrant a Presidential declaration of an emergency or major disaster, or a DHS declaration of an Incident of National Significance. Such an inconsistency in planning perpetuates the confusion of who is in charge. I look forward to the second panel, comprised of industry, academic and State agricultural officials, giving us a more local perspective of what uncoordinated efforts mean for our communities. Further, I look forward to discussing State and industry involvement throughout all of the coordinating and planning. Reports indicate that they do not have the ability and information to fulfill their assigned roles in protecting agriculture.

Though I am pleased to hear that strides have been made in CARVER + Shock technology in hardening our infrastructure against an international attack, technology is only as good as its application. Unless the relevant agencies begin to take HSPD-9 a step further, the United States will lack a coordinated national approach to protect against agroterrorism, possibly resulting in gaps and needless duplication of effort. By overcoming these challenges, the United States will be in better position to protect against and respond to a food-borne disease outbreak, whether natural or intentional.

Thank you, Mr. Chairman, and I yield back.

[The statement of Mr. Thompson follows:]

PREPARED STATEMENT OF THE HONORABLE BENNIE G. THOMPSON, CHAIRMAN,
COMMITTEE ON HOMELAND SECURITY

The theme of this hearing is extremely fitting given the circumstances this past year, where our nation has had to deal with issues of pet food, spinach, peanut butter, and more recently bans on toothpaste, and even the FDA ban of seafood products.

The major threat to the food agriculture sector is a crisis of confidence, where a poorly prevented or recognized event causes people to question the safety of food regionally or nationally. The time to address whether our federal infrastructure is designed to mitigate vulnerabilities is before an occurrence and not after the fact. We have been extremely fortunate that our agriculture has been safe, but we've got work to do if we want to be more secure.

Currently, 15 agencies collectively administer at least 30 laws related to food safety, causing ineffective oversight, inefficient coordination, and inconsistent agency leadership. One concern I look forward to hearing our witnesses address today, is the current agency leadership structure in place in the event of a food-borne emergency.

HSPD-9 sets out to address this by establishing the Department of Homeland Security as having the lead role in policy coordination in an event of national significance. However, a recent GAO report says that USDA is not planning for DHS to assume the lead coordinating role if an outbreak among poultry occurs that is sufficient in scope to warrant a presidential declaration of an emergency or major disaster, or a DHS declaration of an Incident of National significance.

Such an inconsistency in planning perpetuates the confusion of who's in charge. I look forward to the second panel—comprised of industry, academic and state agriculture officials—giving us a more local perspective of what uncoordinated efforts mean for our communities. Furthermore, I look forward to discussing State and industry involvement throughout all of the coordination and planning. Reports indicate that they do not have the ability and information to fulfill their assigned roles in protecting agriculture. Though I am pleased to hear that strides in CARVER+SHOCK technology have been made in hardening our infrastructure against an intentional attack, technology is on as good as its application.

Unless the relevant agencies begin to take HSPD-9 a step further, the United States will lack a coordinated national approach to protect against agroterrorism,

possibly resulting in gaps or needless duplication of effort. By overcoming these challenges, the United States will be in a better position to protect against and respond to a food-borne disease outbreak, whether natural or intentional.

Mr. LANGEVIN. I thank the Chairman.

Other members of the subcommittee are reminded, under the rules, opening statements may be submitted for the record. Before I turn to the panel. I ask unanimous consent that the gentlelady from Ohio, Ms. Kaptur, be allowed to participate in today's hearing. I thank her for her attendance. Under the committee rules, Ms. Kaptur will be recognized for questions after the committee members.

I think it is appropriate to recognize here that Ms. Kaptur serves on the Appropriations Subcommittee of Agriculture, Rural Development, and Food and Drug Agencies, and actually introduced H.R. 2997, the Assured Food Safety Act of 2007, that would require a seal approval of imported foods coming into the country by seal of approval by USDA or FDA. And I was proud to cosponsor the legislation with the gentlelady. So I ask unanimous consent she be allowed to participate in the hearing.

STATEMENT OF DAVID ACHESON, M.D., F.R.C.P., ASSISTANT COMMISSIONER FOR FOOD PROTECTION, FOOD AND DRUG ADMINISTRATION

Mr. LANGEVIN. Without objection, I welcome the first panel of witnesses.

Our first witness is Dr. David Acheson, Assistant Commissioner of Food Protection, Food and Drug Administration, at the U.S. Department of Health and Human Services. Dr. Acheson provides advice and counsel to the Commissioner on strategic and substantive food safety and food defense matters. Dr. Acheson has published extensively, and is internationally recognized both for his public health expertise in food safety and his research in effective diseases.

Welcome, Dr. Acheson.

Our second witness, Dr. Carol Maczka, is the Assistant Administrator, Office of Food Defense and Emergency Response, Food Safety Inspection Service, at the U.S. Department of Agriculture. Dr. Maczka has more than 20 years of experience in the field of risk assessment.

Our third witness, Dr. Tom McGinn, Office of Health Affairs, Department of Homeland Security. Dr. McGinn is the Director of Veterinary and Agriculture Security for the Office of the Chief Medical Officer. In his position, he is responsible for internal and external coordination of DHS veterinary and agricultural programs.

Welcome to you as well.

Our fourth witness is Dan Baldwin, Assistant Commissioner, Office of International Trade, Customs and Border Protection, Department of Homeland Security. Mr. Baldwin's office directs the national trade policy and national trade program functions at CBP and provides uniformity and clarity for the Department of CBP's national strategy to facilitate legitimate trade.

Without objection, the witnesses' full statements will be inserted into the record.

I want to welcome the panel here. Thank you for your testimony and your presence. And I now recognize each witness to summarize his or her statement for 5 minutes, beginning with Dr. Acheson.

Dr. ACHESON. Good morning, Chairman Langevin, and members of the subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection of the FDA.

FDA appreciates the opportunity to discuss our food defense activities, and I am pleased to be here today with my colleagues from the Department of Homeland Security and the Department of Agriculture.

The Commissioner of Food and Drugs, Dr. Andrew von Eschenbach, recently appointed me to the new position of Assistant Commissioner For Food Protection. My first priority in this position is to develop a new strategy for the integration of food safety and food defense that will address changes in the global food safety and food defense system, identify our most critical needs and serve as a framework to help us address the challenges we face.

Food safety and food defense continue to be top priorities for this administration. A terrorist attack on the food supply could have both severe public health and economic consequences, while damaging the public's confidence in the food we eat. To promote the safety of imported products, last week the President established an interagency working group to review the procedures, regulations and practices that are in place to make sure that imported food and other products are safe. Secretary of Health and Human Services Michael Leavitt will chair this working group. FDA will play a key role in the group's activities. The group expects to report back to the President within 60 days with its recommendations.

At FDA, ensuring the products we regulate are safe and secure is a vital part of our public health mission. The agency regulates everything Americans eat, except meat, poultry and processed egg products, which are regulated by USDA. A great deal has been done in the past few years to enhance the safety and defense of the food supply in the United States. FDA has worked with other Federal, State, local, and tribal food safety agencies, as well as law enforcement and intelligence-gathering agencies, and with industry to significantly strengthen the Nation's food safety and defense systems across the entire distribution chain, from farm to table, to better protect our food supply against deliberate and accidental threats. This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreak of food-borne illness.

FDA is working closely with DHS and other Federal agencies to implement the President's Homeland Security Presidential Directives. The HHS and USDA Secretaries, or their designees, exercise key responsibilities as food-sector-specific agencies. DHS serves as the coordinator of the food agriculture sector with the Government Coordination Council. HHS and USDA serve as co-leads for the food sector, and USDA serves as the lead for the agriculture sector. With the close working relationship of FDA and USDA and the other government and industry collaborators, the Food and Agriculture Sector activities to protect critical infrastructure have set the organizational and operational standard for other critical infra-

structure sectors. DHS recently released our sector-specific plants. To implement HSPD-9, FDA has been involved in numerous activities.

For example, to increase lab surge capacity, FDA, in coordination with USDA, established the Food Emergency Response Network, or FERN, to include a substantial number of Federal, State and local labs that are capable of analyzing large numbers of food samples for agents of concern. At present, the FERN network includes 134 laboratories, representing all 50 States and Puerto Rico. FDA has also developed an online food defense awareness training course in partnership with USDA. We have completed 13 vulnerability assessments as part of the strategic partnership program on agroterrorism. FDA has also conducted or provided funding for food defense research activities and participated in numerous emergency response exercises. In our food defense activities, FDA works closely with our State partners. For example, earlier this year, FDA conducted a Food Defense Surveillance Assignment for FDA and USDA personnel and participating State and local authorities to conduct food-defense-related inspections and reconciliation exams, and to collect and analyze samples of food products.

This year, FDA, in cooperation with CDC, USDA and State and local organizations representing food, public health and agricultural interests, initiated the ALERT awareness program. It provides a uniform and consistent approach to food defense awareness at any point in the supply chain, from farm to retail. ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination at their facility. In 2003, FDA issued guidance on the security measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious or terrorist actions. FDA issued a general guidance entitled, Food Producers, Processors and Transporters: Food Security Preventive Measures, and a number of others.

Also in 2003, FDA began using the CARVER+Shock analytical tool to perform vulnerability assessments. FDA's approach has been to seek voluntary, mutually beneficial partnerships with various segments of the food industry. We have completed such cooperative assessments with segments of the regulated industry. The CARVER+Shock method to determine the vulnerability of individual food facilities to biological, chemical or radiological attack has resulted in the development of a software tool now available free of charge on the FDA's Web site. In conclusion, due to the enhancements being made by FDA and other agencies, and due to the close coordination between the Federal and State food safety, public health, law enforcement and intelligence-gathering agencies, the United States food defense system is stronger than ever before.

Although we have made progress, we are continuously working to improve our ability to prevent, detect and respond to terrorist threats. Thank you for the opportunity to discuss FDA's food defense activities. I would be happy to answer any questions you may have.

[The statement of Dr. Acheson follows:]

PREPARED STATEMENT OF DAVID ACHESON, M.D., F.R.C.P.

INTRODUCTION

Good afternoon, Chairman Langevin and Members of the Subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the Food and Drug Administration (FDA or the Agency) which is part of the Department of Health and Human Services (HHS or the Department). I am pleased to be here today with my colleagues from the Department of Homeland Security (DHS) and the Department of Agriculture (USDA). FDA appreciates the opportunity to discuss our food defense activities.

A great deal has been done in the past few years to enhance the safety and defense of the food supply in the United States. FDA has worked with other Federal, state, local, and tribal food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry to significantly strengthen the nation's food safety and defense system across the entire distribution chain, from farm to table, to better protect our food supply against deliberate and accidental threats. This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. The Office of Management and Budget and the relevant food safety agencies are collaborating on ways to most effectively address issues raised in the Government Accountability Office's designation of Federal oversight of food safety as a high-risk item in February 2007.

Food safety and food defense continue to be top priorities for this Administration. A terrorist attack on the food supply could have both severe public health and economic consequences, while damaging the public's confidence in the food we eat. The changes in food defense that we have been implementing in the last few years are fundamental enhancements.

The Commissioner of Food and Drugs, Dr. Andrew von Eschenbach, recently appointed me to the new position of Assistant Commissioner for Food Protection. My first priority in this position is to develop a new strategy for the integration of food safety and food defense that will address changes in the global food safety and food defense system, identify our most critical needs, and serve as a framework to help us address the challenges we face. The goal is to ensure a comprehensive and robust food safety and food defense program that is tailored to meet the risks posed by the types of foods we regulate and that focuses on prevention, ensures compliance with preventive controls, and rapidly responds when contaminated food or feed is detected, or when there is possible risk to humans or animals.

In my testimony today, I will first briefly describe HHS' role in counterterrorism activities. Then, I will discuss our collaborative activities with our food safety and defense partners. I will also describe some of FDA's food defense activities to enhance protection of the food supply.

HHS' ROLE IN FOOD-RELATED COUNTERTERRORISM ACTIVITIES

Under the President's National Response Plan, HHS leads Federal public health activities to ensure an integrated and focused national effort to anticipate and respond to biological weapons, emerging diseases, and other threats. HHS is also the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the State and local medical and public health response to mass casualty events.

FDA is the Federal agency that regulates all of the food we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA also is responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as veterinary drugs are safe and effective and that cosmetics are safe.

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. While performing our mission, we play a central and a leadership role in the nation's defense against terrorism. First, terrorists could use an FDA-regulated product, such as food, as a vehicle to introduce biological, chemical, or radiological agents into the U.S. stream of commerce. Second, FDA-regulated products, such as human drugs, vaccines, tissues, blood, blood products, and medical devices, as well as veterinary drugs, will play a central role in preventing or responding to human and/or animal health concerns created by an act of terrorism. It is HHS's goal, with FDA working closely with other HHS agencies and other Federal agencies, and with State, local, and tribal governments, industry, and the public, to reduce the likelihood that an FDA-regulated product could be used to poison or otherwise harm Americans. We also help ensure that the nation's public health system is prepared to deter a potential threat and is ready to respond to an act of terrorism.

By way of background, although FDA has the lead responsibility within HHS for ensuring the safety of food products, the Centers for Disease Control and Prevention (CDC) has an important complementary public health role. As the lead Federal agency for conducting disease surveillance, CDC monitors the occurrence of illness in the U.S. attributable to the entire food supply. The disease surveillance systems coordinated by CDC provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness.

COLLABORATION WITH FOOD SAFETY AND FOOD DEFENSE PARTNERS

In its food safety and defense efforts, FDA has many partners—Federal, State, local, and tribal agencies, academia, and industry. FDA is working closely with our Federal partners such as USDA, DHS, the Homeland Security Council at the White House, the Department of State, the Central Intelligence Agency (CIA), and the Federal Bureau of Investigation (FBI) to have the best information possible and to be prepared to act as needed. I also want to emphasize FDA's close working relationships with its sister public health agency, CDC, with Customs and Border Protection (CBP) in DHS, and with USDA's Food Safety and Inspection Service (FSIS). Some of our many Federal partners include USDA's Animal and Plant Health Inspection Service (APHIS), USDA's Foreign Agriculture Service, USDA's Agricultural Research Service, USDA's Food and Nutrition Service, Department of the Army Veterinary Services Activity, the Environmental Protection Agency (EPA), and the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau.

FDA's activities in a public health emergency are coordinated through the HHS Secretary's Operations Center. This relationship facilitates communication among all HHS Operating Divisions, the Department, and other Federal agencies and departments, including DHS. FDA also has worked closely with the Interagency Food Working Group of the White House Homeland Security Council on three initiatives—development of a national network of food laboratories, identification of vulnerabilities and subsequent mitigations for commodities of concern, and the development of a national incident management system. Further, FDA worked in partnership with EPA, USDA, DHS, and the Department of Defense (DoD) to describe general Federal roles and responsibilities for decontamination and disposal in response to animals, crop, and food incidents.

In addition, FDA's Office of Criminal Investigations (OCI) maintains professional relationships with domestic and foreign law enforcement agencies as well as the intelligence community so that it can receive and act on any information regarding the intentional contamination of FDA-regulated products. OCI has a specialized counterterrorism staff with the clearances, capabilities, and backgrounds to analyze information from law enforcement and intelligence community agencies and to assist those agencies in conducting terrorism-related threat assessments involving FDA-regulated products. OCI has agents assigned to selected FBI Terrorism Task Forces throughout the United States.

FDA is working closely with DHS and other Federal agencies to implement the President's Homeland Security Presidential Directives (HSPDs). The Secretary of DHS is responsible for coordinating the overall national effort to enhance the protection of the critical infrastructure and key resources of the nation, including food and agriculture defense. The President has issued HSPD-7, -8, and -9, which identify critical infrastructures, improve response planning, and establish a national policy to defend the agriculture and food systems against terrorist attacks, major disasters, and other emergencies. Among other things, HSPD-9 calls for the development of a National Veterinary Stockpile (NVS). FDA and CDC participate in NVS Steering Committee activities.

The HHS and USDA Secretaries or their designees exercise key responsibilities as food sector-specific agencies. DHS serves as the coordinator of the Food and Agriculture Sector within the Government Coordination Council (GCC). The GCC is charged with coordinating agriculture and food defense strategies, activities, and communication across government and between the government and the private sector partners.

Within the GCC, HHS and USDA serve as co-leads for the food sector, and USDA serves as the lead for the agriculture sector. The Food and Agriculture Sector is a public-private partnership that combines expertise from several Federal agencies (FDA, USDA, EPA, DoD, Department of Commerce, Department of the Interior, and the Department of Justice) as well as that of state, local, and tribal officials (representing agriculture, public health, and veterinary services), and the private sector (more than 100 trade associations and individual firms participate). As part of the HSPD-7 National Infrastructure Protection Plan (NIPP) development, FDA and USDA developed sector-specific plans with input from states and the private sector.

DHS recently released the sector specific plans. With the close working relationship of FDA and USDA and the other government and industry collaborators, the Food and Agriculture Sector activities to protect critical infrastructure have set the organizational and operational standard for other critical infrastructure sectors. DHS has applauded the Food and Agriculture Sector's organizational structure, consensus building, and the steps it has taken to improve food defense.

FDA also is working closely with our state partners to enhance food defense. For example, earlier this year, FDA conducted a Food Defense Surveillance Assignment for FDA and USDA personnel and participating state and local authorities to conduct food defense-related inspections and reconciliation examinations (to verify the accuracy of declarations in the shipping documents by comparing them with the actual products) and to collect and analyze samples of food products that may have an elevated risk for intentional contamination. The activities in this exercise were planned in cooperation and collaboration with USDA and a number of organizations representing state and local interests including the Association of American Feed Control Officials, Association of Food and Drug Officials, Association of Public Health Laboratories, Association of State and Territorial Health Officials, National Association of County and City Health Officials, National Association of Local Boards of Health, National Association of State Departments of Agriculture, National Environmental Health Association, and United States Animal Health Association. The purpose of this assignment was to deter intentional contamination of food through heightened and targeted preventive activities at various points in the food supply and to test the system for responding to an increased risk from food so that gaps in the system can be identified and addressed. This assignment enhanced multiple Federal, state, and local government agencies' preparedness for a future threat involving an FDA-regulated product. Since that time, FDA has issued a Protein Surveillance Assignment (PSA) to increase food defense awareness and assess the safety of the human food and animal feed supply following the finding of contaminated vegetable protein concentrate coming into the country from China. FDA continues to further integrate our food defense activities into our food safety work.

In addition, FDA and CDC have collaborated with the Council of Association Presidents to develop a nationwide food defense awareness training program. This Council, which consists of ten of the major state and local public health and regulatory professional associations, has an outreach capability to reach virtually all state and local public health officials. The training program, which began in March 2006 with a satellite downlink nationwide broadcast, has helped to raise food defense awareness at the local, state, and Federal levels. This program is now available for streaming download on the website of FDA's Center for Food Safety and Applied Nutrition.

Now, I would like to describe some of FDA's other food defense activities.

INDUSTRY GUIDANCE AND PREVENTIVE MEASURES

This year, FDA, in cooperation with CDC, USDA, and state and local organizations representing food, public health, and agriculture interests, initiated the ALERT awareness program. It provides a uniform and consistent approach to food defense awareness at any point in the supply chain, from farm to retail establishment.

ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination at their facility: They are:

- **A.** How do you ASSURE that the supplies and ingredients you use are from safe and secure sources?
- **L.** How do you LOOK after the security of the products and ingredients in your facility?
- **E.** What do you know about your EMPLOYEES and people coming in and out of your facility?
- **R.** Could you provide REPORTS about the security of your products while under your control?
- **T.** What do you do and who do you notify if you have a THREAT or issue at your facility, including suspicious behavior?

We have prepared ALERT materials in several languages and offer training on the ALERT system on our website that is suitable for state, local, and industry stakeholders.

In 2003, FDA issued guidance on the security measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. FDA issued a general guidance entitled "Food Producers, Processors, and Transporters: Food Security Preventive Measures." The guidance is designed as an aid to firms that produce, process, store, re-pack, re-label, distribute or transport food or food ingredients. In addition, we have issued

specific security guidance for the milk industry, for importers and filers, for retail food stores and food service establishments, and for cosmetic processors and transporters. During domestic inspections and import examinations, FDA's field personnel, as well as our state counterparts, continue to hand out and discuss these guidance documents.

To help reduce the risk of an attack on the food supply, FDA and our partners at USDA developed a web-based food security awareness training program entitled, "Protecting the Food Supply from Intentional Adulteration: An Introductory Training Session to Raise Awareness." The training is directed at individuals who play an important role in defending our nation's food from attack: Federal, state, local, and tribal food-industry regulators; school food authorities; and nutrition assistance program operators and administrators. Representatives from the food industry and individuals essential in responding to a food emergency due to an intentional attack—such as law enforcement, public health, and homeland security officials—also are encouraged to participate in the training program. The program is available to any interested individuals free of charge.

VULNERABILITY AND THREAT ASSESSMENTS

FDA's risk-based approach to food defense helps the Agency determine where to focus its resources. As part of its efforts to anticipate threats to the food supply, FDA has conducted extensive scientific vulnerability assessments of different categories of food, determining the most serious risks of intentional contamination with different biological or chemical agents during various stages of food production and distribution. FDA's initial assessment utilized an analytical framework called Operational Risk Management (ORM) that considers both the severity of the public health impact and the likelihood of such an event taking place. As part of this process, FDA has incorporated threat information received from the intelligence community.

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

The ORM approach provided a high-level view of foods and agents that were of greatest concern. Since the completion of the ORM, FDA has undertaken more in-depth vulnerability assessments of specific food commodities using a method called CARVER+Shock. This method uses processes adapted from techniques developed by DoD for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments are being used to develop technology interventions and countermeasures, identify research needs, and provide guidance to the private sector.

In 2003, FDA began using the CARVER+Shock analytical tool to perform vulnerability assessments to identify what an individual or group, intent on doing damage to the food and agriculture sector, could potentially do based on the person's or group's capability, intent, and past history. The CARVER+Shock methodology was modified under Homeland Security Council leadership for use in the food and agriculture sector by FDA, USDA, and DoD with coordination by DHS, CIA, and FBI. FDA's approach has been to seek voluntary, mutually beneficial partnerships with various segments of the food industry. We have completed such cooperative assessments with segments of the regulated industry that involve bottled water, fluid dairy products, juice products, and infant formula. FDA also has collaborated with USDA to provide assistance to the USDA Food and Nutrition Service on the use of this analytical tool on specific commodities in the school lunch program.

Since 2005, FDA has been part of a joint Federal initiative along with USDA, DHS, and the FBI called the Strategic Partnership Program on Agroterrorism (SPPA). The SPPA initiative is again using the CARVER+Shock tool and, through industry and state volunteers, is taking the tool to local venues. Local industry, FBI, DHS, FDA, USDA, State Departments of Health, and State Departments of Agriculture participate in these assessments. These assessments not only identify vulnerabilities in other food commodities but also build local infrastructure around food defense issues. The SPPA program will run for approximately two years and has a goal of completing 40–50 assessments during this period. The results from these assessments will be used to identify mitigation strategies and to focus food defense research questions. These assessments included yogurt, export grain, baby food—applesauce, frozen entrees/pizza, bottled water, fresh cut produce, apple juice, fluid milk processing, milk at retail, infant formula, flour, stadium retail food service, and animal feed.

Just last month, FDA released a new CARVER + Shock software tool to help processors, manufacturers, warehouseers, and transporters in the food industry utilize the CARVER+Shock method to determine the vulnerability of individual food facilities to biological, chemical, or radiological attack. The software tool is available free of charge on FDA's website.

LABORATORY ENHANCEMENTS

An additional step in enhancing our response capability is to improve our laboratory capacity. An important component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of food samples that could potentially be contaminated for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with USDA's FSIS to establish the Food Emergency Response Network (FERN) to include a substantial number of laboratories capable of analyzing foods for agents of concern. We are seeking to expand our capacity through agreements with other Federal and state laboratories. At present, the network includes 134 laboratories representing all 50 states and Puerto Rico. Participation continues to grow. Once it is operating at full capacity, FERN will encompass a nationwide network of Federal, state, and local laboratories working together to build the capacity to test the safety of thousands of food samples, thereby enhancing the nation's ability to swiftly respond to a terrorist attack.

Last fall, the FERN network proved to be a critical asset in the *E. coli* O157:H7 outbreak associated with fresh spinach. FERN expanded our laboratory capacity to handle the large number of food samples being tested. In addition, FERN analysts worked closely with CDC's Laboratory Response Network personnel to harmonize and approve a modified FERN method for detecting *E. coli* O157:H7 in spinach. This method allowed for substantially improved testing of spinach samples as it allowed for the detection of *E. coli* O157:H7 at lower levels. The FERN program also supplied the necessary reagents to the laboratories performing the testing.

More recently, on April 30, 2007, FDA issued a domestic vegetable PSA, in conjunction with our state and local regulatory partners, to test a variety of protein concentrates commonly found in the U.S. food and animal feed supply for the presence of melamine. Eight State FERN laboratories are involved in the analysis of the samples being collected.

IMPORTS

To manage the ever-increasing volume of imported food shipments, FDA utilizes risk-management strategies in the review of foods that are being imported or offered for import into the United States. Currently, working with information submitted either through CBP's electronic systems used for import entries or through FDA's Internet-based Prior Notice System Interface, FDA screens shipments electronically before they arrive in the U.S. to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. This electronic screening allows FDA to better determine how to deploy its limited physical inspection resources at the border on what appear to be higher-risk food shipments while allowing lower-risk shipments to be processed in accordance with traditional import procedures after the electronic screening. FDA is working to enhance its targeting ability by utilizing data from a much wider range of sources to inform our entry decisions.

These are just a few of the many activities we have underway to enhance protection of the food supply.

CONCLUSION

In conclusion, due to the enhancements being made by FDA and other agencies and due to the close coordination between the Federal and state food safety, public health, law enforcement, and intelligence-gathering agencies, the United States' food defense system is stronger than ever before. Although we have made progress, we are continuously working to improve our ability to prevent, detect, and respond to terrorist threats.

Thank you for this opportunity to discuss our food defense activities. I would be pleased to respond to any questions.

Mr. LANGEVIN. Thank you, Dr. Acheson. I appreciate your testimony.

The chair now recognizes Dr. Maczka to summarize your statement for 5 minutes.

**STATEMENT OF CAROL MACZKA, PH.D., ASSISTANT
ADMINISTRATOR, OFFICE OF FOOD DEFENSE AND
EMERGENCY RESPONSE, FOOD SAFETY INSPECTION
SERVICE, USDA**

Ms. MACZKA. Hello, Mr. Chairman and members of the sub-committee. I am pleased to appear before you today to discuss the issues of defending our food supply. I am Dr. Carol Maczka, Assistant Administrator for the Office of Food Defense and Emergency Response at USDA's Food Safety and Inspection Service, FSIS.

My office manages all food defense activities within FSIS and coordinates its activities through DHS, FDA, other Federal and State agencies as well as industry. FSIS is the public health agency in USDA responsible for ensuring that meat, poultry and egg products are safe, secure, wholesome and correctly labeled and packaged. Inspection personnel form the backbone of FSIS's food safety system. FSIS has more than 7,000 inspectors at Federal meat, poultry and egg products plants and import establishments. FSIS also has program investigators nationwide who conduct food safety and food defense investigations and enforcement. Consistent with Homeland Security Presidential Directive 9, the agency works with government and industry on improving awareness and warning systems, vulnerability assessments, mitigation strategies, response planning and recovery, and research and development. FSIS uses a comprehensive system to ensure that imported meat, poultry and egg products are safe and secure. It includes an initial determination of the equivalence of a country's inspection systems, on-site audits, and reinspection of all meat and poultry products coming into the United States. FSIS import inspectors ensure shipments are properly labeled and examined. Import surveillance offices conduct surveillance activities at ports and in commerce, and coordinate with other agencies, such as Customs and Border Protection. The agency also works with Customs' National Targeting Center to develop rule sets for targeting high-risk shipments entering the country, and is moving forward on a system that will allow the sharing of import tracking data by FSIS, Customs, and DHS.

FSIS and FDA co-chair the Food Emergency Response Network, FERN. It is a coordinated effort between Federal, State and local laboratories to provide ongoing surveillance, as well as detection and surge capacity for large-scale food-related events. The agency has developed specific procedures for sampling food, depending upon the threat level designated by DHS. The agency also engages in active surveillance through a series of food defense verification procedures that are performed daily in all FSIS-regulated facilities. The agency's Consumer Complaint Monitoring System and national surveillance system monitors food-related consumer complaints, which assist the agency in identifying potential attacks on the food supply. FSIS has conducted food defense awareness training nationwide with State and local inspectors, and in cooperation with FDA with Federal agencies. FSIS has created and distributed model Food Defense Plans for use by meat, poultry and egg products facilities, and import establishments. These plans identify the types of preventive steps that establishments might take to minimize food defense risks. The agency has also held numerous workshops and Web casts on Food Defense Plans to reach out to small

plants. In the area of responding to food emergencies, FSIS has developed State response plans and conducted six exercises with industry and State and Federal agencies to test emergency response procedures. A total of 15 exercises are planned, which will take into account 50 States. FSIS also continues to enhance its readiness for a possible outbreak of avian influenza. The agency has conducted an exercise and developed a testing protocol for detecting high path avian influenza in poultry meat.

In addition, FSIS has actively engaged its partners in developing pandemic plans. This spring, FSIS worked closely with FDA to respond to the discovery that some swine and poultry had been fed pet food scraps containing melamine. FSIS quickly ensured that swine and poultry were held under State quarantine or voluntarily by owners. A joint risk assessment concluded that the potential exposure to the public, even in the worst case scenario, was well below any level of public health concern. Subsequently, FSIS cleared animals on farms in question for inspection and processing.

In conclusion, Mr. Chairman and members of the subcommittee, I want to thank you for this opportunity to discuss FSIS's leadership role in protecting the food supply. We take pride in knowing that our Nation's food supply is among the safest in the world, but we also realize that it is vital to continue to improve our system. I am happy to answer any questions you may have.

[The statement of Ms. Maczka follows:]

PREPARED STATEMENT OF CAROL MACZKA, PH.D.

Mr. Chairman and Members of the Subcommittee, I am pleased to appear before you today to discuss the issue of defending our food supply system from farm to table. I am Dr. Carol Maczka, Assistant Administrator for the Office of Food Defense and Emergency Response at the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS).

The program area within FSIS that I lead is the Office of Food Defense and Emergency Response (OFDER), which manages all homeland security activities within FSIS. OFDER makes sure that policy makers, scientists, field staff and management are prepared to prevent and respond to any food security threat. OFDER develops and coordinates all FSIS activities to prevent, prepare for, respond to, and recover from non-routine emergencies resulting from intentional and non-intentional contamination affecting meat, poultry, and processed egg products. OFDER also serves as the agency's central office for homeland security issues and ensures coordination of its activities with the USDA Homeland Security Office, the Department of Homeland Security (DHS), the FDA, other Federal and State government agencies with food-related responsibilities, and industry.

FSIS is the public health agency in the USDA responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, secure, wholesome, and correctly labeled and packaged. FSIS is charged with administering and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act, and the regulations that implement these laws. FSIS also ensures compliance with the Humane Methods of Slaughter Act, which requires that all livestock be handled and slaughtered in a humane manner. The Agency is responsible for determining equivalence to Federal standards at the State level and among our foreign trading partners.

FSIS plays a key role in the nation's food safety system, which also includes agencies such as the Department of Health and Human Services' Food and Drug Administration as well as state, tribal and local food safety partners. FSIS works closely with these agencies and other partners to share information and protect public health.

Our inspection program personnel form the backbone of FSIS' public health infrastructure in laboratories, plants, and import houses throughout the country. FSIS has more than 7,600 inspectors and veterinarians in approximately 6,000 Federal meat, poultry, and processed egg product plants, and at approximately 130 import

establishments every day to prevent, detect, and respond to food-related emergencies. In fiscal year 2006, inspection program personnel performed antemortem and postmortem inspection procedures to ensure public health requirements were met in the processing of more than 46 billion pounds of livestock carcasses, almost 57 billion pounds of poultry carcasses, and about 4.4 billion pounds of liquid egg products.

In fiscal year 2006, FSIS inspection program personnel conducted more than eight million procedures to verify that establishments met food safety and wholesomeness requirements. In addition, during fiscal year 2006, approximately 3.9 billion pounds of meat and poultry and about 5.9 million pounds of egg products were presented for import inspection at U.S. ports and borders. FSIS also has Program Investigators nationwide who conduct food safety, food defense, and outbreak investigations and enforcements.

The Agency also engages in active surveillance through a series of food defense verification procedures performed daily in all FSIS-regulated facilities. With a strong food safety verification system in place, FSIS has been focusing on fortifying existing programs with a greater emphasis on food defense and improving internal and external lines of communication, including the integration of the food defense system databases with the larger public health data infrastructure.

Homeland Security Presidential Directives most relevant to our work are:

- HSPD-5: Management of Domestic Incidents;
- HSPD-7: Critical Infrastructure Identification, Prioritization, and Protection;
- HSPD-8: National Preparedness; and especially
- HSPD-9: Defense of U.S. Agriculture and Food.

HSPD-9 was signed on January 30, 2004, and establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. It directs the Secretary of Agriculture to work with other Federal department and Agency leaders on improving awareness and warning systems, vulnerability assessments, mitigation strategies, response planning and recovery, outreach and professional development, and research and development.

FSIS uses a comprehensive system to ensure that imported meat, poultry, and processed egg products are safe and secure. It includes a thorough analysis of each country's food laws and inspection systems to determine initial equivalence; on-site audits of each country's food safety system to ensure equivalence is maintained; and port-of-entry inspection on all meat, poultry, and processed egg products coming into the United States. It is enhanced by FSIS' Import Surveillance Liaison Officers, who conduct a broader range of surveillance activities at import facilities and in commerce, and serve as liaisons to improve coordination with other agencies like U.S. Customs and Border Protection (CBP).

Every day, FSIS personnel are at U.S. ports, inspecting shipments as they come in and pulling out samples. The Agency focuses on stopping illegal shipments at their point of entry. When meat and poultry imports enter the United States, FSIS import inspectors ensure that each shipment is properly certified, examine each lot for general condition and labeling, and conduct reinspection as directed by a centralized computer system, the Automated Import Information System. Using protocols developed by FSIS with USDA's Office of Inspector General and the Animal and Plant Health Inspection Service (APHIS), 111,000 pounds of ineligible product were detected and 1,766,050 pounds of product detained in fiscal year 2006 out of 9 billion pounds of meat and poultry and about 5.9 million pounds of egg products presented for import inspection at U.S. ports and borders.

The Agency also worked with CBP's National Targeting Center to develop rules for targeting high-risk, FSIS-regulated shipments entering the country. This effort included a two month pilot program in 2006 in which a total of 3,229 shipments were screened at two ports using the rule sets. The Agency is also moving forward on a system which will allow the sharing of import tracking data by FSIS, CPB, and DHS to further strengthen our ability to ensure the safety and security of imported meat, poultry and processed egg products through better and more rapid access to data on imports.

FSIS is currently working with other Federal government agencies to integrate its International Trade Data Systems (ITDS) design requirements with the ePermits system developed by Animal and Plant Health Inspection Service (APHIS) and the larger Automated Commercial Environment under development by US Customs and Border Protection. Ultimately, these efforts would result in a Federal-government wide linkage of all inspection and border control data systems, meeting FSIS' regulatory needs along with those of sister agencies.

FSIS and FDA are leading the development of the Food Emergency Response Network, a joint effort of national, State, and local laboratories to provide ongoing surveillance and monitoring of food and to promptly respond to a foodborne illness out-

break or intentional contamination that targets the Nation's food supply. In addition, FERN is a critical source of data for the FSIS public health data infrastructure.

FERN enables FSIS to utilize State and local laboratories in handling the numerous samples required to be tested in the event of an attack on the food supply, a natural outbreak, or even a hoax, involving a meat, poultry, or egg product. It is vital for the Agency to respond rapidly to such emergencies to not only protect the public's health, but also to ensure public confidence in the safety of the food supply. The first line of this rapid response is the laboratories, which must be provided with training, methodology, and state-of-the-art laboratory equipment.

FERN provides ongoing surveillance, as well as detection and surge capacity for large-scale food-related events. It enables not only the sharing of standardized methodologies and proficiency testing but also a secure electronic reporting system for lab results. Four Federal Labs and 18 existing State labs are currently under FSIS cooperative agreements. Additionally, FSIS has cooperative agreements targeting total of 25 State labs geographically located across the country. The FERN laboratories will eventually be proficient to screen for the same threat agents as Federal labs, some with capability to do confirmation testing. FSIS primarily focuses on microbiological agents with our partners at FDA focusing on chemical and radiological agents.

Another example of interagency coordination and collaboration by FSIS is participation in the integrated consortium of lab networks developed by DHS. This consortium ensures coordination among Federal and State partners focused on both food and agriculture. The consortium ensures consistency of methods development, reporting of lab results and the sharing of lab results among all Federal and State partners.

The Agency has developed specific procedures on monitoring and sampling to be taken depending on the threat level as determined by the DHS. The appropriate testing is based on vulnerability or risk-based assessments for selected domestic and imported food products, which allows the Agency to rank food products and potential contaminating agents in order of highest concern. The Agency's enhanced Consumer Complaint Monitoring System (CCMS), a national surveillance system that monitors food-related consumer complaints which will eventually be integrated with other data systems, also assists in the Agency's efforts to track potential attacks on the food supply.

FSIS' comprehensive and ongoing training and education efforts ensure that every FSIS employee fully understands their role in preventing, or responding to, an attack on the food supply. Food defense awareness training is also conducted at locations nationwide with State and local inspectors and in cooperation with other Federal agencies. Training courses were also developed in conjunction with the FDA; USDA's Food and Nutrition Services; and the Department of Transportation (in development) to focus specifically on food defense for each agency's respective workforce.

FSIS has created and distributed model food security plans that meat, poultry and processed egg products facilities and import establishments can use to develop and implement a Food Defense Plan. These plans identify the types of preventive steps that establishments might take to minimize food security risks for products under their control. A simplified version of guidance on food defense plans was developed in consultation with industry trade groups. This guidance provides an easy three-step process which will result in a completed food defense plan. The Agency has also held numerous workshops and Webcasts on Food Defense Plans to reach out to as many small and very small plant owners and operators as possible; Webcasts specifically targeted to State officials; efforts to reach various targeted audiences, such as Spanish speakers and various industry and trade associations.

As it is widely understood that the response to most large-scale food emergencies will be initiated at the State level, FSIS and FDA have worked with the National Association of State Departments of Agriculture (NASDA) to develop, test, and implement an emergency response template.

FSIS continues to enhance readiness for a possible outbreak of avian influenza. The agency's goal is to ensure that all appropriate preparations are being made for the potential spread of the H5N1 strain of the virus to the United States, whether in birds or in humans. FSIS has also carried out a tabletop exercise on avian influenza with other Federal and State agencies, as well as industry and consumer groups.

USDA is playing many important roles in this effort. The Department's four-part approach to combating avian influenza includes limiting the spread of the virus overseas through international outreach. Second is educating the American public through a proactive campaign to inform without causing alarm. Third is USDA's

and the Department of Interior's aggressive surveillance program in partnership with States, which includes wild birds, live bird markets, backyard flocks and thanks to the cooperation of industry—testing of commercial flocks. The fourth aspect is to practice executing our response plan. As you may know, USDA has a long and successful history of dealing with highly pathogenic avian influenza.

It should be noted, of course, that detection in birds does not signal the start of a human pandemic. This virus is not easily transmitted from person to person. Most human illnesses that we've seen overseas have resulted from direct contact with sick or dead birds. No human illnesses have been attributed to properly handled and cooked poultry. This is another area where FSIS and USDA have been actively engaged with our partners in government, industry and the consumer community to make sure concerns related to any possible pandemic are addressed before that ever happens.

As part of its coordinated response plan with the Animal and Plant Health Inspection Service (APHIS), the Agency has developed a product testing protocol for detecting Highly Pathogenic Avian Influenza in poultry meat. It should be stressed, however, that cooking poultry to an internal temperature of 165 degrees kills all viruses and all other foodborne pathogens, including avian influenza.

In fiscal year 2006, FSIS' activities better prepared the Agency and its stakeholders to detect, respond, and recover from food-related emergencies. In the area of food defense, FSIS conducted about 1,200,000 daily food defense verification procedures in FSIS-regulated and State-inspected facilities. The Agency also conducted six tabletop exercises with stakeholders and other local, State, and Federal agencies to test and validate standard operating procedures and directives for responding to non-routine (emergency) incidents. A total of 15 tabletop exercises are planned, which will take into account all 50 states.

In April and May of this year, FSIS worked together closely with FDA to respond to the discovery that some swine and poultry in the human food supply chain had been fed animal feed supplemented with pet food scraps that contained melamine and related compounds. FSIS and FDA alerted the public and investigated the source and extent of the situation. As soon as the situation arose, we also ensured that swine and poultry on farms known to have received or suspected of receiving contaminated feed that had tested positive for melamine and melamine-related compounds were held under State quarantine or voluntarily by the owners. After a risk assessment conducted by scientists from FSIS and FDA, in consultation with scientists from CDC, the Environmental Protection Agency and DHS, concluded the potential exposure to the public, even in a highly unlikely worst-case scenario, was 250 times lower than the dose considered safe and therefore well below any level of public health concern, FSIS cleared the animals in question for inspection and processing.

FSIS has also developed and implemented a series of FSIS directives (two of which have been updated thus far in fiscal year 2007) for each of the agency's eight program areas that prescribe how protective measures defined by Homeland Security Presidential Directive 3, Homeland Security Advisory System are to be implemented. Directive 3 established a threat advisory system to effectively communicate the level of risk of a terrorist attack to the American people. It prescribes that agencies develop appropriate "Protective Measures" in response to each of the five threat levels established. The measures developed by FSIS include active surveillance through a series of food defense verification procedures performed daily in all FSIS-regulated facilities, including import inspection facilities and in-distribution facilities. Results of the verification procedures are reported to and are analyzed by the agency. The results of the analysis direct outreach and guidance initiatives and countermeasures development.

The Office of Management and Budget and the relevant food safety agencies are collaborating on ways to most effectively address issues raised in GAO's designation of Federal Oversight of Food Safety as a high-risk item in February 2007.

USDA, the Department of Health and Human Services, and DHS are working together to create a comprehensive food and agriculture policy that will improve the government's ability to respond to dangers to the food supply. For fiscal year 2008, the Agency has proposed a budget which includes \$31 million to further improve FSIS' ability to detect and respond to intentional or accidental contamination of the food supply.

While food defense is critical to our work, another threat to the food supply is naturally-occurring pathogens. Our work identifying and limiting pathogens in the food supply will also help mitigate vulnerabilities in food defense.

In conclusion, Mr. Chairman and all Members of the Subcommittee, I want to thank you again for this opportunity to explain the vital role played by USDA and FSIS in protecting the nation's food supply. We take pride in knowing that our na-

tion's food safety and food defense system for meat, poultry, and processed egg products is the best and safest in the world. But we also realize that it is vital not to stand still but instead to continue improving our nation's food safety and food defense systems. We take this stand not only as public health professionals but also as everyday Americans who ourselves rely on the results of what we do. I am happy to answer any questions you may have.

FSIS FOOD Defense Mission and Initiatives

- To prevent, prepared for, respond to, and recover from an intentional attack on the food supply and large scale food-related emergencies.
- Consistent with HSPDs 5,7, and 9.

Outreach and training to prepared stakeholders to protect the food supply.	-Security guidance materials for food processors, transporters, & distributors. -Self assessment and food defense plan tools for industry, including training. -Food defense awareness training for employees, industry, and other Federal and State government agencies.
Assessing Food System vulnerabilities for developing countermeasures.	-Ten FSIS vulnerability assessments conducted-identified products, agents, and nodes of highest concern, as well as countermeasures. -Participate in Strategic Partnership Program on Agroterrorism (DHS, FBI, FDA) to conduct vulnerability assessments (includes States & industry) -Workshops for industry, G8 task force, & APEC economies on methodologies to conduct vulnerability assessments to protect imports and exports. Collaborated with FDA and State Department on the workshops for G8 countries and APEC economies

FSIS Food Defense Initiatives

Developing countermeasures to mitigate vulnerabilities.	-Coordinating with ARS, CSREES, DHS on filling research needs relating to critical food defense data gaps (e.g., detection methods, feasibility, and agent characterization studies). -Working directly with industry and through DHS's Sector Coordinating Council to develop countermeasures.
Conducting surveillance to identify attack on the food supply.	-Daily testing of samples for specified threat agents. -Homeland security directives—direct personnel on what food defense verification procedures to perform on a daily basis in federally-inspected establishments and in distribution. working with industry to harden infrastructure. -Targeting illegal & high-risk shipments with Customs and Border Protection.
Managing food defense & food safety emergencies.	-Created the Emergency Management Committee & a Non Routine Incident Management System for managing & tracking non-routine incidents. -Conduct food defense exercises with States, industry, consumer groups, & other federal agencies (eg; FBI, DHS, FDA). 6 conducted to date, 4 planned in FY07, and 5 in FY08. Conducted and A1 outbreak exercise in FY 06 and planning a Pandemic exercise in FY 07. -Guidance for industry on the disposal of food products & facility decontamination. -Template for developing State response plans for food emergencies. -Provide training on Incident Command System and ESF 11 for key personnel.

FSIS Food Defense Initiatives—Continued

Ensuring Agency Continuity of Operations.	<ul style="list-style-type: none"> -Conduct agency-wide COOP exercises. -SOPs to ensure critical essential functions are maintained. -Established alternative relocation sites, designated essential personnel, and identified vital records. Developed All-Hazards, Avian Influenza, & Human Pandemic plans.
---	---

Mr. LANGEVIN. Thank you for your testimony, Dr. Maczka.

The chair now recognizes Dr. McGinn for 5 minutes to summarize your statement.

STATEMENT OF TOM MCGINN, D.V.M., DIRECTOR, AGRICULTURE AND VETERINARY DEFENSE, OFFICE OF HEALTH AFFAIRS, DHS

Dr. MCGINN. Thank you, Mr. Chairman, and members of the subcommittee. I appreciate the opportunity to talk to you today about the safety of our national food system. My name is Dr. Tom McGinn, and I serve as the Director of Food, Agriculture and Veterinary Defense within the Department of Homeland Security's Office of Health Affairs, which is led by the Acting Assistant Secretary and Chief Medical Officer, Dr. Jeff Runge. My job is to be the primary point of contact within DHS to synchronize our food, agriculture and veterinary assets. One of our responsibilities within the Office of Health Affairs is to coordinate 30 programs within DHS that address some aspect of food, agriculture and veterinary defense. I am pleased to testify today with Dr. Acheson, with Carol and with Dan Baldwin from Customs and Borders as well. These are valued friends and colleagues.

FDA and USDA represent the sector-specific agencies with the subject matter expertise and the legal authority for the protection of the food in our country. Together with the private sector and our State and local and academic partners, who you will hear from later today, we all provide food defense for the United States. Together we cultivate a complex, effective set of resources that are becoming better known to each of us and better able to be integrated into a National Incident Management System.

I will highlight the following three areas: one, the contribution of DHS to food defense; two, the Office of Health Affairs' strategic plan to further implement HSPD-9; and three, the way forward for food defense.

DHS's contribution to food defense: Food defense includes activities beyond our borders and across our domestic food supply chain, as well as in our homes. It involves everyone, from the local ice cream shop to the most capable sector-specific agencies of the Department of Health and Human Services and the U.S. Department of Agriculture. The large majority of incidences involving food issues are handled at the private, State and local level, with the leadership of HHS and USDA. DHS makes its resources available to instances involving food when requested by Federal agencies or the President or when multi-agency involvement requires the integration of Federal, State and local resources to preserve the security of our Nation. DHS also makes its resources available to its

Federal partners and to its Centers of Excellence to do research in the area of threat. It makes its resources available to States to build surge capacity to reduce the risk to the food supply, and to train and exercise food defense systems.

Secretary Chertoff created the Office of Health Affairs as part of a reorganization on January 11th, 2007. Its mission is to protect the health and security of the American people, and the coordination and collaboration of the DHS components with Federal, State and local partners and the private sector. With specific reference to agroterrorism, the Secretary appointed the chief medical officer to be the official accountable for the implementation of the Department's responsibilities for veterinary, food and ag security, and it includes the coordination of the Department's responsibilities for the implementation of HSPD-9, the defense of U.S. agriculture and food.

Number two, in the area of post-harvest preparedness and HSPD-9, the enormity and complexity of the food sector poses substantial challenges to food defense and critical infrastructure. These challenges include overlapping roles and responsibilities among Federal departments and agencies, and the Office of Management and Budget, but the relevant food agencies are collaborating to address these issues. DHS brings unique and complementary tools and expertise to bear, and such tools as the National Security Risk Assessments and the integration of surveillance. The Department of Agriculture and FDA provides tools and expertise in the area of food and agricultural critical infrastructures. The Food and Drug Administration and USDA work closely with Customs and Border Patrol on a day-to-day basis in imported food inspections and laboratory analysis.

As a highlight, I would like to mention that these agencies worked well together during the recent melamine incident, which is consistent with the intention of HSPD-9. HSPD-9 was issued to establish a national policy to defend the Nation's food and agricultural systems against terrorist attacks, major disasters and emergencies. DHS has 17 of the 21 tasks designated to us, and we lead or co-lead in 12 of these tasks. The landscape of food safety and defense is changing. Evolving risks include a tremendous growth of imported food markets.

Federal and State regulatory programs, as well as laboratories, are currently the backbone of our Nation's food safety network. Threats to the food supply typically cross State borders and have national implications. We need to be diligent in coordinating planning involving the key stakeholders, importantly including State and local authorities and the private sector. Realistic exercises help to develop the relationships, plans and preemptive tools we need to prevent, mitigate and respond to food system events. An alignment of resources at the interagency level with local, State and national governments, with strong collaboration with the private sector is, or needs to be, continually strengthened.

Number three, the way forward: We are focusing our efforts more completely on resilience within the food chain. DHS is currently studying key components of the Nation's food chain in partnership with the FBI, USDA and FDA in programs with the industries and the States to better understand the vulnerabilities of 50 major food

and agricultural commodities. The challenge is sharing this information in an appropriate manner with all relevant stakeholders. FDA has a great example of a Web-based tool as a first step. Another tremendous first step—

Mr. LANGEVIN. Dr. McGinn, if you could summarize your statement. We are way over the 5 minutes.

Dr. MCGINN. Okay. Thank you. In summary, a more resilient food infrastructure is a most important way to build resilient communities. The recent Mayor of Gulfport said that a simple way of building resiliency is the restoration of a favorite restaurant. It gives a place for his people to rest in a tragedy, such as in recent hurricanes, and spend a few minutes outside of a familiar place with familiar food, and finding confidence that the rest of his community will be restored. He clearly understood that food system resilience is part of community resilience.

Mr. Chairman, I will stop with those comments, and I will be happy to entertain any questions as we go forward. Thank you.

[The statement of Dr. McGinn follows:]

PREPARED STATEMENT FOR DR. TOM MCGINN, DVM

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to talk with you about the safety, and in particular the post-harvest defense, of our food supply. The United States has not only the most bountiful food production capacity in the world, but it is among the safest as well. Safety is not an inherent quality of U.S. food production—it takes continual dedication to ensure the safety and security of the food supply. I appreciate the chance to highlight the contributions of the Department of Homeland Security (DHS) to Food, Agriculture and Veterinary (FAV) Defense. I will also discuss the role that DHS played in the recent pet food contamination incident as demonstration of the diversity of DHS programs. Finally, I will discuss the Office of Health Affairs' (OHA) strategic plan to further implement Homeland Security Presidential Directive 9 (HSPD-9) along with state and local governments and the private sector. Importantly, managing any event will not be a federal issue alone. Success in the realm of food safety and defense will depend upon coordination among states, local and private entities, and national programs that utilize our Nation's resources effectively.

DHS OFFICE OF HEALTH AFFAIRS (OHA)

Secretary Chertoff created the Office of Health Affairs as part of the departmental reorganization on January 18, 2007 in response to P.L. 109-295 §516. OHA was created to protect the health and security of the American people in coordination and collaboration with other DHS components, federal, state and local partners, and the private sector. Responsibilities and activities of OHA do not duplicate or supplant activities currently being provided by other components of DHS or the departments and agencies of the Executive Branch. The Chief Medical Officer (CMO) has the following responsibilities:

- To serve as the Secretary's principal medical and veterinary authority for DHS;
- To coordinate DHS biodefense activities, to include policy, planning, strategy, requirements, operational programs and metrics;
- To ensure internal/external coordination of DHS' medical [including veterinary] preparedness and response activities;
- To serve as the primary DHS point of contact for federal/state/local/tribal governments and the private sector on medical [including veterinary] and public health issues; and
- To discharge DHS' responsibilities under Project BioShield, in coordination with the Science and Technology (S&T) Directorate.

The Department serves as the integrator of federal, state and local resources that are needed to preserve the security of the Nation. With specific reference to agroterrorism preparedness, in a memo dated March 28, 2007, Secretary Chertoff designated OHA's Assistant Secretary and Chief Medical Officer as the DHS official accountable "for the implementation of the Department's responsibilities of veterinary, food and agriculture security. . . [who] will also coordinate the Department's

responsibilities for implementation of Homeland Security Presidential Directive 9, Defense of the United States Agriculture and Food.”

Within OHA, I serve as the Director of Food, Agriculture and Veterinary (FAV) Defense. FAV goals are to ensure that the food and agriculture sectors are actualized as Critical Infrastructure; understand and strengthen public confidence in food protection through assessment and enhancement; ensure critical stakeholders are functionally aligned; and assist all DHS Food, Agriculture and Veterinary programs in attaining operational capability. OHA/FAV Defense activities are working to foster efficiency and effectiveness across DHS regarding food, agricultural and veterinary defense.

HSPD-9, Defense of United States Agriculture and Food, was issued to establish a national policy to defend the nation’s agriculture and food systems against terrorist attacks, major disasters, and other emergencies. HSPD-7, *Critical Infrastructure Identification, Prioritization and Protection*, identifies DHS as “responsible for coordinating the overall national effort to enhance the protection of the critical infrastructure and key resources of the United States,” and recognizes the DHS Secretary as “the principal federal official to lead, integrate and coordinate implementation of efforts.” HSPD-9 assigns to the DHS Secretary tasks in this area that are specific to the defense of food and agriculture. These tasks include mitigation of vulnerabilities in food, agriculture and water systems, as well as developing robust biological threat awareness capacity. Of the 21 tasks for which DHS has been designated some degree of responsibility, we have the lead for 12. Those 12 activities fall under the following five pillars:

- (1) *Awareness and Warning*—Includes intelligence operations and biological threat assessment and analysis activities
- (2) *Vulnerability Assessments*—DHS, in coordination with USDA and HHS, is to conduct comprehensive studies to determine the nation’s vulnerability to a wide variety of foodborne pathogens and adulterants
- (3) *Mitigation Strategies*—DHS will aid in prioritizing, developing and implementing, as appropriate, mitigation strategies and shall build upon existing efforts to expand development of screening and inspection procedures at the borders
- (4) *Response Planning & Recovery*—Includes activities involving local response capabilities and coordinated response planning
- (5) *Outreach and Development*—Includes information sharing and analysis mechanisms, specialized training in agriculture and food protection, continued development and research for countermeasures against introduction of animal/plant diseases, plans to provide biocontainment labs for researching capabilities and establishing university-based Centers of Excellence.

All five pillars, in fact, are being undertaken across all sectors, in collaboration with all Federal agencies.

THE PET FOOD CONTAMINATION INCIDENT

Approximately sixty percent of American households contain pets. Early this year, the U.S. government became aware that high levels of low-grade melamine, which contained not just pure melamine, but additional melamine analogues, were intentionally added to products labeled as “wheat gluten” and “rice protein concentrate.” These products were imported from China into the U.S. and subsequently incorporated into many pet food products. In addition, certain salvaged pet food products that were melamine contaminated were unknowingly fed to some food producing animals. This combination of contaminants was not detected until it was learned that certain pet foods were sickening and killing cats and dogs. In addition to the illness and death burden, many lessons observed were highlighted by this incident are also being addressed.

Contaminated “wheat gluten” and “rice protein concentrate” were imported into the United States in the fall of 2006. Menu Foods, the producer and distributor of many brands of pet foods nationally and internationally, became aware of reports of illness and death in pets and began recalling certain brands of pet food in March 2007. Chinese sources admitted to intentionally adding melamine to increase nitrogen content in rice products and wheat gluten, which falsely elevated protein measurements. In addition to pet food products, melamine-laced feedstuffs were also fed to production animals in the U.S. These animals could have entered the human food chain. Compounds fed to food-producing animals may, through tissue adulterant residues, make it into the human food chain. An interagency risk assessment considered the risk to humans from melamine-contaminated products fed to food producing animals and concluded that this was very unlikely to cause harm to humans.

While more research is needed on the exact cause of the illnesses in cats and dogs, this melamine event demonstrated a potentially significant vulnerability to the human food supply due to the global nature of our food and agricultural systems.

COLLABORATION AMONG DHS ENTITIES

OHA worked to organize the Department's various components soon after the pet food contamination incident began. Initial meetings generated a comprehensive list of capabilities that each component could leverage to respond to this incident. It also identified methods of sharing timely information. As the situation evolved and the true scope emerged, an Interagency Working Group (IAG) met at the DHS National Operations Center. The IAG established the process for a national-level Situational Report (SITREP), as well as the corresponding flow of information. OHA took the lead in forming the IAG and worked with the Operations Directorate to produce and disseminate the SITREP.

Heretofore, DHS had not established a formalized process for reporting on issues such as a food contamination event. The National Biosurveillance Group (NBSG), composed of the National Biosurveillance Integration System (NBIS) member Federal agencies, developed and implemented a formalized process. This was accomplished by coordinating information flow among DHS, the components and headquarters of Department of Health and Human Services (DHHS), and USDA, as well as other affected DHS entities. The efforts of other DHS offices assisted in the coordinated response. These efforts are summarized below:

Customs and Border Protection (CBP)—CBP used its FDA-coordinated, automated systems and laboratory analytic capabilities to identify, target, sample and test additional incoming shipments of wheat, corn, and rice gluteins for the presence of melamine. During the enforcement operation, CBP tested samples of products from 23 countries shipped by suppliers and producers that account for over 59 percent of the imported volume of the merchandise in the previous 12-month period. That contributed to a greater degree of assurance that products coming into the U.S. were free of the contamination and that the melamine issue was isolated to a few Chinese producers.

National Protection & Programs Directorate (NPPD)—The Homeland Infrastructure Threat & Risk Analysis Center (HITRAC) is a shared program between NPPD and the Office of Intelligence and Analysis. HITRAC monitored intelligence and related infrastructure information from open sources and classified reporting. HITRAC shared this information with the members of the IAG for use in their analysis.

Science and Technology (S&T)—The S&T National Science, Technology and Threat Awareness Reachback (NSTTAR) service provided real time, technical information and analysis reachback capability. This was provided to the homeland security community for anticipating, evaluating and responding to foodborne threats. NSTTAR, the Biodefense Knowledge Center, the Chemical Security Analysis Center located at the US Army facility in Edgewood, MD and the Department Of Energy Field Intelligence Establishment (intelligence division) were all called upon for technical and threat support relating to melamine toxicity, contamination paths, effects in food chains, production sites and the potential for intentional misuse. The National Center for Food Protection & Defense, one of the DHS Centers of Excellence, prepared and provided a continuous assessment of the situation. The assessment included potential impact on the domestic food chain, international trade, and public confidence. It also addressed the incident relative to the overall trade situation with China and an on-going timeline of events.

COLLABORATION AMONG FEDERAL ENTITIES

As a result of the pet food contamination incident, DHS/OHA fostered senior level engagement to enhance partnerships in homeland security. DHS brought unique and complementary tools and expertise to bear, such as tools for national security risk assessment and investment. Other agencies, such as the Department of Agriculture and the Food and Drug Administration, provided tools and expertise regarding the Food and Agriculture Critical Infrastructure. The Food and Drug Administration also worked closely with CBP on a day-to-day basis in food inspections and laboratory analysis. In addition, OMB and the relevant food safety agencies are collaborating on ways to most effectively address issues raised in GAO's designation of Federal Oversight of Food Safety as a high-risk item in February 2007.

Another point of synergy was the overall public communication effort. The huge volume of information requests generated by governmental and private sources was handled through interagency press conferences. During one such call, nearly 200 members of the press participated. The government presented a common access point for information—questions, concerns, and suggestions.

AREAS OF FUTURE ENGAGEMENT

In a recent report by the DHS Office of the Inspector General (OIG), four main limitations in the Department's food defense and security efforts were identified. First, DHS must improve internal coordination. Second, DHS needs to engage its public and private food sector partners more effectively. Third, DHS could do more to prioritize resources and activities based on risk. Finally, DHS must fully discharge its food sector responsibilities.

In response to the OIG report, our Chief Medical Officer has the responsibility for food and agriculture efforts including:

- Working to ensure collaboration with the Food Information Sharing and Analysis Center (ISAC)
 - Seeking improvement in DHS' relationship with food sector partners
 - Expanding national infrastructure coordinating center outreach efforts
 - Evaluating the feasibility of providing financial support and/or facilitating the detailing of state or local government and private sector representatives to OHA and NPPD
 - Developing and maintaining a DHS report on sector research and development initiatives
 - Expediting the review of existing food sector assessments
 - Expanding food sector modeling
 - Evaluating the integration of additional federal foodborne illness reporting, surveillance and detection systems
 - Continuing to develop and disseminate information about food subsystem specific operational protective measures and best practices with FDA and USDA
- Areas the OIG identified that are still in need of attention include:
- Developing a grant process to support non-urban, multi-jurisdictional preparedness
 - Working with DHHS and USDA to prepare integrated food defense budget for fiscal year 2009
 - Considering collaboration of food-specific criteria and guidelines for Customs—Trade Partnership Against Terrorism with food industry with USDA/FDA
 - Studying the integration of food defense awareness into transportation security and considering additional research to improve the security of food in transit
 - Expanding efforts to sponsor food contamination event exercises with an emphasis on exercises spanning multiple state and local jurisdictions

COLLABORATION WITH THE PUBLIC AND PRIVATE SECTORS

The landscape of food safety and defense is changing. Evolving risks include the tremendous growth of imported food markets from countries that have limited regulatory oversight. Federal and state regulatory programs and laboratories are currently the backbone of the nation's food safety network. However, threats to the food supply typically cross state borders and have national implications.

A concerted communication strategy for these types of operations is essential, and falls within the purview of DHS. Additionally, information flow is typically much faster than anticipated, frequently outpaces the ability to analyze and interpret, and comes in from various sources. Frequently, information is made available to the private sector before the government is informed. DHS is building the mechanism through its National Operations Center (NOC), the National Biosurveillance Integration Center (NBIC) and the National Infrastructure Coordination Center (NICC) to gather and analyze such information in real time. DHS is forming partnerships with members of the food sector and its academic centers of excellence to improve information sharing and mutual awareness.

CONCLUSION

The food chain infrastructure is rapidly globalizing, which demands a commensurate improvement in our preparedness posture. This globalization, manifested by both the vertical integration of certain commodity groups such as poultry and grain, and the seemingly opposite phenomenon of 'subcontracting' various pieces of common production processes (as in the pet food contamination incident), outlines why it is so important that our planning efforts be comprehensive and all-inclusive of intelligence, disciplined information sharing with states and local governments and the private sector, coordinated incident management, and maintenance of public confidence.

Mr. Chairman, thank you for the opportunity to address the Subcommittee. I look forward to continuing my working relationship with you, and I am happy to address any questions or concerns that may arise regarding this topic.

Mr. LANGEVIN. Thank you, Dr. McGinn.

The chair now recognizes Mr. Baldwin, to summarize your statement for 5 minutes.

**STATEMENT OF DAN BALDWIN, ASSISTANT COMMISSIONER,
OFFICE OF INTERNATIONAL TRADE, U.S. CUSTOMS AND
BORDER PATROL**

Mr. BALDWIN. Thank you, Mr. Chairman, members of the subcommittee. I am pleased to appear before you today to discuss the actions we are taking at Customs and Border Protection to ensure the safety of imported food.

My name is Daniel Baldwin, and I am the Assistant Commissioner in the Office of International Trade at U.S. Customs and Border Protection. My office holds the responsibility of formulating CBP's trade policy, developing programs and enforcing the U.S. import laws. The food and agriculture industry contributes significantly to the United States' economy. And as the value and complexity of our food imports continues to grow, CBP recognizes the challenges we face to maintain a safe and secure food supply.

CBP has taken great strides towards securing America's borders, including the protection of our food supply, and the economic health of American agriculture. Since September 11th, 2001, CBP's primary mission has to be to secure the Nation's borders from terrorists and terrorist weapons, while facilitating the flow of legitimate travel and trade. In support of this mission, CBP has designed strategies to manage the risk of an agricultural product contamination that may cause harm to the American public or damage the Nation's economy. CBP has worked extensively to coordinate activities and enforcement actions with USDA and HHS. As the guardian of our Nation's borders, CBP has broad authority to interdict imports of food and agriculture products at the ports of entry. We frequently interact with FSIS and FDA on questions regarding enforcement actions, as those agencies house the subject matter expertise on food and agriculture admissibility.

CBP is able to rely on the statutory authority of other Federal agencies, with the specific mandate of enforcing food safety regulations to finalize enforcement actions on those food safety issues. As with our approach to antiterrorism, CBP has taken a multi-layered approach to protect the safety of America's food imports.

In my testimony today, I would like to highlight the three key aspects that CBP has utilized in its effort to date: CBP's National Trade Strategy, CBP targeting methodologies, and CBP personnel. After briefly discussing these three topics, I can highlight some of our experiences with these food safety operations.

Pursuant to our twin goals of fostering legitimate trade and travel while securing America's borders, CBP has developed a National Trade Strategy to help our agencies successfully fulfill our trade facilitation and trade enforcement mandate. Our National Trade Strategy is based upon six Priority Trade Initiatives. These PTIs are antidumping and countervailing duty protection; intellectual property rights enforcement; textile and wearing apparel enforcement; revenue protection; punitive actions; and of course, agriculture and food safety. Under the terms of our Trade Priority Strategy, we focus CBP resources in our efforts to address these

key areas of trade. I would like the committee to know that agriculture is one of our key six priority issues.

The goals of our National Agriculture Strategy are, first, to detect and interdict any instances of agro and bioterrorism; second, to detect and prevent unintentional introduction of pests or diseases into the United States; third, to detect and prevent unintentional introduction of adulterated, contaminated or unsafe agriculture and food products; and fourth, to promote our Nation's economic security through the enforcement of these trade laws. To support this national strategy, CBP employs several robust targeting methodologies, ensuring the compliance and safety of our food and agriculture products imported into the United States.

CBP, in coordination with FSIS and FDA, utilizes the following mechanisms to ensure safety of the American food supply. First, our Automated Targeting System, which is based on various algorithms and rules, and is a flexible, constantly evolving targeting system that integrates enforcement and commercial databases. ATS is essential to CBP's ability to target high-risk cargo entering the United States based upon advance manifest information. Another system CBP uses is our Automated Manifest System, which provides us with the advance cargo information, to be used for targeting and screening of all imported merchandise. We utilize AMS to ensure appropriate coordination with other regulating agencies. And finally, the Automated Commercial System, ACS, CBP's automated system of record for entry processing and cargo clearance allows us to screen for additional food and agriculture risks.

I would also like the committee to know, the majority of the targeting criteria present in the system today are intended to prevent the introduction of contamination, pests or disease. Approximately 87 percent of the criteria used in our ACS systems are agriculture related.

In addition to these CBP systems, CBP also maintains the National Targeting Center. The NTC is the facility at which personnel from several separate government agencies are co-located to review advance cargo information on all inbound shipments. Personnel from CBP, FDA, FSIS, APHIS, are all stationed at the NTC.

In addition to the sophisticated targeting systems and coordination between the agencies, CBP maintains a diverse workforce that is specially trained to detect and prevent imports that may be harmful to the health of the American public. CBP officers and CBP agriculture specialists receive specific training on ag/bioterror incidents. We currently have the ability to rapidly deploy more than 18,000 CBP officers, 2,000 agriculture specialists and 1,000 import specialists in response to emerging threats to our agriculture and food supply. Furthermore, CBP's Laboratory and Scientific Services maintains eight separate laboratories around the country, with a 24/7 technical reachback center.

While we have found various examples recently where we have coordinated with FDA and HHS and DHS along the lines of melamine, toothpaste, seafood imports, we are finding that that level of cooperation has been very important in ensuring the safety of our Nation's food supply. Food defense and food safety concerns will only increase as world trade in food and agriculture continues to grow and diversify. CBP will continue to approach this as a chal-

lenge worthy of a combined government effort. We will continue to partner with other Federal agencies in order to refine our targeting skills and ensure the prevention of contaminated products entering the United States.

Thank you, Mr. Chairman, ranking member, other members of committee for this opportunity to testify today, and I would be happy to answer any of your questions.

[The statement of Mr. Baldwin follows:]

PREPARED STATEMENT OF DANIEL BALDWIN

INTRODUCTION

Mr. Chairman and members of the Subcommittee, I am pleased to appear before you today to discuss the actions we are taking at Customs and Border Protection (CBP) to ensure the safety of imported food. My name is Dan Baldwin and I am the Assistant Commissioner in the Office of International Trade at U.S. Customs and Border Protection. My office holds the responsibility of formulating CBP's trade policy, developing programs, and enforcing U.S. import laws. The food and agriculture industry contributes significantly to the United States economy. As the value and complexity of our food imports continues to grow, CBP recognizes the challenges we face to maintain a safe and secure food supply. To meet this challenge, OMB and the relevant food safety agencies are collaborating on ways to most effectively address issues raised in GAO's designation of Federal Oversight of Food Safety as a high-risk item in February 2007.

CBP has taken great strides toward securing America's borders, including the protection of our food supply and the economic health of American agriculture. Since September 11, 2001, CBP's priority mission has been to secure the nation's borders from terrorists and terrorist weapons while facilitating the flow of legitimate travel and trade. In support of this mission, CBP has designed strategies to manage the risk of an agricultural product contamination that may cause harm to the American public or damage to the nation's economy.

CBP has worked extensively to coordinate activities and enforcement actions with USDA and HHS, and in particular the FDA. As the guardian of our nation's borders, CBP has broad authority to interdict imports of food and agricultural products at the Port of Entry. We frequently interact with USDA and FDA on questions regarding enforcement action, as those departments house the subject matter expertise on food and agriculture admissibility standards. CBP is able to rely on the statutory authority of other federal agencies with the specific mandate of enforcing food safety regulations to finalize enforcement actions on food safety issues.

CBP'S CURRENT ENFORCEMENT STRATEGY

As with our approach to anti-terrorism, CBP has taken a multi-layered approach to protect the safety of America's food imports. In my testimony today, I would like to highlight the three key aspects that CBP has utilized in its efforts to date: CBP's National Trade Strategy, CBP Targeting, and CBP Personnel. After briefly discussing these three topics, I will discuss our experience with food safety operations.

NATIONAL TRADE STRATEGY: AGRICULTURE ESTABLISHED AS PRIORITY TRADE INITIATIVE

Pursuant to our twin goals of fostering legitimate trade and travel while securing America's borders, CBP has developed a National Trade Strategy to help our agency successfully fulfill our trade facilitation and trade enforcement mandate. Our National Trade Strategy is based upon six Priority Trade Initiatives (PTI), these PTI's are: Antidumping and Countervailing Duty, Intellectual Property Rights, Textiles and Wearing Apparel, Revenue, Agriculture, and Penalties. Under the terms of our trade prioritization strategy we focus CBP resources in our efforts to address areas of key trade importance. I would like the committee to note that Agriculture is one of our six PTIs.

The goals of the agriculture trade strategy include:

- (1) The detection and prevention of agro-terrorism and bio-terrorism, i.e., the intentional contamination of an agricultural product or food, or the intentional introduction of diseases or pests intended to cause harm to the American public, American agriculture, or the nation's economy.
- (2) The detection and prevention of the unintentional introduction into the United States of pests or diseases that would cause harm to the American public, American agriculture, or the nation's economy.

- (3) The detection and prevention of the unintentional introduction of adulterated, contaminated, or unsafe agricultural and food products into the United States that would cause harm to the American public, American agriculture, or the nation's economy.
- (4) The promotion of our nation's economic security through the facilitation of lawful international trade and enforcement of regulatory trade laws.

TARGETING

CBP uses various targeting mechanisms to ensure the compliance and safety of food and agricultural products imported into the U.S. These mechanisms are specifically designed to incorporate the food safety concerns of USDA and HHS.

One of the systems used is our Automated Targeting System (ATS). ATS, which is based on algorithms and rules, is a flexible, constantly evolving system that integrates enforcement and commercial databases. ATS is essential to CBP's ability to target high-risk cargo entering the United States. ATS is the system through which we process advance manifest information to detect anomalies and "red flags," and determine which cargo is "high risk" and should be scrutinized at the port of arrival.

Another system CBP uses is the Automated Manifest System, which provides us with advanced cargo information to be used for targeting and screening of all imported merchandise. This advance information allows CBP to identify shipments of interest in advance of arrival. By identifying shipments in advance, CBP is better able to focus resources on those shipments which may be of concern, prevent their introduction into the commerce, and ensure appropriate coordination with other regulatory agencies.

The Automated Commercial System (ACS), CBP's automated system of record for entry processing and cargo clearance, allows us to screen for additional food and agricultural risks. The majority of the targeting criteria present in this system are used to prevent the introduction of contamination, pests, or diseases. Approximately 87% of the cargo criteria in ACS are agriculture related.

In addition to these CBP automated systems, CBP maintains the National Targeting Center (NTC). The NTC is the facility at which personnel from several separate government agencies are co-located to review advanced cargo information on all inbound shipments. At the NTC, CBP personnel are able to quickly coordinate with personnel from other federal agencies such as the FDA, Food Safety and Inspection Service (FSIS), and Animal Plant Health Inspection Service (APHIS) to target high risk food shipments.

Furthermore, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA) authorized FDA to receive prior information to target shipments of food for human or animal consumption prior to arrival. The BTA gave CBP the opportunity to assist FDA with the prior notice requirements. CBP worked in concert with FDA to augment an existing automated interface to institute a prior-notice reporting requirement with minimal disruption to the trade. In addition, under the BTA, we worked with FDA to commission over 8,000 CBP officers to take action on behalf of the FDA. This commissioning allows FDA to assert a 24/7 presence to enforce the Act at all ports.

PERSONNEL

In addition to sophisticated targeting systems and coordination between agencies, CBP maintains a diverse workforce that is specially trained to detect and prevent imports that may be harmful to the health of the American public. CBP Officers and CBP Agriculture Specialists receive specific training on ag/bio-terror incidents. We currently have the ability to deploy more than 18,000 CBP Officers, 2,000 Agricultural Specialists, and 1,000 Import Specialists in response to emerging threats to our agriculture and food supply. Furthermore, CBP's Laboratory and Scientific Services (LSS) maintains seven separate laboratories around the country, with a 24/7 technical reach back center. LSS employs approximately 220 chemists, biologists, engineers, and forensic scientists.

Our diverse workforce enables CBP to mount rapid and effective responses to protect U.S. agricultural resources by utilizing the specialized training of CBP Officers, Agriculture Specialists, Import Specialists, International Trade Specialists, and Laboratory Technicians. Each of these CBP occupations works together to gather intelligence, establish target criteria, gather and test samples, and analyze and report results. Because of their specialized training in the use of personal protective equipment for handling potentially hazardous or infectious materials, CBP Agriculture Specialists play a vital role during food safety operations.

FOOD SAFETY OPERATIONS

Trade analysis and targeting methodologies designed to ensure the safety of the food supply allow CBP to proactively identify shipments containing possible food

contamination prior to its arrival. This targeting allows us to fulfill our mission while allowing us to facilitate legitimate trade.

While food safety has recently grown in importance in the public eye, CBP has been involved in food safety related initiatives for the past several years.

In 2006, CBP was involved in the detection of numerous incidents of food contamination or smuggling of prohibited food products from China. A significant number of shipments of Chinese poultry products were seized including 45 containers smuggling prohibited product. CBP developed a food safety operation to combat the smuggling by targeting known smugglers of prohibited poultry products.

In April 2007, it was discovered that food from China was contaminated with melamine potentially harmful to animals as well as humans. CBP initiated a special operation to determine the scope of the potential problem. The nature of the operation was to augment FDA's focus with the intention to assess the risk of contamination from countries worldwide and to identify possible transshipment of Chinese product. CBP sampled and conducted laboratory analysis, the results of which were coordinated with FDA.

In this most recent action, CBP targeted and detained 928 entries (shipments) over a four-week period. Samples were pulled on 202 entries, comprising over 400 separate production lot samples, and sent to CBP's laboratories for analysis. All samples tested negative for the presence of melamine. As a result of the operation, CBP tested samples of product from 23 countries and shipped by suppliers/producers that account for over 59% of the imported volume of the merchandise in the previous 12-month period. This scientific data gives the government and the public assurance that the melamine issue relating to imports was in fact isolated to a few Chinese suppliers, and not a widespread, global problem. In coordination with FDA, CBP developed a follow-up monitoring program that uses a computer-generated statistical sample to measure ongoing compliance.

This high profile enforcement effort has helped CBP refine its methodology to conduct future food safety operations and enhance our working relationship with other federal agencies. In response, CBP has developed a Concept of Operations Document for food safety to institutionalize our communication and cooperation as well as the methods, processes, and procedures. Additionally, this food safety incident has brought to the forefront the need to maximize the power of the government to respond to future food safety issues.

As you are well aware, there have been further contamination issues, for example, with imported toothpaste and selected seafood. Based on lessons learned from the melamine incident, we are coordinating with FDA to develop an appropriate action plan commensurate with the threat.

CONCLUSION

Food defense and food safety concerns will only increase as world trade in food and agriculture continues to grow and diversify. One of the methods CBP will use to ensure the safety of the food supply is to use statistical sampling to monitor for compliance. CBP will continue to approach this as a challenge worthy of a combined government effort. We will continue to partner with other federal agencies in order to refine our targeting skills and ensure the prevention of contaminated products from entering the U.S.

Mr. LANGEVIN. Thank you, Mr. Baldwin. I want to thank the witnesses for their testimony. I will remind each member, he or she will have 5 minutes to question the panel.

And I now recognize myself for questions. I think the one thing that is on everyone's mind today is, how secure are we in terms of preventing what happened in terms of contaminated food and products coming out of China entering the food supply again? Are we there yet to ensure that it can't happen again? So my question is, what efforts are underway to ensure that the Chinese don't continue to intentionally add melamine or other dangerous products to their exports? What is the U.S. doing to sanction China? And what does HHS expect yet out of its meeting with China at the end of the month? Pose that to the panel.

Dr. ACHESON. This is David Acheson of FDA. Maybe I could take the first shot at that, since you specifically addressed HHS. Since the melamine issue, and in fact before that in relation to a number of technical issues, we have worked very closely with Chinese au-

thorities to try to address specific food safety concerns. Clearly, the melamine situation was something that we did not predict. Since that has happened, there has been an ongoing, and continues to be, close dialogue with Chinese authorities to address this problem, to deal with it.

I think we have to accept that their food safety system, the Chinese food safety system, is not the same as that in the United States. It is a rapidly expanding economy. They are exporting a lot of food to the United States. And we have to work with the government and build systems to essentially address that challenge. To that end, there are ongoing meetings with Chinese government officials. There will be one occurring at the end of this month. There will be another one in August. There is a further one planned for September. All towards trying to develop a memorandum of understanding that will focus on how to address these problems.

Mr. LANGEVIN. Do you see them moving aggressively to mitigate these problems to ensure that it is not going to happen again?

Dr. ACHESON. I think, within the capacity of the Chinese government to attain those goals, yes. I think they are very committed to try to prevent it. But as I said, they are dealing with a very fragmented system. So one of the things they are trying to put in place, I think very deliberately, is a system of certification or authorization that will ensure that products that are exported do meet a certain level of safety and security to ensure that they won't harm American consumers.

Mr. LANGEVIN. And since we can't rely necessarily on the Chinese to fully solve this problem because the system is so fragmented, then what are we doing to step up our efforts? Are we there yet to ensure that the food coming in or product coming into the United States is secure?

Dr. ACHESON. Well, again, we are obviously focusing on the areas that are of the greatest concern. Using a risk-based strategy, we focused on testing products that we had concerns about, either historically or because of human illness. That was what led to the recent announcement of the import alert in relation to aquacultured fish of five different species related to the use of specific drugs. And as you know, there is now in place a hold so that we have to test that material.

Clearly, the melamine and wheat gluten was something that we weren't anticipating. We learn from these things constantly and are, as we move forward, trying to focus our strategies based on risk. Ultimately, where we need to take this, though, however, is to focus it on prevention. We need to prevent these problems from happening in the first place, as opposed to reacting when they do.

Mr. LANGEVIN. I agree.

Dr. Maczka?

Ms. MACZKA. Well, I think FSIS does have a very robust import system where we are able to ensure the safety of food coming into the United States. It involves an initial determination of a country's equivalence to our systems. It also involves on-site audits and then reinspection of all products coming into the United States. If something were to go wrong with a particular product, we can increase audits in a country. We can step up reinspection of products coming into our country. We also, one of the things that we are

working on collectively together here with Customs and Border Protection, DHS and FDA and the Centers of Excellence is a study on melamine and other pathways that can be used for economic adulteration, and so that we can put protective measures in place.

Mr. LANGEVIN. Thank you.

Dr. McGinn?

Dr. MCGINN. We are stronger and more secure than we have ever been in our food supply, yet incidences like melamine give us an opportunity to get even stronger. Since this incident, our Center of Excellence you will hear from this afternoon has been looking extensively at food imports from China, and doing that in collaboration with USDA and FDA and Customs and Borders, as well as the intelligence community. So we are actually doing a review of the imported foods to see what additional concerns there are. We are certainly going to be able to make those available to you.

Mr. LANGEVIN. Thank you.

And Mr. Baldwin?

Mr. BALDWIN. Very quickly, just to echo the comments made earlier, I think we do have the safest food supply security system in the world. And targeting and intelligence gathering, I think, is one of the key components, so that even when you do detect an incident like this, that we are able to have a concept of operations in place how to deploy, how to proceed so we can mitigate any of these circumstances and anticipate any future developments.

Mr. LANGEVIN. I thank the panel.

The chair now recognizes the ranking member, Mr. McCaul, the gentleman from Texas, for 5 minutes.

Mr. MCCAUL. I thank the chair. Just as a follow-up on the food imports from China, particularly the seafood, and maybe Dr. Acheson, you are the expert to address this. How confident are you that these imports coming into the country now from China, as I understand they have not been banned, what is your comfort level that there is no contamination, particularly given the fact that one of the certifying labs that qualifies to certify that it is not contaminated is actually from China?

Dr. ACHESON. FDA is very comfortable that those five fish that we have the import alert are essentially being held. You are correct in saying that it is not a ban. It is not intended to be a ban. What it is intended to be is a hold at the port of entry in some way, or in some holding situation, preventing it from going into commerce until FDA has seen clear evidence that the fish does not contain any of the antimicrobial agents that we have concern about.

Now you point out, what can we do if we don't believe the lab results? Well, we can check the lab results. We can test it ourselves. We can ensure that the samples were taken correctly, that the assays were done correctly, that the controls were done correctly by reviewing the paperwork. And if we are not comfortable, it doesn't proceed.

Mr. MCCAUL. You said, you can test it yourselves. I mean, do you?

Dr. ACHESON. We have certainly done that. We challenge things on a regular basis in terms of—I mean, import alerts are not new. We have been doing them for years. And we have many out there.

Mr. McCAUL. Let me just say, let's say it is certified in China that it is not contaminated. It comes to our country. Do you have any systems to perhaps do any sampling to ensure that this food is safe coming into the United States?

Dr. ACHESON. Yes, indeed, we do. We undertake sample assignments on top of import alerts. To give you a case in point, several years ago, we had problems with cantaloupe from Mexico. There was a countrywide import alert, much like China. We worked with the government of Mexico to fix it. Once the country was coming off the import alert, we continued to test cantaloupe. It was fine for a couple years. We then found a problem, and we worked with the government again to fix it. So, yes, simply the import alert is not it. We will continue to follow-up, and we will continue to test, and we will continue to look more widely.

Mr. McCAUL. How was this discovered in the first place? How did you discover that, gee, we have food coming in from China that is contaminated?

Dr. ACHESON. With the melamine or with—

Mr. McCAUL. The anti—or the microbe agents that were found in the fish.

Dr. ACHESON. Through testing programs. Those testing programs go back to 2001, where we first started to see problems and we were putting individual companies on import alert. And we have been doing that for some time. And we have essentially been ramping up, adding more and more companies, to the point at which we said, this isn't working. The technical discussions with China aren't solving the problems. We need to make this country-wide to protect the American consumer.

Mr. McCAUL. Mr. Baldwin, another topic. We have a farm bill coming up this week in Congress, and there is some discussion, in fact some Members of Congress would like to move inspection authority away from Customs and Border Patrol and give it back the USDA at the inspections being done at ports of entry on the border. Can you comment, even though the USDA does not want that mission, by the way—not something that I support—but can you comment on that and then also comment on the transition that did take place between USDA to CBP at the border? And how well is that transition going, and how well are your inspections at the border?

Mr. BALDWIN. Sure. First off, I would offer that I believe a transfer of our CBP agriculture specialists back to USDA would in fact be a detriment to our food supply security efforts. We have a significant number of diverse workforce that we have at the border that we can leverage and use for a diverse array of food supply chain issues. I think we have had tremendous success in the few short years since CBP agriculture specialists have been at the border with our CBP officers, who look for immigration issues, cargo issues, and agriculture and pest contamination issues. I think we are underestimating the tremendous improvements we have made with USDA in forming our task force and working with our bioterrorism act personnel with FDA and soon FSIS and our NTC. I think we are making tremendous headway in solidifying our efforts and creating the best food supply chain security efforts at the bor-

der. I think a move back, this reaction would be a detriment to our efforts.

Mr. MCCAUL. Thank you. I see my time has expired.

Mr. LANGEVIN. Thank the gentleman.

The chair now recognizes the gentlelady from the Virgin Islands, Mrs. Christensen, for 5 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Thank you for holding this hearing and making sure it happened, despite the fact that we had to put it off. And thank the panelists again for your flexibility in being here this morning. I have a lot of concerns about our food safety, given all of what has already been referenced here by my colleagues, and what seems to be a tremendous increase in food contamination, and sometimes the length of time it takes to find out what the source is and so forth. So I am hearing that coordination is improving and so forth. I hope so.

I have a quick question for Dr. McGinn. The Office of Health Affairs, how does that relate to the Chief Medical Officer? Is that the same office? Is there some coordination there? What is their role in the food safety issue?

Dr. MCGINN. The Chief Medical Officer is the head of the Office of Health Affairs. The Chief Medical Officer is a position that is about a year old within DHS, and then most recently, that has become the Office of Health Affairs.

Mrs. CHRISTENSEN. Okay. I just wanted to know.

Dr. MCGINN. And the veterinary component is a component of the medical component within DHS.

Mrs. CHRISTENSEN. Okay.

And Dr. Acheson, you talk about the laboratories that are in the FERN, in the network. And they include the 50 States and Puerto Rico. How does that network address issues with the territories, either the Virgin Islands or the ones in the Pacific?

Dr. ACHESON. The network is constantly expanding. And at this stage, I don't have specific information as to what is on tap in those, but I can certainly find that information and get that back to you specifically on that question. But that network has worked well. We used it in spinach, and we used it in melamine.

Mrs. CHRISTENSEN. Okay. And, apparently, a week ago or so, there was another hearing in one of the Energy and Commerce subcommittees, and what was reported there is a cause for a lot of concern, one that—and I read about this in the paper either Sunday or Monday as well—that FDA inspects about 1 percent of the food over which it has jurisdiction. This is what was reported at the subcommittee. And of that 1 percent, just a fraction is actually sampled, that the agency sometimes allows importers to take possession of suspect foods and arrange for the testing by private laboratories that may or may not be approved by FDA. This is from testimony given in a hearing at a House subcommittee last week.

And the other issue is the fact that you have 13 laboratories that test for these kinds of problems, and seven of them FDA intends to close. Can you just help me figure out, can you just respond to those concerns that were raised in another subcommittee hearing?

Dr. ACHESON. Sure. You raised a lot of points there. Let me try to cover them briefly.

Mrs. CHRISTENSEN. The 1 percent.

Dr. ACHESON. Yeah.

Mrs. CHRISTENSEN. The private labs testing for suspect goods, private labs that are not FDA approved, and also the closing of 7 out of 13 laboratories that are used. And it goes on; inspectors, the number of inspectors are less, but the food imports have doubled, you know.

Dr. ACHESON. First of all, the 1 percent is correct. In order for a product to be imported, a food product to be imported into the United States, there are a number of things that has to happen. The paperwork for that, usually submitted electronically, is 100 percent through our prior notice center, in collaboration with Customs and Border Protection. What that does is, it will target certain foods that are of concern from a food defense and bioterrorist perspective. And if we see anything anomalous there, it gets put to one side in terms of potentially a hold or an inspection. On the food safety side, again, all that food is screened electronically. Some of it, where we have never seen a problem historically—

Ms. CHRISTENSEN. So 100 percent is screened, but 1 percent is inspected. Is that what you are saying?

Dr. ACHESON. Yes, 100 percent is screened electronically. About 80 percent of that electronic screening is then diverted for an FDA individual to look at it and make a determination, should this be inspected or should it not be inspected, based upon experience? Now a lot of that is stuff that goes through really quickly because, again, it is high volume. It is things we have never seen problems with. And that is how the 1 percent then gets picked out. It is based upon risk. It is based upon areas where we have seen problems, and it is based upon concerns that we have either had in the past or currently have. So it is vetted 100 percent, but you are correct in saying that only 1 percent is actually physically inspected.

In terms of the private labs, yes, private labs do get used, as they are allowed to be used for import alerts. But, again, FDA is able to look at the data from the private labs. They have to ensure that the samples are collected properly, under the appropriate conditions, that the testing is done correctly, that the assays are validated, that the controls are appropriate. And if there are any problems with that, FDA will refuse to take that data and do. I could not tell you what percentage that we refuse, but I can find that out for you. But we do do that.

Finally, on the lab closures that you mentioned, yes, you are correct, there is a current consideration of consolidating labs. Those labs were developed and situated in the days when shipping samples around was much more complex than it is now. We can obviously, as you all know, ship materials across the U.S. very easily. The goal here is to improve efficiency, to improve through put and to do more faster, cheaper, so that, at the end of the day, even though physically some labs will close, we envisage that what we will be able to do here is to get more samples tested faster for less money, thus increasing overall efficiency, simply because of the way things move in modern technology.

Mrs. CHRISTENSEN. Thank you for your answer.

Mr. Chairman, I think that this bears some looking into, just so that we can be sure that we are giving the proper oversight for

some of these changes, closing of the labs and the low percentage of inspections and some of the other issues raised.

Mr. LANGEVIN. I couldn't agree more, and I promise you that we will continue to exercise aggressive oversight in this area. And this hearing will be the first of what I intend to be several hearings on the subject.

The chair now recognizes the gentlelady from Ohio, Ms. Kaptur.

Ms. KAPTUR. Mr. Chairman, I want to thank you very much for permitting me to come here today and participate in this very important hearing. Thank you for your leadership on this issue. And it is a pleasure to join the panel, if only briefly.

Thank you for your focus on food safety, an issue that I have followed for quite a number of years. I would like to ask any of the panelists to respond to very specific questions here.

Do any of you know what percent of the U.S. food supply is currently imported and what percent of the U.S. drug supply is currently imported or even, generally speaking, what that might be?

Dr. ACHESON. This is David Acheson, FDA.

Let me start on the food supply because I can speak to that. For drugs, I do not have that information, but we could certainly get that for you.

Overall, about 13 to 15 percent of the U.S. food supply is imported, but it varies greatly with commodities. Seafood is about 80 percent. Others are much less. Produce varies with the time of year, but it can be 30 to 40 percent.

Mr. BALDWIN. I would just like to add that I think it is somewhere between 4 to 5 percent of all imports in the United States that are actually, you know, our food supply, our food products. Four to 5 percent of all imports of all products are food products.

Ms. KAPTUR. What about drugs?

Mr. BALDWIN. That information I do not have specifically, but I would be happy to get that for you.

Ms. KAPTUR. Does anybody want to take a guess? I am talking about the components of those products, not just the final product.

Mr. Acheson, you do not want to comment on that?

Dr. ACHESON. I did not come armed with information to specifically discuss the importation of drugs, but as I have said, I would be very happy to get that information to you.

Ms. KAPTUR. Is it your sense that the majority comes from offshore on the drug side?

Dr. ACHESON. I know that drug ingredients are imported, but yes, in terms of finished drugs, I think it is not a huge number.

Mrs. KAPTUR. I think the American people were very surprised to find that large amounts of our medications and, perhaps, vitamins are comprised of ingredients that come from offshore. I think it is quite a significant number, and it is surprising to me that you do not really have that at the top of your fingertips here today.

Dr. ACHESON. Well, I apologize. I am focused on food and feed as opposed to drugs, but I promise we will get that information to you.

Mrs. KAPTUR. Is it your impression that food imports and drugs imports into the United States are growing?

Do any of the panelists want to answer that?

Ms. MACZKA. On the meat, poultry and egg side, no. As far as your first question—

Mrs. KAPTUR. Meat and—excuse me?

Ms. MACZKA. Meat, poultry. Meat and poultry, which is what FSIS regulates, 6 to 8 percent is imported. That is in response to your first question.

Dr. ACHESON. In response to your question about is it increasing, certainly, on the food side, yes, it is.

Mrs. KAPTUR. Yes. With 1 percent or less inspected, as a country we have been pretty lucky, actually.

I wanted to ask you: Who are the worst offenders by nation in terms of food safety and then drug safety? If you were to kick off those who have been cited the most times, which three countries would be at the top of your list or which five countries would be at the top of your list as the worst offenders on the food side and then the worst offenders on the drug side?

Dr. ACHESON. In the context of the foods that the FDA regulates—and we inspect and refuse foods on a regular basis. For example, in June, the FDA refused foods from 80 different countries. China and India were at the top of the list and, certainly, in recent months have been at the top of the list. Part of that is related to the volume of products that are imported. We do import a lot of foods from China and from India, so there is a denominator component to this.

I suspect where you are going is the proportion or the percentage of foods from individual countries that are unsafe, and I do not have all of the denominator information at hand, but again, you know, we could provide that.

Mrs. KAPTUR. To provide the inspection, do you focus on key importers?

Dr. ACHESON. In terms of the inspections, there are a lot of parameters that are weighed into this. From a food defense perspective, yes. The intelligence, the country of origin, the foods, those kinds of things on the food safety side, again, yes, in relation to proprietary records, the history of problems with the importers or the foods.

Mrs. KAPTUR. There is very little time remaining in my 5 minutes, but I did want to place on the record the distinction between what the U.S. Department of Agriculture calls a “recall” if we find something that is out there that we are troubled with. There are all of these stories that come out in the paper that we are going to recall certain products.

The problem is that we recover almost none of it. Five percent or less is ever recovered, so we might read that something is recalled, and people say, “Oh, I feel so safe. The toothpaste is recalled or the steak is recalled or the hamburger is recalled or the fish is recalled.” Yet, the truth is that the Department of Agriculture, speaking for the Department of Agriculture, is able to recover almost none of it. So it is still out there. It is still out there.

So I just wanted to place on the record in this very important subcommittee the fact that some of the language that is used is very misleading to the public.

I believe my time has expired, Mr. Chairman.

Mr. LANGEVIN. Well, the gentlelady raises a very important point, and the American people need to be aware of this, and we need to see what we can do to step up efforts to enhance the recall effort to make sure it actually has meaning and that the product is actually recovered. I could not agree more. I thank the gentlelady.

The Chair now recognizes the gentleman from North Carolina, Mr. Etheridge, for 5 minutes.

Mr. ETHERIDGE. Thank you, Mr. Chairman, and thank you for holding this hearing. I think it is vitally important.

Let me ask the panelists. You know this is a critical issue to the American people, and I want to go back so I can come forward.

In November of 2003, the GAO had a report titled Bioterrorism: A Threat to Agriculture and the Food Supply, and they found that most of USDA's and the FDA's field staff had not received training on security matters, and although the field staff were instructed to be vigilant and on heightened alert, they were also told not to document or to report their observations regarding security at the plants because the information could be obtained under a Freedom of Information Act request. My question is this:

Has this policy changed? Number two, can you confirm that staff were instructed not to document or to report observations? Number three, do field staff currently receive security-specific training?

Who wants to tackle that first? Okay.

Ms. MACZKA. Thank you, Congressman.

Well, we perform food defense verification procedures in our plants every day, and I do not have the numbers with me, but hundreds of verification procedures are performed, and we document the results of those in what we call a Memorandum of Interview. The inspection personnel are supposed to take the results of that and discuss it with plant management so that countermeasures can be put in place. So I think our system there is quite strong.

Mr. ETHERIDGE. Well, let me ask you a question. You did not answer my question.

Number one, has the policy changed? Was that correct what GAO put out in 2003 or was that incorrect?

Ms. MACZKA. The policy has not changed. We have been doing these food defense verification procedures since the events of 9/11, and we continue to do them, and our staff does get ongoing training, by the way. We have food defense awareness training of all of our field staff as well as headquarters staff.

Mr. ETHERIDGE. So we do document?

Ms. MACZKA. Yes, we do document.

Mr. ETHERIDGE. We do report the observations?

Ms. MACZKA. Yes, we do.

Mr. ETHERIDGE. To whom?

Ms. MACZKA. To the trade associations and to industry so that countermeasures can be put in place, and we also analyze the information at headquarters to look at trends.

Mr. ETHERIDGE. So it does come to the Department?

Ms. MACZKA. Absolutely.

Mr. ETHERIDGE. Okay. Does anyone else want to comment on that?

The FDA.

Dr. ACHESON. Yes. This is David Acheson. I will speak on the FDA side.

In terms of the training, we have been aggressively adopting a training program with our inspectors, mainly focused on raising awareness and having them understand the importance of giving out guidances to the industry in terms of what they can do to ensure the security of the food supply.

As I mentioned in my oral, we have developed a program called ALERT, which is heavily focused on raising awareness. It basically operates from farm all the way through to retail. Virtually every inspector has been trained on ALERT. We have developed a Web-based training system for that, suitable for both industry and for our inspectors. Certainly, about 2 months ago, we were up to—about 95 percent, 96 percent of the inspectors had received that training and were implementing it, and we have used this in some of our assignments as well.

Mr. ETHERIDGE. Okay. So it is currently an operation that is ongoing?

Dr. ACHESON. Yes, that is correct.

Mr. ETHERIDGE. Thank you.

Dr. MCGINN. Can you describe what steps the Department has taken to lead an interagency in response to an act of agroterrorism or other disasters in the agricultural sector? Because, obviously, your department would have that charge. Specifically, what plans have you developed, what training exercises have you done, and what are the staffing changes in the Department to accomplish the mission in your department?

Dr. MCGINN. Okay. As it relates to the staffing issues, our office is new, the Office of Health Affairs, and currently we are an issuer and are actually adding people in the area of food as well as in animal agriculture, in public health, and agro threat. This year, we are hoping to, as the IG report said, add the persons who are needed to actually staff up this coordinating role up to about 11 people the first year, and then by the end of 2009 we are looking to add up to about 40 people to actually do this coordinating role and several million dollars to do this effort. That is not a lot considering it is one-sixth of the economy and that this is a critical infrastructure for our country.

In terms of the exercising and the planning and in terms of attacks on our country, one of the main ways that we within the Department of Agriculture are preparing for that is in actually assisting the States to be prepared because any incident that is going to be of national significance is going to be in a lot of States at the same time. So one of our key responsibilities is to provide grants to the States to be able to then utilize and to actually do the training and exercising and build the kinds of capacities that we need to have in order to be able to respond in multiple States at any given time.

Mr. ETHERIDGE. Can you tell us where we are along that track in terms of getting that done?

Dr. MCGINN. In terms of the grand analysis, that is one of the key things, that I add personnel to our office, which I intend to do. We have already begun the analysis of this, and we are looking at what States are actually spending on those grants in terms of

building this kind of preparedness, and the research capacity within the labs as well as the field personnel are critical, as you know.

In order to effectively do this kind of analysis with the grants, I am going to need some additional—the personnel that we are bringing on staff right now to actually do that, and I will be able to follow through on it. My intention is to do an annual review of those grants and then to be able to share that information back with the States so that they will be able to do a better job of competing for those resources to build capacity in the States.

Mr. ETHERIDGE. Thank you, Mr. Chairman. My time has expired.

Mr. LANGEVIN. I thank the gentleman.

Given the import of this issue and the fact that I know Chairman Thompson wanted to question—he is on his way back—with the panel's indulgence, we are going to go to a second round of questions. So, with that, I will begin recognizing myself.

I wanted to inquire of Dr. McGinn: The Inspector General released a report in February on the role of DHS in post-harvest food security. The IG noted that there are four main limitations in DHS' efforts. First, DHS must improve internal coordination. Second, DHS needs to engage its public and private food sector partners more effectively. Third, DHS could do more to prioritize resources and activities based on risk. Finally, DHS must fully discharge its food sector responsibilities.

So my question is how many staffers has DHS dedicated to this mission, and how have you worked to improve these areas?

Dr. MCGINN. Within the 30 programs across DHS, there are several people who are actually involved, but in our office currently, I am an office of one, but I have the ability to actually add up to five people as FTEs and then some detailees as well to get to eleven by the end of this first year that we are in place so that the IG Office or the IG report recommended that we have a very limited number of staff and that we need to actually add to our resources to actually be able to discharge our responsibilities, not just for HSPD-9 but for the other HSPDs, as well as other issues as were mentioned by the Executive order and the Office of Budget and Management. There are lots of different issues that we are actually working to synchronize our resources in.

Mr. LANGEVIN. Do you feel that level of resources in staffing is going to be adequate to complete your mission?

Dr. MCGINN. It is very adequate to start the job in this first year of our existence. We are a new office, and we are rapidly developing capabilities, not just in the veterinary area but also in the medical area as well. Coordinating those responsibilities across all of DHS is a huge task as well. So, yes, we have got the resources to start the job, and then our ramp-up over the next couple of years will in fact give us the full capability to discharge those responsibilities.

Mr. LANGEVIN. To the panel, Mr. Kennedy's testimony that we will hear later suggests that food and ingredient movement is not well characterized across firms—or food and ingredient products. He states that a clearinghouse for such information that would be accessible for research and threat purposes would be a significant step forward.

What efforts are underway to create such a tool?

Dr. ACHESON. This is Dr. Acheson at FDA.

I am not sure I quite understand the scope of the question. Is it suggesting that the traceability is inadequate?

Mr. LANGEVIN. That is what he is suggesting, yes.

Dr. ACHESON. Okay. Under the Bioterrorism Act, there is a requirement for certain facilities to maintain records of one up and one back; in other words, where they receive the material from and where they send it. That has served us well in relation to recent outbreaks. Obviously, we have not had to test it in a terrorist situation, but that structure has allowed us to, essentially, trace forward and trace back when an outbreak occurs, to determine origins and where food has gone.

Mr. LANGEVIN. Would anybody else on the panel care to comment?

Ms. MACZKA. We also have procedures in place to trace forward and to trace back.

Mr. LANGEVIN. Thank you.

Let me ask this last question within the time that I have left.

China has claimed that the U.S. is raising unnecessary alarm about the safety of their food products. According to one of their ministers, "one company's problem does not make it a country's problem. If some food products are below standard, you cannot say all of the country's food is unsafe," end quote. Do you agree?

Dr. ACHESON. Let me take the first shot at that.

I would agree that one company's problem does not mean that there is a problem nationwide. However, if we return to the example of the imported fish, we have been putting one company at a time on import alert as we have been demonstrating that their products are problematic and of concern to the public health in the United States. Beginning last October, we expanded our surveillance of these categories of fish and did a lot of testing, and overall, about 25 percent of the species that we had concerns about from a variety of different companies contained these unapproved antimicrobial agents. So that was clearly not just one company, and it was at the point where we had to say this had to be countrywide. It is correct to say it is not 100 percent, but I do not believe for 1 minute that we are overreacting. I think it is very important that we do this.

Mr. LANGEVIN. Anybody else on the panel?

Ms. MACZKA. Our process is such that we not only determine if a country's system is equivalent to us and is eligible to export to us, but we also look into whether establishments should be certified. So we take it on an establishment-by-establishment basis as well as a country basis.

Mr. LANGEVIN. I thank the panel.

The Chair now recognizes the gentleman from Texas, Mr. McCaul, for 5 minutes.

Mr. MCCAUL. Thank you, Mr. Chairman.

Dr. McGinn, I look forward to seeing your office go from a one-man shop to many hirees in your office and in ramping up your efforts. I know you are under a lot of—I will not say "stress"—but a lot of responsibilities for one person to bear, so I look forward to seeing that progress.

My second round of questioning has to do with something that impacts probably more of my home State of Texas, and that is foot and mouth disease. When I go down to some of the border towns, you actually see cattle going back and forth between Mexico and Texas. It has been going on for a long time, and obviously the threat of contamination is real. In Minnesota, we had a recent scare of foot and mouth disease which, actually, turned out not to be foot and mouth disease, but it did provide, I think, an opportunity for the USDA and the DHS to sort of test their efforts in working together on this. My question is to the panel.

Could you comment on the coordination between the USDA and the DHS on that issue in this particular case? Then if you could comment also on the overall threat, if you will, of foot and mouth disease, which would have a real damaging impact not only on border States but on the whole ranching industry?

Dr. MCGINN. I will lead off.

As it relates to that recent incident that you were describing, it was an excellent opportunity, as most incidences are, to develop additional strengthening capability. Some of the encouraging things that we did in a collaborative sort of way was we were immediately on the cell phones with each other. We have each other's cell phone numbers. We call each other any time, day or night. Certainly, when the incident was brought to our attention it was in the evening, and the questions or the requests that came to us were of an intel nature, and so what we were asked to do was to look at the intentional aspects of this to rule out or to rule in these sorts of things early on because the sooner you can determine if there is an intentional component, particularly in a biological or in a chemical situation, you are much farther ahead of the ability to contain that situation. So we were asked, and we worked through the night, actually, on behalf of the USDA to actually determine the issues of risk around intentional disruption.

Another thing that was, really, very encouraging that was done was Customs and Borders Protection and the USDA worked together to look at if in fact we were to have an incident that would progress, that we would need to be able to know in the last few weeks what animals had actually come across the border so that we would know the size of the tracing-out that needed to be done, and it was incredibly encouraging how quickly that information was able to be brought together from their joint efforts, and they got not just all of the cattle and swine, but they got down to the camels and the goats and everything else that had come into the country over that period of time.

So those two are two great examples of some increased collaborative work that was done.

One more that I would add to that is the Center of Excellence—and you will hear from Shaun Kennedy this afternoon—which worked closely with the plant owners in Minnesota to actually deal with that situation, so that there is a feedback loop from the private sector that these Centers of Excellence are so helpful in creating for all of us. That was a part of that incident as well. So those are three examples of increased and excellent coordination.

Mr. McCAUL. That is good to hear.

Mr. Baldwin, do you have any comments?

Mr. BALDWIN. I would just echo what Dr. McGinn has said. I think that we have found that our cooperation with the USDA, especially on the foot and mouth issue, has been tremendous. I mentioned earlier in my testimony that I think that 87 percent of our criteria in our automated commercial systems are dedicated to agriculture and food systems, and I will tell you that those are predominantly on the foot and mouth issue that we have been addressing for quite a few years. So I think that the work we have done in the past few years on foot and mouth with the USDA has been a tremendous example of how cross-cutting work with the agencies is really the way to go and how it has proven to be successful, and we are always working to improve that.

Mr. MCCAUL. Dr. Maczka, you mentioned in your opening statement the avian flu in poultry. Obviously, that is of great concern as the risks can be very high. We have talked a lot about the fish coming from China as being contaminated.

How much of our poultry is actually imported from Asian countries?

Ms. MACZKA. Right now, we receive—none of our products are—no products are coming in from China. No meat, poultry or egg products, FSIS-inspected products, are imported from China, and no establishments, processing establishments, are certified to export to us.

Mr. MCCAUL. That is good to hear.

In terms of poultry that is imported, I would assume most of the poultry is homegrown in the United States, that most of the poultry consumed in the U.S. is actually raised in the United States.

Ms. MACZKA. The numbers that I gave before, 6 to 8 percent, of our poultry and meat are exported, and I do not have the breakdown of what is meat and what is poultry, but I can get that to you.

Mr. MCCAUL. In terms of what Americans consume, most of that is homegrown in the United States and is raised and not imported?

Ms. MACZKA. That is correct.

Mr. MCCAUL. I see my time has expired.

Mr. LANGEVIN. I thank the gentleman.

The Chair is now pleased to recognize the chairman of the full committee, the gentleman from Mississippi, Mr. Thompson, for 5 minutes.

Mr. THOMPSON. Thank you very much, Mr. Chairman.

One of the issues I think the committee is grappling with is who would be in charge if something happened, and I guess I will go with Dr. McGinn first by saying:

If an incident of national significance were declared along the lines we have talked about, who would be in charge?

Dr. MCGINN. Well, if an incident of national significance is declared, then the Department of Homeland Security is the coordinator of the overall response. Therefore, we would be in a leadership role as it relates to that. The technical leads come from whatever emergency support function is involved with the incident. In this particular situation, if it were both the FDA and the USDA as technical leads, then we would be coordinating with them in terms of the subject matter expertise and the legal responsibilities within

our responsibilities for an incident of national significance to coordinate under the National Response Plan.

Mr. THOMPSON. So is your definition of “coordination” the equivalent of being in charge or just serving as the traffic cop for the particular incident?

Dr. MCGINN. Well, “being in charge” is exactly what it means, but it also recognizes that the subject matter expertise, whether we are talking transportation or whether we are talking food or health as sectors—recognizing that those expertises are needed in that emergency support function actually leads to support in that particular area. We definitely hope when an incident occurs, whether it is food—or agriculture-related, that we would be first, and most of them are incidents at the local level. The progression of most incidents is, if it progresses to the place where it is at the State level, then the State would be in charge. If it progresses further, then either the FDA or the USDA is actually in charge. So as the incident progresses—and they can progress very fast or they can progress slowly—who is in charge changes as it does within any incident command system-type responsibility, as you know from your work in firefighting.

Mr. THOMPSON. Dr. Acheson, you have heard Dr. McGinn’s comments about the coordinating role of DHS.

Is that your understanding?

Dr. ACHESON. Absolutely, yes, yes.

Mr. THOMPSON. And there is no conflict between who is in charge and who is the lead in this scenario?

Dr. ACHESON. No. I mean, as Dr. McGinn pointed out, things tend to build up at some speed or another. For example, spinach. The FDA was in charge of that. It was not declared a national emergency. We stayed in charge and we took care of it. We worked with other Federal agencies during the course of that.

Melamine was slightly different. Again, there were very close coordination efforts between the FDA, the USDA, the DHS, and a whole variety of other Federal agencies in that context. So, absolutely. Depending on the level of the emergency, it will vary who is in charge, but we are totally in sync with that.

Mr. THOMPSON. Dr. Maczka, would you like to respond to that?

Ms. MACZKA. I am in agreement with my colleagues here that that is pretty much the way it works, and actually we have tested it out in some of our State district exercises where we have invited our colleagues to these exercises, and it has played out that way.

Mr. THOMPSON. So you all have basically said that there is no gray area as we proceed along this line in terms of who is in charge, whether the protocols are already established and all of that?

Dr. ACHESON. Yes.

Ms. MACZKA. Yes.

Dr. MCGINN. Yes.

Mr. THOMPSON. Thank you.

I think, as we go forward, you will see, Mr. Chairman, some other comments relating to this, but I wanted to make sure we were on the record with that issue.

I yield back.

Mr. LANGEVIN. I thank the chairman.

I want to thank the witnesses for their valuable testimony and the members for their questions. The members of the subcommittee may have additional questions for the witnesses, and we will ask you to respond expeditiously in writing to those questions.

At this time, the first panel of witnesses is dismissed, and the Chair now calls up our next panel. Thank you.

I would like to welcome our second panel of witnesses. Thank you for being here today.

Our first witness is Shaun Kennedy, the Deputy Director of the National Center for Food Protection and Defense at the University of Minnesota. The University of Minnesota is a DHS Center of Excellence. We are so happy to have you here today, Mr. Kennedy.

Our second witness is Dr. Lee Myers, State Veterinarian and Assistant Commissioner of the Animal Industry Division in the Georgia Department of Agriculture. Dr. Myers has spearheaded numerous initiatives to improve the States' and the Nation's capacity to prevent and to respond to agricultural emergencies, including acts of agroterrorism. I welcome you here today as well.

Our third witness is Dr. Craig Henry, Senior Vice President and Chief Operating Officer of Scientific and Regulatory Affairs of the Grocery Manufacturers Association and Food Products Association. Dr. Henry, we thank you for being here, and please send our regards to Dr. Matthys, who was going to testify before we switched the schedule on him, so we appreciate your filling in.

Without objection, the witnesses' full statements will be inserted into the record, and I will now ask each witness to summarize his or her statement for 5 minutes beginning with Mr. Kennedy.

**STATEMENT OF SHAUN KENNEDY, DEPUTY DIRECTOR,
NATIONAL CENTER FOR FOOD PROTECTION AND DEFENSE,
UNIVERSITY OF MINNESOTA—TWIN CITIES CAMPUS**

Mr. KENNEDY. Mr. Chairman and members of the subcommittee, I would like to thank you for giving me the opportunity to discuss recent events involving the food system in the United States and our future needs for reducing the possibility of intentional disruption or contamination of this system.

As you have noted, I am here today as a representative of the university community that is committed to finding new solutions to protecting the food system and also as the co-director of the National Center for Food Protection and Defense.

At the Center, we are focused on fundamental and applied research to develop new strategies, tools and approaches to address the threat of intentional food contamination. The university research community is one important partner with the public and private sectors in developing innovative solutions to the threat presented by intentional food contamination.

Food terrorism is not a new threat. In fact, the use of food as a weapon is actually one of the oldest weapons that is still of concern for catastrophic harm. However, a more global food system now means that intentional contamination of one location can literally reach around the country or across the globe to cause economic harm, illness and even death in multiple locations simultaneously.

I have been personally struck by the degree to which the public intuitively understands the threat of intentional contamination of

the food system. One group of NCFPD researchers found that consumers would allocate more funding to protect the food system than a range of other critical infrastructures even though they perceive the relative probability of an attack on the food system to be lower than those other infrastructures. Upon reflection, this is not surprising. The food system is the one critical infrastructure where we cannot take ourselves out of the target population.

The implications of this are not trivial. I think it is important to consider that a long history of Federal, State and local food safety regulations and enforcement has allowed us to be confident, not only in the safety of our food but in the quality of our government. A loss of public confidence in our ability to deliver a safe food supply could challenge both public trust in government and public confidence in the integrity of our food system.

There is, unfortunately, however, no silver bullet for fortifying the food system. The strengths of our system—affordable and fresh fruits, vegetables, meat, poultry, eggs, and dairy all year long—also represent the challenges of this complex system. The Federal and State agencies and the private sector which own and manage the food system have all made dramatic strides in protecting the food system from potential terrorism since it became a front and center concern. There is, however, much more to be done, and we should not be surprised by this.

Protecting our food supply from intentional contamination represents a far more difficult challenge than the Mother Nature problems we are used to dealing with since it involves things that should not happen. While zero risk is, by definition, unachievable, through intensive and targeted research we can reduce the risk. Research themes that I believe to be central to this effort, that NCFPD are actively engaged in, include the following:

The first is event modeling. That is how we can stay ahead of terrorists and others who want to cause us harm. One of the criticisms from the 9/11 Commission was that various Federal agencies suffered from a lack of imagination. In short, terrorists had explored more innovative threat scenarios than those for which the government had prepared. Having learned this lesson once, we cannot afford to do so again. Realistic, flexible and dynamic models of potential food system events are thus an invaluable tool for vulnerability and consequence assessment, intervention prioritization, resource allocation, and decision support during an event.

The second area of focus is in agent and food matrix interactions. We know a great deal about how conventional foodborne pathogens interact with food and the environment, and yet it is still not entirely clear how the *E. coli* 0157:H7 contaminated the spinach in last year's outbreak. Intentional contamination of food for public health or economic harm or economic opportunism elevates the challenge of understanding how agents interact with the food system to an entirely new level. Efforts are, unfortunately, complicated by the fact that traditional "select agents" comprise only a small subset of the agents of concern. With the food itself serving as a very effective and efficient delivery vehicle, the agents of concern go well beyond those of traditional chemical and biological weapons considerations.

All of you are undoubtedly familiar with the “sniffer” at Ronald Reagan National Airport, which represents a great stride forward in detecting potential explosives to prevent them from being taken onto airplanes. Detecting potential explosives in air samples, however, is very different than rapidly detecting agents of concern in frozen cream of broccoli soup or hot dogs, let alone a truck of produce. Novel sample acquisition and pre-analytical processing strategies are therefore a crucial link in any effective detection strategy.

Third, the food system is very much that, a system. As such, it presents inherent challenges with respect to risk and vulnerability assessments as well as the prioritization of investments to enhance food system protection. Unlike many of the 17 critical infrastructures and key resources, it is primarily composed of complex systems, and it is specific elements within these systems and the interdependencies of these systems that are of most concern.

In conclusion, Mr. Chairman and members of the subcommittee, thank you again for the opportunity to talk with you about recent food system events and the challenges they represent for protecting and defending our food supply. We need better food system intelligence, more flexible and responsive prevention, preparedness, response, and recovery strategies, and an expanded armamentarium of technologies and trained professionals to meet these new challenges. The university research community is an important partner in this national imperative. As Co-Director of the National Center for Food Protection and Defense, I am honored to have had this opportunity to provide you with my perspective.

Thank you.

[The statement of Mr. Kennedy follows:]

PREPARED STATEMENT OF SHAUN P. KENNEDY

Mr. Chairmen and Members of the Subcommittee, thank you for giving the National Center for Food Protection and Defense, a Department of Homeland Security funded Center of Excellence, based at the University of Minnesota (NCFPD) the opportunity to discuss recent events involving the food system in the United States and our future needs for reducing the possibility of intentional disruption or contamination of the U.S. food system. The rapid globalization of our food supply chain has added demands upon our existing food safety systems. The threat of intentional contamination of the U.S. food system represents a further significant increase in the challenges that must be addressed to reduce the probability of public harm. Building upon prior experiences with challenges in the United States, one of the important pillars of an effective defense is fundamental and applied research to develop new strategies, tools and approaches to address the threat. This program would include preparation, prevention, response, and recovery. The university research community is one important partner with the public and private sectors in developing innovative solutions to the problems presented by intentional food contamination. The National Center for Food Protection and Defense is honored to have the opportunity to provide one perspective on both the continuing research needs and also how university researchers such as those participating in NCFPD can help address the considerations of intentional attacks on the food system.

Before moving into specific concerns and future needs, some historical perspective is provided on food system contamination to position the challenges ahead of us. While the horrific events of September 11, 2001 have changed our national view on nearly everything, food terrorism is not a new threat.

The use of food as a weapon is actually one of the oldest weapons that is still of concern for catastrophic harm. The Athenians' contaminated the drinking water for the city of Kirrha of the Amphictyonic League in 590–600 B.C., taking advantage of the resulting severe gastrointestinal illness of all inhabitants to overtake the city. A similar strategy was employed by the Carthaginian General Maharbal, utilizing contamination of wine left for his enemy which then rendered them defenseless to

his ensuing attack. In more modern times, the Japanese Army experimented with the use of food for the delivery of pathogens such as *Bacillus anthracis*, *Shigella* spp, *Vibrio cholerae*, *Salmonella Paratyphi* and *Yersinia pestis*.

Frequently cited examples of intentional contamination of food for political gain or intentional harm in the U.S. include the 1984 Rashnisee cult contamination of salad bars in Oregon and the disgruntled grocery worker who contaminated ground beef in Michigan in 2002. Importantly, these historical examples all represent local contamination. Our ever more global food system means that intentional contamination at one location does not limit the impact of such an act to its immediate environment or a single geographic location. As illustrated by recent foodborne illness outbreaks as well as the recent contamination of wheat gluten with melamine from China, food adulteration from around the world can now have direct consequences across the nation. The challenges of our global, just-in-time food system represent a unique area of concern which was recognized by the Administration in implementing Homeland Security Presidential Directive 9 (HSPD-9).

The public, independent of sophisticated risk and vulnerability assessments, intuitively understands the concerns associated with intentional contamination of the food system. In a survey conducted by NCFPD supported researchers at the University of Minnesota in 2005, consumers ranked the probability of an intentional attack on the food system behind attacks on air transportation, all other public transportation, the energy grid, national monuments and the release of a threat agent in an urban area. In contrast, however, consumers ranked the food system as the infrastructure of this list in which they are most concerned about an attack based on their recommendation that more funds be invested in food protection than in the other sectors. This apparent paradox is actually not surprising. The food system is the one critical infrastructure that reaches into every home, every day, with the potential for those of ill will to cause direct, widespread harm. It is the one critical infrastructure where you can not take yourself out of the target population.

The intuitive insight of the public into the importance of attending to the defense of the food system does not, unfortunately, translate into easy, readily available solutions to close potential vulnerabilities. The federal and state agencies involved in the food system have made dramatic strides in protecting the food system from potential terrorism since it became a front and center concern. Similarly, the private sector, which owns and manages the food system, has also worked incredibly hard to identify and address potential food system vulnerabilities. There is, however, much more to be done, and we should not be surprised by this.

For many of us, Upton Sinclair's exposé and novel "The Jungle" was our introduction to food safety and the need for private and public sector efforts to ensure a safe food supply. After more than one hundred years experience with the food safety regulations that this groundbreaking book helped push forward, food safety continues to pose a significant public health challenge. In the last year, foodborne illness outbreaks associated with spinach, lettuce and peanut butter, among others, have reminded us of these concerns. This spring the melamine contamination of vegetable proteins, diethylene glycol contamination of toothpaste and drug residues in fish serve as surrogate models of how intentional food adulteration can pose a far more significant challenge than unintentional food contamination. There is thus much more work to be done to protect the food system. Some of these research needs that are central to effective and full implementation of HSPD-9 are addressed by NCFPD.

Event Modeling

One of the primary criticisms from the 9/11 Commission was that the various federal agencies suffered from a "lack of imagination". In short, terrorists had explored more innovative threat scenarios than those for which the government had prepared. Having learned this lesson once, we can not afford to do so again. The recent melamine contamination provides a stark reminder, even though it was a simple case of economic subterfuge. Although not its apparent intent, the event outlined a pathway of contaminating a pet food raw material as a means of getting a contaminant into animal feed so that it could make its way into the human food supply. While no public harm resulted from this non-obvious scenario, it did demonstrate the ability to contaminate the U.S. food system from afar. It is therefore worth further investigation if only for the economic and psychological consequences of such an event.

Realistic, flexible and dynamic models of potential food system events are thus a very important tool for consequence and vulnerability assessment, development of shields and mitigation strategies, resource allocation and decision support during an event. One such modeling system has been developed through collaboration of NCFPD investigators, the Food and Drug Administration—Center for Food Safety

and Applied Nutrition (FDA-CFSAN), the U.S. Department of Agriculture—Food Safety Inspection Service (USDA-FSIS), the Centers for Disease Control (CDC) and a broad range of state agency experts and the private sector. Although highly successful, including its use for the 2008 Bioterrorism Report from the National Bioterrorism Analysis and Countermeasures Center, efforts on this and other models have highlighted some significant challenges. While there are specific research projects already underway in each of these areas, there is still far more to do:

- Food and ingredient movement is generally very well understood within firms, but it is not well characterized across firms or food and ingredient products. This importantly includes the degree to which the federal, state and local agencies can access specific details on movement either in real time or for planning purposes. Given that supply chain management is the core competency of many food system companies, it is unrealistic to expect them to provide details on how the system works in real time without clear assurances of the protection of such information. A clearinghouse for such information that would be accessible for research and threat assessment purposes, but with no potential for private sector competitive disadvantage, would be a significant step forward;
- Imported products, especially ingredients, represent a special challenge with which the current data and information systems were not designed to deal. The Department of Commerce data on imported food products is based on a categorization system designed to ensure compliance with various tariffs, duties and import/export restrictions. Efforts by USDA such as the Offshore Pest Inspection System (OPIS) and the FDA's Operational and Administrative System for Import Support (OASIS) are significant strides forward, but more robust systems to both enable analysis of product and country specific imports over time as well as real time targeting for inspection based on such analyses would be beneficial;
- Like all catastrophic event models, food system event models are based on a broad range of assumptions of how the various stakeholders in an event would respond—from the impacted food company to potential patients and everyone in-between. Event models would be much more useful for all involved if there were a more robust, exercise driven database on probable responses and their potential effectiveness.

Agent Behavior

One of the outstanding questions from the *E-coli* 0157:H7 outbreak associated with spinach last year is how was the spinach actually contaminated—did the bacteria come from the soil, animal feces, process/harvest cross—contamination, irrigation/surface water contamination or some other source? This challenge stems at least partially from limited understanding of the bacteria's interaction with such diverse environments, something which the industry has stepped forward to address through a competitive research program. Intentional contamination of food for public health or economic harm elevates the challenge of understanding how agents interact with the food system to an entirely new level. This importantly encompasses agent/matrix based vulnerability assessments, new detection and diagnostic strategies and potential event response.

DHS, EPA, FDA and USDA, among others, have probed various aspects of this select agent/matrix challenge. Fundamental projects at both FDA and USDA on some select agents and other contaminants of concern, and how they might impact product characteristics or survive in food products, have increased our knowledge base. NCFPD investigators' efforts on detection (e.g., botulinum neurotoxin detection technologies, micro-fluidic pre-analytical sample processing), inactivation (e.g., *Bacillus anthracis* process inactivation) and decontamination (multiple agents in complex systems) are important steps forward but also illustrative of the challenges ahead, including:

- Traditional "Select Agents" comprise only a small subset of the agents of concern. With the food itself serving as a very effective and efficient delivery vehicle, the agents of concern go well beyond those of traditional chemical and biological weapons considerations. If the food can be used to deliver nutritionally important, targeted levels of vitamins and minerals, agents that can cause harm could also be thus delivered. The range of agents that need to be well understood consequently is far longer than the Select Agents of general concern;
- The range of potential agents highlights a detection challenge. Melamine is a good example of a potential agent that would only have been found in the wheat gluten if you knew to look for it. Conventional quality assurance test methods would not have highlighted its presence. This would also be true for a broad range of food/agent combinations so there is a need for both specific de-

tection technologies for specific agents of concern and broadly useful techniques to rapidly identify that something is amiss and thus requires further testing;

- Understanding how such agents behave in complex food matrices and processes is a nascent area of research, and one that is not traditionally rewarded. Knowing that a particular chemical will turn a certain fluid food product a strange color, thus eliminating that combination as a potential threat, is an incredibly valuable finding for removing a food/agent combination from the list of those of concern. It is not, however, the subject of traditional federally-funded research. Results in this area, nevertheless, will make a significant difference in enabling focus on a smaller set of agent/food combinations;

- Private companies, academia, national laboratories and a range of agencies have devoted a great deal of effort to novel detection technologies, pushing the scientific frontier forward in innumerable ways. All of you undoubtedly are very familiar with the “sniffer” at Ronald Reagan National Airport, which represents a great stride forward in detecting potential explosives to prevent them being taken onto airplanes. Food systems, however, provide a unique challenge due to the complexity of the food matrix itself. Food systems from frozen cream of broccoli soup to hot dogs make the challenge ever more so difficult than air or bodily fluids. Novel sample acquisition and pre-analytical processing strategies are therefore a crucial link in any effective detection strategy.

Systems Strategies

The systems-based nature of the food system presents inherent challenges with respect to risk and vulnerability assessments as well as prioritization of investments to enhance food system protection. Unlike many of the seventeen critical infrastructures and key resources, it is primarily composed of complex systems and it is the interdependencies of these systems that are of most concern in the food system, not specific assets at a location with an address. This is the very reason that DHS is funding several projects to look at new approaches for determining criticality and assessing risk and vulnerability for systems-based infrastructures. While working toward new additions to the tool kit for risk and vulnerability assessments for the food system, there are a number of other systems focused efforts that can both deliver near term improvements as well as form the foundation for long term fundamental improvements. Current projects at NCFPD in food supply chain security and transportation system resiliency are being coupled with economic assessment tools to help focus potential investments. In addition, new approaches to both public health systems surveillance/response and social sciences such as risk communication are important ongoing NCFPD research efforts and aim at closing other research gaps. Examples include:

- For many foodborne illness outbreaks today, the detection system that identifies that a food has been contaminated is the public health system. For the melamine contamination it was veterinarians identifying unusual patterns of illness and for the *E-coli* 0157:H7 associated with spinach outbreak last year it was the public health authorities at state and local level. In both cases, however, much of the food had already been consumed before anyone identified the problem. Any approach that could therefore decrease the time from first presentation of illness to recognition of the outbreak could dramatically reduce the potential consequences.

An ongoing example of such efforts that includes investigators from NCFPD, other academic institutions and collaborators across federal agencies and associations is an examination of how various local, state and federal agencies respond to and manage foodborne illness disease outbreak investigations. The goal is to develop a set of performance standards that result in an even more rapid response to any food related disease outbreak than is already provided today;

- Reducing the potential vulnerability within any specific food supply chain, including its distribution system, first requires characterizing how that system functions in the interdependent infrastructures we have today. Once characterized, more effective vulnerability and risk assessments are possible, thus highlighting points for the most effective introduction of interventions by either the private or public sector. Projects are underway that look at best practices in the food industry as a starting point. These studies will be complemented by recently initiated efforts on more detailed analyses of the transportation system and imported product pathways. Perhaps more so here than in any other area, public-private partnerships are crucial to moving things forward as each group has detailed information in different areas that have to be brought together for an effective outcome;

- A challenge for all investments in terrorism prevention, response and recovery is determining how much should be spent to reduce the probability or the consequences of an attack. In either the private or the public sector, there is a limited amount of potential funding available and it has to be focused on the points of greatest impact. This is perhaps even more important in the food system than in some of the other critical infrastructures because of its complicated, globally dispersed and highly dynamic, privately held, nature. Secondary benefits for food defense-motivated investments, alternative investment returns through vehicles such as insurance/re-insurance and better means of capturing the potential impact of events at the firm and system level are all areas of ongoing research that should help guide future investments;
- In the focus on “hard” tools for event prevention and response, the importance of “soft” tools such as risk communication is often overlooked. Effective risk communication before, during and after an event will significantly reduce the consequences of the event itself. Food, because of its very personal nature, requires that any such risk communication strategies take into account the very different information and communication needs of the range of groups and cultures in the U.S. Research on how to communicate most effectively with various underserved and non-traditional audiences is highlighting the range of strategies required. This research importantly includes the current collaboration of NCFPD investigators and other experts with the various federal, state, local and private sector groups who are front and center in any food system event. Products such as the NCFPD developed Risk Communication Best Practices are only a start in the significant effort to use risk communication as an effective intervention strategy.

Summary

Outstanding progress has been made by both the private and public sectors in reducing the probability and potential impact of intentional food contamination. Much more, however, is needed for full and effective implementation of HSPD-9. This includes the need for ongoing basic through applied research to address each of the primary policy areas identified in HSPD-9 for effective protection of the food system:

- Prioritization of the critical food protection and defense needs is a continual process due to the dynamic nature of our food system. As the system changes, our research strategies, prevention efforts and preparedness must change. Supply and demand changes, new products, new markets, and new consumer demands drive the ever changing nature of our food system. The shift of corn from animal feed to ethanol production illustrates this well;
- Forewarned is forearmed. Understanding changes underway and anticipating their impacts underpins effective early warning systems and robust prevention and preparedness. Public-private partnerships can support robust food system intelligence to recognize potential threats. While imports of wheat gluten from China nearly doubled between 2005 and 2006, and economic adulteration was rampant, we were unaware;
- Mitigating vulnerabilities at critical production, processing, distribution and other nodes builds off of the identification and prioritization of critical elements and resources within the food system, but includes the need to develop new mitigation strategies as the vulnerabilities continue to evolve. Collaboration across DHS, EPA, FDA, USDA, state/local agencies, the private sector owners of the food system and academia will be an important ongoing partnership for vulnerability mitigation strategy/technology development and cost effective deployment;
- Melamine contamination, antibiotic residues in imported fish and other imported product adulterations illustrate the need for enhanced screening procedures for imported products. Foodborne illness outbreaks associated with domestically sourced products reinforce that the same need exists for domestic production. Unfortunately it is just as unlikely to successfully “test in” food system defense as it is to “test in” food safety. Enhanced procedures for targeting inspection and detection will continue to be important from the farm (wherever in the world it is) through distribution to the final containment point, prior to consumer access;
- Given the degree to which the global food system is necessarily open and therefore potentially vulnerable, efforts must include enhancing response and recovery procedures to deal with the realistic probability that there will be an actual food system event. Both public/private partnerships and very innovative strategies for preparedness will be required for effective response and recovery efforts;

- Determining the right way to communicate to underserved communities is best not done in the face of a crisis just as designing practical facility decontamination and contaminated product disposal protocols is best not done when you have contaminated facilities and products. It will take continual effort to develop flexible strategies to make response and recovery efforts most effective;
- Across all of these policy goals for HSPD-9, the need to develop the future leaders in food protection and defense is central to creating the enduring capability that is needed in the future. The students, from high school through post-doctoral, that are engaged in NCFPD and other academic programs in food protection and defense are how the policy goals outlined by HSPD-9 and addressed above are made sustainable over the long haul.

In conclusion, Mr. Chairmen and Members of the Subcommittee, thank you again for the opportunity to talk with you about recent food system events and the challenges they represent for protecting and defending our food supply. The threat of intentional contamination of our food is real. While we all have come to enjoy an abundant, affordable, diverse and safe food supply as our birthright, our overall successes have made us complacent. Our food system is global and will always be global: we all demand coffee and chocolate; bananas and bonita. . .and our year-round cornucopia of food results from an ever-changing global supply chain. Ironically, the very advances that afford us these luxuries also create new dilemmas: a small intentional contamination can become a national foodborne disease outbreak due to the scale of production and wonder of the supply chain. We need better food system intelligence, more flexible and responsive prevention, preparedness, response and recovery strategies, and an expanded armamentarium of technology, training professionals and tested interventions to meet these new challenges. The university research community is an important partner in this national imperative. As Co-Director, on behalf of the National Center for Food Protection and Defense (NCFPD), we are honored to have provided you with our perspective on continuing research needs and how university researchers can help address this global threat to food system and American way of life, and defend the safety of the food system through research and education.

Mr. LANGEVIN. Thank you, Mr. Kennedy.

The Chair now recognizes Dr. Myers for 5 minutes.

**STATEMENT OF DR. LEE M. MYERS, STATE VETERINARIAN
AND ASSISTANT COMMISSIONER OF ANIMAL HUSBANDRY,
GEORGIA DEPARTMENT OF AGRICULTURE**

Dr. MYERS. Mr. Chairman and members of the committee, thank you for the opportunity to testify as to the State involvement in protecting our Nation's food and agricultural systems. My name is Lee Myers. I am the State Veterinarian and Assistant Commissioner with the Georgia Department of Agriculture, and I am appearing here today on behalf of the National Association of the State Departments of Agriculture and as President of the United States Animal Health Association. NASDA represents the commissioners, secretaries and directors of agriculture in the 50 States and 4 territories, and the USAHA has served as the Nation's animal health forum for well over a century. I would like to outline the critical role that State agriculture departments play in defending agriculture and food in our country and describe our efforts and challenges to build capacity to combat food and agricultural emergencies.

State agriculture departments license, permit, inspect, and oversee activities along the entire farm to fork continuum in cooperation with our Federal partners, with the USDA and the FDA. You may be surprised to hear that 80 percent of all food inspections nationwide are conducted by representatives of State and local authorities. State employees by the thousands are on the ground each day, inspecting agricultural facilities at the operational level. We own farms; we own buying stations, slaughterhouses, food proc-

essors, cold and dry storage units, warehouseers, wholesalers, retail and food service establishments. We also oversee the transportation of agricultural commodities and products between all of these entities. Our employees collect samples, analyze those samples in State laboratories, and issue seals of approval that commodities or products meet the government standards to be transported, planted, processed or otherwise consumed by the general public.

When problems arise, such as these recent recalls that have been discussed earlier today of spinach, peanut butter, canned meat products, and pet foods, it is the employees of the State Departments of Agriculture who respond within hours to track down these contaminated products, assure that these recalled items are removed from the grocery shelves, and directly oversee their destruction. Also, State Departments of Agriculture are the primary agencies responsible for the protection, response and recovery to animal and plant pests and diseases, natural disasters and other hazards that can harm the agricultural industry.

We must recognize that 99 percent of emergencies are not incidents of national significance and are managed by State and local authorities, not the Federal Government. This includes an outbreak of a foreign animal disease, which would be managed through a unified command structure with our colleagues in the USDA, utilizing State-issued quarantines and State requirements for carcass disposal and State requirements for debris removal. The DHS recognizes that State regulatory programs and laboratories are the backbone of the Nation's public network for ag and food safety.

What I have described, gentlemen, is the boots on the ground, front-line defense for our Nation's food and ag. This is "a day in the life" of the State Department of Agriculture. Although the vast majority of resources and these tactical operations and interfaces with the private sector are realized at the community level, States are the most underfunded component of the national food and ag security strategy. Available funding is irregular; it is modest and on a catch-as-catch-can basis. So how can Congress help us get it right and overcome the challenges of building the necessary capability to combat food and ag emergencies?

Firstly, there is an urgent need for Congress to provide consistent and sustained funding to State agricultural authorities, to develop agricultural security programs and abilities within each State. The USAHA at its last annual meeting passed a resolution urging Congress to appropriate funding to States for the development of animal emergency management plans and the implementation of sustainable capabilities. It is difficult to rationalize that the U.S. Government doles out billions to protect our ability to surf the World Wide Web, and yet, the March 2007 Congressional Research Service Report indicates that agriculture has received on average 2 percent of the nondefense Homeland Security budget over the last 5 years to assure that we have a safe and secure food supply, one of the primal essentials to sustain life. Ag and food defense must become a national priority and require that it be named as a State priority on State strategic plans. We believe that resources should be directed to each State agency and that Congress and

Federal departments should develop a detailed, integrated budget with sustainable dollars.

Secondly, we recommend that Congress request Federal departments to work with States to expedite the development and the implementation of tools to identify critical infrastructure and key resources and conduct vulnerability assessments. NASDA, in cooperation with the USDA, the FDA and the DHS, announced the availability of a model food emergency response template over a year ago, and this template provides a guidance for managing food emergencies of varying magnitudes. However, State government agencies need assistance to develop and to implement their food emergency plans, and we believe it is cost-effective to invest in State and local governments with these valuable tools. NASDA has also partnered with other stakeholders to develop similar tools for the animal and plant sectors, but again, resources are short to complete the development and the implementation for tactical work in the States.

Thirdly, there is no operational, comprehensive and secure communication network for agriculture to share these alerts of threats and linking local, State, Federal, and private partners with the appropriate security clearances. The DHS has identified strengthening information-sharing and collaboration as a specific priority, but quite frankly, progress is moving at a snail's pace, and as a consequence we have these duplicative communication systems that rarely communicate with each other. A single integrated Homeland Security communication network for all sectors, including ag and food, should be imperative and a time certain established. The fulfillment of these three requests would be a good start in mitigating the current crisis of confidence that was referenced earlier.

In conclusion, the State Departments of Agriculture and the USAHA appreciate the efforts of Congress and the administration to enhance the safety and security of our food supply, but yet there is a lot of work that needs to be done, and we want to be in full partnerships with our Federal colleagues to help ready America to prepare for, to plan for and to stay informed during significant agricultural or food emergencies.

Thank you, Mr. Chairman, for the opportunity to share a State perspective with the committee.

[The statement of Dr. Myers follows:]

PREPARED STATEMENT OF DR. LEE M. MYERS

Mr. Chairman and members of the Committee, thank you for the opportunity to testify on the safety and protection of our Nation's food and agriculture system against terrorist attacks, major pests and diseases and other emergencies. My name is Lee Myers. I am the State Veterinarian and Assistant Commissioner of Animal Industry for the Georgia Department of Agriculture, and I appear here today on behalf of the National Association of State Departments of Agriculture (NASDA).

NASDA represents the commissioners, secretaries and directors of agriculture in the fifty states and four territories. States clearly form the first line of defense against the threat of a terrorist attack against our food supply. Today, I would like to broadly outline the critical role the state agriculture departments play in food safety and defense, and describe our efforts and challenges to prepare for food and agriculture emergencies.

Complexity of Regulation for Food and Defense of the Agriculture Sector

The "farm to table" food supply chain is a complex system that includes millions of acres of cropland, billions of livestock and poultry, thousands of feedlots, proc-

essing plants, warehouses, and packaging and distribution networks that bring food from around the nation and the world to neighborhood markets and restaurants across the nation.

The threat of a terrorist attack on the food and agriculture industries is likely to involve the contamination of commodities rather than the destruction of infrastructure. However, the diverse and widespread nature of the industry makes it extremely difficult to identify and secure every facility that might be a potential target. In the case of food, for example, introduction of minute levels of certain hazardous agents could cause widespread harm, including serious economic and social disruption. Local, state and federal partners as well as the industry itself have already taken important steps to help protect the food and agriculture industry from terrorist attack. NASDA believes there needs to be a greater linkage at all levels of government and the private sector of resources, expertise, and initiatives to achieve our shared security and emergency preparedness goals.

Roles of State Agriculture Departments in Food Safety and Defense

Protecting the nation's food and agriculture industry demands the coordinated effort of public, private and university partners in the same way that all of these stakeholders have cooperated for decades on issues of food safety, animal health and plant protection. In the area of food safety, for example, the statistics are surprising: while this is the shared responsibility of all partners, approximately 80% of all food safety inspections are conducted by state and local agencies.

State agriculture departments need sufficient field inspection forces to promote biosecurity of food and agriculture businesses; enhance prevention by enforcing uniform food and agriculture safety and security laws with industry; provide routine surveillance of food, plant and animal products; respond quickly in the event of an attack; and provide the means to restore confidence in the food and agriculture sector. States agriculture departments are the lead agencies in the prevention, detection and eradication of plant and animal pests and diseases in accordance with the national and state response plans.

Vulnerability

Recent food safety events have made regulatory agencies and industry realize the landscape of food safety and defense is changing. Risks include the tremendous growth of the imported foods market with limited regulatory oversight and centralized food production, processing and storage. According to USDA's Foreign Agriculture Service (FAS) statistics, 48 percent of America's agricultural consumption was imported in 2007. This includes "bulk" products such as wheat and cotton, "intermediate" products such as oils and livestock, "consumer oriented" products such as butchered meat and vegetables, and "other" products such as timber and seafood.

State regulatory programs and laboratories are currently the backbone of the Nation's food safety network. However, threats to the food supply typically cross state borders and have national implications. There are limited resources to develop preparedness and response plans for animals and plants (i.e. crops, hay, pasture, and rangeland). "Point source" facilities exist in agriculture (plans to protect them are similar to other fixed facilities). The "nonpoint sources" are more difficult to plan for, but need to be carefully considered in any agriculture preparedness and response plans.

Vulnerability Assessments in the Food and Agriculture Sector

The assessment of terrorist threats to food and agriculture and evaluation of the agriculture industry's vulnerabilities will form the basis for developing a preparedness and response strategy for the Nation's food and agriculture industry. The challenge is to determine the likelihood of various forms of attack and identify on a priority basis the gaps in the existing systems.

The states have been conducting this activity for several years. In July 2004, NASDA and its affiliate organization, the Association of Food and Drug Officials (AFDO) conducted a survey of states to collect information about homeland security activities in state departments of agriculture. The purpose of the survey was to obtain a baseline assessment of state initiatives, including emergency response and planning, vulnerability assessments, specific funding for agriculture and food defense, and training. All fifty states responded to this baseline survey. The survey data found that many states had completed a substantial number of vulnerability assessments utilizing a variety of methods from formal surveys and expert panels to informal assessments during regular inspections. The survey found that many states had developed plans across all sectors of the plant, animal, and food areas to mitigate perceived vulnerabilities. The survey also found that states have participated in dozens of exercises or drills to test emergency response capability and most included other state or federal agencies. Specific highlights of the survey results are:

- 52% of respondents indicated that their food program had received some level of funding for food security initiatives.
- 56% or 28 states have developed a written food emergency response plan.
- 44% or 22 states have conducted some type of food and agriculture vulnerability assessment.
- 18% or 9 states have developed some type of vulnerability reduction plan to address food and agriculture vulnerabilities.

The baseline survey results indicate that states are engaged in many areas of food and agriculture defense, but more needs to be done.

In addition, states are working with our federal partners in several activities. We are participating in the Administration's Food and Agriculture Coordinating Council (FACC) and Government Coordinating Council (GCC) to help meet the goals of Homeland Security Presidential Directive 9 (HSPD-9). Many state agriculture departments have participated in vulnerability assessments through the Strategic Partnership Program on Agroterrorism (SPPA), and we commend USDA for this collaboration. SPPA is a Federal Bureau of Investigation (FBI)-led partnership with FSIS, the Food and Drug Administration (FDA) and the Department of Homeland Security (DHS) that brings a variety of stakeholders together to conduct vulnerability assessments on a variety of food commodity systems. One goal of the SPPA initiative is to identify countermeasures that need to be developed.

However, state departments of agriculture need access to the findings of SPPA to help develop cost-effective measures to enhance our ability to prevent an attack, detect an attack at the earliest possible time, respond to protect both the public health and industry and recover from an attack by restoring public confidence and the economic viability of affected sectors. NASDA urges USDA, FDA, DHS, and other federal partners to complete risk and vulnerability assessments in all areas of the food and agriculture industry and share information relevant to the development of specific state preparedness strategies. Such information sharing is imperative as states develop and refine individual State Homeland Security Strategies (SHSS) and will be important for the seamless integration of state plans into the National Homeland Security Strategy.

These initial efforts have strengthened our ability to prevent, rapidly detect, and respond to bioterrorism incidents, but need to be expanded. One key issue at the state level is the amount of effort required to accomplish this huge task. DHS, FDA, and USDA have funding to accomplish vulnerability assessments, but the availability of funding is a "catch as catch can" basis from state to state. Funds need to be targeted directly to the state departments of agriculture to accomplish this work.

Without better targeted and consistent funding, we will have to compete with other non-agriculture in-state homeland security entities. For example, the state homeland security grants have an 80/20 split, with the local governments receiving 80% of the funding. We realize that all emergencies are local, and for the most part this is a model that works well. However, there is no local authority for agriculture agencies as exists for public health, fire services, or law enforcement. The agricultural authority in most states rests with the state agriculture department; but since these departments are considered a "state" entity, they do not qualify for the local funding. This discrepancy needs to be remedied to benefit state food defense capability.

Challenges for State Departments of Agriculture

• Emphasis Needed on Food Defense

The President's National Homeland Security Strategy recognizes the importance of securing the Nation's food supply and designated agriculture as a "critical infrastructure." However, "food defense" is difficult to achieve and needs to be considered one of the highest priorities for DHS. NASDA has been concerned that the emphasis on homeland security in border protection overshadows the need to remain vigilant in protecting the food and agriculture industry from the introduction of pests and disease at the border. We strongly believe that prevention of animal and plant terrorism and protection for the Nation's food supply must be considered a critical priority of DHS.

• Federal Funding and Support

Managing the short and long term consequences of an attack on the food supply is among the responsibilities of state and local government supplemented by the resources of the federal government. Issues related to activities such as initial response, animal and plant quarantines, withhold orders, tracing of contaminated product, secure communications following an event, and short and long term recovery are some of the many responsibilities faced by state governments.

To date, federal support for state departments of agriculture for agriculture and food defense has been very limited and inconsistent. Modest USDA support was provided to enhance animal and plant laboratories and to begin work on projects including rapid notification and other systems. While almost a billion dollars in FY03 was provided through the Centers for Disease Control (CDC) to state health agencies for uses including food security, agriculture departments have been excluded from receiving funds. In June 2003, NASDA released a state resource survey conducted by AFDO. The survey data indicated that of \$960 million federal counter-terrorism funding given to states, a mere \$43 million (4.5%) went to Plant and Animal Disease Response, Surveillance and Testing; and \$3.6 million (0.4%) was devoted to protecting all other elements of the food supply, such as manufacturing, processing, distribution, storage and retail levels for food.

Federal funds should be better targeted and consistent to help states accomplish many of the tasks described above. The Congressional Research Service (CRS) issued a Report to Congress on March 12, 2007 titled "Agroterrorism: Threats and Preparedness." The report notes that "as a percentage of non-defense budget authority for homeland security, agriculture receives about 2.1% of the total." The report further notes that "regular appropriations for agriculture in DHS are irregular and tied to particular initiatives, such as university research grants or facility construction."

- **DHS Grant Program**

NASDA has been very concerned that the overall decreased funding available to states under the DHS Homeland Security Grant Program will have a significant impact on states' abilities to prepare for emergencies affecting food and agriculture. The problem is further complicated by the fact that the grant program is currently one of the only sources of funding to states to support homeland security preparedness in all sectors. DHS could address this problem by assuring that the risk calculation—which is one of two components that is used to determine each state's allocation under the grant program—fully considers the risks, vulnerabilities, and impacts associated with threats to our food and agriculture sector.

With appropriate funding, states could:

- develop programs dedicated to food defense, animal defense, and plant defense;
- improve inspection, testing and surveillance activities;
- conduct additional threat, vulnerability and risk assessments;
- work with industry to identify critical infrastructure, key resources, and develop mitigation strategies and defense capabilities.

- **Food and Agriculture Defense Planning**

The states are particularly interested in one activity where DHS could assist in food defense planning and preparedness training for state agriculture, health and emergency management agencies. In February 2006, NASDA, in cooperation with USDA's Food Safety Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Department of Homeland Security (DHS), announced the availability of a model Food Emergency Response Plan Template. The template is a tool that will enhance the protection of the Nation's agricultural industry and food security through increased prevention, detection, response, and recovery planning.

The template provides states with a guide for developing a food emergency response plan. It is designed to assist states with development of either a stand-alone plan for responding to a food-related emergency or an addendum to an existing all-hazard state emergency response plan. Because a food emergency could occur at any point in the food chain from farm to fork, including pre-harvest production and transportation, the application of this template assists in managing emergencies with varying magnitude and scope.

The template is also a "building block" in the national effort to develop a seamless system of food defense from local, state and federal perspectives. It identifies how these efforts will be effectively integrated with the National Response Plan (NRP) and state response plans, including descriptions for responding to, mitigating and recovering from a domestic incident. In addition, the template provides a baseline structure for preparing state-level plans to protect critical infrastructure and key resources identified through the National Infrastructure Protection Plan (NIPP).

The state agriculture departments and other state government agencies need assistance to develop and implement their food emergency plans, along with preparedness training and education. NASDA has asked DHS to provide initial funding for this activity. We believe it is cost-effective to provide state and local governments with a valuable readiness tool to facilitate seamless regional and national responses to food emergencies.

In addition to the food defense template, NASDA has partnered with others at the state and regional level to develop animal and plant defense planning and re-

sponse templates. These templates are in a final stage of development, but additional funding is needed for full implementation and associated training. These templates should be incorporated into the context of an all-hazards approach.

• **Communications and Coordination of State and Federal Resources**

Providing the means for the food and agriculture sector to communicate during all phases of emergency management, particularly during a response, is the foundation for overall preparedness. There is a vital need to establish a well coordinated and efficient communication strategy that links agriculture stakeholders and allows for the rapid dissemination of information. Since local and state agriculture or health departments will often be the first to respond to a food emergency, communication channels between local, state and federal partners must be clearly defined and practiced. The same is true for any animal or plant emergency as well. Some of the information that needs to be efficiently shared includes: specific threat alerts from intelligence partners; incident notifications from field staff, industry or others; routine surveillance information from inspections, laboratory analyses and other local and state sources; and other information deemed critical to preventing human illness, death or serious economic harm to the industry from a terrorist attack at any juncture from farm to fork.

State and federal governments must effectively communicate and coordinate resources in an emergency using the Incident Command Structure (ICS). Despite the federal emphasis on ICS, the response to the recent melamine contaminated proteins was not managed using ICS. States had no situational awareness and could not effectively respond to their constituents. The Nation's slow response eroded consumer confidence in the pet food industry and threatened the confidence of the human food supply. While not a replacement for ICS in this event, NASDA set up and operated an information network to keep directly affected states informed.

The use of ICS would have allowed the federal government to leverage state resources during the response to the melamine incident and other national recalls. Resources include animal diagnostic laboratories, food testing laboratories, and regulatory and administrative personnel to respond to and support the concerted effort. As we strengthen our laboratory resources and other response capabilities, management of resources on a national scale using ICS will become increasingly important.

At present, there are serious impediments to establishing such a system which need to be addressed. These include:

- The loss of information through unnecessary "classification" of documents, and the inefficient processing of security clearances for state agriculture officials;
- Federal resistance to accepting investigation results, recalls and other actions from nationally accredited state and local laboratories;
- The lack of an operational, comprehensive and secure communications network to share threat alerts and other information linking local, state, federal and private partners, with appropriate security clearance;
- The lack of a comprehensive incident notification process for the food and agriculture industry;
- The lack of adequate risk communications preparedness and response planning and training; as a result, states are hampered in their ability to disseminate adequate safety and technical information to the media and public during an incident.

Many state agriculture officials have experienced substantial delays in the processing of their security clearances. In order for NASDA to function as an important organization, assisting in the liaison between state and federal governments, and participate fully in the homeland security initiatives of the food and agriculture sector government coordinating council, key staff have a need to know certain sensitive information. There is an immediate need for DHS to expedite security clearance applications for key state agriculture personnel.

NASDA also believes more effort is needed to address the communications gap between state and federal partners in the sharing of critical information and intelligence. Federal agencies should review currently classified information and make determinations about whether it needs to remain classified for security purposes. The results of state and local inspections and laboratory analyses found to be consistent with federal requirements should be recognized as equivalent to federal inspections and analyses. Development of rapid communications and incident notification systems should have top priority and include both public and private sector decision-makers.

NASDA supports ongoing work being done by DHS to implement the Homeland Security Information Network (HSIN). HSIN could be a significant communications

tool for local, state and federal partners, but the system is not yet operational, despite years in the making.

Another important area is the need to protect the confidentiality of information. Because the majority of agricultural assets are in the private sector, necessary information may be proprietary or pertain to trade secrets or business operations. Congress should require that such information obtained from the states be maintained as confidential.

Recommendations to Enhance Food and Agriculture Defense Capabilities

As we have emphasized throughout our testimony, states clearly form the first line of defense against the threat of a terrorist attack against our food supply. The federal government should capitalize on the proven strengths of the state programs by providing funding, guidance, and coordination of resources to effectively protect the agriculture and food sector. NASDA offers the following recommendation to enhance our food and agriculture defense capabilities:

- Congress and federal departments should develop a detailed integrated budget for food and agriculture defense, as requested by HSPD-9.
- DHS should survey state departments of agriculture to determine homeland security requirements; further DHS should fund these requirements as a priority through state grants or other federal legislation that directs resources for food and agriculture defense.
- DHS should develop an action review process for agriculture and food incidents of national importance; such review should identify the gaps, lessons learned, and solutions to improve response and coordination.
- DHS Office of Health Affairs should review the Homeland Security State Grant Program for food and agriculture defense and publish annual guidance for this sector to better target resources.

Conclusion

The state agriculture departments appreciate the efforts by Congress and the Administration to enhance the safety and security of the Nation's food supply and the agricultural production system which supports it. As partners in the federal system, we stand ready to work with the Committee and Congress to accomplish these goals.

Mr. LANGEVIN. Thank you, Dr. Myers.

The Chair now recognizes Dr. Henry to summarize his statement for 5 minutes.

STATEMENT OF DR. CRAIG HENRY, SENIOR VICE PRESIDENT AND CHIEF OPERATING OFFICER, SCIENTIFIC AND REGULATORY AFFAIRS

Mr. HENRY. Thank you, Mr. Chairman and members of the subcommittee, for inviting GMA to participate in this hearing to discuss Federal efforts to mitigate vulnerabilities to the food supply chain.

The food industry is committed to assuring the safety and security of the U.S. food supply. Food defense addresses the intentional adulteration of food products and/or ingredients using chemical, biological, radiological agents. This requires a vigilant effort from the food manufacturer to know how to identify the vulnerabilities and to adopt effective mitigation strategies.

The food industry has worked collaboratively with various Federal agencies for several years now to ensure the best practices are identified and disseminated and to develop mechanisms for Federal agencies to share intelligence with the food industry that can enable companies to target their vigilance.

In preparing for a deliberate attempt to contaminate the food supply, food companies have participated in vulnerability assessments with government officials, with industry trade associations or independently, and participated as well in Table Top Exercises designed to simulate an actual attack on the food supply.

Food safety and food defense are the ultimate goal of all food companies, and achieving that goal requires the cooperative efforts of the regulatory agencies; that is Federal, State and local, as well as the food industry.

Deliberate contamination of the food supply is still viewed as a relatively low potential risk but a serious concern versus food safety concerns from conventional contamination or product mishandling or mislabeling, which also includes economic adulteration, which has the potential to be a food safety event.

I would like to mention the Strategic Partnership Program on Agroterrorism. The "SPPA," as it is referred to, is a cooperative initiative among Federal and State government agencies and private sector volunteers to provide government and industry with more a complete, sector-wide perspective of food and agricultural defense. Under the initiative, vulnerability assessments are conducted in the food and agriculture sector using CARVER+Shock evaluation to help distinguish between real and perceived food defense vulnerabilities and risks.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, otherwise known as the "Bioterrorism Act," provided the FDA with the authority to promulgate regulations concerning the registration of food facilities, the establishment and maintenance of records, prior notice of imported food shipments, and the administrative detention of food. The FDA rules are in place and are being enforced. Unfortunately, funding for the 600-plus additional inspectors initially provided to the Center for Food Safety and Applied Nutrition to better enforce the regulations has evaporated, and the Agency has had to reduce staffing to cover the budget. This has largely negated any gain in efficiency the Agency perceived by having prior notice of all food imports so they could coordinate sampling and inspection efforts. Agency funding is critical to enforcement operations.

The GMA is an active member of the Food and Agriculture Sector—Government Coordinating Council. This is a self-organized, a self-run and a self-governed committee composed of members in the food and agricultural sectors, and it serves as the government's point of entry into each sector for developing and coordinating a wide range of infrastructure protection activities and issues.

There is also the Food and Agriculture Sector Joint Committee on Research. This committee has identified a number of private sector needs such as better vulnerability assessment tools. As mentioned previously today, the FDA recently released a CARVER+Shock software tool that provides a means for all companies to conduct a vulnerability assessment of their operations. CARVER+Shock vulnerability assessment tool is used to assess the vulnerabilities within a system or infrastructure to an attack. As you may know, "CARVER" is an acronym for Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability.

A seventh attribute, "Shock," has been added to the original six to assess and combine health, economic, psychological impacts of an attack within the food industry.

Lastly, I would like to mention another valuable tool, which is the Table Top Exercise. Joint industry, regulatory agency, health

department, and law enforcement officials participate in training exercises simulating an intentional product contamination event.

Thank you for the opportunity to be here with you today, and I am pleased to answer any questions you may have.

[The statement of Mr. Matthys follows:]

PREPARED STATEMENT OF DR. ALLEN W. MATHYS

Mr. Chairman and Members of the Subcommittee

I am Allen Matthys, Vice President, Federal and State Regulations, Grocery Manufacturers Association (GMA). Thank you for inviting GMA to participate in this Hearing to discuss Federal efforts to mitigate vulnerabilities in the food supply chain. The food industry is committed to assuring the safety and security of the U.S. food supply. This includes company or third part audits as well as a review of any government inspection reports.

Food safety concerns deal with identifiable risks and incorporate mitigation steps (including Hazard Analysis Critical Control Point (HACCP) evaluations, time/temperature processes, etc.) to control or reduce the likelihood of a problem occurring. Food defense addresses the intentional adulteration of food products and/or ingredients using chemical, bacteriological and/or radiological agents. This requires a vigilant effort from the food manufacturer to know how to identify the vulnerabilities and to adopt effective mitigation strategies.

The food industry has worked collaboratively with various federal agencies for several years to ensure that best practices are identified and disseminated and to develop mechanisms for federal agencies to share intelligence with the food industry that can enable companies to target their vigilance.

In preparing for a deliberate attempt to contaminate the food supply, food companies have participated in vulnerability assessments with government officials (the Strategic Partnership Program Agroterrorism (SPPA)), with industry trade associations, or independently and participated in Table Top Exercises designed to simulate an actual attack on the food supply. The SPPA program introduced industry to the CARVER + Shock vulnerability assessment but the information was available only to those companies that participated in the SPPA event. FDA recently released a CARVER + Shock software tool that provides a means for all companies to conduct a vulnerability assessment of their operations.

Food safety and food defense are the ultimate goal of all food companies. Achieving that goal requires the cooperative efforts of the regulatory agencies (federal, state, and local) and the food industry.

Food Industry Action

When information surfaced indicating that the food and agriculture sector was considered as a potential target for terrorist organizations, regulatory officials communicated this information to the industry. FDA officials indicated that they had conducted an internal analysis of several food product categories using the CARVER + Shock analyses and identified a number of considerations that affect the risk that a food, at a particular point in its production, could become the target of intentional contamination. The following four characteristics were common to each of the food products identified as being at a higher risk:

- Large batch size, resulting in large number of servings
- Short shelf life or rapid turnaround at retail and rapid consumption
- Uniform mixing of contaminant into food
- High accessibility to the critical node of production, processing or distribution

The "higher risk" foods received priority attention by FDA for the identification and implementation of preventive measures. Likewise, USDA began a similar analysis of meat and poultry products. [The initial reports were then provided to Department of Homeland Security (DHS) officials and duly classified as "Top Secret" and thus became inaccessible to food industry representatives.]

Points to Cover:

Deliberate Contamination still viewed as a low potential risk versus food safety concerns from conventional contamination or product mishandling or mislabeling (also economic adulteration has potential to be a food safety event).

Strategic Partnership Program Agroterrorism (SPPA)

Individual food companies have volunteered to participate in the SPPA program for several commodity groups identified by FDA/USDA as fitting the potential target profile. The SPPA is a cooperative initiative among federal and state government

agencies and private sector volunteers to provide government and industry with a more complete sector-wide perspective of food and agriculture defense. Under the initiative, vulnerability assessments are conducted in the food and agriculture sector using CARVER + Shock* evaluation to help distinguish between real and perceived food defense vulnerabilities and risks within the food and agriculture sector. It also assists in identifying potential mitigation measures and strategies that may be appropriate for the food and agriculture sector. In addition, the SPPA has assisted in the identification of research needs and the allocation of research investments to address priority needs.

These vulnerability assessments with industry on a variety of foods regulated by the Food and Drug Administration a number of research questions were generated. The commodities evaluated were dairy products, fruit juices, bottled water, water used for food processing, and infant formula. The research questions fell into the following general categories:

- partitioning of chemical compounds into the water or lipid fractions of a food;
- thermal stability of chemical and microbiological agents;
- stability of chemical and microbiological agents to acidic and alkaline pH;
- changes in food conductivity upon exposure to chemical agents;
- UV inactivation of biological agents;
- effectiveness of disinfection agents against chemical and biological agents;
- oral toxicity of chemical agents; and
- filtration to eliminate or reduce chemical and biological agents

A summary of the main research results released to date is provided at

<http://www.cfsan.fda.gov/dms/defres05.html>

Regulatory Requirements under Bioterrorism Act

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) provided FDA with the authority to promulgate regulations concerning registration of food facilities, establishment and maintenance of records, prior notice of imported food shipments and administrative detention of food. FDA rules are in place and being enforced. Unfortunately, funding for the 600+ additional inspectors initially provided to CFSAN to better enforce the regulations has evaporated and the agency has had to reduce staffing to cover the budget. This has largely negated any gain in efficiency the agency received by having prior notice of all food imports so they could coordinate sampling and inspection efforts. Agency funding is critical to enforcement operations.

GMA is an active member of the *Food and Agriculture Sector—Government Coordinating Council (FASCC)*. FASCC

A self-organized, self-run and self-governed committee, composed of members in the food and agriculture sector that serves as the government's point of entry into each sector (i.e., plant and animal producers, processors/manufacturers, restaurants/food service, retail, warehouses and agriculture production) for developing and coordinating a wide range of infrastructure protection activities and issues (e.g., research and development, outreach, information sharing, vulnerability assessments/prioritization, shielding and recovery).

GCC FASCC: The government counterpart to the SCC that is established to enable interagency coordination of agriculture and food defense strategies and activities, policy, and communication across government and between the government and each sector to collaborate and develop consensus approaches to the CI/KR protection. Membership is comprised of various levels of government (Federal, State and Territorial, local and tribal).

Food and Agriculture Sector Joint Committee on Research

Guidelines available to industry

Materials available from FDA, USDA, and industry

<http://www.cfsan.fda.gov/dms/defguids.html>

Private Sector Needs

- Better vulnerability assessment tools (FDA software tool attempts to address this need)
 - Efficient area surveillance technologies
 - Chemical/biological agent detection sensors—must be rapid, inexpensive, low false positive, low false negative, multi-agent, multi-food, easy to use, low acquisition and operation costs
 - Definitive cleaning/sanitizing and decontamination methods
 - Traceability tools
 - Robust communication tools between the food industry and federal, state and local authorities

- A clear understanding of how a bioterrorist event will be communicated to consumers and coordinated with other stakeholders
- Basic understanding of CBR agents
- Coordinated activities between the various federal agencies are still confusing and needs to be clarified including how state authorities are integrated into the food defense strategies and tactics

CARVER + Shock Vulnerability Assessments—Tools for individual company evaluations

*CARVER + Shock is an offensive targeting prioritization tool adapted from the military version (CARVER) for use in the food industry. The tool can be used to assess the vulnerabilities within a system or infrastructure to an attack. It allows the user to think like an attacker to identify the most attractive targets for an attack. By conducting a CARVER + Shock assessment of a food production facility or process, the user can determine the most vulnerable points in their infrastructure, and focus resources on protecting the most susceptible points in their system. Conduct vulnerability assessment; identify critical nodes, under take mitigation steps to reduce vulnerability.

CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:

- Criticality—measure of public health and economic impacts of an attack
- Accessibility—ability to physically access and egress from target
- Recuperability
- ability of system to recover from an attack
- Vulnerability—ease of accomplishing attack
- Effect—amount of direct loss from an attack as measured by loss in production
- Recognizability—ease of identifying target

A seventh attribute, Shock, has been added to the original six to assess the combined health, economic and psychological impacts of an attack within the food industry.

The attractiveness of a target can then be ranked on a scale from one to ten on the basis of scales that have been developed for each of the seven attributes. Conditions that are associated with lower attractiveness (or lower vulnerability) are assigned lower values (e.g., 1 or 2), whereas, conditions associated with higher attractiveness as a target (or higher vulnerability) are assigned higher values (e.g., 9 or 10). Evaluating or scoring the various elements of the food sector infrastructure of interest for each of the CARVER-Shock attributes can help identify where an attack is most likely to occur in that infrastructure. Federal agencies, such as FDA and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), have used this method to evaluate the potential vulnerabilities of farm-to-table supply chains of various food commodities. The method can also be used to assess the potential vulnerabilities of individual facilities or processes.

Table Top Exercise

Joint industry/regulatory agency/health department/law enforcement officials participate in training exercises simulating an intentional product contamination event.

Mr. LANGEVIN. Thank you, Dr. Henry. I am glad that you brought up the CARVER+Shock program. I was reading in my briefing material about this program, and it is an important tool, obviously.

Again, I want to thank all of the witnesses for their testimony. I will now recognize myself for 5 minutes.

To the panel, based on your work with the Federal Government over the years, how would you grade the Federal effort on food security?

We will start with you, Mr. Kennedy.

Mr. KENNEDY. I have been greatly encouraged by the collaboration we have received since we started with the National Center for Food Protection and Defense and how all three of the primary agencies are very much working with us on advancing the research to try and further protect the food system. We work very closely with FSIS, with CFSAN and with the Office of Health Affairs and DHS, and as I believe Carol Maczka mentioned in the first panel,

we are now working together on an imported foods research project specifically related to China and to other foreign countries.

Mr. LANGEVIN. Thank you.

Dr. Henry.

Mr. HENRY. From the industry perspective, I would say the process that has been put forth by the Federal Government has certainly matured and improved since the onset of 9/11 initially, and I think during the early years the industry saw a real challenge amongst the various agencies to have, if you will, nice, coordinated communications so that each agency knew what was going on, how the funding was being applied, what the net results were going to be, and I think that that has really portrayed itself very well in recent years. Currently, through the SPPA initiative and other integrated stakeholder programs, we are much better set now to execute a program, should it occur, with an event that develops within the United States.

Mr. LANGEVIN. Dr. Myers.

Dr. MYERS. I believe there have been tremendous efforts put forward by the Federal Government. However, there still remains a large disconnect between the Beltway here in the Washington area and Federal departments and what is happening in the real world—boots on the ground level—with State governments. State governments need to be brought in as full working partners, many times at the developmental stage rather than at the end of the process where we are asked for casual comments very often on short timelines. We want to be full working partners throughout the continuum, developing from the initial policy development stage to full implementation.

So there has been tremendous effort, I think, particularly a working collaboration between Federal Governments, but there needs to be great enhancement of reaching out and working with local and State partners.

Mr. LANGEVIN. So to quantify this a little more, I want to ask each of you to assign a letter grade to the Federal Government's efforts on food security.

Mr. Kennedy.

Mr. KENNEDY. I would say a "B" at this point.

Mr. LANGEVIN. Dr. Henry.

Mr. HENRY. I would concur. A "B" would be appropriate.

Dr. MYERS. I concur, a "B."

Mr. LANGEVIN. Thank you.

Mr. Kennedy, the University of Minnesota has a great food security simulation that has been funded by DHS.

How has this simulation been put to work, and can you tell us about some problems that your scientists are most concerned about today?

Mr. KENNEDY. The simulation that, I believe, you are referring to is something called the Consequence Management System, and it is built by obtaining data from the private sector in how food actually moves within the system, both internationally and in the United States, combined with public health system response data on how we would expect an actual outbreak to progress. So it allows us to provide more realistic evaluations of how potential intentional food contaminations would unfold, what would the con-

sequences be, and therefore, how would certain interventions change that outcome to reduce the possible consequences.

One of the challenges in developing a system like this is that it is very dependent upon the private sector data, and quite understandably, the private sector needs to check that information, so we do not have an easy vehicle to ensure that we have all of the appropriate data into the models on private sector food movement.

The second challenge that we encounter is we do not have a good idea of exactly how the public health system will respond if there is an event. As a simple example, in a research study 2 years ago, the researcher found that emergency room physicians when presented with a case history got *Bacillus anthracis* right 75 percent of the time on the first try and botulinum neurotoxin right 50 percent on the first try. How fast will we know when it actually happens? That is an unknown in our models.

Mr. LANGEVIN. Thank you.

Briefly, Dr. Henry, you spoke about the CARVER+Shock program. I know one of your biggest issues of the private sector is a better vulnerability assessment tool.

So can you expand upon how the CARVER+Shock software tool is helping you and what more the private sector is looking for in this area?

Mr. HENRY. Certainly.

The CARVER+Shock tool now being brought to bear online by the FDA is a very positive step forward. As you know, a number of our members are large as well as small and very small production facilities. They do not have the luxury of coming to various places, especially like Washington, D.C., to obtain training in the area of CARVER+Shock. This online tool will provide an excellent vehicle for them to capture that information and match it against their own in-house food defense program. We see the CARVER+Shock program, of course, being enhanced through additional efforts such as the one that we will be carrying forth with GMA later on this year where we will be doing an online Web and are basically open to certainly our members and others, where they can gain hands-on input, ask questions and try to expedite the utilization of that tool.

Mr. LANGEVIN. Very good. Thank you, Dr. Henry.

I thank the panel.

The Chair now recognizes the ranking member, Mr. McCaul of Texas, for 5 minutes.

Mr. MCCAUL. Thank you.

When we look at this threat, I see two scenarios. One is man-made. One could be intentional, deliberate, an act of terrorism. The other, probably more likely, scenario is accidental. It could be natural. It certainly could be manmade but not an intentional act.

I agree with you, Dr. Henry, that the threat level of a deliberate attack is low, and let us hope it stays that way, but the risk could be very high. Dr. McGinn and I discussed, you know, one nightmare scenario of botulism being put in an ice cream factory which distributes all throughout the country, and of course children would be the primary consumers, and I know there are all sorts of nightmare scenarios. My first question is:

We just heard from the panel of Federal experts—the FDA, the DHS, the USDA—about their efforts. One of the biggest, more recent concerns is the importation of contaminated fish from China. That could be just as damaging as a deliberate attack. So whether we are importing from a country that actually intentionally wants to harm us through that vehicle or whether it is just accidental, how confident are you—and this is to the panel as a whole—that our ability to screen and sample as our imports come into this country—how confident are you in terms of our ability to secure and make safe the food coming into this country?

Ms. MYERS. I may take an initial stab at that. That is one of the things we are struggling with at the State level, is the increase in ethnic and diversity of foods, many times that have foreign labels that are difficult for us to translate, with symbols we don't understand. And these type of foods are increasing at an alarming rate through imports.

So I think we are very concerned about the type of foods, the volume, and the different mechanisms by which they land on the shelves. Our ability can only be as good as we are informed and trained. And so, again, I point to the disconnect that we really need better information sharing; we need better training tools. A lot of these are actually tested in State laboratories. And I may use the melamine as a recent example. You may remember, actually, it was the veterinary community that discovered the problem initially in companion animals. And so there is a disconnect again between companion animal surveillance, what we might see there. The majority of these diseases through animals are zoonotic; they are contagious from animals. So we have a lot of shoring up to do. There are a lot of lessons learned and gaps that we need to overcome. And a lot of this was discovered in State veterinary labs first. So as was pointed out, I think our main gap is the ability to quickly detect that something is there before we diagnose it or recognize it as an outbreak.

Mr. MCCAUL. Thank you, Dr. Myers.

Dr. Henry?

Mr. HENRY. Yes. I think the foremost issue here on dealing with imports or any other products coming into the United States, but particularly focusing today on food, is funding. As you may be aware, GMA is a member of the Coalition for a Stronger FDA. Many efforts have been put forth here on the Hill to try to have Congress focus on the lack of funding that is necessary, as was brought up in my testimony. Funding, tied with proper resource allocation, is paramount to getting the job done. I think that, as Dr. Acheson testified earlier, that when you have known agents, it makes it a lot easier to go out there and try to make sure your screening and your inspection process is adequate and efficacious. Certainly the situation with melamine, the food industry, along with the Federal Government and the State agencies, we are all kind of scratching our head, and we are working very diligently right now to try to identify what the unknown agents are. And in this case, of course, it was pretty well defined as not an intent of harm, but more as an intent of economic adulteration to create a low-grade product into a high-grade product and then command a higher price.

I think, as we go through this process, we also need to look at the funding, which Dr. Myers brought to bear. In the case of CARVER+Shock or the SPPA meetings or anything else, the State agencies certainly are not getting the funding they need and many times do not have the resources to attend a lot of these events. And I think that that is paramount, especially if we are going to maintain a close communication and operating system to address these things.

I certainly want to touch upon two other areas, and that is the importance of risk-based inspection and allocating risk among both USDA and the Food Safety Inspection System directly and FDA. As you may know, GMA leads the Coalition for Risk-Based Inspection, and certainly would look forward to Congress moving that along, because that is an excellent platform for the United States to embrace today. We also are driving now forth with our industry on a Food Safety Task Force, and later this fall, we will be holding a special symposium here on suppliers' best practices. And that workshop is really to get down and try to define what we are doing right and what we could do better to make sure the imports coming into the United States are safe and meet the quality that the consumer expects today. Thank you.

Mr. MCCAUL. Thank you.

Mr. Kennedy, do you have any comments?

Mr. KENNEDY. In addition to concurring with the other panelists, I would just like to point out one item of additional concern, which is that, as you look at the box of food that you are eating tonight or the can that you pick up, look at that list of ingredients and recognize how many of those ingredients we don't know necessarily from what country they came from when they are in that finished product. So as Mr. Langevin pointed out earlier, and in my written testimony, there is a comment on a repository for information on where food comes from, how it moves, that we can trace. Right now, if there were intelligence indicating that a specific country's source of ingredients were of concern, a food company may not actually know that their ingredient comes from that particular company or country. We don't have that supply chain verification mandated all the way back to the primary supplier.

Mr. MCCAUL. I see my time has expired. Mr. Chairman, I thank you for holding this hearing. I look forward to working with you on legislation to address this important issue.

Mr. LANGEVIN. Likewise, and I thank the ranking member. I want to thank the witnesses for their valuable testimony and, again, the members for their questions.

The members of the subcommittee may have additional questions for the witnesses, and I would ask that you respond expeditiously in writing to those questions. Your presence here was important, and I thank you for that. Hearing no further business, the subcommittee now stands adjourned.

[Whereupon, at 12:24 p.m., the subcommittee was adjourned.]

APPENDIX

ADDITIONAL QUESTIONS AND RESPONSES

RESPONSES FROM DR. DAVID ACHESON

Submitted by Stephen R. Mason, Acting Assistant Commissioner for Legislation



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Bennie G. Thompson
Chairman
Committee on Homeland Security
House of Representatives
Washington, D.C. 20515

OCT 24 2007

Dear Mr. Chairman:

Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the July 24, 2007, hearing entitled "Federal Efforts to Mitigate Vulnerabilities in the Food Supply Chain." This letter provides responses for the record to follow-up questions from the hearing and to questions raised during the hearing.

We have repeated the questions in bold below, followed by the Agency's response.

The Honorable James Langevin

1. Under the National Response Plan, DHS is supposed to be a "coordinating agency" during a terrorist attack, major disaster, or other emergency involving the nation's agriculture or food systems. Please detail your agency's experience in DHS carrying out its role as coordinating agency? Has this been an effective process? If not what have been the challenges?

FDA's primary experiences with the Department of Homeland Security's (DHS) role as a coordinating agency in the situations you mentioned include responding to hurricanes, tornadoes and floods. In addition, FDA participates in the TOPOFF series of counterterrorism exercises, for which DHS is the coordinating agency. These exercises provide an opportunity to test, among other things, the effectiveness of coordination during an emergency situation. Following each exercise, a report is prepared that identifies successes and areas that need improvement. The TOPOFF exercises are an important mechanism for testing and strengthening coordination during emergencies.

FDA's experience with DHS's coordination role under the National Response Plan (NRP) also includes the development of the Food and Agriculture Incident Annex (Annex) to the NRP. The Annex outlines FDA's actions, roles, and responsibilities associated with a potential or actual incidence requiring a Federal coordinated response involving contaminated food, infected animals or plants. The procedures are based on the core coordinating structures of the NRP. The primary functions of the Annex include supporting effective and

coordinated communication between Federal, state, and local responders; minimizing public health and economic impacts; and providing a smooth transition from response to rapid recovery following a food and agriculture-related incident.

2. With more than 15 agencies administering at least 30 laws related to food safety, how has your Department prepared against vulnerabilities? What type of coordination or information sharing do you routinely practice?

Prior to the tragic events of September 11, 2001, FDA had begun conducting vulnerability assessments of the food and cosmetics supply. However, shortly after the events of September 11, 2001, FDA quickly expedited the process of assessing the vulnerabilities and prioritizing the assets of the food and cosmetics industries regulated by the Agency. FDA held meetings with the major food and cosmetics trade associations to solicit industry perceptions of vulnerabilities in the U.S. food and cosmetics production, processing and distribution system. Feedback from these meetings, coupled with input from Agency experts, led to the development of a list of foods that warranted a formal evaluation of risk. At that time, FDA also began conducting significantly more research focused on new methods, prevention technologies, agent characteristics, and dose response/threat assessments (i.e., ability of foodborne threat agents to cause mass casualties).

The National Strategy for Homeland Security and the Homeland Security Act of 2002 served to mobilize and organize our Nation to secure the homeland from terrorist attacks. The homeland security goals to prepare for and respond to such events are set forth in Homeland Security Presidential Directives (HSPDs) 5, 7, 8 and 9. HSPD-5 ensures that all levels of government responding to an incident of national significance have the capability to work efficiently and effectively together using a common national domestic incident management approach, and HSPD-8 provides guidance on how to prepare for such a response, including prevention activities. HSPD-7 focuses on issues concerning protection of all national critical infrastructures and key resources, the majority of which are owned and operated by the private sector. HSPD-9 represents a major step toward establishing a comprehensive national policy to defend the food and agriculture system against "terrorist attacks, major disasters and other emergencies."

Significant progress in the Food and Agriculture Sector, one of the identified Critical Infrastructures on homeland security goals, can only be accomplished through a partnership effort between all levels of government and those who own the Critical Infrastructure. The Food and Agriculture Sector Coordinating Council (SCC) was formed as part of the private sector response. The SCC is a self-governing body representing the food and agriculture industry that provides a forum for the private sector to discuss infrastructure protection issues among themselves and to communicate with the government through the Government Coordinating Council (GCC). The GCC, with representation from Federal, state, tribal and local governments, is the public sector component of the food and agriculture public-private partnership framework. The objective of the GCC is to provide effective coordination of food and agriculture security strategies and activities, policy, and communication across government and between the government and the Sector to support the Nation's homeland security mission. The GCC conducts monthly conference calls to discuss infrastructure protection issues. Also, monthly calls are held between the leadership for the GCC and SCC to discuss infrastructure protection issues. The Food and Agriculture Sector holds a joint face-to-face GCC/SCC

meeting each quarter to discuss issues of concern. Finally, the Food and Agriculture Sector is also populating an electronic notification system with contact information for the GCC and SCC members so that we can convene a meeting of the sector members on short notice.

In July 2005, DHS, the U.S. Department of Agriculture (USDA), FDA, and the Federal Bureau of Investigation (FBI) announced a new collaboration with private industry and the states in a joint initiative, the Strategic Partnership Program Agroterrorism (SPPA) Initiative. The SPPA Initiative is a true partnership program, where an industry member, trade association or state may volunteer to participate in this vulnerability assessment program utilizing the "CARVER + Shock" method. The desired results of the SPPA Initiative include sharing:

- Reports that detail identified vulnerabilities, possible mitigation strategies, and warnings and indicators for each site. The reports will be distributed to all site participants.
- Reports that outline sector-wide vulnerabilities and lessons learned to effectively and appropriately prioritize national assets and resources. The reports will be distributed to DHS, USDA, FDA, and FBI.
- The "CARVER + Shock" assessment tool, and adapt, if necessary, to its unique production, processing, retail, warehousing, and transportation system for each sub-sector.
- Lessons learned.
- Assessment templates for each "system" by sub-sector that can be exported to other sites to identify vulnerabilities that incorporate existing tools.
- Sector-specific investigative templates and field guides for the food and agriculture/intelligence sector.
- Data to the National Infrastructure Protection Plan (NIPP). NIPP working groups for further development of the NIPP and national preparedness plans.
- R&D initiatives related to the food and agriculture sector.

This year, FDA in cooperation with the Centers for Disease Control and Prevention (CDC), USDA, and state and local organizations representing food, public health, and agriculture interests announced a new food defense awareness initiative, ALERT. The ALERT initiative is designed to provide a uniform and consistent approach to food defense awareness at any point in the food supply chain, from farm to retail establishment. ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination. The five points are enumerated in FDA's written testimony. We have prepared ALERT materials in several languages and offer training on our website that is suitable for state, local, and industry stakeholders.

FDA has issued guidance documents on food defense for the food industry. These documents identify the kinds of preventive measures that may be taken to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. FDA issued a general guidance entitled "Food Producers, Processors, and Transporters: Food Security Preventive Measures." The guidance is designed as an aid to firms that produce, process, store, re-pack, re-label, distribute or transport food or food ingredients. In addition, we have issued specific security guidance for the milk industry, for importers and filers, for retail food stores and food service establishments, and for cosmetic processors and transporters. During domestic

inspections and import examinations, FDA's field personnel, as well as our state counterparts, distribute and discuss these guidance documents.

As part of its activities to implement the provision in the Public Health Security and Bioterrorism Preparedness and Response of 2002 that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the U.S., FDA developed an electronic prior notice system interface (PNSI). It can receive prior notices from any submitter from anywhere in the world with Internet access on an around-the-clock basis. Submitters also may file the required prior notice with the U.S. Customs and Border Protection's (CBP) Automated Commercial System (ACS). PNSI and ACS are linked together. FDA/CBP currently receive approximately 175,000 prior notices per week. The notices give FDA advance notice of what foods are being imported or offered for import into the U.S. and allow FDA to match these data against targeting information and focus its inspection resources. This advance notice enhances FDA's ability to discover and act on foods that present a significant public health threat.

In addition, FDA founded and hosts monthly meetings of the Agriculture Intelligence Working Group. Participating agencies include the FBI, the Central Intelligence Agency (CIA), USDA, FDA, the Department of Defense (DoD), the Environmental Protection Agency (EPA), and DHS. The agencies share information and coordinate activities to prevent and respond to agroterrorism threats.

These are just a few of the many activities FDA has undertaken to protect against vulnerabilities and to coordinate and share information with our food defense partners.

Also in the Department of Health and Human Services (HHS), CDC has surveillance of and epidemiologic response to disease as the foundation of its activities. Routine disease surveillance systems coordinated by CDC provide an essential early-information network to detect dangers in the food supply. PulseNet is a national network of public health and food regulatory agency laboratories coordinated by CDC and consists of state health departments, local health departments, USDA, and FDA. PulseNet plays a vital role in surveillance for and investigation of foodborne illness outbreaks that were previously difficult to detect. Participants perform standardized molecular subtyping (or "fingerprinting") of foodborne disease-causing bacteria which are submitted electronically to a dynamic database at CDC. When similar DNA patterns are identified for foodborne disease-causing bacteria, scientists can determine whether cases of illness are linked to the same food source, even if the affected persons are geographically far apart. Outbreaks can often be detected in a matter of days rather than weeks. As a consequence, CDC can more rapidly alert FDA and USDA about implicated food products associated with foodborne illness so that all three agencies can take protective public health action.

A public health laboratory infrastructure that can provide test results in hours rather than days is critical in the event of terrorism. The Laboratory Response Network (LRN) was created in 1999 by CDC, the Association of Public Health Laboratories (APHL), and FBI. The LRN is a national network of local, state and Federal public health, military, food testing, veterinary diagnostic, and environmental testing laboratories that provides the laboratory infrastructure and

capacity to respond to biological and chemical terrorism and other public health emergencies. The approximately 150 laboratories in the LRN are affiliated with Federal agencies, military installations, international partners, and state and local public health departments.

3. What type of staffing challenges (vacancies, retention, recruitment, expertise, etc.) exists within your Department in carrying out your food safety/defense mission?

Reducing the risk of foodborne illness and protecting the security of the nation's food supply requires directing resources to the highest public health priorities and developing and maintaining effective partnerships. FDA's food safety/food defense program is flexible enough to deal with emerging issues through collaboration with other Federal agencies, the states, and other stakeholders. One example of the ways in which we leverage Federal resources to enhance security is the Memorandum of Understanding that CBP and FDA signed in December 2003. It commissions CBP officers to conduct examinations and investigations on FDA's behalf pursuant to information obtained through the prior notice requirements at ports where FDA may not currently have staff or to augment FDA staff at ports that do have an FDA presence. This FDA/CBP collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade. Another example is the coordination and collaboration we do with government and private partners to address our priority research needs for food defense.

4. In a November 2003 GAO Report titled "Bioterrorism: A Threat to Agriculture and the Food Supply," GAO found that most of USDA's and FDA's field staff had not received training on security matters. And, although the field staffs were instructed to be vigilant and on "heightened alert," they were also told not to document or report their observations regarding security at the plants because the information could be obtained under a Freedom of Information Act request.

a. Has this policy changed?

In 2004, FDA incorporated food defense aspects into all food inspections by requiring investigators to issue food defense documents to managers and to have discussions with firm management about any identified security-related issues. The policy on documenting security observations remains not to disclose the specific vulnerabilities identified during inspections in public documents like Establishment Inspection Reports (EIRs) or FDA 483s (Inspectional Observations). This policy was enacted to prevent security breaches from such information being obtained under the Freedom of Information Act. In addition, FDA's food safety authorities extend to the regulation of physical facility security measures to the extent that food safety and food defense overlap.

b. Can you confirm that staff are instructed not to document or report observations?

Yes. FDA's Investigations Operations Manual (IOM) directs the staff not to document or report security-related observations, and instead, discuss these issues with the management at the firm.

As discussed above, this policy was enacted to guard against security breaches from information being obtained under the Freedom of Information Act.

c. Do field staffs currently receive security specific training?

Yes. FDA has provided instructions to our field staff regarding security training. This training occurred soon after FDA published the 2003 Food Security Guidance documents that were developed for industry. As FDA's food security/food defense program grew over time from 2002 to 2007, FDA trained field staffs accordingly. During 2003, we also conducted joint training with USDA to address the food security measures outlined in the Food Security Guidance documents. In addition to guidance for industry, FDA also took an active role in assuring food security/food defense by conducting food security surveillance inspections with our state and Federal partners. As our food security/food defense programs have grown, we have continued to update field staff in understanding their responsibilities in these programs. This includes our most recent ALERT Food Defense Initiative, which is a food defense program developed jointly by Federal and state agencies, as the uniform method through which investigations/inspectors should discuss security-related issues with the regulated food industry. FDA trained over 1,200 field investigators in the ALERT Food Defense Initiative via classroom courses, video broadcasts and on-line courses. This program provides examples of the type of conversations regulatory personnel should be having with the owners and operators of food establishments, businesses and organizations. ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination at their facility. These are enumerated in our written testimony.

In summary, the Agency has incorporated food defense aspects into all food inspections and has trained its field staff on these procedures.

The Honorable Donna M. Christensen

How does the FERN laboratory network cover the U.S. Virgin Islands and other territories?

FDA has established the Food Emergency Response Network (FERN) to enhance our response capability by improving our laboratory capacity. An important component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of food samples that could potentially be contaminated for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with USDA's Food Safety and Inspection Service to ensure that FERN includes a substantial number of laboratories capable of analyzing foods for agents of concern. We are seeking to expand our capacity through agreements with other Federal and state laboratories. At present, the network includes 134 laboratories representing all 50 states and Puerto Rico and participation continues to grow. Once it is operating at full capacity, FERN will encompass a nationwide network of Federal, state, and local laboratories working together to build the capacity to test the safety of thousands of food samples, thereby enhancing the nation's ability to swiftly respond to a terrorist attack.

During an emergency event, staff in any FERN laboratory would be available to assist a U.S. Territory. FERN staff would coordinate sample shipment from the territory to the FERN lab. Depending on the emergency, FDA may also be able to provide kits, reagents and technical assistance to any labs located in the territory to expedite sample analysis. In past emergencies, FDA FERN labs have provided reagents and technical assistance to non-FERN labs, which has contributed to our ability to respond to the given crisis.

The Honorable Marcy Kaptur

What percentage of drugs are imported? Not just finished product, but components of drugs.

Exact data on the percentage of drugs imported in the U.S. is not available. However, imported human drugs, excluding mail and baggage shipments, accounted for 198,000 import entry lines in FY 2005 and over 222,000 import entry lines in FY 2006.

For reference, below is a brief explanation of an import entry line.

Import Entry Line -- When merchandise is delivered or offered for delivery into a Customs Territory of the U.S., it is assigned an 11 character entry number for future references to the entry. An entry is simply an accounting entity used by Customs for assessing tariff. Within a CBP entry there may be one or more lines, which represent a breakdown of the different products in that entry. Each line represents a different product or the same product but a different manufacturer, country of origin, etc.

Are imports of drugs growing?

Yes. Between FY 2002 and FY 2006, there has been a 75% increase in human drug import lines, excluding mail & baggage shipments.

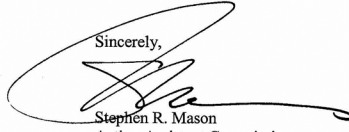
Which countries are the worst offenders?

FDA does not have a definition for "worst offender." However, the two enclosed tables provide two measures based on import line refusals (i.e., total refusals and percent of total refusals over the time period of FY 2002 – FY 2007 year to date). The first table provides the number of human drug import line refusals by foreign country of declared origin and fiscal year. The table is sorted by total refusal counts in descending order. The second table provides the percentage (%) of lines refused for the same time period sorted by percentage in descending order by foreign declared country of origin.

Please note that the data in the enclosed tables include courier but exclude mail & baggage shipments.

Thank you again for the opportunity to provide testimony at the hearing. We look forward to continuing to work with you and your staff on these important food safety and food defense issues.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

cc: The Honorable Peter T. King
Ranking Minority Member

The Honorable James Langevin
Committee Member

The Honorable Donna M. Christensen
Committee Member

The Honorable Marcy Kaptur
Member of Congress

TABLE

1

FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin*
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	2002	2003	2004	2005	2006	2007 YTD	Refused FY 2002- 2007 YTD
India	273	327	1,093	651	662	497	3,503
Canada	570	670	523	392	530	176	2,861
Mexico	370	286	273	210	138	271	1,548
United Kingdom	348	312	137	144	251	158	1,350
China (Mainland)	121	148	180	304	210	295	1,258
France	231	119	99	140	179	171	939
Germany, Federal Republic of	138	150	123	132	143	129	815
Italy	174	99	77	86	115	114	665
Philippines	39	66	134	135	139	55	568
Spain	57	97	76	72	91	35	428
Switzerland	61	36	37	78	102	79	393
Dominican Republic	113	66	56	48	59	27	369
Colombia	27	34	62	103	111	22	359
Korea, Republic Of (South)	13	28	69	55	78	44	287
Brazil	39	53	39	41	42	67	281
South Africa	69	53	30	44	32	47	275
Nigeria	63	42	26	41	26	73	271
Venezuela	61	40	37	60	48	24	270
Taiwan, Republic Of China	27	36	94	55	34	19	265
Guatemala	3	5	4	55	181	13	261
Belgium	53	31	65	49	42	17	257
Netherlands	24	12	45	25	60	33	199
Japan	41	34	43	28	27	20	193
Australia	25	27	30	53	43	12	190
Pakistan	14	18	22	33	51	24	162
Ukraine	4	6	5	121	9	8	153
Israel	16	19	34	38	34	9	150
Poland	3	72	18	14	24	15	146
Ireland	34	18	12	45	22	12	143
Thailand	23	24	20	29	22	15	133
Argentina	8	8	19	30	52	14	131
Russia	3	15	14	27	14	50	123
Hong Kong	6	13	30	28	27	16	120
Ghana	16	17	16	32	21	17	119
Greece	27	13	6	43	13	15	117
Egypt	5	6	11	42	23	29	116
New Zealand	9	31	13	10	6	40	109
Saudi Arabia	10	8	17	20	14	32	101
United Arab Emirates	16	3	7	26	22	23	97
Peru	13	12	11	15	40	4	95
Panama	17	23	18	19	9	7	93
Costa Rica	18	18	18	6	12	19	91
Indonesia	13	4	14	25	17	17	90
Turkey	29	2	6	24	17	9	87
Singapore	14	9	9	11	34	6	83
Denmark	7	4	35	16	10	6	78
Jordan		20	6	18	23	7	74
Sweden	11	9	7	9	12	14	62

FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin*
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	2002	2003	2004	2005	2006	2007 YTD	Refused FY 2002- 2007 YTD
Austria	3	5	17	12	11	8	56
Trinidad & Tobago	18	13	3	7	13	2	56
Haiti	2	6	26	4	1	15	54
Ecuador	1	12	2	18	17	3	53
Chile	8	7	5	9	9	13	51
Hungary	7	1	5	22	7	8	50
El Salvador	1	1	1	16	22	5	46
Malaysia	6	5	4	11	14	4	44
Bolivia	14			18	7	4	43
Guyana	12	10	4	2	13	2	43
Honduras			5	7	25	6	43
Lebanon	3	1	4	13	13	9	43
Barbados	21	3	4	2	4	1	35
Jamaica	4	5	7	10	7		33
Cameroon		3	3	18	5	1	30
Czech Republic	3	4	2	9	3	7	28
Bulgaria	11	2	5	6	2	1	27
Zimbabwe	3		1	13	7	3	27
Nepal		3	4	14	2	2	25
Romania	2	6	9	4	4		25
Vietnam	1	5	11	5		3	25
Portugal	1	2	9	4	3	5	24
Bangladesh	4	5		7	1	5	22
Monaco	2		1	9	3	7	22
Norway	11	1	1	3	1	5	22
Sri Lanka	2	1	4	5	3	7	22
Tanzania, United Republic Of		10	3	4	3	2	22
Ivory Coast	3	13	2		1	2	21
Kenya	3	3	7	2	3	1	19
Finland	2	2	2	5	2	5	18
Macau		1	2	12		2	17
Uruguay	1	1		5	8	1	16
Croatia		2	8	3	1	1	15
Senegal	1			11	1		13
Syrian Arab Republic	1	2		6	4		13
Cyprus	1			6	2	3	12
Bahamas	1		2	5	3		11
Guadeloupe		3	3	1	2	2	11
Morocco	1		3	3	3	1	11
Aruba	4		2		4		10
Kuwait	3	1	1	1	2	2	10
Netherlands Antilles	1	1		7		1	10
Belize		7	2				9
British Virgin Islands	5	3		1			9
Mongolia					9		9
Fiji	2	1		3		2	8
Macedonia				1	3	4	8
Nicaragua	1		2	1	2	2	8

FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin *
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	2002	2003	2004	2005	2006	2007 YTD	Refused FY 2002- 2007 YTD
Paraguay					5	3	8
Iraq				7			7
Zambia	1	1	1	2	1	1	7
Turkmenistan			6				6
Antigua & Barbuda	1	2	1			1	5
Armenia	1		1	3			5
French Polynesia		3	2				5
Iceland		3			2		5
Kampuchea					5		5
Saint Lucia	3	1				1	5
Sierra Leone				3	1	1	5
Slovenia				1	2	2	5
Tunisia	1			1	3		5
Yemen			2	2	1		5
Albania	4						4
Bosnia-Herzegovina				4			4
Lao Peoples Democratic Repblc.						4	4
Slovakia	1			2	1		4
Algeria				1	2		3
Botswana			2	1			3
Burkina Faso			2		1		3
Byelarus	2			1			3
Cayman Islands				1	2		3
Georgia	2					1	3
Guinea		1		2			3
Latvia		1		1	1		3
Liberia		1	1			1	3
Martinique			1	2			3
Namibia						3	3
Qatar	1	2					3
Azerbaijan					1	1	2
Bahrain				1		1	2
Benin	1	1					2
Bermuda		2					2
Congo, Dem Rep of (Kinshasa)	1				1		2
Dominica	1					1	2
Grenada	1		1				2
Lithuania		2					2
Luxembourg	1					1	2
Malawi				2			2
Moldova				1		1	2
Saint Christopher & Nevis				2			2
St. Vincent & The Grenadines		1	1				2
Sudan				1	1		2
Swaziland	1				1		2
Tajikistan					2		2
Uganda			1	1			2
Uzbekistan					2		2

FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin *
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	2002	2003	2004	2005	2006	2007 YTD	Refused FY 2002- 2007 YTD
Yugoslavia				1	1		2
Andorra				1			1
Angola			1				1
Burma					1		1
Congo (Brazzaville)						1	1
French Guiana						1	1
Kazakhstan			1				1
Madagascar				1			1
Mali					1		1
Malta & Gozo	1						1
Mauritius				1			1
Oman						1	1
Afghanistan							0
Burundi							0
Cape Verde							0
Central African Republic							0
Chad							0
Christmas Islands (Indian Ocn)							0
Cocos Islands							0
Cook Islands							0
Country Code Unavailable							0
Cuba							0
Czechoslovakia							0
East Timor							0
Eritrea							0
Estonia							0
Ethiopia							0
Falkland Islands							0
French Southern Antarctic							0
Gambia, The							0
Georgia							0
Gibraltar							0
Guinea-Bissau							0
Iran							0
Kyrgyzstan							0
Lesotho							0
Libya							0
Liechtenstein							0
Maldives							0
Mauritania							0
Mozambique							0
Multiple Countries							0
Nauru							0
New Caledonia							0
Niger							0
Reunion							0
Serbia							0
Seychelles							0

FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin *
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	2002	2003	2004	2005	2006	2007 YTD	Refused FY 2002- 2007 YTD
Solomon Islands							0
Somalia							0
Surinam							0
Togo							0
Tokelau Islands							0
Turks & Caicos Island							0
Vanuatu							0
Vatican City State							0
Yemen, Democratic (South)							0
TOTAL	3,450	3,315	3,920	4,053	4,159	2,989	21,886

* Foreign Declared Country of Origin means the products were manufactured outside of the U.S., Puerto Rico, U.S. Virgin Islands, American Samoa and Guam.

TABLE

2

Percent of FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin *
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	Refused FY 2002- 2007 YTD	Lines FY 2002- 2007 YTD	Percent Lines Refused
Tajikistan	2	2	100.0%
Turkmenistan	6	6	100.0%
Sudan	2	3	66.7%
Burkina Faso	3	5	60.0%
Bolivia	43	80	53.8%
Ghana	119	224	53.1%
Tanzania, United Republic Of	22	42	52.4%
Cameroon	30	59	50.8%
Andorra	1	2	50.0%
Angola	1	2	50.0%
French Guiana	1	2	50.0%
Guinea	3	6	50.0%
Guyana	43	86	50.0%
Namibia	3	6	50.0%
Swaziland	2	4	50.0%
Haiti	54	109	49.5%
Ukraine	153	345	44.3%
Macedonia	8	19	42.1%
Kampuchea	5	12	41.7%
Aruba	10	25	40.0%
Malawi	2	5	40.0%
Nigeria	271	692	39.2%
Mongolia	9	23	39.1%
Armenia	5	13	38.5%
Senegal	13	34	38.2%
Zimbabwe	27	73	37.0%
El Salvador	46	134	34.3%
Albania	4	12	33.3%
Belize	9	27	33.3%
Madagascar	1	3	33.3%
Iraq	7	22	31.8%
Dominica	2	7	28.6%
Sierra Leone	5	18	27.8%
Peru	95	352	27.0%
Pakistan	162	605	26.8%
Fiji	8	30	26.7%
Ivory Coast	21	80	26.3%
British Virgin Islands	9	35	25.7%
Azerbaijan	2	8	25.0%
Yemen	5	20	25.0%
Guatemala	261	1,048	24.9%
Paraguay	8	33	24.2%
Dominican Republic	369	1,584	23.3%

Percent of FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin *
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	Refused FY 2002- 2007 YTD	Lines FY 2002- 2007 YTD	Percent Lines Refused
Algeria	3	13	23.1%
United Arab Emirates	97	421	23.0%
Costa Rica	91	402	22.6%
Moldova	2	9	22.2%
French Polynesia	5	23	21.7%
Botswana	3	14	21.4%
Saudi Arabia	101	474	21.3%
Greece	117	581	20.1%
Georgia	3	15	20.0%
Lao Peoples Democratic Repblc.	4	21	19.0%
Syrian Arab Republic	13	70	18.6%
Russia	123	675	18.2%
Honduras	43	239	18.0%
Ecuador	53	298	17.8%
Barbados	35	200	17.5%
Jamaica	33	190	17.4%
Poland	146	862	16.9%
Burma	1	6	16.7%
Nicaragua	8	48	16.7%
St. Vincent & The Grenadines	2	12	16.7%
Bosnia-Herzegovina	4	25	16.0%
Vietnam	25	171	14.6%
Lebanon	43	297	14.5%
Antigua & Barbuda	5	36	13.9%
Byelarus	3	22	13.6%
Martinique	3	22	13.6%
Egypt	116	855	13.6%
Kuwait	10	74	13.5%
Nepal	25	185	13.5%
Bahrain	2	15	13.3%
Cayman Islands	3	23	13.0%
Mali	1	8	12.5%
Saint Lucia	5	40	12.5%
Bahamas	11	94	11.7%
Jordan	74	637	11.6%
Panama	93	816	11.4%
New Zealand	109	985	11.1%
Turkey	87	788	11.0%
Netherlands Antilles	10	92	10.9%
Trinidad & Tobago	56	519	10.8%
Venezuela	270	2,514	10.7%
Philippines	568	5,332	10.7%
Congo, Dem Rep of (Kinshasa)	2	19	10.5%

Percent of FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin *
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	Refused FY 2002- 2007 YTD	Lines FY 2002- 2007 YTD	Percent Lines Refused
Liberia	3	29	10.3%
Guadeloupe	11	108	10.2%
Qatar	3	30	10.0%
South Africa	275	2,859	9.6%
Romania	25	260	9.6%
Argentina	131	1,464	8.9%
Colombia	359	4,046	8.9%
Kenya	19	227	8.4%
Sri Lanka	22	263	8.4%
Hong Kong	120	1,441	8.3%
Uruguay	16	198	8.1%
Thailand	133	1,686	7.9%
Zambia	7	89	7.9%
Iceland	5	64	7.8%
Bulgaria	27	360	7.5%
Monaco	22	296	7.4%
Kazakhstan	1	15	6.7%
Benin	2	31	6.5%
Luxembourg	2	32	6.3%
Morocco	11	178	6.2%
Uganda	2	34	5.9%
Cyprus	12	208	5.8%
Korea, Republic Of (South)	287	4,990	5.8%
India	3,503	61,502	5.7%
Brazil	281	4,944	5.7%
Mauritius	1	18	5.6%
Oman	1	19	5.3%
Bangladesh	22	440	5.0%
Bermuda	2	42	4.8%
Congo (Brazzaville)	1	22	4.5%
Yugoslavia	2	45	4.4%
Chile	51	1,153	4.4%
Grenada	2	46	4.3%
Macau	17	391	4.3%
Indonesia	90	2,216	4.1%
Uzbekistan	2	53	3.8%
China (Mainland)	1,258	33,720	3.7%
Tunisia	5	138	3.6%
Slovakia	4	117	3.4%
Lithuania	2	60	3.3%
Taiwan, Republic Of China	265	8,357	3.2%
Mexico	1,548	51,654	3.0%
Spain	428	14,951	2.9%

Percent of FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin *
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	Refused FY 2002- 2007 YTD	Lines FY 2002- 2007 YTD	Percent Lines Refused
Australia	190	7,360	2.6%
Saint Christopher & Nevis	2	80	2.5%
Latvia	3	121	2.5%
Czech Republic	28	1,534	1.8%
Hungary	50	2,813	1.8%
Croatia	15	905	1.7%
Belgium	257	16,011	1.6%
United Kingdom	1,350	86,223	1.6%
Italy	665	44,375	1.5%
Singapore	83	5,677	1.5%
Netherlands	199	14,477	1.4%
Switzerland	393	30,193	1.3%
France	939	83,098	1.1%
Austria	56	5,512	1.0%
Germany, Federal Republic of	815	80,559	1.0%
Portugal	24	2,391	1.0%
Malaysia	44	4,623	1.0%
Canada	2,861	386,799	0.7%
Denmark	78	11,274	0.7%
Malta & Gozo	1	145	0.7%
Japan	193	28,840	0.7%
Finland	18	3,058	0.6%
Norway	22	3,747	0.6%
Sweden	62	12,603	0.5%
Ireland	143	33,646	0.4%
Israel	150	42,340	0.4%
Slovenia	5	4,332	0.1%
Afghanistan		1	0.0%
Burundi		1	0.0%
Cape Verde		1	0.0%
Central African Republic		1	0.0%
Chad		2	0.0%
Christmas Islands (Indian Ocn)		1	0.0%
Cocos Islands		2	0.0%
Cook Islands		4	0.0%
Country Code Unavailable		78	0.0%
Cuba		3	0.0%
Czechoslovakia		2	0.0%
East Timor		1	0.0%
Eritrea		2	0.0%
Estonia		34	0.0%
Ethiopia		8	0.0%
Falkland Islands		1	0.0%

**Percent of FY 2002-2007 (Aug 26 07) Human Drug And Antibiotic Import Lines Refused
by Foreign Declared Country of Origin ***
(Mail & Baggage Shipments excluded; Courier Shipments included)

Country	Refused FY 2002- 2007 YTD	Lines FY 2002- 2007 YTD	Percent Lines Refused
French Southern Antarctic		1	0.0%
Gambia, The		1	0.0%
Georgia		1	0.0%
Gibraltar		12	0.0%
Guinea-Bissau		1	0.0%
Iran		31	0.0%
Kyrgyzstan		10	0.0%
Lesotho		2	0.0%
Libya		4	0.0%
Liechtenstein		11	0.0%
Maldives		4	0.0%
Mauritania		10	0.0%
Mozambique		1	0.0%
Multiple Countries		5	0.0%
Nauru		2	0.0%
New Caledonia		1	0.0%
Niger		11	0.0%
Reunion		1	0.0%
Serbia		3	0.0%
Seychelles		4	0.0%
Solomon Islands		5	0.0%
Somalia		2	0.0%
Surinam		3	0.0%
Togo		20	0.0%
Tokelau Islands		2	0.0%
Turks & Caicos Island		6	0.0%
Vanuatu		13	0.0%
Vatican City State		3	0.0%
Yemen, Democratic (South)		1	0.0%
TOTAL	21,886	1,135,884	1.9%

* Foreign Declared Country of Origin means the products were manufactured outside of the U.S., Puerto Rico, U.S. Virgin Islands, American Samoa and Guam.

QUESTIONS FROM THE HONORABLE JAMES LANGEVIN, CHAIRMAN, SUBCOMMITTEE ON
EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

RESPONSES FROM DR. CRAIG HENRY

Question 1.: Under the National Response Plan, DHS is supposed to be a “coordinating agency” during a terrorist attack, major disaster, or other emergency involving the nation’s agriculture or food systems. Please detail your agency’s experience in DHS carrying out its role as coordinating agency? Has this been an effective process? If not what have been the challenges?

Question 2.: With more than 15 agencies administering at least 30 laws related to food safety, how has your Department prepared against vulnerabilities? What type of coordination or information sharing do you routinely practice?

Question 3.: What type of staffing challenges (vacancies, retention, recruitment, expertise, etc.) exists within your Department in carrying out your food mission?

1. GMNFPA experience with DHS as a coordinating agency.

DHS serves as the coordinating agency for the Critical Infrastructure Sector Coordinating Councils. Food and Agriculture is one of seventeen identified Critical Infrastructures as identified in Homeland Security Presidential Directive 7. DHS works in concert with FDA, USDA, State and local officials and food industry representatives (through the Food and Agriculture Sector Coordinating Council (FASCC) and its Sub-Councils) in addressing food defense issues. As the assigned

regulatory agencies, USDA and FDA play a major role in food defense efforts. FDA is responsible for implementing regulations under the Bioterrorism Act of 2002 (Registration of Food Facilities, Establishment and Maintenance of Records, Prior Notice of Imported Food Shipments, and Administrative Detention). Likewise, Food Safety and Inspection Service (FSIS) and Agricultural Marketing Service (AMS) have implemented directives and guidelines for meat and poultry establishments and government purchase contracts respectively that incorporate food defense initiatives into the plant environment. FDA has prepared a single source web link to assist the food industry in meeting its food defense obligations <http://www.cfsan.fda.gov/~dms/defterr.html>.

2. GMNFPA experience in addressing food industry vulnerabilities.

GMNFPA, in partnership with the Juice Products Association and representatives of juice processing companies conducted a vulnerability assessment of the juice industry using the method. In 2006–07 the association participated in the Strategic Partnership Program Agroterrorism (SPPA) vulnerability assessments for juice, baby food, and breakfast cereal with representatives from DHS, FDA, USDA, FBI, State and local food regulators. The results of these vulnerability assessments are classified and not directly available to the industry. FDA and USDA contracted to have appropriate software developed to permit private industry vulnerability assessments without access to the actual agents of concern. The software was beta tested by interested GMNFPA members who provided suggestions which led to appropriate modification and a more user friendly product. The software is now available on the FDA web page for downloading to a company computer for use to further safeguard individual company vulnerability assessments. Additional information on possible corrective actions.

3. GMA/FPA staffing challenges to accomplishing food defense mission.

GMA/FPA has one FTE assigned to represent the association on the FASCC and Sub-council and to deal with food defense related regulations and legislation. A significant portion of staff deal with various food safety issues including participation in industry training initiatives.

QUESTIONS FROM THE HONORABLE R. LANGEVIN, SUBCOMMITTEE ON EMERGING
THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

RESPONSES FROM DR. TOM MCGINN

Question 1: Under the National Response Plan, DHS is supposed to be a “coordinating agency” during a terrorist attack, major disaster, or other emergency involving the nation’s agriculture or food systems. Please detail your agency’s experience in DHS carrying out its role as coordinating agency? Has this been an effective process? If not what have been the challenges?

Response: Secretary Chertoff created the position of Chief Medical Officer (CMO) within the Preparedness Directorate of the Department as part of the Second Stage review in July 2005. The office of the CMO officially commenced operations in September 2005 with a staff of three people. Since becoming operational, the office exceeded many of its original goals and milestones in 2006. On January 18, 2007, in response to the changing domestic security needs of the Nation, and recognizing the cross-cutting potential for responsibilities within the Department, Secretary Chertoff further expanded the role of the CMO and proposed that the Office be renamed the Office of Health Affairs (OHA) reporting directly to the Secretary through the Deputy Secretary.

OHA’s role as the coordinator of DHS’s efforts related to protecting the Nation’s food supply focuses on Homeland Security Presidential Directive—9 (HSPD–9) (Food and Agro-Defense). Under this Presidential Directive, OHA leads the coordination for HSPD–9 implementation efforts. To assist OHA with broader access to expertise in its coordinating role, Deputy Secretary Michael Jackson requested “In the interest of coordination. . .that each Directorate and Office with primary expertise related to HSPD–9 (S&T, NPPD, I&A, CBP, and FEMA) assign a subject matter expert for each HSPD–9 provision.”

OHA also has coordinated the support of subject matter experts from the DHS/S&T managed Centers of Excellence at the University of Minnesota and Texas A&M University to provide advice, incident monitoring, event assessments and the capturing of lessons learned during several recent food and agriculture sector incidents, such as the recent foot and mouth disease (FMD) outbreak in the United Kingdom.

Also of note is the fact the OHA was tasked to chair and coordinate the inter-departmental working group to prepare the DHS response to the Presidential Executive Order on Import Safety.

Question 2.: With more than 15 agencies administering at least 30 laws related to food safety, how has your Department prepared against vulnerabilities? What type of coordination or information sharing do you routinely practice?

Response: DHS is working with USDA and FDA to conduct comprehensive risk assessments for agricultural and food commodities, which can then be used to identify protective measures and research and development gaps. Additionally, we are working with those agencies and sector partners to exercise communications, response and recovery efforts. OHA also coordinates 30 programs within 6 Directorates, including S&T and IP. A major threat in the food and agriculture sectors is a crisis of confidence, where a poorly prevented or recognized event causes people to question the safety of food regionally or nationally. Therefore, a swift confidence-building response is a critical objective of our planning and exercising efforts.

The Department of Homeland Security (DHS), U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), and the Federal Bureau of Investigation (FBI) are collaborating with the private industry and the states in a joint initiative referred to as the Strategic Partnership Program for Agroterrorism (SPPA) Initiative. The SPPA Initiative is a true interagency coordinated partnership program, where an industry member or trade association and a state volunteer to participate. Each assessment involves a site visit followed by facilitated discussions between industry and government representatives. During the course of this program, every Food and Agriculture Sector sub-sector will be studied (i.e. production, processing, retail, warehousing, and transportation) in order to assess vulnerabilities across the entire farm-to-table continuum. The primary purpose of the program is, in full partnership with the private sector and the states, to validate or identify vulnerabilities at specific points within the agriculture and food supply chain and the sector as a whole. These visits are built upon the work done by the Sector Specific Agencies (SSAs) in order to assist in implementing the National Infrastructure Protection Plan (NIPP) and the food and agriculture Sector Specific Plans (SSP). All of the visits are being conducted on a voluntary basis.

A sector focused information sharing strategy that addresses incident information reporting, sector defense guidance and event lessons learned, such as those from the SPPA program, is essential. Such information sharing programs fall within the purview of DHS.

It is also important to note that information sharing must be based upon accurate and timely data. Often, open source information from developing events typically flow much faster than anticipated, frequently outpaces the ability to validate, analyze and interpret such information. As a result, information is sometimes made available to the private sector before the government is informed. Therefore, several important information sharing channels have been developed that will aid the sector. For example, while not yet mature and fully functional, a sector specific portal on the Homeland Security Information Network (HSIN) is being developed.

Significantly, DHS is leading an interagency effort to establish a National Biosurveillance Integration Center (NBIC). NBIC's mission is to provide situational awareness and facilitate early recognition of biological events, to include natural disease outbreaks, accidental or intentional use of biological agents, and emergent bio-hazards through the acquisition, integration, analysis and dissemination of information from existing human disease, food, agriculture, water, meteorological, and environmental surveillance systems and relevant threat and intelligence information. NBIS will coordinate and gather biosurveillance information across the federal government and disseminate biosurveillance information to contributing partners for use by senior decision-makers.

In response to the mandates specified in HSPD-9 and HSPD-10, reflected in the above mission statement, DHS established the NBIS Program and by December 2005 achieved a nascent operational capability with a 24/7 Watchdesk in the National Operations Center (NOC). Concurrently, development of the NBIS Operational Display System (NODS) IT system began. In September 2006, a contract was awarded for development and fielding of the NBIS 2.0 IT system as a follow-on to the initial NBIS NODS System. Throughout this period to the present, the program has continued to add subject matter expertise while negotiating increased involvement and participation from prospective future member departments and agencies. In January 2007, Memorandums of Understanding (MOUs) were established with the Departments of State, Agriculture, Defense, Interior, and Health and Human Services. Subsequently Department of Transportation was added

through an existing umbrella MOU. As the program evolves, an estimated five additional Federal NBIS Member Agencies (NMAs) will be added (11 total), in addition to select private sector and international organizations.

With the passage of Public Law 110–53 on August 3, 2007, the NBIS mission and the role of the partner agencies have been reinforced and codified.

Question 3: What type of staffing challenges (vacancies, retention, recruitment, expertise, etc.) exists within your Department in carrying out your food safety/defense mission?

Response: In the near term, OHA is actively recruiting five additional staff and leveraging the support of NPPD and SMEs from the sector specific Centers of Excellence. The FY08 budget funds enough personnel to continue a focus on the veterinary and agro-defense policies, modestly expand partnership efforts and enhance operational and strategic planning efforts, as well as ad-hoc incident coordination. In FY 2009, the OHA Food, Agriculture and Veterinary (FAV) Defense Office will continue to be involved with policy, planning and preparedness efforts, as well as sector specific strategic planning at the Federal, state and local levels. The OHA FAV Defense Office will continue to lead coordination efforts between DHS entities, as well as between other Federal, state, local and private level entities.

One challenge to current coordination efforts is that preparations for a FAV-related emergency are, as is often the case, simultaneous with real-time events. This requires that DHS have enough staff capability to plan, coordinate, communicate, and respond to events and responsibilities now, as well as plan, coordinate, and communicate for future emergencies. Further, events such as infected swine importation from Canada into Minnesota, and the U.K. FMD outbreak have shown that an incident does not have to be intentional to cause great harm at a national level. These recent events all required a direct or indirect role for the OHA FAV Defense Office. These incident management activities have included interagency coordination, information/event reporting and providing advice directly to the Secretary and White House Homeland Security Council. These incidents have also required OHA to lead the coordination and integration of effort within DHS, and with state, local and private sector entities.

The OHA FAV Defense office must continue its efforts to work with FDA, USDA, and our other partners to protect our homeland against food, agricultural and veterinary threats. This includes the implementation and coordination of over 30 DHS-specific biodefense/agrodefense activities under HSPD–9.

Question 4: Dr. McGinn, do you believe your Department needs additional authorities to fulfill your HSPD–9 responsibilities?

Response: None at this time. However, as OHA expands its engagement with the private sector and the states, other authorities may be required to protect sensitive private sector information that is critical to understanding and sharing sector specific risk, threat, criticality, vulnerability, sector component shielding and mitigation strategies.

Question 5: Dr. McGinn, can you describe what steps the Department has taken to lead an interagency response to an act of agro-terror or other major disasters in the agriculture sector? Specifically, what plans have you developed and what training exercises have you completed?

Response: DHS, in accordance with HSPD–5, has drafted a revised National Response Framework (NRF) that provides the policy and operational framework for response to all major incidents and disasters, including those that might occur with the food and agriculture infrastructure. Under DHS guidance and coordination, each sector specific agency has developed annexes to provide sector specific guidance for the response to such events. The National Response Framework is in the comment period. OHA is working with NPPD to gather state and industry response to the documents.

The Framework is designed to simplify the National Response Plan for senior officials. OHA co-lead a working group on animal issues as part the revisions to the NRP in February of 2007. While the proposed Framework document does add some information about service and companion animals, it does not include recommendations from the animal issue working group for a mission area[0] that would address the disaster management needs of the broader livestock and pet populations. This is a short coming for the private sector and does not provide the needed guidance for federal, state and local governments when dealing with the needs of these populations in times of disaster.

DHS, in accordance with HSPD–7, has developed and published the National Infrastructure Protection Plan (NIPP) that provides guidance for developing protection and event mitigation plans for our critical infrastructures. In addition, USDA and

FDA, developed the Sector-Specific Plans (SSP) for agriculture and food. These SSPs provide an overarching planning framework for a cooperative effort between Federal, state, local and tribal governments and the private industry to protect agricultural and food systems from the effects of major disasters or a terrorism event that targets or impacts the food and agriculture sector.

DHS is also advancing scientific research and analysis through several national facilities. The Plum Island Animal Disease Center (PIADC) is one such facility that provides diagnostic, research, and teaching services to prevent the introduction and spread of foreign animal diseases. As PIADC is aging and becoming increasingly costly to operate, DHS is working with USDA to build the next-generation laboratory that will allow advanced research to understand and develop better preventions against the threats to humans, crops, and animals. DHS sponsors two university Centers of Excellence to study emerging issues related to food and agro defense. One center at the University of Minnesota, conducts research on food defense and actually has developed a tool that allows rapid analysis of the probable distribution footprint for a contaminated food product and of the potential human morbidity and mortality from such events. The other is a Center of Excellence at Texas A&M University where research into the potential threats to animal agriculture is conducted.

DHS also wants to integrate the various border defenses and enhance them with human and technological capabilities to defend this country against the deliberate or accidental introduction of foreign pathogens or pests that could affect the viability of our crops and animals. One key part of our border defense is the agricultural specialists within DHS' Customs and Border Protection (CBP). These inspectors are specifically trained and capable of focusing on reducing the risk from imported foods, plants, or animals. Agricultural inspectors intercept more than 4,000 prohibited meat, plant, and animal products every day at US ports of entry. DHS recently formed a task force with the USDA to address the concerns of agricultural stakeholders and to identify and close gaps in the inspection process.

In March of 2004, after a series of facilitated conferences, firms and organizations representing a broad range of constituents across the food and agriculture sector created the Food and Agriculture Sector Coordinating Council (FASCC). Shortly after the formation of the FASCC, DHS, USDA and FDA agreed to form a government counterpart to the FASCC called the Government Coordinating Council (GCC). The two councils work collaboratively on sector defense initiatives and information sharing. The industry sector coordinating council (SCC) is comprised of private companies and associations representing key components of the food system. The SCC has seven sub-councils spanning the farm-to-table continuum—agricultural input, animal producers, plant or crop producers, food processors, retail operations, warehouses and import/export establishments. The government coordinating council (GCC) is comprised of Federal, state, tribal and local governmental agencies responsible for a variety of activities including agricultural, food, veterinary, public health, laboratory, and law enforcement programs. In simple terms, the SCC and GCC are the liaison bodies that will plan, coordinate, and implement homeland security policies and programs for the food and agriculture sector. These bodies pre-date the NIPP and were created to build upon the Information Sharing Analysis Center (ISAC) approach to information sharing.

DHS has also engaged the Centers of Excellence at the University of Minnesota and Texas A&M to assist in developing food and agriculture disease and product adulteration event modeling tools, as well as training tools and programs. Additionally, the DHS Office of Grants and Training has funded several university and community college training and training tool development efforts that are focused on the food and agriculture sector. Finally, there have been numerous regional and state sector specific response exercises funded by DHS, such as High Plains Guardian, an exercise conducted by the State of Kansas.

Question 6.: According to a February 2007 DHS Inspector General report, DHS does not have a clearly defined system of authorities or adequate staffing to carry out food sector responsibilities. What has been done to address this issue?

Response: With the assignment of departmental responsibility for coordinating DHS roles and missions under HSPD-9, OHA FAV Defense Office is currently expanding its staff base and mission capability. The present office staff expansion is focused on the recruitment and hiring of 5 additional sector specialists in the near term and to continue the growth of the sector focused staff in FY08. OHA has a Senior Sector Specialist that has joined the FAV team under an American Association for the Advancement of Science (AAAS) Fellowship and is also negotiating with the DHS/S&T Office of University Programs for an additional Fellow within this

specialty to be assigned to work out of the FAV Defense Office to work the intersection of the Research, Development (S&T) and the OHA Operational missions.

Question 7: According to the 2007 DHS Inspector General report, “until DHS develops a method to adequately track federally funded research efforts, the United States will lack a coordinated national approach to protect against agroterrorism, possibly resulting in gaps or needless duplication of effort.” Are there currently any coordinated efforts to track federally funded research?

Response: Initial steps have been taken to track federally funded food and agricultural defense research. DHS has provided FDA and USDA with a summary of each of its projects in this area for use by the Food and Agricultural Sector Joint Committee on Research and for inclusion in the 2007 Food and Agricultural Sector Critical Infrastructure/Key Resources Protection Annual Report. “In addition, an effort has been initiated at the DHS sponsored National Center for Food Protection and Defense to develop a combined database listing all DHS, USDA, and FDA, academic and industry programs in this area.

Question 8: GAO issued two reports in 2002—on foot-and-mouth disease and on mad cow disease—examining U.S. measures for preventing those diseases from entering the United States. Because of the sheer magnitude of international passengers and cargo that enter this country on a daily basis and the inspection resources that are available, completely preventing the entry of those diseases may not be feasible. GAO found that USDA did not provide timely guidance to border inspectors for screening cargo and international passengers after foot-and-mouth disease struck Europe in 2001.

What federal efforts have been taken to address this vulnerability?

How has communication improved between USDA and border inspectors?

Our nation’s ports could be unnecessarily vulnerable to the intentional introduction of a disease or pest, unless the Department is able to analyze the reasons for declining agricultural inspections and streamline the flow of information between USDA and DHS inspectors at ports of entry.

What federal efforts have been taken to address this vulnerability?

Response: The United States Department of Agriculture (USDA) and U.S. Customs and Border Protection (CBP) developed a joint procedure that specifically identified the roles and responsibilities of CBP Agriculture Specialists (CBPAS) at the ports of entry regarding products received from restricted countries. Both agencies agreed to amend their existing Memorandum of Understanding (MOU), which addresses the agencies’ respective functional responsibilities and requirements for coordination at Headquarters and in the field. The MOU was signed on February 9, 2003 which gave CBP the authority to enforce USDA restrictions.

As a result, CBP and USDA performed an assessment of the controls in place to prevent shipments listed as being on hold in CBP’s database from exiting ports of entry without proper authorization. Animal and Plant Inspection Services (APHIS) and CBP have established that if CBP has any questions about a shipment, they will contact the APHIS subject matter expert to request guidance on clearance. Currently, CBP personnel thoroughly review the documentation associated with shipments received from Foot-and-Mouth Disease (FMD) affected countries to ensure that prohibited product is refused entry, when appropriate. As necessary, CBP requests guidance or technical expertise from USDA on imported products. Agriculture Programs and Liaison (APL) has issued alerts, musters, and memoranda updating the field with the latest information and instructing CBP personnel to thoroughly review the documentation associated with shipments received from FMD-affected countries.

How has communication improved between USDA and border inspectors?

Response: CBP recognizes the importance of communicating and working collaboratively with USDA to identify, address and develop measures to exclude harmful plant pests and foreign animal diseases in protecting American agriculture. The revised MOU stipulates that the headquarters Agriculture Programs and Liaison (APL) office will continue to assist CBP Directors of Field Operation (DFOs) with any significant changes in operational procedures that require consultation with USDA in accordance with the MOA prior to implementation.

CBP and USDA communicate relevant and vital information between both agencies. The USDA, APHIS is in a unique position of being both a partner and ally to CBP in fulfilling its agricultural mission. Conversely, CBP collects and maintains valuable information that contributes to the USDA’s scientific knowledge base, upon which the USDA determines national policies and procedures to protect this country

from agro-terrorism and other forms of agricultural economic harm. CBP has arranged training for USDA employees at the National Targeting Center (NTC) to hone their skills in targeting. There is presently one USDA liaison at the NTC to assist with the development of the agro-terrorism rule concepts and certain agricultural health and safety concerns. Data sharing allows USDA to develop specific alerts and targeting information for CBP, which are used at the ports of entry (POEs). Targeting plans call for CBP to enhance advance targeting systems support to collect information that will better identify, monitor, and report on current and emerging threats.

Daily communications between CBP and APHIS Headquarters, monthly meetings between executive Directors from APL and APHIS, quarterly meetings between the Assistant Commissioner Office of Field Operations and APHIS Deputy Administrator, as well as quarterly meetings between the Commissioner and APHIS Administrator, all provide timely opportunities to discuss and share information at various levels. USDA and CBP are responsible for communicating relevant and important agricultural information up and down their respective chain of command, as needed. This protocol enables every level of management to remain fully apprised of USDA information and to assess its potential impact at the local level.

QUESTIONS FROM THE HONORABLE JAMES LANGEVIN, CHAIRMAN, SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

RESPONSES FROM LEE M. MYERS, DMV, MPH, DIPL. ACVPM

Please Note: The responses below are submitted on behalf of the National Association of State Departments of Agriculture. The statements are intended to represent state agriculture departments as a whole and not any individual state agency.

Question 1: Under the National Response Plan, DHS is supposed to be a "coordinating agency" during a terrorist attack, major disaster, or other emergency involving the nation's agriculture or food systems. Please detail your agency's experience in DHS carrying out its role as coordinating agency. Has this been an effective process? If not what have been the challenges.

Response: The National Association of State Departments of Agriculture (NASDA) believes that it is too early to project the effectiveness of DHS as a coordinating agency during an agriculture or food emergency. Hurricane Katrina has been the only major emergency since the formation of DHS and there are many reports detailing the lessons learned to this disaster. State agriculture representatives from Louisiana and Mississippi expressed frustration about the lack of federal government coordination and slow assistance to the agriculture sector during Hurricane Katrina. Many individuals, businesses, and agencies have not yet received financial compensation from the federal government as a result of hurricane damage.

One of the primary issues that Congress has not yet resolved is the application of agriculture to the Stafford Act. The provisions of agriculture and food should be clearly outlined in the Stafford Act and should not be subject to individual interpretation. In the event of natural disaster, the agriculture and food sector should receive emergency assistance and compensation to help minimize disruption of the food supply. The responsibilities of federal agencies for agriculture and food during an emergency should be codified to minimize competing interests and agency conflicts.

Question 2: With more than 15 agencies administering at least 30 laws related to food safety, how has your Department prepared against vulnerabilities? What type of coordination or information sharing do you routinely practice?

Response: State agriculture agencies have completed a substantial number of vulnerability assessments utilizing a variety of methods, although states are relying upon the federal government to provide consistent tools for data collection and assessment. The joint efforts of the FBI, DHS, USDA, and FDA to develop a Strategic Partnership Program Agroterrorism (SPPA) initiative are encouraging. NASDA appreciates the FDA providing the assessment tool on-line for use by private industry in the food sector, and encourages the USDA to complete a similar on-line version for production agriculture. Only through consistent data collection and analysis in each state can a national threat matrix be formulated. State government agencies need additional resources to conduct these assessments, and develop and implement their food emergency plans. States need assistance in implementing cost-effective measures that enhance our ability to prevent an attack, detect an attack at the earliest possible time, respond to protect both the public health and industry and re-

cover from an attack by restoring public confidence and the economic viability of affected sectors.

As indicated in my written and oral testimony, there is no operational, comprehensive and secure communications network for agriculture to share threat alerts and other information linking local, state, federal, and private partners, with appropriate security clearances. Current methods of routine communication are primarily through a hodge-podge system of emails and conference calls, neither of which provide a secure environment.

Question 3: What type of staffing challenges (vacancies, retention, recruitment, expertise, etc.) exists within your Department in carrying out your food safety/defense mission?

Response: States are in dire need of additional human resources to fully implement their food safety/defense duties. State appropriations specifically for agriculture defense have been limited and the homeland security duties in most states are being assumed by personnel with full schedules in traditional regulatory programs.

Recruitment and succession planning is vital for the success of state food defense programs. It is critical that states successfully attract highly qualified career employees. With the majority of state employee salaries well below the market midpoint, recruiting and retaining a workforce to develop new programs and ensure business continuity is challenging to say the least.

The development and implementation of a national food defense strategy must be identified as a national priority and the compensatory resources allocated to state agriculture authorities from Congress.

